

Surgical site infection

prevention and treatment of
surgical site infection

Clinical Guideline

October 2008

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Surgical site infection

prevention and treatment of
surgical site infection

National Collaborating Centre for Women's
and Children's Health

Commissioned by the National Institute for
Health and Clinical Excellence

Evidence tables

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Abbreviations

| | |
|------------------|--|
| AAS | aqueous alcohol solution |
| Ab | antibiotics |
| AOPW | acidic oxidative potential water |
| ASA | American Society of Anesthesiologists |
| BMI | body mass index |
| BNF | British National Formulary |
| CABG | coronary artery bypass graft |
| CDC | Centers for Disease Control and Prevention |
| CFU | colony-forming unit |
| CI | confidence interval |
| COPD | chronic obstructive pulmonary disease |
| CPPL | closed saline postoperative peritoneal lavage |
| DAB | a solution containing 0.5 g of neomycin sulfate, 0.1 g of polymyxin B sulfate and 80 mg of gentamicin sulfate per litre of normal saline |
| FiO ₂ | fraction of inspired oxygen in an inhaled gas |
| GDG | Guideline Development Group |
| GP | general practitioner |
| HCAI | healthcare-associated infection |
| HCHS | Hospital and Community Health Services |
| IBD | inflammatory bowel disease |
| ICER | incremental cost-effectiveness ratio |
| ICU | intensive care unit |
| IV | intravenous |
| MBP | mechanical bowel preparation |
| MRSA | meticillin-resistant <i>Staphylococcus aureus</i> |
| NHS | National Health Service |
| NICE | National Institute for Health and Clinical Excellence |
| NINNS | Nosocomial Infection National Surveillance System |
| NNIS | National Nosocomial Infection Surveillance |
| O ₂ | oxygen |
| OR | odds ratio |
| PSA | probabilistic sensitivity analysis |
| PU | permeable polyurethane |
| QALY | quality-adjusted life year |
| quasi-RCT | quasi-randomised controlled trial |
| RCT | randomised controlled trial |
| RTI | respiratory tract infection |
| SD | standard deviation |
| SENIC | Study on the Efficacy of Nosocomial Infection Control |
| SHR | surgical hand rubbing |
| SHS | surgical hand scrubbing |
| SSI | surgical site infection |
| UK | United Kingdom |
| USA | United States of America |
| UTI | urinary tract infection |
| WMD | weighted mean difference |

3 Definitions, surveillance and risk factors

3.3 Risk factors

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---|--|---|---|---|---|
| Aboud 2004 29 | Prospective cohort with case-control EL = 2+ | Total no of patients: <i>n</i> = 127 Cases: <i>n</i> = 39 with SSI Controls: <i>n</i> = 78 without SSI Age matched controls Ratio 1:2 | Inclusion criteria: Age > 18 years, patients undergoing cardiac surgery (coronary arteries, mitral valve, congenital or with association of diseases) Exclusion criteria: Pts undergoing cardiac transplantation or with incomplete data or missing records. | Risk factors for SSI Data collected a) pre-op Sex, weight, height, BMI, obesity, diabetes, smoking (up to 3 months pre-op), hypertension, dyslipidaemia, COPD, previous corticoid or antibiotic use, permanent pacemaker, renal insufficiency, secondary diagnoses, acute MI (up to 1 month pre-op), angina, coronary stent, ejection fraction, functional class, previous sternotomy, type of surgery, use of beta-adrenergic drugs, pre-op hospital stay length b) intra-op (not relevant here) c) post-op (not relevant here) | Mediastinitis identification using CDC definition a) pre-op No significant difference Sex, smoking, hypertension, COPD, previous corticoid or antibiotic use, permanent pacemaker, renal insufficiency, unstable angina, ejection fraction, functional class, previous sternotomy, type of surgery, use of beta-adrenergic drugs, pre-op hospital stay length Significant difference Mean BMI Cases 29.4 Controls 25.3 <i>P</i> < 0.0001 Obesity Cases 18/39 Controls 9/78 <i>P</i> < 0.0001 Diabetes Cases 17/39 Controls 19/78 <i>P</i> = 0.034 Dyslipidaemia Cases 20/39 Controls 24/78 <i>P</i> = 0.031 | Study duration Jan 95 to Jan 2001 Funding: not stated |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|--|--|---|---|--|--------------------------|
| | | | | | Secondary diagnosis Cases 16/39 Controls 15/78 P = 0.012 Previous acute MI Cases 16/39 Controls 17/78 P = 0.029 Stable angina Cases 22/39 Control 23/78 P = 0.005 Independently assoc w mediastinitis Obesity (OR 6.49, 95% CI 2.24 to 18.78) Infection at another site (OR 8.86 [(95% CI 1.86 to 42.27)]) Smoking (OR 3.27, 95% CI 1.04 to 10.20) | |
| Cruse 1973 23 | Prospective observational EL = 2+ | Total no of patients n = not stated | Inclusion criteria: Surgical wounds from procedures conducted at Foothills Hospital | Risk factors for SSI | SSI – one trained nurse observed wounds for 28 days post-op. Infected wounds discharged pus | Applicable to UK: yes |
| Canada | | Total no of wounds = 23 649 Infected wounds: n = 1,124 (4.8%) Uninfected wounds: n = 22 525 | Exclusion criteria: Oral, rectal and vaginal operations, burns and circumcisions | Wound contamination Age Diabetes Obesity Malnutrition Steroids | Wound contamination All wounds 1124/23649 infected (4.8%) Clean wounds 329/18090 infected (1.8%) Clean-contaminated wounds 367/4106 infected (8.9%) Contaminated wounds 166/770 (21.5%) Dirty wounds 262/683 (38.3%) SSI incidence by Age (clean wounds only, read from graph) 0–1 years 0.8% | Funding: Not stated |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------------------|--|---|---|---|--|--|
| | | | | | 1–14 years 0.6% 15–20 years 1.8% 21–50 years 2.7% 51–65 years 2.2% 66+ years 3.7% | |
| | | | | | In clean wounds only, SSI incidence rate Diabetes 10.7% Obesity 13.5% Malnutrition 16.6% Steroids 2.6% | |
| Culver 1991 17 USA | Retrospective comparative observational EL = 2+ | Total no of operations <i>n</i> = 84691 SSI infection rate: <i>n</i> = not stated No SSI infection: <i>n</i> = not stated | Inclusion criteria: Hospital data from 44 National Nosocomial Infections Surveillance System hospitals Exclusion criteria: Not stated | Risk factors for SSI Wound class ASA score | SSI – defined according to the 'detailed' surveillance data collection protocol Wound class (no of SSI/100 operations) Clean 2.1/100 Clean-contaminated 3.3/100 Contaminated 6.4/100 Dirty-infected 7.1/100 ASA score (no of SSI/100 operations) 1 1.5/100 operations 2 2.1/100 operations 3 3.7/100 operations 4 5.5/100 operations 5 7.1/100 operations | Applicable to UK Yes Funding: Not stated |
| Friedman 2007 25 USA | Retrospective Case-control EL = 2- | Total no of patients <i>n</i> = 123 Cases: <i>n</i> = 41 Patients who developed SSI within 30 days or within 1 year of surgery if spinal implant given, during 1991–2001 (organ space SSI included) Controls: <i>n</i> = 82 Patients who did not | Inclusion criteria: Patients from 2 teaching hospitals undergoing spinal laminectomy Exclusion criteria: Not stated Cases and controls similar for mean age and sex distribution. | Risk factors for SSI: Race BMI Comorbidities | SSI – inpatient and lab based surveillance of all post laminectomy patients by infection control practitioners, post discharge identification by orthopaedic surgeons SSI incidence rate Hospital 1 = 1.1% (792 procedures) Hospital 2 = 0.9% (5573 procedures) Non-white race Cases 14/41 Controls 14/82 OR 2.4 <i>P</i> = 0.04 Multivariate analysis OR 2.5 <i>P</i> = 0.08 | Applicable to UK: yes Funding: National Institute of Aging |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------------------|--|---|--|--|--|---|
| | | develop SSI matched by year of surgery, NNIS score and hospital (not matched by laminectomy level) | | | BMI >35 Cases 12/41 Controls 5/82 OR 6.37 $P = 0.004$ Multivariate analysis OR 7.1 $P = 0.08$ Median ASA score $P = 0.28$ Presence of diabetes Cases 8/41 Controls 6/82 OR 2.94 $P = 0.06$ Multivariate analysis OR 4.2 $P = 0.04$ Median fasting blood glucose Cases 119.5 (106 – 161) Controls 107 (90.5 – 126.5) $P = 0.006$ Malignancy Cases 2/41 Controls 4/82 OR 1 $P = 1$ | |
| Gravante 2008 32 UK | Prospective observational EL = 2+ | Total no of patients $n = 87$ Cases: $n = 43$ smokers Controls: $n = 44$ non smokers | Inclusion criteria Prospective recruitment of all patients undergoing breast reductions. Patients confirmed as having stopped smoking 4 weeks prior to surgery Exclusion criteria previous bariatric surgery, ongoing clinical infections, antibiotic course in 6 months prior to surgery, steroid therapy, systemic diseases impairing oxygenation and wound repair, Baseline similar for age and BMI | Risk factors for SSI a) Smoking b) Amount of breast tissue removed (not relevant here) | SSI – clinical and microbiological confirmation required, within 30 days post-op SSI smokers – 16/43 SSI nonsmokers – 8/44 (37.2% vs 18.2% OR 2.04 $P < 0.05$) Within smoking group: Smokers with SSI estd overall cigarette consumption = mean 146 000 range 29 200–228 125 Smokers without SSI estd overall cigarette consumption = mean 10 950 range 9,125–54 750 ($P < 0.001$) | Applicable to UK Funding: not stated |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|--------------------------------|-----------------------------------|---|---|---|---|----------------------------------|
| | | | | | Smokers with SSI pack years = mean 20, range 4–31 Smokers without SSI pack years = mean 2, range 1–8) (<i>P</i> < 0.001) | |
| Kaye 2005 24 USA | Prospective Cohort EL = 2+ | Total no of patients <i>n</i> = 144 485 Patients with SSI: <i>n</i> = 1684 (1.2%) Patients without SSI: <i>n</i> = 142 801 | Inclusion criteria: Patients undergoing surgery at 11 hospitals Exclusion criteria: Age < 17 Pre-existent infection at operative site | Risk factors for SSI Age Type of surgery Wound class ASA score Duration of procedure | SSI – Infection control practitioners observation using CDC criteria. 5% superficial SSI 95% deep or organ space SSIs Mean Age SSI: 57.1 +- 16.9 No SSI: 52.3 +- 17.8 <i>P</i> < 0.01 Number of patients age ≥ 65 years SSI: 666/1684 No SSI: 40 865/142 801 OR 1.6, 95% CI 1.5 – 1.8 <i>P</i> < 0.01 Linear trend for SSI with increasing age by decade, peaking at age 65–74 (1.7 SSI cases/100 participants), then decreasing SSI trend with age. Following adjustment for NNIS variables, type of procedure and hospital, Derivation cohort n = 72 143 Between ages 17–65, SSI risk increased by 1.1%/year (<i>P</i> = 0.02) At age ≥ 65, SSI risk decreased by 1.2%/year (<i>P</i> = 0.08 relative to risk at age < 65 years) Validation cohort n = 72 342 Between ages 17–65, SSI risk increased by 0.8%/year (<i>P</i> = 0.02) At age ≥ 65, SSI risk decreased by 1.3%/year (<i>P</i> = 0.02 relative to risk at age < 65 years) | Applicable to UK Funding: |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|--------------------------------------|------------------------------------|--|---------------------------------|--|--|
| | | | | | Number of patients with wound class >2 SSI: 183/1684 No SSI: 7105/142 801 OR 2.3, 95% CI 2.0 to 2.7 $P < 0.01$ | |
| | | | | | Number of patients with ASA score ≥ 3 SSI: 984/1684 No SSI: 46 859/142 801 OR 3.0, 95% CI 2.6 to 3.2 $P < 0.01$ | |
| | | | | | Median duration of procedure in minutes (IQR) SSI: 155 (88, 259) No SSI: 92 (50, 165) $P < 0.01$ | |
| | | | | | Number of patients with operation duration >NNIS 75th percentile cutoff SSI: 734/1684 No SSI: 37305/142 801 OR 2.2, 95% CI 2.0 to 2.4 $P < 0.01$ | |
| Latham 2001 | Prospective cohort with case-control | Total no of patients $n = 1044$ | Inclusion criteria: All patients referred to cardiothoracic surgeons in hospital for CABG or cardiac valve procedures | Diabetes risk factors for SSI | SSI identification by infection control specialist using CDC definition | Study duration Nov 1998 to Sep 1999 |
| 27 | EL = 2+ | Cases: $n = 74$ with SSI | | History of diabetes | History of diabetes | |
| USA | | Controls: $n = 970$ without SSI | | Diabetes control | SSI Cases 43/76 | Funding: not stated |
| | | Ratio 1:14 | | Previously undiagnosed diabetes | No SSI Control 283/970 (OR 2.76 95% CI 1.64 –4.66) | |
| | | | | | Diabetes control – among known diabetics | |
| | | | | | Diabetics with SSI | |
| | | | | | Mean A1c 8.44% | |
| | | | | | Diabetics without SSI | |
| | | | | | Mean A1c 7.80% | |
| | | | | | ($P = 0.9$) | |
| | | | | | Previously undiagnosed diabetes | |
| | | | | | Unknown diabetes + SSI: 3/42 | |
| | | | | | Known diabetics with SSI: 17/300 | |
| | | | | | $P = 0.72$ | |
| Neumayer 2007 | Prospective cohort | Total no of patients | Inclusion criteria: | Risk factors for SSI | SSI – superficial and deep SSIs consistent with | Applicable to UK: |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|--|---|---|--|
| 21 USA | EL = 2+ | n = 163 624 Patients with SSI: n = 7035 Patients without SSI: n = 156 589 | Patients undergoing major general or vascular procedures at 128 Veterans Affairs Medical Centres and 14 private hospitals 36 and 40 patients respectively included over 8 day recruiting cycles by trained nurses Proportion of common procedures limited eg breast biopsies and hernia Exclusion criteria: Not stated | Type of surgery Age Gender Race >2 alcoholic drinks/day Dependent functional status Smoking Comorbidities Laboratory findings | CDC definitions measured at 30 days post-op. Independent Statistically Significant SSI Risk Factors from 81 638 observations Age over 40 years OR 1.24 95% CI 1.07 to 1.44, P= 0.004 Diabetes mellitus OR 1.33, 95% CI 1.22 to 1.45, P < 0.0001 Dyspnoea OR 1.23, 95% CI 1.12 to 1.35 P < 0.0001 Steroid use OR 1.39, 95% CI 1.18 to 1.63, P < 0.0001 Radiotherapy in prior 90 d OR 1.37, 95% CI 1.08 to 1.74, P= 0.01 Smoking OR 1.23, 95% CI 1.14 to 1.32, P < 0.0001 Bilirubin >1.0 mg OR 1.14, 95% CI 1.03 to 1.26 P= 0.0118 Pre-op albumin ≤ 3.5 g/dl OR 1.13, 95% CI 1.04 to 1.22, P= 0.004 Emergency procedure OR 1.5 95% CI 1.35 to 1.67, P < 0.0001 ASA score compared with class 1 ASA score 2 OR 1.56, 95% CI 1.22 to 2.01, P= 0.0005 ASA score 3 OR 1.97, 95% CI 1.53 to 2.54, P < 0.0001 ASA score 4/5 OR 1.77, 95% CI 1.34 to 2.32, P < 0.0001 Procedure type integumentary vs mouth/palate OR 2.02, 95% CI | yes Funding: Agency for Healthcare Research and Quality |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---|---|--|---|---|--|
| | | | | | 1.47 to 2.77, $P < 0.0001$ stomach/intestines vs mouth/palate OR 1.64, 95% CI 1.23 to 2.17, $P = 0.0007$ | |
| | | | | | Wound class clean-contaminated OR 1.40, 95% CI 1.26 to 1.56, $P < 0.0005$ contaminated OR 1.71, 95% CI 1.45 to 2.00, $P < 0.0001$ Dirty OR 1.58, 95% CI 1.28 to 1.95, $P < 0.0001$ | |
| Olsen 2008 31 | Retrospective Nested Case-control EL = 2+ | Total no of patients $n = 391$ Cases: $n = 81$ Women who developed SSI or endometritis Controls: $n = 310$ Women who did not develop SSI or endometritis randomly selected from cohort (1605 participants) | Inclusion criteria: Women undergoing low transverse caesarean section (identified by ICD-9 code) at a tertiary hospital Exclusion criteria: Not stated | Risk factors for SSI Age Race BMI at admission Diabetes STD presence Alcohol Tobacco Illicit street drugs Corticosteroids ASA score | SSI – Women with SSI or endometritis as identified from notes (validated by O&G doctor where needed). CDC compliant definition of SSI. 75/81 superficial SSI 4/81 deep SSI 2/81 organ space SSI No significant differences between cases and controls for all risk factors except for: Median BMI at admission Cases 36.4 Controls 31.8 $P = 0.003$ Multivariate analysis OR 1.1 95% CI 1.0 to 1.1 $P = 0.003$ | Applicable to UK: yes Funding: Centres for Disease Control and Prevention (CDC) and National Institutes of Health |
| Olsen 2003 30 | Retrospective case-control EL = 2- | Total no of patients $n = 220$ Cases: $n = 41$ with SSI Controls: $n = 179$ without SSI Ratio 1:4 | Inclusion criteria ; Patients undergoing laminectomy, spinal fusion or both, performed by a neurosurgeon in tertiary care hospital Exclusion criteria Other neurosurgical procedures, laminectomies and fusions performed by orthopaedic surgeons | Risk factors for SSI Data collected: a) pre-op age, sex, race, BMI, diabetes, glucose > 200 mg/dl, smoking history, previous spinal op, spinal cord compression, incontinence, steroid therapy, preop radio/chemotherapy, transfusions, ASA score, paralysis, recent injury, preop hospitalisation. b) intra-op (not relevant here) c) post-op (not relevant here) | SSI identification by infection control specialist using CDC/NNIS definitions a) pre-op No significant difference sex, steroid therapy, Significant difference smoking history Cases 15/41 Controls 54/178 $P = 0.006$ | Study duration Jan 96 – Dec 99 Funding: not stated |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|----------------------------------|---|-----------------------------------|--|------------------------------------|
| | | | | | BMI BMI 25–35 no significant difference Cases BMI >35 13/41 Controls BMI > 35 14/178 P = 0.003 Pre-op chemotherapy Cases 3/41 Controls 2/178 P = 0.047 Pre-op irradiation Cases 6/41 Controls 5/178 P = 0.007 Incontinence Cases 10/41 Controls 16/178 P = 0.012 ASA score 3 or 4 Cases 29/41 Controls 58/178 P < 0.001 Paralysis Cases 5/41 Controls 6/178 P = 0.035 Independently assoc w SSI BMI > 35 P = 0.001 Not reported: age, race, diabetes, glucose > 200 mg/dl, previous spinal op, spinal cord compression, transfusions, recent injury, preop hospitalisation | |
| Ridderstolpe 2001 | Retrospective comparative | Total no of patients n = 3008 | Inclusion criteria Adult patients undergoing cardiac surgery in a named hospital | Risk factors for SSI a) pre-op | SSI identification by using CDC definition Risk factors with P < 0.15 were further examined by | Study duration Jan 96 to Sep 99 |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---------------------------------------|---|--|--|---|--|
| Sweden | | <p>Patients with SSI: n = 291</p> <p>Patients without SSI: n = 2717</p> | <p>Exclusion criteria</p> <p>Death within 48 hours, left ventricular device in situ</p> | <p>Age, gender, obesity, diabetes, smoking, COPD, dialysis, PVD, Angina, NYHA score, LV dysfunction, anaemia, serum creatinine, prior cardiac surgery, preoperative stay</p> | <p>multivariate logistic regression analysis</p> <p>For all sternal wound infection: Obesity (BMI ≥ 30) OR 2.10, 95% CI 1.51 to 2.92</p> <p>IDDM OR 2.91, 95% CI 1.96 to 4.30</p> <p>Smoking OR 1.39, 95% CI 1.05 to 1.86</p> <p>For superficial wound infection: Age < 75 years OR 1.90, 95% CI 1.10 to 3.30</p> <p>Obesity (BMI ≥ 30) OR 1.74, 95% CI 1.17 to 2.60</p> <p>For deep sternal infection: Obesity (BMI ≥ 30) OR 2.65, 95% CI 95% CI 1.54 to 4.56</p> <p>IDDM OR 5.82, 95% CI 95% 3.30 to 10.28</p> <p>Smoking OR 2.41, 95% CI 95% 1.42 to 4.10</p> <p>PVD OR 2.11, 95% CI 1.09 to 4.09</p> <p>New York Heart Assocn score ≥ 3 OR 3.36, 95% CI 1.19 to 9.47</p> | <p>Funding: not stated</p> |
| Ridgeway 2004 | Prospective comparative observational | Total no of procedures n = 24 808 | Inclusion criteria: Patients undergoing hip arthroplasty or surgical revisions in 102 participating hospitals | Risk factors for SSI | SSI – SSI cases identified within postoperative hospital stay were included. | Applicable to UK Yes |
| 10 | EL = 2+ | No of infected wounds: n = 758 | Exclusion criteria: Not stated | <p>Age</p> <p>BMI</p> <p>ASA score</p> <p>Duration of surgery</p> <p>Wound class</p> | <p>Age (years) < 65 OR 1 65–74 OR 1.13, 95% CI 0.85 to 1.5) 75–79 OR 1.56, 95% CI 1.16 to 2.10</p> | <p>Funding: No benefits received from commercial parties</p> |
| UK | | No of uninfected wounds: | | | | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|--|--|--|---|---|--------------------------------------|
| | | <i>n</i> = 24 050 | | | <p>≥ 80 OR 1.66, 95% CI 1.24 to 2.21</p> <p>BMI</p> <p>< 20 OR 0.4, 95% CI 0.14 to 1.13</p> <p>20–30 OR 1.00</p> <p>>30 OR 0.93, 95% CI 0.32 to 2.69</p> <p>ASA score</p> <p>Class < 3 OR 1</p> <p>Class ≥ 3 OR 1.36, 95% CI 1.04 to 1.79</p> <p>Duration of surgery (minutes)</p> <p>< 60 OR 0.93, 95% CI 0.71 to 1.22</p> <p>60–89 OR 1</p> <p>90 – 119 OR 1.08, 95% CI 0.75 to 1.57</p> <p>≥ 120 OR 0.87, 95% CI 0.46 to 1.65</p> <p>Wound Class</p> <p>Clean OR 1</p> <p>Other OR 2.31, 95% CI 0.98 to 5.44</p> | |
| Russo 2002 28 | Prospective comparative EL = 2+ | Total no of patients <i>n</i> = 2345 | Inclusion criteria: All patients undergoing CABG surgery within cardiothoracic unit at named hospital | Risk factors for SSI Pre-op | SSI identification by ICP and a cardiovascular surgeon or infection control physician where necessary | Study duration Dec 96 to Sep 00 |
| Australia | | Patients with SSI: <i>n</i> = 199 Patients without SSI: <i>n</i> = 2146 | Exclusion criteria ; Not stated | gender, obesity, diabetes, smoking, COPD, hypercholesteraemia, renal failure, , hypertension, cerebrovascular accident or disease, immunopressive treatment, PVD, CHF and cardiogenic shock | Risk factors determined by multivariate logistic regression analysis Obesity OR 1.78, 95% CI 1.24 – 2.55 Peripheral or cerebrovascular disease OR 1.64, 95% CI 1.16 – 2.33 IDDM OR 2.29, 95% CI 1.15 to 4.54 | Funding: not stated |
| Scott 2001 22 | Retrospective observational EL = 2- | Total no of patients <i>n</i> = 9016 | Inclusion criteria: All patients receiving prophylactic antibiotics prior to a surgical procedure during study period at named hospital | Risk factors for SSI Data collected a) pre-op | Early infection defined as a new antibiotic regimen starting 2–7 days post op. (potentially over inclusive) | Study duration Mar 95 – Dec 97 |
| USA | | Cases: <i>n</i> = 1354 with SSI (split into two groups early infection | Exclusion criteria | age, gender, date or surgery, prophylactic antibiotic, serum albumin (closest to day | No significant difference gender, date of surgery, , serum creatinine (closest | Funding: not stated Potential |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|-------------------------|--|--|---------------------------------|
| | | (<i>n</i> = 1133) and readmission for infection (<i>n</i> = 221) | Not stated | of surgery) serum creatinine (closest to day of surgery) | to day of surgery) | overestimation of SSI incidence |
| | | Controls: <i>n</i> = 7728 without SSI | | | Significant difference Age Rate of early infection per decade increase in age OR 1.22 <i>P</i> < 0.001 Serum albumin Rate of early infection per gram % decrease OR 2.27 <i>P</i> < 0.001 Prophylactic antibiotic Ampicillin-aminoglycoside (OR 0.38 <i>P</i> < 0.05), Cephalosporin-based (OR 3.29 <i>P</i> < 0.001), Penicillin-based (OR 2.53 <i>P</i> < 0.05), cefazolin (OR 0.65 <i>P</i> < 0.001) | |

4 Information for patients and carers

4.1 Information for patients and carers

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up, effect size | Comments |
|--|-------------------------------|--|---|---|--|---|
| Whitby 2007 33 Australia | RCT EL = 1+ | Total no. of participants <i>n</i> = 588 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 292 <u>Control group</u> <i>n</i> = 296 | Patients who had undergone surgical procedures (breast, cardiac, chest, colo-rectal, endocrine, general, O&G, orthopaedic, urology, vascular). The surgical procedures chosen were based on the requirement for a substantial SSI rate and on the need for patients to be able to make a visual inspection of the surgical wound. Exclusion criteria: Patients not living within 40 km of their hospital. No written consent, agreement to complete post-discharge survey forms and to receive home visits from the infection control professional. | <u>Intervention group</u> Education provided on how to self-diagnose an SSI (usual post-discharge advice plus oral and visual instruction on signs and symptoms of SSI) <u>Control group</u> Hospital's normal post-discharge advice Comparison <i>C1</i> SSI events correctly self-diagnosed in the intervention ('educated') group vs SSI events correctly self-diagnosed in the control ('non-educated') group <i>C2</i> number of non-infected wounds correctly identified as non-infected in the intervention ('educated') group vs number of non-infected wounds correctly identified as non-infected in the control ('non-educated') group | Follow-up Four weeks Outcome SSI rates (CDC definition criteria) Effect size <i>C1</i> <u>Intervention group</u> 83.3% <u>Control group</u> 83.3% <i>C2</i> <u>Intervention group</u> 93.7% <u>Control group</u> 98.1% | Funding Grant from Queensland Health Comments The study examined the reliability on self-diagnosis of SSI among those patients receiving education on signs and symptoms for an SSI. All the surgical wounds were assessed by experienced infection control professionals once a week for four weeks. The SSI events self-diagnosed by the patients were therefore compared against the ICP diagnosis ('gold standard'). |

5 Preoperative phase

5.1 Preoperative showering

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---|---|---|--|--|---|---|
| Webster 2007 34 Australia | Systematic review with meta-analysis EL = 1+ | Six trials included in the review (total $n = 10389$): Byrne 1992 – Total 3733 patients, two arm trial, CHX vs placebo detergent Earnshaw 1989 – Total 64 patients, two arm trial CHX vs soap Hayek 1987 – Total 2015 patients, three arm trial CHX vs placebo detergent vs soap Randall 1983 – Total 94 patients, three arm trial CHX vs soap vs no shower Rotter 1988 – total 2953 patients, two arm trial CHX vs placebo detergent Wihlborg 1987 – total 1530 patients, three arm trial CHX full wash vs CHX partial wash vs no wash | Adults and children (M and F) from age 9 to 90 undergoing elective surgery in hospital setting. Operations included orthopaedic, vascular, biliary tract, inguinal hernia, breast, vasectomy and general surgery. Incidence of surgical site infection was the primary outcome measure in all studies although definitions varied among studies. | Comparison 1: Antiseptic wash vs no wash Comparison 2: Antiseptic vs non-antiseptic bar soap or detergent Comparison 3: Antiseptic total body wash vs antiseptic partial body wash The only antiseptic used in the included studies was chlorhexidine | Outcome for all analyses: Surgical Site Infection Rate (CDC compliant) Comparison 1: Two RCTs compared the effect of showering with 4% chlorhexidine vs no showering. Trial 1 ($n = 64$) CHX shower group 12/32 no shower group 9/32 (RR 1.33, 95% CI 0.65 to 2.72) Trial 2 ($n = 978$) CHX shower group 9/451 no shower group 20/437 (RR 0.36, 95% CI 0.17 to 0.79) Comparison 2: 5 RCTs compared the effect of showering with 4% chlorhexidine compared with non-antiseptic bar soap or detergent Trial 1 ($n = 3489$) CHX shower group 256/1754 Detergent/soap group 272/1735 Trial 2 ($n = 66$) CHX shower group 8/31 Detergent/soap group 4/35 Trial 3 ($n = 2015$) CHX shower group 62/689 Detergent/soap group 163/1326 Trial 4 ($n = 62$) CHX shower group 12/32 Detergent/soap group 15/30 | UK, Sweden and European multicentre trials included Applicable to UK Funded by: Royal Brisbane and Women's Hospital, Australia |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---------------|-------------------------|------------------------------|--|----------|
| | | | | | Trial 5 (<i>n</i> = 2813) CHX shower group 37/1413 Detergent/soap group 33/1400 Overall (RR 0.90, 95% CI 0.79 to 1.02) | |
| | | | | | Comparison 3: One RCT (<i>n</i> = 1093) compared total body to partial body washing with Chlorhexidine Total wash group 9/541 Partial wash group 23/552 Overall RR 0.40, 95% CI 0.19 to 0.85 favouring total body wash | |

5.2 Hair removal

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|--------------------------------------|---|---|--|--|--|
| Tanner 2006 37 | Systematic review with meta-analysis | 11 RCTs were included in the review (total $n = 4627$) | Participants were adults undergoing surgery in a designated operating theatre | Comparison 1: Any hair removal method vs no hair removal | Outcome for all analyses: Surgical Site Infection Rate Definitions varied: 3 trials required presence of pus, no trial referred to CDC definition | One UK, one Thailand and 4 US studies included |
| UK | EL = 1+ | Breiting 1981 $n = 52$, two arms shaving vs cream Goeau-Brissonniere $n = 100$, two arms shaving vs cream Powis 1976 $n = 92$, two arms shaving vs cream Rojanapirom 1992 $n = 80$, two arms shaving vs no hair removal Thorup 1985 $n = 50$, two arms shaving vs cream Balthazar 1983 $n = 200$, two arms shaving vs clipping Court Brown 1981 $n = 418$, three arms shaving vs cream vs no hair removal Seropian 1971 $n = 406$, two arms shaving vs cream Thur de Koos 1983 $n = 253$, two arms shaving vs cream Alexander 1983 $n = 1013$, two arms shaving vs clipping Ko 1992 $n = 1980$, two arms shaving vs clipping | Seven studies stated that patients were undergoing general surgery, one included orthopaedic surgery, one included cardiac surgery and two listed excluding amputations, vaginal, urological, gynaecological, burns, skin grafts, proctological, circumcision and abscess operations. | Comparison 2: Any hair removal method vs any other hair removal method Comparison 3: Timing of hair removal 1 vs timing of hair removal 2 | Comparison 1: a) Shaving vs no hair removal Two RCTs reported compared the effect of shaving with no hair removal (total $n = 358$ adults) Trial 1 Shaved group 17/137 No hair removal group 11 /141 Trial 2 Shaved group 0/40 No hair removal group 0/40 Overall, RR 1.59, 95% CI 0.77 to 3.27 b) Depilatory cream vs no hair removal One trial compared depilatory cream with no hair removal. Trial 1 Depilatory cream group 10/126 No hair removal group 11/141 RR 1.02, 95% CI 0.45 to 2.31 No studies compared clipping to no hair removal Comparison 2: <i>a) Shaving vs clipping</i> Three RCTs compared the effect of shaving to clipping of hair (total $n = 3193$) Trial 1 Shaving group 31/537 Clipping group 14/476 | Two Danish and one French translation required Applicable to UK Funds received from: The Theatre Nurses' Trust Fund, UK and The Association for Perioperative Practice UK |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---------------|-------------------------|------------------------------|--|----------|
| | | | | | Trial 2 Shaving group 2/100 Clipping group 1/100 | |
| | | | | | Trial 3 Shaving group 13/990 Clipping group 6/990 | |
| | | | | | <i>b) Shaving vs cream</i> Seven trials compared the effect of shaving to depilatory cream for hair removal (total $n = 1213$) | |
| | | | | | Trial 1 Shaving group 0/29 Depilatory cream group 0/23 | |
| | | | | | Trial 2 Shaving group 17/137 Depilatory cream group 10/126 | |
| | | | | | Trial 3 Shaving group 11/49 Depilatory cream group 9/51 | |
| | | | | | Trial 4 Shaving group 12/46 Depilatory cream group 9/46 | |
| | | | | | Trial 5 Shaving group 14/249 Depilatory cream group 1/157 | |
| | | | | | Trial 6 Shaving group 1/23 Depilatory cream group 0/24 | |
| | | | | | Trial 7 Shaving group 10/137 Depilatory cream group 9/116 | |
| | | | | | No studies compared clipping to cream | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|--|---|---|--|
| | | | | | <p>Comparison 3:</p> <p>a) Shaving on day of surgery vs shaving one day preoperatively at day 15 day of surgery shaving group 14/271 one day pre-op shaving group 17/266 at day 30 day of surgery shaving group 23/260 one day pre-op shaving group 26/260</p> <p>b) Clipping on day of surgery vs clipping one day preoperatively at day 15 day of surgery clipping group 10/250 one day pre-op clipping group 4/226 at day 30 day of surgery clipping group 18/241 one day pre-op clipping group 7/216</p> | |
| Celik 2007 38 | RCT EL = 1+ | Total no of participants: 789 adults | Inclusion criteria: patients undergoing spinal surgery | Comparison 1: Any hair removal method vs no hair removal | Comparison 1: a) Shaving vs no hair removal | Study duration: Jan 2000 and Sept 2004 Applicable to UK |
| Turkey | | Randomised into two treatment arms Group 1 n = 371 preoperative shaving Group 2 n = 418 no preoperative shaving | Exclusion criteria defined: Allergy or hypersensitivity to antibiotics Surgery in the month prior to spinal operation Antibiotic treatment within 7 days prior to surgery Suboptimal skin conditions eg acne, a local sebaceous cyst, a furuncle, or a hairy nevus Baseline characteristics similar in each group | | Shaved group 4/371 No hair removal group 1/418 (RR 4.51, 95% CI 0.51 to 40.14) Infection definition: When any of the following signs or symptoms developed: a purulent discharge from the surgical wound; increasing pain, tenderness, or redness around the incision line in addition to hematologic test results showing a high polymorphonuclear lymphocyte count or an increasing erythrocyte sedimentation rate; clinical features of meningitis; or an abscess identified via control magnetic resonance imaging studies and the results of hematologic tests. | No statement made regarding funding. 47 patients were lost to follow up. These were all in the shaved group (original allocation to shaved group n = 418) |
| | | | | | Wound infection monitored 'continuously': no further detail given. | |

5.4 Staff theatre wear

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---|--|--|----------------------------------|--|----------|
| Lipp 2002 44 | Systematic review with meta-analysis EL = 1+ | 2 quasi RCTs were included in the review (Chamberlain 1984 and Tunevall 1991) (Total $n = 3129$) | Tuneval 1991 Patients were undergoing a range of surgeries including breast, acute and vascular operations. Clean surgery ($n = 1429$) Group 1 –masks worn Group 2 – no mask worn Chamberlain 1984 Patients were women undergoing gynaecological surgery ($n = 41$) Group 1 –masks worn Group 2 – no mask worn | Comparison 1: Mask vs no mask | Tunevall 1991 SSI Group 1 13/706 Group 2 10/723 (OR 1.34, 95% CI 0.58 to 3.07). When the results for clean and dirty surgeries in the Tunevall 1991 study are combined to include all patients, SSI occurred in 73/1537 patients in the masked group and in 55/1551 of patients in the unmasked group. (OR 1.36, 95% CI 0.95 to 1.94) Chamberlain 1984 r SSI Group 1 – 0/31 Group 2 – 3/10 (OR 0.07, 95% CI 0.00 to 1.63). | |

5.6 Nasal decontamination

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|--|---|--|
| Kalmeijer 2002 45 | RCT EL = 1+ | Total no of participants = 614 | Inclusion criteria: All patients undergoing elective orthopaedic surgery during which prosthetic implant material was used (i.e., hip, knee, or back surgery) and patients undergoing a revision operation of the same type. | Group 1 Nasal decontamination with mupirocin nasal ointment (Glaxo-SmithKline; lot 550150/96G04) contains 2.15% weight/weight mupirocin calcium in a soft, white ointment base consisting of paraffin and a mixture of glycerin esters (Softisan 649) | Primary outcome: SSI rate SSI definition – measured up to 0 days, culture confirmation | Duration January 1997 through July 1999. |
| Netherlands | | Randomised into two treatment arms Group 1 = 315 Group 2 = 299 | Exclusion criteria: Patients with an active infection at the moment of inclusion and who had received antibiotic treatment in the previous 24 hours. Baseline comparability good | Group 2 The placebo ointment was produced in the hospital pharmacy from paraffin (Bufa; lot 96H16GR) and Softisan GlaxoSmithKline; lot 5051293), according to the GlaxoSmithKline protocol. | Comparison 1 Mupirocin vs Placebo nasal decontamination SSI rate overall: Gp 1 = 12/315, Gp 2 = 14/299 RR 0.81 (95% CI 0.38 to 1.73) | Applicable to UK Funding: no information supplied |
| Suzuki 2003 48 | RCT EL = 1+ | Total number of participants = 395 | Inclusion criteria: patients undergoing abdominal digestive surgery | Group 1: 30 mg mupirocin calcium hydrate ointment (Bactroban SKB Pharmaceuticals, Japan) via Q-tip swab to each nostril 3 x/day on each of 3 days prior to operation. | Primary outcome: infectious complications SSI definition – CDC compliant | Duration June 1998 to Dec 2000 |
| Japan | | Randomised into two treatment arms Group 1 = 193 Group 2 = 202 | Exclusion criteria: colorectal and laparoscopic procedures. Baseline comparability good | Group 2: No nasal decontamination | Comparison Mupirocin vs no nasal decontamination Overall SSI rate: Group 1 = 28/193 Group 2 = 22/202 | Applicable to UK Funding: no information supplied |
| | | | All patients received broad spectrum iv antibiotics for at least 24 hours after surgery | | RR 0.59 (95% CI 0.20 to 1.79) | |

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|----------------------------------|-------------------------------|--|--|---|---|---|
| Segers 2006 49 Netherlands | RCT EL = 1+ | Total number of participants = 954 Randomised into two treatment arms Group 1 = 485 Group 2 = 469 | Inclusion criteria: patients undergoing sternotomy for cardiothoracic surgery Exclusion criteria: emergency procedures; preoperative infection, preoperative use of antimicrobials, or both; hypersensitivity to chlorhexidine gluconate; absence of written informed consent; or treatment with an alternative prophylactic regimen like selective decontamination of the digestive tract, hospitalisation less than 1 day pre-surgery, Baseline comparability good Antibiotics: Cefuroxime (1.5-g intravenously) was administered prophylactically 30 minutes before incision and another dose was added to the priming fluid of the extracorporeal circulation. If surgical procedures exceeded 4 hours, an additional dose was administered. Cefuroxime was continued for 24 hours postoperatively. | Group 1: 0.12% chlorhexidine gluconate solution was used as an oral rinse and as a gel for nasal application. Group 2: Placebo oral rinse and nasal gel The oropharyngeal solution (10 ml) was used as a mouth rinse and applied to buccal, pharyngeal, gingival, and tooth surfaces for 30 seconds 4 times daily. The nose ointment was applied 4 times a day in both nostrils. The protocol was continued until the nasogastric tube was removed, usually the day after surgery. The experimental drug and the placebo were of comparable color, taste, and smell | SSI definition – CDC compliant Comparison Chlorhexidine mouthwash and nasal decontamination vs placebo mouthwash and nasal decontamination Overall SSI rate: Group 1: 48/485 Group 2: 52/469 Adverse events Group 1: 1/485 (Stained teeth) Group 2: 0/469 | Duration: August 1, 2003, and September 1, 2005 Applicable to UK No funding received. Drugs provided by pharmacy dept |
| Konvalinka 2006 47 Canada | RCT EL = 1+ | Total number of participants = 257 Randomised into two treatment arms Group 1 = 130 Group 2 = 127 | Inclusion criteria: patients admitted for elective open-heart surgery with nasal carriage of <i>S. aureus</i> . Exclusion criteria: patients admitted for elective open-heart surgery with no nasal carriage of <i>S. aureus</i> . Baseline comparability good except COPD signif higher in Gp 1 (10% vs 1.6%) Antibiotics: routine prophylaxis starting just before surgery – cefazolin 1 g every 8 h (or clindamycin in those with penicillin allergy) for 24 h | Group 1: 2% mupirocin ointment intranasally (contained in base of polyethylene glycol 400 and polyethylene glycol 3350) Group 2: Identical appearing placebo ointment intranasally (polyethylene glycol 400 and polyethylene glycol 3350) Administered with Q-tip cotton applicator to the vestibule of both nares twice daily for 7 d before surgery. | SSI definition: occurrence within 8 weeks of one of presence of wound exudate, wound erythema beyond 2 cm of wound margin with inflammatory signs or physician confirmation in notes of one of the above Comparison Mupirocin vs placebo nasal decontamination Overall SSI rate: Group 1 = 18/130 Group 2 = 10/127 SSI rate due to <i>S. aureus</i> : Gp 1 = 5/130 Gp 2 = 4/127 | Duration: March 1997 to March 2003 Applicable to UK Funding: Cardiovascular Surgery Research Grant and St Micheal's Hospital Foundation Grant |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|-------------------------------------|--|---|---|---|
| Perl 2002 | RCT | Total number of participants = 3864 | Inclusion criteria: patients admitted for elective and nonemergency cardiothoracic, general, oncology, gynaecologic or neurologic surgical procedures. open-heart surgery with nasal carriage of <i>S. aureus</i> . | Group 1 – 2% mupirocin calcium ointment | SSI definition – CDC compliant | Time: April 1995 – Dec 1998 |
| 46 | EL = 1+ | Randomised into two treatment arms | Exclusion criteria: patients allergic to mupirocin or glycerin ester, patients who were pregnant or breast feeding, participating in another trial, <i>S. aureus</i> infections in previous month, who had documented disruption of the nasal and facial bones, only having central catheters inserted | Group 2 – identical-appearing placebo ointment | Comparison Mupirocin vs placebo nasal decontamination | Applicable to UK |
| USA | | Group 1 = 1933 Group 2 = 1931 | Baseline comparability good except Group 2 significantly more likely to have had renal disease | Application with cotton swab to the interior of each anterior naris twice daily for up to 5 d before the operative procedure. | Overall SSI rate: Group 1 = 152/1933 Group 2 = 154/1931 SSI rate in <i>S aureus</i> carriers: Group 1 = 44/444 Group 2 = 52/447 <i>S. aureus</i> SSI in <i>S. aureus</i> carriers Group 1 = 17/430 Group 2 = 34/439 | Funding: grant from Smith Kline Beecham |
| | | | Antibiotics: standard perioperative prophylaxis when appropriate | | | |

5.7 Mechanical bowel preparation

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|--|---|--|--|--|
| Brownson 1992 ²³⁶ Liverpool, UK. | RCT EL = 1+ | Total number of participants = 179 Randomised into two treatment arms Group 1 = 86 Group 2 = 93 | Inclusion criteria: patients undergoing elective colorectal surgery.: colorectal cancer: 164/179; other: 14/179 Exclusion criteria: no details. Antibiotics: perioperative intravenous (no more details). | Group 1: Mechanical bowel preparation Group 2: No preparation | Comparison MBP vs no MBP Wound infection: Group 1 = 5/86, Group 2 = 7/93 | Applicable to UK |
| Bucher 2005 ²³⁷ Switzerland | RCT EL = 1+ | Total number of participants = 153 Randomised into two treatment arms Group 1 = 78 Group 2 = 75 | Inclusion criteria: Elective left-sided colorectal surgery Exclusion criteria: immunosuppression, HIV infection and liver cirrhosis, tumours smaller than 2 cm; patients requiring diverting stoma proximal to the anastomosis. | Group 1: Mechanical Bowel Preparation, 3 litres Polyethylene glycol 12–16 h before surgery Group 2: No preparation All patients received broad spectrum iv antibiotics for at least 24 hours after surgery | SSI definition – unclear defined as a wound requiring partial or complete opening for drainage of a purulent collection, or erythema requiring initiation of antibiotic treatment. Comparison MBP vs no MBP Wound infection Group 1 = 10/78 Group 2 = 3/75 | Applicable to UK Funding: no information supplied |
| Burke 1994 ²³⁸ Ireland | RCT EL = 1+ | Total number of participants = 169 Randomised into two treatment arms Group 1 = 82 Group 2 = 87 | Inclusion criteria: patients admitted for elective colorectal surgery with primary anastomosis – 72% colorectal cancer (133/186 cases); 3% inflammatory bowel disease (6/186 cases); 14% diverticular disease (26/186 cases); 2% other (4/186 cases). Exclusion criteria: any patients who could not tolerate the preparation; patients who had had the bowel 'prepared' for another procedure within previous week. Antibiotics: Ceftriaxone 1 gr and metronidazole 500 mg intravenously starting at induction of anaesthesia. Metronidazole 500 mg: 8 and 16 h, after initial doses. | Group 1 Mechanical bowel preparation group: sodium picosulfate 10 mg, the day before surgery (dose at morning and afternoon). Group 2 a normal diet and no other bowel preparation. | Comparison MBP vs no MBP Wound infection: Group 1 = 4/82 Group 2 = 3/87 | Duration: October, 1988 – September, 1992. Applicable to UK |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|---|--|---|--|
| Contant 2007 54 | RCT EL = 1+ | Total number of participants = 1354 Randomised into two treatment arms Group 1 = 670 Group 2 = 684 | Inclusion criteria: indication for elective colorectal surgery Exclusion criteria: acute laparotomy, laparoscopic colorectal surgery, mechanical bowel preparation contraindication, deviating ileal stoma, age under 18 years | Group 1 2-4 litres of polyethylene glycol lavage solution with either bisacodyl or sodium phosphate solution Group 2 No MBP | SSI definition: Mild – erythema or seroma discharge Severe – pus discharge, wound necrosis or dehiscence Comparison MBP vs no MBP Wound infection Group 1 = 41/670 Group 2 = 45/684 | Duration – Apr 1998 to Feb 2004 Applicable to UK No funding information provided |
| Fa-Si-Oen 2005 239 | RCT EL = 1+ | Total number of participants = 185 Randomised into two treatment arms Group 1 = 90 Group 2 = 95 | Inclusion criteria: Adults (M and F) undergoing elective colon surgery Exclusion criteria: previous radio/chemotherapy, idiopathic irritable bowel disease, obstructive tumours, emergency laparotomy, diagnostic MBP given up to 1 wk pre-surgery Antibiotic prophylaxis given | Group 1 – 4 litres of oral polyethylene glycol lavage solution orally Group 2 – no preoperative mechanical bowel preparation. | Wound Infection definition – clinically significant infection of the skin for which the wound had to be evacuated Comparison: MBP vs no MBP Group 1 = 9/90 Group 2 = 7/95 | Applicable to UK No funding information provided |
| Fillmann 1995 240 | RCT EL = 1+ | Total number of participants = 60 Randomised into two treatment arms Group 1 = 30 Group 2 = 30 | Inclusion criteria: patients admitted for elective colorectal surgery with primary anastomosis. Exclusion criteria: no exclusions. . Antibiotics: metronidazole + gentamycin 1 hour before surgery, and during 48 hours. | Group 1 -Mechanical bowel preparation (n = 30): 500 ml mannitol 20% + 500 ml orange juice. Group 2 orange juice. | Comparison: MBP vs no MBP Wound infection: Group 1 = 1/30 Group 2 = 2/30 | Duration: 1992-1993 Applicable to UK |
| Jung 2007 52 | RCT EL = 1+ | Total number of participants = 1343 Randomised into two treatment arms Group 1 = 686 Group 2 = 657 | Inclusion criteria: elective open surgery for cancer, adenoma or colonic diverticular disease involving an anastomosis, ASA score 1, 2, 3 Exclusion criteria: laparoscopic surgery, surgery with stoma, ASA score 4, life expectancy < 6 months Antibiotics given | Group 1 – oral PEG or oral sodium phosphate or enema Group 2 – no MBP | SSI definition – Superficial infection needing surgical intervention in the wound Comparison: MBP vs no MBP Wound infection: Group 1 = 103/686 Group 2 = 106/657 | Applicable to UK No funding information supplied |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|---|--|---|
| Miettinen 2000 241 | RCT | Total number of participants = 267 | Inclusion criteria: all consecutive adults admitted for elective colorectal surgery – colorectal cancer (134/267); benign tumours (24/267); inflammatory bowel disease (32/267); diverticular disease (58/267); other (19/267). | Group 1: Mechanical bowel preparation Polyethylene glycol electrolyte solution, and no solid food on the preoperative day. Group B: no preparations and normal diet. | Comparison: MBP vs no MBP Wound infection: Group 1 = 5/138 Group 2 = 3/129. | Duration: 1994–1996 Applicable to UK |
| Finland | EL = 1+ | Randomised into two treatment arms Group 1 = 138 Group 2 = 129 | Exclusion criteria: patients who had had bowel preparation for colonoscopy one week before surgery ($n = 5$); patients who were unable to drink PEG-ELS ($n = 2$); patients not requiring opening of the bowel ($n = 4$); patient who refused to be randomised ($n = 1$). Antibiotics: ceftriaxone 2 gr + metronidazole 1 gr at the induction of anaesthesia. | | | |
| Pena-Soria 2007 53 | RCT | Total number of participants = 97 | Inclusion criteria: Adults (M and F) over age 18 undergoing scheduled elective colorectal procedure with intraperitoneal anastomosis. | Group 1: 3 litres of oral polyethylene glycol lavage solution orally plus conventional enemas over 24 hours Group 2 – no preoperative mechanical bowel preparation | SSI definition – CDC compliant Comparison: MBP vs no MBP SSI Group 1 = 9/48 Group 2 = 6/49 | Start date: Oct 2001 Applicable to UK No funding information provided |
| Spain | EL = 1+ | Randomised into two treatment arms Group 1 = 48 Group 2 = 49 | Exclusion criteria: Endoscopy in prior week Active immunosuppression Preoperative chemoradiotherapy Diverting stoma Perforated or obstructed tumour Baseline characteristics similar in each group Antibiotic prophylaxis given | | | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|---|---|---|---|
| Santos 1994 242 | RCT | Total number of participants = 149 | Inclusion criteria: Patients admitted for elective colorectal surgery.: 43% colorectal cancer (68/157); 34% mega colon (53/157); 6% inflammatory bowel disease (9/157); 3% diverticular disease (5/157); 2% familial adenoma polyposis (3/157); 7% other (11/157). Exclusion criteria: patients that had taken antibiotics for at least 15 days before surgery or if there was evidence of infection or any associated disease requiring antibiotic therapy; and patients that the mechanical bowel preparation was not feasible. Antibiotics: Cefalotin 2 gr and metronidazole 1 g intravenously at 2 h before induction of anaesthesia. Cefalotin 1 gr was given 6 and 12 h, and metronidazole 500 mg, 8 and 16 h after the initial dose. | Group A: Mechanical bowel preparation LAXATIVE (mineral oil, agar and phenolphthalein) 15 ml taken by mouth three times a day for 5 days before surgery; mannitol (1 litre as a 10% solution) taken by mouth at the rate of 100 ml per 5 minute at 16:00 hours on the day before surgery. ENEMA (water, 900 ml; glycerin, 100 ml) given once a day for 2 days before surgery. children: enema of water and glycerin (9:1) twice a day for 2 days before surgery. Group B a low-residue diet and no other mechanical bowel preparation. | Comparison: MBP vs no MBP Wound infection: Group 1 = 17/72 Group 2 = 9/77 | Duration: October, 1991 – December, 1992. Applicable to UK |
| Tabusso 2002 243 | RCT | Total number of participants = 47 | Inclusion criteria: patients with colorectal cancer, submitted an elective colorectal surgery. Exclusion criteria: no details. | Group 1 – Mechanical bowel preparation: mannitol or polyethylene glycol electrolyte solution + liquid diet 48 hours before surgery. Group 2 – No mechanical bowel preparation: liquid diet 48 hours before surgery. | Comparison: MBP vs no MBP Wound infection: Group 1 = 2/24 Group 2 = 0/3 | Duration: October 1999 – January 2001. Applicable to UK |
| Zmora 2003 244 | RCT | Total number of participants = 380 | Inclusion criteria: Patients admitted for elective colon and rectal surgery Exclusion criteria: Not described | Group 1 - Mechanical bowel preparation with polyethylene glycol Group 2 - No preparation | Comparison: MBP vs no MBP Wound Infection: Group 1 = 12/187 Group 2 = 11/193 | Applicable to UK |
| Brazil | EL = 1+ | Randomised into two treatment arms Group 1 = 72 Group 2 = 77 | | | | |
| Peru | EL = 1+ | Randomised into two treatment arms Group 1 = 24 Group 2 = 23 | | | | |
| Israel | EL = 1+ | Randomised into two treatment arms Group 1 = 187 Group 2 = 193 | | | | |

5.9 Hand jewellery, artificial nails and nail polish

Systematic review

| Bibliographic details | Study type and evidence level | Study details | Participants characteristics | Intervention and comparisons | Outcomes, follow-up and effect size | Comments |
|--|----------------------------------|---|--|--|---|---|
| Authors Arrowsmith V.A. <i>et al</i> 55 | Systematic Review EL = 1+ | 102 patients in one single RCT, Wynd 1994 (USA) | Scrub nurses. No attempt to standardise nail length. Surgical scrub observation test based on a modified hand scrub protocol applied to attempt to standardise procedure. Different surgical solutions used. | RCT with three arms Group 1 (n = 34) fresh nail polish applied within 2 days Group 2 (n = 34) chipped nail polish applied 4 days before data collection. Group 3 (n = 34) natural nails Comparisons Unpolished nails vs Freshly polished nails Unpolished vs Chipped polished nails Freshly polished nails vs Chipped polished nails | Outcome Colony-forming units (CFUs) Nails swabbed for colony forming units pre- and post-surgical scrub, using sterile cotton tipped applicators SSI rate was not reported Follow-up no follow-up after surgery Effect Size (weighted mean difference) <i>Unpolished nails vs Freshly polished nails</i> Pre-scrub 20211.77, 95% CI -20131.73 to 60555.27 Post-scrub -284.12, 95% CI -692.37 to 124.13 <i>Unpolished vs Chipped polished nails</i> Pre-scrub -352.65, 95% CI -1047.24 to 341.94 Post-scrub 457.06, 95% CI -457.06 to 1369.65 <i>Freshly polished nails vs Chipped polished nails</i> Pre-scrub 20564.00, 95% CI -19774.03 to 60902.03 Post-scrub -741.00, 95% CI -1582.29 to 100.29 | Source of funding Stoke Mandeville Hospital NHS The Theatre Nursing Trust Fund UK Comments The review found no trials that compared the wearing of finger rings with the removal of finger rings and SSI. The allocation concealment in the RCT included was unclear |

5.10 Antibiotic prophylaxis

Systematic reviews

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---|--|---|---|---|---|
| Andersen 2005 77 | Systematic review with meta-analysis EL = 1+ | 45 trials were identified for inclusion. (Total $n = 9576$ participants) Quality varied –RCTs, and CCTs (4 trials were of topical antibiotics) | Participants were adults and children with suspected appendicitis based on either clinical conditions or intraoperatively diagnosed by the surgeon. None of the 45 trials specifically excluded children. Seven trials reported exclusively on children ($n = 776$) | Any antimicrobial regime vs placebo administration, before, during or after appendectomy. | Outcome: Wound infection – discharge of pus from the wounds although there was variation in definition in the 45 trials included in the review. Outcomes were described according to the nature of the appendix – simple or complicated. Where pathology was not stated data was placed in a general category 'appendix'. Comparison 1: Systemic A/B vs Placebo (Clinical) <i>Significantly favoured A/B</i> Appendicitis 21 trials (Peto OR 0.31, 95% CI 0.24 to 0.42) Simple appendicitis 26 trials (Peto OR 0.37, 95% CI 0.30 to 0.46) Complicated appendicitis 25 trials (Peto OR 0.28, 95% CI 0.29 to 0.38) Overall (Peto OR 0.33, 95% CI 0.29 to 0.38) Comparison 2: Systemic A/B vs Placebo (Pathoanatomic) <i>Significantly favoured A/B</i> Normal appendix 21 trials (Peto OR 0.28, 95% CI 0.18 to 0.44) Perforated appendix 6 trials (Peto OR 0.47, 95% CI 0.22 to 1.00) Overall (Peto OR 0.32, 95% CI 0.22 to 0.47) Comparison 3: Preoperatively administered single agent, single dose Antibiotics vs Placebo <i>Significantly favoured A/B</i> Appendicitis 2 trials (Peto OR 0.34, 95% CI 0.14 to 0.80) Simple appendicitis 9 trials (Peto OR 0.37, 95% CI 0.25 to 0.54) Complicated appendicitis 8 trials (Peto OR 0.29, 95% CI 0.18 to 0.47) Overall (Peto OR 0.34, 95% CI 0.25 to 0.45) Comparison 4: Preoperatively administered multiple agent, single dose | Applicable to UK Funds received from External Danish Pharmacy Foundation of 1991 Danish Institute for Health Technology Assessment Internal Copenhagen Hospital Corporation |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---------------|-------------------------|------------------------------|---|----------|
| | | | | | Antibiotics vs Placebo <i>Significantly favoured A/B</i> Appendicitis 1 trial (Peto OR 0.12, 95% CI 0.02 to 0.61) Simple appendicitis 1 trial (Peto OR 0.16, 95% CI 0.04 to 0.59) Complicated appendicitis not estimable Overall (Peto OR 0.14, 95% CI 0.05 to 0.39) | |
| | | | | | Comparison 5. Per-operatively administered single agent, single dose Antibiotics vs Placebo <i>Significantly favoured A/B</i> Appendicitis 6 trials (Peto OR 0.37, 95% CI 0.22 to 0.60) Simple appendicitis 6 trials (Peto OR 0.52, 95% CI 0.37 to 0.73) Complicated appendicitis 5 trials (Peto OR 0.35, 95% CI 0.21 to 0.58) Overall (Peto OR 0.43, 95% CI 0.34 to 0.55) | |
| | | | | | Comparison 6. Per-operatively administered multiple agent, single dose Antibiotics vs Placebo Appendicitis 3 trials (Peto OR 0.24, 95% CI 0.11 to 0.52) <i>Significantly favoured A/B</i> Simple appendicitis 1 trial (Peto OR 0.19, 95% CI 0.04 to 0.89) <i>Significantly favoured A/B</i> Complicated appendicitis 1 trial (Peto OR 0.25, 95% CI 0.03 to 2.52) NS Overall (Peto OR 0.43, 95% CI 0.34 to 0.55) <i>Significantly favoured A/B</i> | |
| | | | | | Comparison 7. Operatively single agent and postoperatively single agent, single dose Antibiotics vs placebo <i>Significantly favoured A/B</i> Appendicitis 3 trials (Peto OR 0.16, 95% CI 0.07 to 0.36) Simple appendicitis not estimable Complicated appendicitis not estimable Overall ((Peto OR 0.16, 95% CI 0.07 to 0.36) | |
| | | | | | Comparison 8. Operatively single agent and postoperatively single agent, multiple dose Antibiotic vs Placebo <i>Significantly favoured A/B</i> | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|--------------------------------------|---|---|---|---|--------------------------|
| | | | | | <p>Appendicitis 8 trials (Peto OR 0.45, 95% CI 0.30 to 0.68)</p> <p>Simple appendicitis 6 trials (Peto OR 0.46, 95% CI 0.30 to 0.70)</p> <p>Complicated appendicitis 6 trials (Peto OR 0.47, 95% CI 0.35 to 0.60)</p> <p>Overall (Peto OR 0.46, 95% CI 0.35 to 0.60)</p> | |
| | | | | | <p>Comparison 9.</p> <p>Operatively multiple agent and postoperatively multiple agent, multiple dose Antibiotic vs Placebo</p> <p><i>Significantly favoured A/B</i></p> <p>Appendicitis 1 trial (Peto OR 0.25, 95% CI 0.10 to 0.62)</p> <p>Simple appendicitis 4 trials (Peto OR 0.20, 95% CI 0.11 to 0.35)</p> <p>Complicated appendicitis 5 trials (Peto OR 0.08, 95% CI 0.03 to 0.22)</p> <p>Overall (Peto OR 0.18, 95% CI 0.11 to 0.27)</p> | |
| | | | | | <p>Comparison 10.</p> <p>Systemic antibiotics vs Placebo in children</p> <p>Appendicitis 1 trial (Peto OR 0.98, 95% CI 0.39 to 2.44) NS</p> <p>Simple appendicitis 6 trials (Peto OR 0.92, 95% CI 0.33 to 2.57) NS</p> <p>Complicated appendicitis 3 trials (Peto OR 0.31, 95% CI 0.12 to 0.77) <i>Significantly favoured A/B</i></p> <p>Overall (Peto OR 0.64, 95% CI 0.37 to 1.10) NS</p> | |
| Andreasen 2006 | Systematic review with meta-analysis | 4 out of 6 RCTs in this review were relevant (total $n = 461$) | Patients were undergoing surgery for mandibular or facial fractures | Comparison: Antibiotic vs placebo or no treatment | Outcome – Wound infection – not clearly defined in one of four studies (no details provided) | Applicable to UK |
| 58 | EL = 1+ | | | | | Funds received from: |
| Denmark | | Zallen 1975, two treatment arms $n = 62$ | | Antibiotic used only named in one study (Chole 1987 IV cefazolin) | Comparison: Antibiotic vs placebo or no treatment | Information not provided |
| | | Aderhold 1983, three treatment arms, $n = 120$ | | | SSI Group 1 = 21/300 Group 2 = 53/161 (OR 0.18, 95% CI 0.10 to 0.32) | |
| | | Gerlach 1988, four treatment arms, $n = 200$ | | | | |
| | | Chole 1987, two treatment arms, $n = 79$ | | | | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---------------------------------|---|--|--|--|---|--|
| Barker II, FG 1994 56 USA | Systematic review with meta-analysis EL = 1+ | 8 out of 8 RCTs in this review were relevant (total $n = 2075$) Savitz 1976 Geraghty 1984 Young 1987 Blomstedt 1988 Bullock 1988 Van Ek 1988 Djindjian 1990 Gaillard 1991 | Inclusion criteria; Participants underwent a craniotomy Exclusion criteria: Spinal operations, transphenoidal procedures, procedures with intentional opening of an air-containing sinus and peripheral nerve procedures | Antibiotic prophylaxis vs placebo Group 1: Antibiotics used were clindamycin, vancomycin/gentamicin, cefazolin/gentamicin, vancomycin, piperacillin, cloxacillin, oxacillin, and cefotiam Group 2: Placebo (no details given) | Outcome: Wound infection – no definition given in systematic review. No distinction drawn between superficial and deep infections. Comparison: Antibiotic vs placebo Group 1 = 19/1014 Group 2 = 93/1061 (OR 0.20, 95% CI 0.12 to 0.33) | Applicable to UK Funds received from: Information not provided |
| Barker II, FG 2002 57 USA | Systematic review with meta-analysis EL = 1+ | 6 out of 6 RCTs in this review were relevant (total $n = 843$) Pavel 1977 Geraghty 1984 Young 1987 Bullock 1988 Djindjian 1990 Rubenstein 1994 | Inclusion criteria:: Participants had spinal procedures as part of general neurosurgery, orthopaedic and spinal surgery Exclusion criteria: anterior cervical discectomy and non-spinal procedures | Antibiotic prophylaxis vs placebo or no treatment Group 1 Antibiotics used were cefaloridine, vancomycin/gentamicin, cefazolin/gentamicin, piperacillin, oxacillin and cefazolin Group 2 Four trials used a placebo, two used no treatment | Outcome: Wound infection – varying definitions but most studies required the presence of purulent drainage and positive bacteriological cultures Comparison: Antibiotic vs placebo or no treatment SSI Group 1 = 10/451 Group 2 = 23/392 | Applicable to UK Funds received from: Information not provided |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---------------------------------|---|--|---|--|---------------------------------------|
| Classen 1992 | Prospective observational study | Total no of patients <i>n</i> = 2847 | Inclusion criteria: | Risk factors for SSI | Sex Female = 1758 Male = 1089 | Study duration May 185 to Nov 1986 |
| USA | | Pts assigned to groups according to the time between their first dose of antibiotic prophylaxis and the initial surgical incision | Inpatients undergoing clean or clean-contaminated elective surgery at a named teaching hospital | Data collected Sex Time elapsed between initial antibiotic and surgery Distribution of antibiotic types across groups Overall SSI rate Group SSI rates (for RRs, referent was preoperative group.) | Wound classification Clean = 1359 Clean-contaminated = 1488 | Funding: not stated |
| | EL = 2+ | Early group 2–24 hours pre-incision | Exclusion criteria: Surgery >48 hours post hospital admission, no antibiotic given, antibiotics given < 24 hours before or after surgery, pre-existing infection, antibiotic prophylaxis not recommended for surgery, >1 operation during hospital stay | | Early group 369 pts 14 SSI cases RR 6.7, 95% CI 2.9 – 14.7 Log regression – OR 4.3, 95% CI 1.8 – 10.4 | |
| | | Preoperative group 0–2 hours pre-incision | Antibiotics administered Cefazolin – 56% Cefonicid – 12% Cefoxitin – 10% Cefamandole – 6% | | Preoperative group 1708 pts 10 SSI cases | |
| | | Perioperative group 3 hours post incision | | | Perioperative group 282 pts 4 SSI cases RR 2.4, 95% CI 0.9 – 7.9 Log regression – OR 2.1, 95% CI 0.6 to 7.4 | |
| | | Postoperative group 3–24 hours post incision | | | Postoperative group 488 pts 16 SSI cases RR 5.8, 95% CI 2.6 – 12.3 Log regression – OR 5.8, 95% CI 2.4 – 13.8 | |
| | | | | | Similar distribution of antibiotic types across groups | |
| | | | | | All pts received antibiotics for 24 hours post-surgery (80% for 48 hours) | |
| | | | | | 44/2847 developed SSI 1.5% overall SSI incidence rate | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-------------------------------|---|--|--|---|--|---|
| Cunningham 2006 61 UK | Systematic review with meta-analysis EL = 1+ | 6 of 6 RCTs included in this review were relevant (total <i>n</i> = 1286). All trials had two treatment arms Group 1 = 657 Group 2 = 649 Platt 1990 (<i>n</i> = 606) Wagman 1990 (<i>n</i> = 118) Amland 1995 (<i>n</i> = 76) Bold 1998 (<i>n</i> = 141) Gupta 2000 (<i>n</i> = 313) Chow 2000 (<i>n</i> = 48) | Inclusion criteria: Participants with breast cancer undergoing breast surgery with or without reconstruction as part of their treatment Exclusion criteria: All trials had similar exclusion criteria – no further details given | Group 1 Any pre- or peri-operative antibiotic used as prophylaxis. Antibiotics used were azithromycin single dose, cefonicid 1 g (two trials), clarithromycin 500 mg 2 xdaily for 5 days, co-amoxiclav 1.2 g, cefazolin 25 mg/kg x6 doses, Group 2 Pre- or perioperative antibiotic compared with no antibiotic or placebo | Outcome: Wound infection – ideally defined as using outcomes from validated assessment tool such as ASEPSIS or using CDC definition criteria. Comparison 1: Antibiotic vs placebo Group 1 = 58/629 Group 2 = 88/625 RR 0.66, 95% CI 0.48 to 0.89 Comparison 2 Antibiotic vs none (Chow 2000) Group 1 = 0/24 Group 2 = 0/24 RR = not estimable | Applicable to UK Funds received from: Internal University of Hertfordshire UK |
| Da Costa 1998 63 France | Systematic review with meta-analysis EL = 1+ | 6 of 6 RCTs included in this review were relevant (total <i>n</i> = 2023) Group 1 = 1011 Group 2 = 1012 Muers 1981 (<i>n</i> = 431) Jacobsen 1983/84 (<i>n</i> = 100) Ramsdale 1984 (<i>n</i> = 500) Glieca 1987 (<i>n</i> = 100) Luninghake 1993 (<i>n</i> = 113) Mounsey 1993/94 (<i>n</i> = 473) | Inclusion criteria: Participants were undergoing cardiac pacemaker insertion Exclusion criteria: Antibiotics for overt sepsis, overt wound infection at temporary transvenous pacemaker site, refusal of consent | Group 1 – Pre-, peri- or postoperative antibiotic prophylaxis. Antibiotics used were flucloxacillin/benzylpenicillin, cloxacillin, cloxacillin/amoxycillin and ampicillin/flucloxacillin, cefazolin, cefazedone and flucloxacillin alone Group 2 Place or no treatment (described as 'control' with no further detail) | Outcome – infection, no further detail given. Wound infection definitely included, but also pocket infection, lead infection and possibly septicaemia. Comparison: Antibiotic vs placebo/no treatment Infection Group 1 = 5/1011 Group 2 = 37/1012 OR 0.256, 95% CI 0.10 to 0.656 | Applicable to UK Funds received from: Information not provided |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-------------------------------------|---|---|--|--|---|--|
| Gillespie 2001 84 New Zealand | Systematic review with meta-analysis EL = 1+ | 22 trials were included in this review in total. Only five were relevant (total <i>n</i> = 2825) Group 1 = 1441 Group 2 = 1384 Bergman 1982 (<i>n</i> = 180) Boxma 1996 (<i>n</i> = 2195) Gatell 1984 (<i>n</i> = 284) Hughes 1991 (<i>n</i> = 54) Paiement 1994 (<i>n</i> = 122) | Inclusion criteria: Participants (in the 5 RCTs) were undergoing surgery for long bone and other unspecified closed fractures Exclusion criteria: not stated | Group 1 Antibiotics used were dicloxacillin 2 g × 9 doses, benzyl penicillin 3 million IU × 9 doses, cefamandole 2 g × 5 doses, cefalotin 1 g × 5 doses, cefuroxime 1.5 g, ceftriaxone 2 g IV Group 2 Placebo or no treatment | Outcome – deep, superficial and overall wound infection Comparison: Pre-, peri- or postoperative antibiotic prophylaxis compared with no treatment or placebo Comparison 1 multidose antibiotic vs placebo/no treatment Group 1 = 15/311 Group 2 = 22/275 Comparison 2 single dose antibiotic vs placebo/no treatment Group 1 = 36/1130 Group 2 = 82/1119 | Applicable to UK Funds received from: External Chief Scientist Office, DoH The Scottish Office Health Research Council of New Zealand Internal Healthcare Otago Endowment Trust, New Zealand |
| Gosselin 2004 83 USA | Systematic review with meta-analysis EL = 1+ | 7 out of 7 RCTs included in this review were relevant (total <i>n</i> = 913) Group 1 = 547 Group 2 = 366 Bergman 1982 (<i>n</i> = 90) Braun 1987 (<i>n</i> = 87) Dickey 1989 (<i>n</i> = 96) Patzakis 1974 (<i>n</i> = 300) Rojczyk 1983 (<i>n</i> = 199) Sloan 1987 (<i>n</i> = 40) Suprock 1990 (<i>n</i> = 91) | Inclusion criteria: Participants were of any age with open fractures of the limbs Exclusion criteria: Soft tissue injury data, hand and finger fractures (2 studies). | Group 1 Antibiotic administered before or at the time of primary treatment of the open fracture Antibiotics used were Penicillin/Streptomycin and Cefalotin, Penicillin and Dicloxacillin, Cloxacillin, Cefazolin, first generation Cephalosporin, Dicloxacillin or Erythromycin, or Cefradine. Group 2 two studies used a placebo, five gave no treatment | Outcome – early wound infection, definitions and follow up varied although five studies required microbiological confirmation of infection Comparison 1: Antibiotic vs placebo or no antibiotic Group 1 = 30/547 Group 2 = 49/366 RR 0.41, 95% CI 0.27 to 0.63 | Applicable to UK Funds received from: no details supplied |
| Meijer 1990 73 Netherlands | Systematic review with meta-analysis EL = 1+ | 78 trials were included in this review in total. 42 were relevant to the comparison antibiotic prophylaxis vs 'control' Participant numbers are not given | Inclusion criteria: Participants were undergoing operations on the gallbladder and/or common bile duct, including cholecystectomy, exploration of the common bile duct and choledochostomy. | Antibiotic prophylaxis vs 'control' Group 1 and 2- participant numbers are not given although studies <i>n</i> < 10 were excluded | Outcome: Wound infection – definitions varied although the most common was discharge of pus from the wound Meta-analysis of 42 studies favoured antibiotic prophylaxis OR 0.30, 95% CI 0.23 to 0.38 | Applicable to UK Funds received from: no details supplied |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------------------|---|---|---|--|--|----------|
| Sanchez-Manuel 2007 79 Spain | Systematic review with meta-analysis EL = 1+ | 12 out of 12 RCTs included in this review were relevant (total <i>n</i> = 6705) Group 1 = 4128 Group 2 = 2577 Anderson 1980 (<i>n</i> = 287) Aufnacker 2004 (<i>n</i> = 1008) Celdran 2004 (<i>n</i> = 99) Evans 1973 (<i>n</i> = 97) Lazorthes 1992 (<i>n</i> = 308) Morales 2000 (<i>n</i> = 524) Oteiza 2004 (<i>n</i> = 247) Perez 2005 (<i>n</i> = 350) Pessaux 2006 (<i>n</i> = 2402) Platt 1990 (<i>n</i> = 612) Taylor 1997 (<i>n</i> = 269) Yerdel 2001 (<i>n</i> = 269) | Inclusion criteria: Participants were undergoing hernia repair by hernioplasty or herniorrhaphy. | Group 1 All studies used a penicillin derivative antibiotic given IV (nine studies), IM (one study), subcutaneous/subfascial (two studies) Group 2 5 trials – no treatment 7 trials – placebo Comparison: Antibiotic prophylaxis vs placebo or no treatment 1) In hernioplasty 2) In herniorrhaphy 3) Overall | Outcome: Wound infection, clearly defined in 11/12 studies 1) In hernioplasty SSI Group 1 = 17/1196 Group 2 = 37/1240 OR 0.48, 95% CI 0.27 to 0.85 2) In herniorrhaphy SSI Group 1 = 103/2932 Group 2 = 66/1337 OR 0.71, 95% CI 0.51 to 1.00 3) Overall SSI Group 1 = 120/4128 Group 2 = 103/2577 OR 0.64, 95% CI 0.48 to 0.85 | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|----------------------------|---|--|--|---|---|----------|
| Small 2002 82 Canada | Systematic review with meta-analysis EL = 1+ | Seventy-five (of a total of 81) trials reported on the outcome of wound infection (total <i>n</i> = 11 142) Group 1 = 6237 Group 2 = 4905 | Inclusion criteria: Participants were undergoing a caesarean delivery | Group 1 = Antibiotics were usually administered IV after cord clamping and those most often used were ampicillin, a first generation cephalosporin (usually cefazolin), a second generation cephalosporin (cefoxitin, cefotetan or cefuroxime), metronidazole, an extended spectrum penicillin (eg ticarcillin, or a beta-lactamase inhibitor combination) and an aminoglycoside-containing combination. Group 2 About two thirds of studies used a placebo Comparison: Antibiotic vs placebo or no treatment 1) In elective caesarean 2) In non-elective caesarean 3) Overall | Outcome: Wound infection – Wound infection usually was a clinical diagnosis and generally included induration, erythema, cellulitis or various degrees of drainage. Comparison: Antibiotic vs placebo or no treatment In elective cesarean section (<i>n</i> = 2015) Group 1 = 64/1134 Group 2 = 75/881 RR 0.73, 95% CI 0.53 to 0.99 for non-elective cesarean section (<i>n</i> = 2780) Group 1 = 41/1650 Group 2 = 86/1130 RR 0.36, 95% CI 0.26 to 0.51 for all patients (<i>n</i> = 11 142) Group 1 = 234/6237 Group 2 = 468/ 4905 RR 0.41, 95% CI 0.29 to 0.43 | |
| Song 1998 78 UK | Systematic review with meta-analysis EL = 1+ | 4 of 147 trials included in the review were relevant (total <i>n</i> = 22 927) Group 1 = 171 Group 2 = 122 Gomez Alonso 1984 (<i>n</i> = 66) Gottrup 1985 (<i>n</i> = 135) Schuessel 1984 (<i>n</i> = 60) Utley 1984 (<i>n</i> = 32) | Inclusion criteria: Patients underwent colorectal surgery in RCTs published between 1984 and 1998. | Comparison: antibiotic prophylaxis vs no-antibiotic controls Group 1 Antibiotic prophylaxis (no further details) Group 2 No antibiotic given | Outcome: Wound infection – The wound infection was defined in most cases as 'the presence of purulent discharge' in the surgical wound, with or without positive bacteriological evidence SSI Group 1 = 22/171 Group 2 = 49/122 | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|---|---|---|--|--|----------|
| Southwell-Keely 85 | Systematic review with meta-analysis EL = 1+ | 10 of 14 trials included in this review were relevant (total $n = 2417$) | Participants were undergoing hip fracture surgery | Group 1 Antibiotic prophylaxis administered pre-, peri- and/or postoperatively for treatment of hip fracture. Antibiotics used were, cefotiam, nafcillin, cefazolin, cefalotin, cloxacillin, meticillin, cefotaxime, cefradine, ceftriaxone and cefuroxime. | Outcome: Wound infection – further definition not given although infected wound haematomas not included. Subgroup analysis of superficial and deep wound infection performed. Comparison: Antibiotic vs placebo or no antibiotic treatment. | |
| Australia | | Group 1 = 1244 Group 2 = 1173 Bodoky 1993 ($n = 139$) Boyd 1973 ($n = 280$) Buckley 1990 ($n = 312$) Burnett 1980 ($n = 361$) Ericson 1973 ($n = 171$) Hjortrup 1990 ($n = 185$) Kaukonen 1995 ($n = 149$) Lindberg 1978 ($n = 94$) Luthje 2000 ($n = 224$) McQueen 1990 ($n = 502$) | | Group 2 Placebo or no treatment | Ten trials with a total of 2417 participants examined wound infection Group 1 = 67/1244 Group 2 = 122/1173 (OR 0.55, 95% CI 0.35 to 0.85) Six studies investigated deep infection OR 0.53, 95% CI 0.20 to 1.38 Meta-analysis of studies describing infections as 'major' OR 0.52, 95% CI 0.28 to 0.99 Seven papers investigated superficial infection (OR 0.67, 95% CI 0.44 to 1.01) | |
| Tanos 1994 81 | Systematic review with meta-analysis EL = 1- | 17 out of 17 trials included in this review were relevant (total $n = 2752$) | Inclusion criteria: Women undergoing an elective total abdominal hysterectomy for various non-malignant diseases | Comparison: Antibiotic prophylaxis vs placebo Group 1: received prophylactic cephalosporins cefazolin (10 trials), cefoxitin (4 trials), cefradine, cefotaxime and moxalactam Group 2 Placebo or no treatment | Outcome – Postoperative infection identified using generally accepted definitions Group 1 = 205/2091 Group 2 = 155/661 | |
| Israel | | Group 1 = 2091 Group 2 = 661 | | | | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------------|---|--|--|--|--|--|
| Velanovich 1991 60 USA | Systematic review with meta-analysis EL = 1+ | 3 out of 12 RCTs were included in this review. (3 trials total <i>n</i> = 237) Group 1 = 155 Group 2 = 82 | Inclusion criteria: Participants were undergoing surgery for head and neck cancer | Comparison: Antibiotic prophylaxis vs placebo Group 1 Antibiotics used ampicillin/cloxacillin, cefazolin and cefoperazone/cefotaxime Group 2 placebo | Outcome: Wound infection – further definition not given Comparison: Antibiotic vs placebo Group 1 = 19/155 Group 2 = 35/82 Meta-analysis of three studies OR 0.06, 95% CI 0.02 to 0.18 favouring antibiotic prophylaxis | |
| Austin 1980 64 | RCT EL = 1- | Total no. of patients <i>n</i> = 15 Intervention group <i>n</i> = 6 Control group <i>n</i> = 9 | Included: patients undergoing aorto-coronary bypass Excluded: allergy to penicillin or cephalosporins, refusal of consent, emergency surgery | Gp 1 <i>n</i> = 6 antibiotic Gp 2 <i>n</i> = 9 placebo | Infection definition – sternotomy infection – no further details Gp 1 0/6 Gp 2 4/9 | Duration: Sep 1977 to Sep 1978 Funding: Antibiotic and placebo From Knoll-Made Lab |
| Aznar 1991 68 | RCT EL = 1+ | Total no. of patients <i>n</i> = 127 Intervention group <i>n</i> = 70 Control group <i>n</i> = 57 | Included: patients undergoing pulmonary resection, atypical pulmonary resection, bullectomy, chest wall resection, oesophageal surgery and surgery for mediastinal tumours Excluded: beta-lactam antibiotic allergy, active infection, antibiotic use in previous week | Gp 1 <i>n</i> = 70 1 g cefazolin Gp 2 <i>n</i> = 57 1 g placebo Given 30 minutes pre-surgery | Infection definition – purulent exudates or serous exudates with a positive culture together with inflammatory signs around the wound site Gp 1 2/70 Gp 2 8/57 | Duration: Sep 1986 to August 1988 Funding: Not stated |
| Chang 2006 76 | RCT EL = 1+ | Total no. of patients <i>n</i> = 277 Intervention group <i>n</i> = 141 Control group <i>n</i> = 136 | Included: patients with symptomatic gallbladder stones or polyps disease with or without acute cholestasis who were candidates for laparoscopic cholecystectomy. Excluded: antibiotics 7 days prior to surgery, cephalosporin or beta-lactam allergy, choledocholithiasis, intrahepatic duct stones, gallstone pancreatitis, previous biliary surgery, acute and emergent intervention, open cholecystectomy performed Sample Size: 277 (186 patients excluded as per above) | Gp 1 <i>n</i> = 141 1 g cefazolin given at anaesthetic induction Gp 2 <i>n</i> = 136 10 ml isotonic sodium chloride solution at anaesthetic induction | Infection definition – purulent drainage from surgical sites with or without positive cultures Gp 1 0/141 Gp 2 2/136 | Duration: Aug 2000 to Sep 2002 Funding: Not stated |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|--|---|---|--|
| Evans 1973 69 | RCT EL = 1+ | Total no. of patients <i>n</i> = 762 wounds Intervention group <i>n</i> = 376 wounds Control group <i>n</i> = 386 wounds | Included: patients undergoing general surgery Excluded: age < 16 years, death within 2 weeks of operation Sample Size: 762 wounds (63 wounds from stomach operations) | Gp 1 <i>n</i> = 376 wounds Cefaloridine Gp 2 <i>n</i> = 386 wounds No antibiotic Administration of antibiotic IV during anaesthetic induction, then 2 doses intramuscularly | Infection definition – presence of pus which either discharged or needed to be released from the wound Gp 1 34/376 wounds Gp 2 57/386 wounds For stomach operations: Gp 1 1/33 wounds Gp 2 6/30 wounds | Duration: Not stated Funding: Glaxo supplied cefaloridine |
| Fong 1979 66 | RCT EL = 1+ | Total no. of patients <i>n</i> = 105 Intervention group <i>n</i> = 58 Control group <i>n</i> = 47 | Included: patients undergoing aorto-coronary bypass Excluded: any valvular disease, penicillin allergy, refused to participate Sample Size: 132 (5 died and 22 excluded) | Gp 1 <i>n</i> = 58 1 g methillin IV given at anaesthesia induction, 1 g if operation over 4 hours, then 1 g every 6 hours for 72 hours Gp 2 <i>n</i> = 47 50 ml saline given as per Gp 1 | Infection definition – purulent drainage with signs of inflammation and bacteriological growth Gp 1 2/58 Gp 2 12/47 | Duration: Sep 1976 to Sep 1978 Funding: Not stated |
| Hall 2006 62 | RCT EL = 1+ | Total no. of patients <i>n</i> = 618 Intervention group <i>n</i> = 311 Control group <i>n</i> = 307 | Inclusion: All patients scheduled for non-reconstructive breast surgery Excluded: No consent, penicillin sensitivity, logistic failure, reconstructive surgery, warfarin therapy, antibiotics within 72 h, phenytoin therapy, existing infection Sample size = 618 | Gp 1 <i>n</i> = 311 Single dose of flucloxacillin immediately after anaesthesia induction Gp 2 <i>n</i> = 307 No treatment | Infection definition – discharge of pus or serous discharge containing pathogenic organisms Assessed up to 42 days. Mean presentation of wound infection t 16 days Gp 1 10/311 Gp 2 14/307 | Duration: Not stated Funding: Not stated |
| Ives 1981 67 | RCT EL = 1+ | Total no. of patients <i>n</i> = 211 Intervention group <i>n</i> = 118 Control group <i>n</i> = 93 | Included: patients undergoing major elective general surgery Excluded: allergy to penicillin or cephalosporin, antibiotic use for existing infection Sample Size: 211 | Gp 1 <i>n</i> = 118 Cefalotin 2 g administered by anaesthetist at induction Gp 2 <i>n</i> = 93 Placebo 2 g administered by anaesthetist at induction | Infection definition – pus spontaneously drained or wound was opened for drainage Gp 1 7/118 Gp 2 22/93 | Duration: 1977 – 79 Funding: Not stated |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|---|---|--|
| Kuthe 2006 75 | RCT EL = 1+ | Total no. of patients <i>n</i> = 93 Intervention group <i>n</i> = 40 Control group <i>n</i> = 53 | Included: Patients of ASA score 1 and 2 diagnosed as having gall stone disease undergoing laparoscopic cholecystectomy Excluded: acute cholecystitis, antibiotics 1 wk prior to surgery, long term corticosteroids, choledocholithiasis, cardiac prosthesis, conversion to open cholecystectomy | Gp 1 <i>n</i> = 40 1.5 g cefuroxime in 100 ml saline administered at anaesthesia induction Gp 2 <i>n</i> = 53 Normal saline administered at anaesthesia induction. | Infection definition – presence of erythema, indurations, serous and/or pus discharge from wound site Gp 1 1/40 Gp 2 2/53 | Duration: Jan2003 to Dec 2003 Funding: Not stated |
| Lewis 1979 70 | RCT EL = 1+ | Total no. of patients <i>n</i> = 83 Intervention group <i>n</i> = 41 Control group <i>n</i> = 42 | Included: patients undergoing surgery for gastroduodenal disease divided into 3 treatment arms (1 low risk and 2 high risk. Only high risk arms considered here) Excluded: | Gp 1 <i>n</i> = 41 2 g cefaloridine IV 2 hours preop and 5 hours post op Gp 2 <i>n</i> = 42 No antibiotics | Infection definition – discharge of pus Gp 1 0/41 Gp 2 11/42 | Duration: Nov 75 to Jun 77 Funding: Not stated |
| Nichols 1982 71 | RCT EL = 1+ | Total no. of patients <i>n</i> = 39 Intervention group <i>n</i> = 19 Control group <i>n</i> = 20 | Included: patients undergoing gastroduodenal surgery with a high postoperative risk Excluded: pregnancy, allergy to penicillin or cephalosporins, age < 12 years, pre-existing conditions rendering evaluation difficult., antibiotics in 72 hours prior to surgery | Gp 1 <i>n</i> = 19 2 g IV cefamandole 1 hour pre-op, 1 g at 4 and 8 hours post-op Gp 2 <i>n</i> = 20 Placebo as per Gp 1 | Infection definition – wound and intra-abdominal infections reported together Gp 1 1/19 Gp 2 7/20 | Duration: Jul78 to Jan 80 Funding: Not stated |
| Penketh 1985 65 | RCT EL = 1+ | Total no. of patients <i>n</i> = 38 (recruited in two phases) Intervention group <i>n</i> = 16 Control group <i>n</i> = 22 | Included: Patients undergoing CABG surgery Excluded: allergy to penicillin or cephalosporin, existing infection, diabetes | Gp 1 <i>n</i> = 16 Cephadine 1 g IV at induction and 500 mg IV every 6 hours for 48 hours. Gp 2 <i>n</i> = 22 Placebo no further details | Wound infection definition – not stated Gp 1 1/16 Gp 2 12/22 | Duration: Nov 84 to 1985 Funding: Not stated |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|---|---|--|---|
| Polk 1969 72 | RCT EL = 1+ | Total no. of patients <i>n</i> = 68 | Included: consecutive elective gastroduodenal operations | Gp 1 <i>n</i> = 32 Cephaloradine | Infection definition – wound and intra-abdominal infections reported together | Duration: Oct 1966 to Apr 1968 |
| Location: USA | | Intervention group <i>n</i> = 32 Control group <i>n</i> = 36 | Excluded: biliary tract surgery | Gp 2 <i>n</i> = 36 Placebo | Gp 1 0/32 Gp 2 11/36 | Funding: Eli Lilly & Co, Jupiter-Tequesta Community Fund, Rodrigo Borges Memorial Fund |
| | | | | Intervention given 1 ml IM on call to the operating suite and at 5 and 12 hours later | | |
| Sagunur 1988 59 | RCT EL = 1+ | Total no. of patients <i>n</i> = 20 | Included: patients presenting for major head and neck cancer surgery involving transection of both a mucous membrane and the skin | Gp 1 <i>n</i> = 11 Cefamandole Gp 2 <i>n</i> = 9 Placebo | Infection definition – a wound with purulent discharge (Becker grade 2 or 3) or Becker grade 1. Assessment at up to 4 weeks | Duration: Not stated |
| Location: Canada | | Intervention group <i>n</i> = 11 Control group <i>n</i> = 9 | Excluded: cephalosporin or penicillin allergy, receipt of antibiotics in the week prior to surgery, preoperative fever or infection, serum creatinine >25 mmol/l preoperatively, prothrombin time >1.5 times normal and not correctable with vitamin K, operations where the mucous membrane was not closed, patient refusal. | Intervention given on call to the operating room and again 4 and 8 hours after initial dose | Gp 1 3/11 Gp 2 5/9 | Funding: Not stated |
| | | Sample Size: 25 (5 lost to follow up and trial stopped early because of early significant differences between 2 groups. Initially 40 participants planned) | | | | |
| Sonne-Holm 1985 86 | RCT EL = 1+ | Total no. of patients <i>n</i> = 152 | Included: patients admitted for amputation for arteriosclerosis | Gp 1 <i>n</i> = 77 Five doses of 2 g cefoxitin during first 24 hours, starting 30 minutes before amputation and then every 6 hours | Infection definition – wounds with serous or purulent discharge with and without positive cultures or dry necrosis of the stump within 3 weeks of amputation and incidence of re-amputation within 3 m of index amputation | Duration: Nov 1981 to Mar 1983 |
| Location: Denmark | | Intervention group <i>n</i> = 77 Control group <i>n</i> = 75 | Excluded: antibiotics in previous 48 hours before amputation, pre-existing infection requiring antibiotics, temp >38° C, allergy to cephalosporins, refused consent | Gp 2 <i>n</i> = 75 placebo | Gp 1 13/77 Gp 2 29/75 | Funding: Merck Sharp and Dome provided cefoxitin and placebo |
| Tzovaras 2006 80 | RCT EL = 1+ | Total no. of patients <i>n</i> = 379 | Included: patients undergoing elective open repair of inguinal hernia using mesh | Gp 1 <i>n</i> = 190 a single dose of amoxicillin and clavoulanic acid | Infection definition –purulent discharge (or serosanguinous with positive culture) or spreading erythema indicative of cellulitis wound breakdown with clinical evidence of infection | Duration: Jan200 –Jun 2004 |
| Location: Greece | | Intervention group <i>n</i> = 190 Control group <i>n</i> = 189 | Excluded: allergy to penicillin, antibiotics within 5 d prior to surgery, bilateral hernia operation, pregnancy or lactation, existing ab prophylaxis, renal or liver impairment | Gp 2 <i>n</i> = 189 Normal saline | Gp 1 5/190 Gp 2 9/189 | Funding: Not stated |

6 Intraoperative phase

6.1 Hand decontamination

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | follow-up, outcome, effect size | Comments |
|-----------------------------------|---|---|--|--|--|--|
| Parienti 2002 ⁹³ | Cluster Randomised Trial EL = 1+ | Total no. of patients <i>n</i> = 4823 | Patients having surgery at six surgical services from teaching and non-teaching hospitals in France | Three surgical services were allocated to begin with the hand-rubbing protocol and the other three with the hand-scrubbing protocol. | Follow-up 30 days | Funding French government grant |
| France | | Hand-rubbing Protocol <i>n</i> = 2342 | Exclusion criteria: patients with contaminated or dirty procedures, patients having a second surgery < 15 days after the first intervention | * At the end of 1 month, each service switched to the alternative protocol. The study lasted 16 months | Outcome SSI rate (CDC definition) | Comments 436 patients were excluded after randomisation because of contaminated/dirty surgery (385) or lost to follow-up (51). |
| | | Hand-scrubbing Protocol <i>n</i> = 2481 | | <i>Intervention1: Hand-scrubbing protocol</i> (5 minutes scrub using either 4% povidone-iodine or 4% chlorhexidine gluconate) | Effect size <i>Hand-scrubbing</i> 53/2135 (2.48%) <i>Hand-rubbing</i> 55/2252 (2.44%) | |
| | | 4387 patients were included in the as-treat analysis: hand- scrubbing group <i>n</i> = 2135 hand- rubbing group <i>n</i> = 2252 | | <i>Intervention2: Hand-rubbing protocol</i> (5 minutes hand rub with 75% aqueous alcoholic solution) | | |

6.2 Incise drapes

Systematic review

| Bibliographic details | Study type and evidence level | Study details | Participants characteristics | Intervention and comparisons | Outcomes, follow-up and effect size | Comments |
|--|-------------------------------|--|--|---|---|--|
| Authors Webster and Alghamdi ⁹⁵ 2007 | Systematic Review EL = 1+ | 4195 participants in seven RCTs (Chiu 1993, Cordtz 1989, Dewan 1987, Jackson 1971, Psaila 1977, Segal 2002, Ward 2001). One study was a multicentre study, the others were single centre. | Patients undergoing surgical procedures: general or abdominal surgery (Dewan 1987, Jackson 1971, Psaila 1977), Caesarean section (Cordtz 1989, Ward 2001), cardiac surgery (Segal 2002) and hip surgery (Chiu 1993). None information was available about baseline comparability for Chiu 1993, Cordtz 1989, Jackson 1971, Psaila 1977, Segal 2002 and no data was presented for Ward 2001 and Dewan 1987 | <u>Intervention1</u> Adhesive (incise) drape <u>Intervention2</u> Iodophor impregnated adhesive (incise) drape <u>Control</u> No adhesive (incise) drape Comparisons <i>C1 Adhesive drapes (n = 1556) vs no adhesive drapes (n = 1526)</i> (Chiu 1993, Cordtz 1989, Jackson 1971, Psaila 1977, Ward 2001) <i>C2 iodophor impregnated adhesive drapes (n = 577) vs no drapes (n = 536)</i> (Dewan 1987, Segal 2002) | Outcome SSI rate (for both comparisons) Follow-up Range between 5 days and 6 months (was not reported for Psaila 1977) Effect Size C1: <i>Adhesive drapes vs no adhesive drapes</i> RR 1.23, 95% CI 1.02; 1.48; <i>P</i> = 0.03 C2: <i>Iodophor-impregnated adhesive drapes vs no drapes</i> RR 1.03, 95% CI 0.66; 1.60; <i>P</i> = 0.09 | Source of funding None Comments None of the trials reported were using an intention to treat analysis |

Surgical site infection: evidence tables

RCT

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|---|-------------------------------|---|---|---|---|---|
| Alexander 1985 ⁹⁶ USA | RCT EL = 1+ | Total no. of patients <i>n</i> = 577 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 310 <u>Control group</u> <i>n</i> = 267 | Patients undergoing elective surgery where an incise drape could be applied to the operative site Exclusion criteria operations including perineal area, genitalia, feet, upper extremities, head and neck; dirty wounds. | <u>Intervention group</u> Plastic adhesive (incise) drape (the operation site was covered with a ethylene methacrylate incise drape) <u>Control group</u> no incise drape (<i>cloth towels to the wound edges</i>) comparison plastic adhesive (incise) drape vs no plastic adhesive (incise) drape | Follow-up 30 days Outcome SSI rate (defined as discharge of pus) Effect size <u>Intervention group</u> 8/310 (2.6%) <u>Control group</u> 4/267 (1.5%) (RR 1.72; 95% CI 0.52, 5.66) | Funding ns Comments The trial was a preliminary study where participants were randomised in three arms (we have excluded one arm because of discontinuity of the product during the study) |

6.4 Disposable or reusable drapes and gowns

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|---------------------------------------|-------------------------------|--|--|---|---|---|
| Bellchambers 1999 ⁹⁸ | RCT EL = 1+ | Total no. of patients <i>n</i> = 505 Randomised in two arms: Group1 <i>n</i> = 250 Group2 <i>n</i> = 250 | Patients undergoing elective cardiac surgery Exclusion criteria: no details | <u>Group 1:</u> <i>Disposable, paper drape and gown system</i> <u>Group 2:</u> <i>Re-usable fabric drape and gown</i> Comparison <i>disposable</i> vs <i>Reusable drape + gown</i> * Both groups had a iodophor-impregnated adhesive plastic drape | Follow-up 3 months Outcome SSI rate (Sternal SSI and Leg SSI) assessed with the ASEPSIS score (>20) Effect size <i>Sternal SSI</i> <u>group1</u> 13/250 <u>group2</u> 12/236 <i>Leg SSI</i> <u>group1</u> 27/234 <u>group2</u> 31/216 The infection rate differences between the two groups were not statistically significant | Funding ns Comments 505 patients were randomised but 5 missing after randomisation. Not all the patients randomised were included in the analysis |
| Garibaldi 1986 ⁹⁷ | RCT EL = 1+ | Total no. of patients <i>n</i> = 498 Randomised in two arms: Group1 <i>n</i> = 226 Group2 <i>n</i> = 268 | Patients undergoing elective surgery where an incise drape could be applied to the operative site Exclusion criteria operations including perineal area, genitalia, feet, upper extremities, head and neck; dirty wounds | <u>Group 1</u> <i>Disposable (non woven) gown and drape</i> <u>Group 2</u> <i>Reusable (woven) gown and drape fabrics</i> Comparison <i>Disposable</i> vs <i>reusable drape + gown</i> | Follow-up 7 days Outcome SSI rate (defined as development of pus at the wound site) Effect size <u>Group 1</u> 6/226 (2.2%) <u>group2</u> 2 5/268 (2.2%) (RR 1.72; 95% CI 0.52, 5.66) | Funding Grants from the National Institute of Allergy and Infectious Diseases and from EI Dupont de Nemours Company Comments The allocation concealment was unclear The follow-up only seven days |

6.5 Gloves

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|----------------------------------|-------------------------------|---|---|---|---|---|
| Sebold 1993 ¹⁰⁰ | RCT EL = 1- | Total no. of patients <i>n</i> = 75 | Patients undergoing major joint arthroplasties | <u>Group 1</u> <i>Two pairs of latex gloves</i> | Follow-up ns | Funding ns |
| USA | | Randomised in three arms: Group1 <i>n</i> = 25 Group2 <i>n</i> = 25 Group3 <i>n</i> = 25 | Exclusion criteria: no details | <u>Group 2</u> <i>Perry orthopaedic gloves over regular latex</i> | First outcome Puncture rate innermost gloves and outermost gloves (gloves filled with water and individual digits squeezed) | Comments Not all the patients randomised were included in the analysis. |
| | | | | <u>Group 3</u> <i>Repel cloth gloves between two pairs of regular latex gloves</i> | Secondary outcome SSI (no information given on SSI def criteria) | Four cases excluded because of protocol deviations |
| | | | Comparison Standard double vs latex inner with orthopaedic outer vs double latex with cloth insert | | Effect size <i>Puncture rate (n. punctures out of n. of gloves used)</i> <i>inner glove</i> <u>group1</u> 14 /47 <u>group2</u> 8/51 <u>group3</u> 0/48 <i>outer glove</i> <u>group1</u> 55/58 <u>group2</u> 28/58 <u>group3</u> 67/63 | Only the primary operating surgeon wore the protocol gloves |
| | | | | | SSI Non postoperative SSI was recorded in neither of the groups | |
| Sanders 1990 ⁹⁹ | RCT EL = 1- | Total no. of procedures <i>n</i> = 50 | Procedures included if they involved manipulation of bone or the application of implants, or both. | <u>Group 1</u> Standard double latex gloves <u>Group 2</u> Latex inner glove with cloth outer glove | Follow-up (for infection recording period) ns | Funding none |
| USA | | Randomised in two arms: Group1 <i>n</i> = 25 Group2 <i>n</i> = 25 | | Comparison <i>Standard double latex gloves</i> vs <i>latex inner glove with cloth outer glove</i> | Main outcome Innermost glove perforation (gloves filled with 1000 ml water and suspended individual digits squeezed) | Comments Bias likely |
| | | | | | Secondary outcome SSI (def criteria ns) | |
| | | | | | Effect size <i>Innermost glove perforation</i> <u>Group1</u> 26/58 <u>Group2</u> 2/52 SSI rate No SSI event reported in none of the two groups | |

6.6 Antiseptic skin preparation

| Bibliographic details | Study type and evidence level | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|---|--|--|--|
| Alexander 1985 Definitive Study 96 Location of study: Cincinnati, USA | RCT EL = 1+ | Total of 480 patients undergoing elective surgery. 234 clean surgery 246 non clean surgery Inclusion criteria: ability to apply incise drape and informed consent Exclusion criteria: allergy to iodine, dirty wounds and areas difficult to drape (perineal, genitalia, feet, upper extremities, head and neck) Baseline comparability: sex, surgical service, attending surgeon, resident, type of operation, wound classification, prophylactic antibiotics, hair removal, antibiotic irrigation and suction catheters. | Interventions: Gp 1) One minute scrub 70% alcohol and polyester antimicrobial drape (<i>n</i> = 147) Gp 2) One minute scrub 2% Iodine in 90% alcohol and polyester antimicrobial drape (<i>n</i> = 164) Gp 3) 10 minute scrub Povidone-iodine (Betadine) soap, 2 applications of povidone-iodine (Betadine) paint and cloth drape (<i>n</i> = 169) NB Group 3 excluded from this review as concurrent change of antiseptic and drape | Outcomes Infection Defn – Discharge of pus, with or without positive culture, assessed at 30 days postoperatively. Clean surgery: Gp 1) 1/76 Gp 2) 1/81 Gp 3) 1/77 All three infections were 'superficial' Clean-contaminated surgery: Gp 1) 2/60 Gp 2) 3/72 Gp 3) 2/83 Contaminated surgery: Gp 1) 0/11 Gp 2) 1/11 Gp 3) 0/9 Total: Gp 1) 3/147 Gp 2) 5/164 Gp 3) 3/169 | Study duration: 1983 – 1984 No funding information available Applicable to UK |
| Alexander 1985 Preliminary Study 2 96 Location of study: Cincinnati, USA | RCT EL = 1+ | Total of 115 patients Inclusion: ability to apply incise drape and informed consent Exclusion: allergy to iodine, dirty wounds and areas difficult to drape (perineal, genitalia, feet, upper extremities, head and neck) Baseline comparability: not stated | Interventions: Gp 1) 1 minute scrub with 70% alcohol + iodophor polyester incise drape. (<i>n</i> = 45) Gp 2) 1 minute scrub with chlorhexidine in alcohol (Hibitane) + iodophor drape as above (<i>n</i> = 28) Gp 3) 1 minute scrub with 2% iodine in 50% alcohol + iodophor drape as above (<i>n</i> = 17) Gp 4) 1 minute scrub with 2% iodine in 70% alcohol + iodophor drape as above (<i>n</i> = 12) Gp 5) 1 minute scrub with 2% iodine in 90% alcohol + iodophor drape as above (<i>n</i> = 13) | Outcomes: Infection Defn – Discharge of pus, with or without positive culture, assessed at 30 days postoperatively. Incidence of infection: Gp 1) 2/45 Gp 2) 1/28 Gp 3) 0/17 Gp 4) 0/12 Gp 5) 1/13 Total 4/115 | Location of study: Cincinnati, USA Study duration: 1982 – 1983 No funding information available Applicable to UK |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------------|-------------------------------|---|---|---|---|
| Brown 1984 102 | RCT EL = 1+ | Total of 737 patients 239 obstetric 273 gynaecologic 225 general surgery Inclusion: private and clinical services patients undergoing laparotomy of all types, mastectomy and caesarean Exclusion: did not meet surgical procedure category Baseline comparability: age, diagnosis, type of procedure, presence of major risk factors | Interventions Gp 1) (Experimental) 0.5% Chlorhexidine spray in 70% alcohol (<i>n</i> = 378) Gp 2) (Standard Tx/Control) Scrub (6 minutes) with iodine soap (0.75% iodine) then aqueous povidone-iodine paint (<i>n</i> = 359) | Outcomes: Infection Defn - Minor wound infection classified as superficial separation (less than 1 cm) Major infection with separation of greater than one third of incision site or evidence of purulent exudate or abscess Minor infection: Gp 1) 23/378 Gp 2) 29/359 Major infection Gp 1) 11/378 Gp 2) 6/359 | Study duration: Dec 1979 – Nov 1980 No funding information available Applicable to UK |
| Ellenhorn 2005 106 | RCT EL = 1+ | Total of 234 patients Inclusion: 234 patients undergoing non-laparoscopic abdominal operations Exclusion: active infection, neutropenia, allergy, anticipated insertion of prosthetic material Baseline comparability: Age, obesity, diabetes, perioperative antibiotics, ASA score, procedures (clean, clean-contaminated) Loss to follow-up: Not stated | Interventions Gp 1) 5-minute scrub with povidone-iodine soap, absorption with sterile towel, aqueous povidone-iodine paint (<i>n</i> = 115) Gp 2) povidone-iodine paint only (<i>n</i> = 119) | Outcomes Infection Defn – wound infection (erythema or purulence requiring intervention): Gp 1) 12/115 (10%) Gp 2) 12/119 (10%) | Study duration: not given No funding information Applicable to UK |
| Kalantar-Hormozi 2005 101 | Quasi RCT EL = 1- | Total of 1810 'outpatient patients Inclusion: candidates for elective outpatient surgery (excision of naevus, scar revision, Z-plasty, excision of benign cysts, skin tumours and dermabrasion) Exclusion: immunosuppression states, incomplete follow up and antibiotic usage at time of surgery Baseline comparability: Age and procedure similar, sex significantly different | Interventions Gp 1) Shower with soap before surgery, saline irrigation of operative site, no pre- or postoperative antibiotics (<i>n</i> = 905) Gp 2) Shower with soap before surgery, povidone-iodine to scrub and paint operative site, no pre- or postoperative antibiotics (<i>n</i> = 905) | Outcomes Infection defn – redness, swelling, discharge and wound dehiscence observed within one month Gp 1 – 0/905 Gp 2 – 0/905 Study adequately powered. | Study duration: 1994–2002 No funding information Applicable to UK |

| Bibliographic details | Study type and evidence level | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---|-------------------------------|--|--|---|--|
| Kothuis 1981 | Quasi RCT | Total of 220 patients | Interventions | Outcomes | Study duration: not given |
| ¹⁰³ Location of study: Leyden, Netherlands | EL = 1- | Inclusion: patients undergoing an elective laparotomy Exclusion: not stated Antibiotic prophylaxis given to colorectal and vascular surgery patients. Baseline comparability: sex, age, diagnosis, procedure, clinical features | Gp 1) skin disinfection with alcohol 70% and iodine tincture 2%, then application of iodine tincture to wound edges pre-suturing of skin. Gp 2) skin disinfection with 10% povidone-iodine solution and drying, then 10% povidone-iodine application to skin and subcutaneous wound edges pre-suturing of skin | Wound healing was classified as a) primary and b) complicated wound healing which included erythema, oedema, haematoma, seroma, or the formation of a wound abscess. Observations made for at least 14 days postoperatively Gp 1) 24/102 Gp 2) 23/118 | No funding information Applicable to UK |
| Roberts 1995 | RCT | Total of 200 adult patients All clean surgery | Interventions | Outcomes | Study duration: 1 year |
| Location of study: New Jersey USA | EL = 1+ | Inclusion: consecutive consenting Patients undergoing CABG Exclusion: allergy to iodine Baseline comparability: no difference for age, diabetes, vascular disease or postoperative variables, although sex of patients not stated | Gp 1) Iodophor-in-alcohol, film forming, water insoluble antiseptic painted on chest and each leg and allowed to air dry for 2-3 minutes (n = 104) Gp 2) Aqueous Iodophor scrub (5 to 10 minutes) and paint of chest and legs then blotted dry with sterile towel (control)(n = 96) Iodophor impregnated incise drape on all chest wounds of both groups but not leg wounds. | CDC guidelines – wound appearance, drainage and cultured organisms. Purulent material drained, not necessarily positive culture. Superficial infection being skin, subcutaneous tissue and muscle above fascial layer. Deep infection being below fascial layer. Observed 2 weeks postoperatively and telephoned at 30 days. Gp 1) 10/104 Gp 2) 9/96 | No funding information Applicable to UK |
| Segal 2002 | RCT | Total of 209 adult patients All clean surgery | Interventions | Outcomes | Study duration: not given |
| ¹⁰⁵ Location of study: Houston USA | EL = 1+ | Inclusion: CABG, one or more high risk predictive factor Exclusion: pre-existing infection, allergy to iodine, CPR in progress Baseline comparability: age, type of surgery | Gp 1) Povidone-iodine paint Gp 2) Povidone-iodine five minute scrub then paint Gp 3) One-step iodophor/alcohol water insoluble film Gp 4) One-step iodophor/alcohol water insoluble film with iodine impregnated incise drape | Infection defn – Drainage, redness, tenderness, or sternal instability observed over 6 wk period Gp 1) 7/49 Gp 2) 7/45 Gp 3) 1/49 Gp 4) 3/48 | No funding information Applicable to UK |

6.7 Diathermy

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-------------------------------|-------------------------------|---|---|---|--|---|
| Groot (1994) 108 Canada | RCT EL = 1+ | Total no of participants = 166 Randomised into two treatment arms Group 1 = 250 Group 2 = 242 | Included: 492/672 eligible patients who were undergoing abdominal or thoracic operations Excluded: operative wound not full thickness, morbid obesity, surgeon believed that either of methods was unsuitable for patient (4 patients excluded on this basis) 166 eligible participants – randomisation procedure forgotten | Group 1: Wounds created with scalpel from skin through to fascia, haemostasis left up to surgeon's preference Group 2: Scalpel for skin incision and Valleylab cautery unit used for dividing tissue, muscle and fascia (setting = 6 and coagulation mode) | Infection definition – wounds with purulent discharge or with pathologic organisms cultured and erythema with or without seroma SSI Gp 1 = 38/250 Gp 2 = 30/242 | Funding: Not stated Study duration: Aug 1989 to Nov 1990 |
| Hata 2005 109 Japan | RCT EL = 1+ | Total no of participants = 90 Randomised into three treatment arms Group 1 = 30 Group 2 = 30 Group 3 = 30 | Included: Patients for whom CABG was indicated by a negative finding in a modified Allen test and who were undergoing radial artery harvesting Excluded: uncontrolled DM, PVD, BMI>35, serum creatinine > 2 mg/dl, off pump CABG, emergency surgery. Baseline characteristics: not stated | Group 1: Sharp scissors used to expose all branches of radial artery Group 2: Electrocautery used to expose all branches of radial artery Group 3: Ultrasonic scalpel used to cut all branches of radial artery with surrounding tissue, without exposure of any of the branches | Infection definition – none given SSI Gp 1 = 0/30 Gp 2 = 0/30 Gp 3 = 0/30 | Funding: Not stated Study duration Not stated |
| Johnson 1990 UK 110 | RCT EL = 1+ | Total no of participants = 140 Randomised into two treatment arms Group 1 = 130 Group 2 = 110 | Included: Patients undergoing surgery with an abdominal laparotomy Excluded: patients undergoing reoperation within 1 month of laparotomy and patients with ruptured abdominal aortic aneurysm Baseline characteristics: broadly similar sex ratio, age, elective: emergency surgery ratio, incision type, wound type | Group 1: Scalpel Group 2: Diathermy Midline incisions made using allotted technique through all layers. Muscle cutting incisions were made using the allotted technique for subcutaneous fat and deep fascia, muscle was cut using diathermy Antibiotic prophylaxis used | Infection definition – discharge of pus or fluid containing pathogenic organisms SSI Gp 1 = 11/130 Gp 2 = 5/110 | Funding: Not stated Study duration: Not stated |
| Kearns 2001 Ireland 245 | RCT EL = 1+ | Total no of participants = 100 Randomised into two treatment arms Group 1 = 50 Group 2 = 50 | Included: Patients scheduled for elective abdominal surgery via midline laparotomy Excluded: diabetes, current warfarin use, previous midline laparotomy Baseline characteristics: age, sex ratio, disease similar | Group 1: Scalpel Group 2: Diathermy All layers incised with scalpel or diathermy Antibiotic prophylaxis used | Infection definition – discharge of pus or fluid containing pathogenic organisms SSI Gp 1 = 3/50 Gp 2 = 2/50 | Funding: Not stated Study duration: Not stated |

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------------------|-------------------------------|--|---|---|---|---|
| Pearlman 1991 USA 112 | RCT EL = 1+ | Total no of participants = Randomised into three treatment arms Group 1 = 31 Group 2 = 28 Group 3 = 29 | Included: patients undergoing uncomplicated elective cholecystectomy Excluded: significant co-existing morbidity heart disease, stroke, pancreatitis, haemotological disorder, drug abuse history, known bile duct stones, unplanned exploratory surgery Baseline characteristics: age, sex ratio, weight similar | Group 1: Scalpel incision through all layers Group 2: Diathermy – skin scalpel incision, diathermy of peritoneum Group 3: CO₂ laser – skin scalpel incision, laser of peritoneum Antibiotic prophylaxis used | Infection definition – not given, seroma also included, assessed during hospital stay and at 7 days follow up SSI Gp 1 = 0/31 Gp 2 = 2/28 Gp 3 = 1/29 | Funding: Not stated Study duration: Not stated |
| Rodd 2007 113 UK | RCT EL = 1+ | Total no of participants = 60 Randomised into two treatment arms Group 1 = 30 Group 2 = 30 | Included: standard mastectomy and level 1 axillary sampling for breast Ca Excluded: >1 preceding surgery for breast Ca, bleeding diathesis, anticoagulant medication Baseline characteristics: age, pathology, breast weight similar | Group 1: Scalpel blade technique mastectomy Group 2: Diathermy bipolar scissors technique mastectomy | Infection definition – not given SSI Gp 1 = 3/25 Gp 2 = 3/26 | Funding: £500 donation from Ethicon used for blood tests Study duration: June 97 to May 2004 |
| Steger 1988 114 UK | RCT EL = 1+ | Total no of participants = 21 Randomised into two treatment arms Group 1 = 11 Group 2 = 10 | Included: patients undergoing routine cholecystectomy Excluded: unclear, possibly abnormal liver function test, jaundice, acute cholecystitis within 4 months Baseline characteristics: age, past medical history, sex ratio similar | Group 1: <i>n</i> = 11 Incisions made using steel knife and diathermy Group 2: <i>n</i> = 10 Incisions made using Nd:YAG laser | Infection definition – wound infections documented by positive bacteriology SSI Gp 1 = 1/11 Gp 2 = 5/10 (<i>P</i> = 0.051) | Funding: First author funded by Surgical Laser Technology Study duration: Not stated |
| Tsimoyiannis 2002 115 Greece | RCT EL = 1+ | Total no of participants = 40 Randomised into two treatment arms Group 1 = 20 Group 2 = 20 | Included: patients undergoing elective total or subtotal gastrectomy with D2 dissection for gastric Ca stage II or IIIA Excluded: not stated Baseline characteristics: age, sex ratio, weight, height, body weight loss, serum total protein and serum albumin similar | Group 1: <i>n</i> = 20 Monopolar diathermy Group 1: <i>n</i> = 20 Ultrasonic harmonic shears Antibiotic prophylaxis used | Infection definition – none given SSI Gp 1 = 3/20 Gp 2 = 1/20 | Funding: Not stated Study duration: 1997–1998 |

6.8 Maintaining patient homeostasis

Oxygenation

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up, effect size | Comments |
|-----------------------|-------------------------------|---|--|--|---|---|
| Greif (2000) 116 | RCT EL = 1+ | Total no. of patients <i>n</i> = 500 | Patients from 18 to 80 years old undergoing open elective colorectal resection (for cancer or IBD) | <u>Intervention group</u> 80% FiO ₂ during surgery and for the following 2 hours after the intervention | Follow-up 15 days Outcome Surgical site infection Effect size <u>SSI rate</u> <u>Intervention group</u> 13/250 (5.2%) <u>Control group</u> 28/250 (11.2%) | Funding Source of Funding: National Institutes of Health and Grants from several foundations |
| Austria and Germany | | Intervention group <i>n</i> = 250 Control group <i>n</i> = 250 | Exclusion criteria Minor colon surgery; recent fever or infection; serious malnutrition; bowel obstruction | <u>Control group</u> 30% FiO ₂ during surgery and during the following 2 hours after the operation Comparison Peri-operative 80% FiO ₂ vs Peri-operative 30% FiO ₂ | | |
| Mayzler (2005) 119 | RCT EL = 1+ | Total no. of patients <i>n</i> = 38 | Patients undergoing elective colorectal cancer surgery | <u>Intervention group</u> 80% FiO ₂ during surgery and for the following 2 hours after the intervention <u>Control group</u> 30% FiO ₂ during surgery and during the following 2 hours after the operation Comparison Peri-operative 80% FiO ₂ vs Peri-operative 30% FiO ₂ | Follow-up one Month Outcome Surgical Site Infection Effect size <u>SSI rate</u> <u>Intervention group</u> 2/19 (12.5%) <u>Control group</u> 3/19 (17.6%) | Funding not mentioned |
| Israel | | Intervention group <i>n</i> = 19 Control group <i>n</i> = 19 | Exclusion criteria ASA score 3 or 4; BMI = 35; diabetes mellitus; COPD; serious malnutrition; preoperative immunosuppression therapy. | | | |
| Pryor (2004) 118 | RCT EL = 1+ | Total no. of patients <i>n</i> = 165 | Patients undergoing major intra-abdominal surgery older than 18 years. | <u>Intervention group</u> 80% FiO ₂ during surgery and for the following 2 hours after the intervention <u>Control group</u> 35% FiO ₂ during surgery and during the following 2 hours after the operation | Follow-up 14 days Outcome Surgical Site Infection Effect size <u>SSI rate</u> <u>Intervention group</u> | Funding Cornell University 165 randomised; 80 in the 35% FiO ₂ group and 85 in the 80% FiO ₂ ; 5 patients left the 80% FiO ₂ group after randomisation but before the randomisation was revealed: they were not included in the Analysis. |
| USA | | Intervention group <i>n</i> = 85 Control group <i>n</i> = 80 | Exclusion criteria Laparoscopic procedures; respiratory status requiring FiO ₂ >35%; severe COPD; haemodynamically unstable before surgery; treatment with Bleomycin; ASA score 5 or 5E. | | | |

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up, effect size | Comments |
|-----------------------|-------------------------------|---|--|--|---|--|
| | | | | Comparison Peri-operative 80% FiO ₂ vs Peri-operative 35% FiO ₂ | 20/80 (25%) <u>Control group</u> 9/80 (11.3%) | O2 could be increased as required during procedure to maintain SaO ₂ >94% by pulse oximetry. |
| Belda (2005) 117 | RCT EL = 1+ | Total no. of patients n = 300 | Patients aged 18–80 years who underwent elective colorectal surgery | <u>Intervention group</u> 80% inspired oxygen intra-operatively and for 6 hours after surgery <u>Control group</u> 30% inspired oxygen intra-operatively and for 6 hours after surgery Comparison Peri-operative 80% FiO ₂ vs Peri-operative 30% FiO ₂ | Follow-up 14 days Outcome Surgical Site Infection Effect size <i>SSI rate</i> <u>Intervention group</u> 14.9% (22/148) <u>Control group</u> 24.4% (35/143) RR 0.61 (95% CI 0.38 to 0.98) After adjusting for confounding variables, RR 0.46 (95% CI 0.22 to 0.95) <i>Number of patients with ASEPSIS score >20 on any day</i> <u>Intervention group</u> 16.9% (25/148) <u>Control group</u> 25.9% (37/143) | Funding Institutional support, Air-LiquideMedicinal and Air-Liquide Sante' After randomisation nine patients were excluded; they were not included in the Analysis. |
| Spain | | Intervention group n = 150 Control group n = 150 | Exclusion criteria Minor colon surgery or laparoscopic surgery; expected time of surgery < 1 hour; fever or existing infection; diabetes mellitus; HIV infection; weight loss >20% in previous 3 months; serum albumin < 30 g/L; leucocyte count < 2500 cells/ml | | | |
| Whitney (2001) 120 | RCT EL = 1- | Total no. of patients n = 24 | Participants undergoing cervical fusion and/or excision of cervical intervertebral disk, between 18 and 80 yo, able to speak and write in English and to give informed consent, discharged from PACU without supplemental O ₂ . | <u>Intervention group</u> Supplemental FiO ₂ at 28% during the following 36 hours after discharge from the PACU <u>Control group</u> Standard treatment (room air) after discharged from the PACU Comparison Postoperative supplemental FiO ₂ vs. Standard care without supplemental FiO ₂ | Follow-up one Month Outcome Wound healing/Surgical Site Infection (ASEPSIS score > 20) Effect size <i>SSI rate</i> All patients had ASEPSIS score in range of satisfactory healing (0–10); no significant differences between mean scores of groups (data not shown). | Funding Not mentioned Unclear reporting |
| USA | | Intervention group n = 13 Control group n = 11 | | | | |

Perfusion

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|--|---|--|--|
| Kabon 2005 121 | RCT | Total no. of patients <i>n</i> = 256 | Patients from 18 to 80 years old undergoing open elective colon resection | <u>Intervention group</u> <i>Large fluid management:</i> - 10 ml/kg fluid bolus pre-anaesthesia - lactated Ringer 16–18 ml/kg/h during surgery and for the 1st hour after <u>Control group</u> <i>Small fluid management:</i> - lactated Ringer 8–10 ml/kg/h during surgery and for the 1st hour after Comparison Supplemental fluid therapy vs Standard care | Follow-up 15 days Outcomes - Surgical site infection (CDC definition criteria) - Wound healing (ASEPSIS score) - ICU admission - Hospitalisation <i>SSI rate</i> Intervention group: 8.5% Control group: 11.3% <i>P</i> = 0.462 <i>ASEPSIS score</i> Intervention group: 16 ± 7 Control group: 14 ± 8 <i>P</i> = 0.698 <i>ICU admission</i> Intervention group: 6.2% Control group: 2.4% <i>P</i> = 0.140 <i>Length Hospitalisation (days)</i> Intervention group: 7 ± 5.4 Control group: 7.3 ± 4 <i>P</i> = 0.7 | Funding Supported by several Austrian and US foundations and by US national grants |
| Country USA | EL = 1+ | <u>Intervention group</u> <i>n</i> = 131 <u>Control group</u> <i>n</i> = 125 | Exclusion criteria History of infection or fever, malignant hyperthermia, congestive heart failure, diuretic therapy, renal failure, pulmonary oedema. | | | |

Perioperative blood glucose control

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|--|---|---|--|--|
| Bilotta 2007 ¹²³ Italy | RCT EL = 1+ | Total no. of patients <i>n</i> = 78 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 40 <u>Control group</u> <i>n</i> = 38 | Patients with acute SAH admitted to a postoperative neurosurgical ICU after surgical clipping of intracranial aneurysm Exclusion criteria: No written inform consent; Endotracheal intubation; Rankin disability score > 1 | <u>Intervention group</u> <i>Intensive insulin therapy</i> (adjusted to maintain glycaemia within 80 and 120 mg/dl) <u>Control group</u> <i>Standard insulin therapy</i> (adjusted to maintain glycaemia within 80 and 220 mg/dl) Comparison <i>Intensive blood glucose control</i> vs <i>Standard blood glucose control</i> | Follow-up on the patient's discharge from the ICU or on postoperative day 14 (mean duration) Intensive insulin group: 9.2 ± 1.9 days Standard insulin group: 11.4 ± 1.7 days Outcome Overall infection –pneumonia, sepsis, urinary and wound infection (NNIS definition criteria) * Wound infection was reported as a percentage of the overall infection rate Effect size <i>Total infection rate</i> <u>Intervention group</u> 11/40 (27%) <u>Control group</u> 16/38 (42%) <i>P</i> < 0.001 Wound infection (% of total infection rate) <u>Intervention group</u> 11% <u>Control group</u> 13% | Funding Departmental research funds Comments other outcomes reported in the study: infection rate, mortality, vasospasm and neurological status Two patients in the intensive insulin group and four in the conventional insulin group were not given insulin therapy because blood glucose never exceeded the defined thresholds. The Surgical site infection outcome was unclearly reported |
| Grey 2004 ¹²² USA | RCT EL = 1- | Total no. of participants <i>n</i> = 61 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 34 <u>Control group</u> <i>n</i> = 27 | Adult patients of a general surgical ICU and requiring treatment for hyperglycaemia Exclusion criteria: No written informed consent; Patients expected to have a brief stay in the unit or not expected to survive beyond 48 hours; patients with active infections, disseminated cancer or receiving chemotherapy, irradiation or corticosteroids | <u>Intervention group</u> <i>Strict glucose control</i> (serum glucose values between 80–120 mg/dl) <u>Control group</u> <i>Standard control group</i> (serum glucose values between 180–220 mg/dl) Comparison <i>Strict blood glucose control</i> vs <i>Standard glucose control</i> | Follow-up n.s. (duration of the surgical ICU stay) Outcome SSI (CDC definition criteria) Effect size <u>SSI</u> Intervention group: 30% *estimated from histogram Control group: 7% *estimated from histogram | Funding Ns Comments Other outcomes reported in the study: serum glucose values and nosocomial infections (among which SSI) Exact SSI rates were not reported |

6.9 Wound irrigation and intracavity lavage

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|------------------------------------|--|--|---|-------------------------------------|
| Al-Shehri 1994 124 | RCT EL = 1+ | Total no of participants = 249 | Included: patients undergoing appendectomy through gridiron incision for clinically suspected acute appendicitis | Gp 1 Wounds irrigated with 100 ml of sterile normal saline at closure | Infection definition – presence of purulent discharge in the wound | Study duration: Not stated |
| Saudi Arabia | | Randomised into two treatment arms | Excluded: ampicillin allergy, diseases requiring systemic antibiotics | Gp 2 Wounds irrigated with 1 g ampicillin powder dissolved in 100 ml sterile normal saline | SSI – assessed within 30 days post-op Gp 1 7/132 | Funding: Not stated |
| | | Group 1 = 132 | Baseline characteristics: age, sex ratio, severity of appendicitis, duration of symptoms similar | Antibiotic prophylaxis given to both groups | Gp 2 1/117 | |
| Baker 1994 129 | RCT EL = 1+ | Total no of participants = 300 | Included: patients undergoing elective colorectal surgery | Gp 1 Peritoneal lavage with 250 ml of 2% tauridine in 5% polyvinyl pyrrolidone | Infection definition – spontaneous or incisional discharge from the wound of either pus or serous fluid, with an infective organism positively identified on culture. | Funding: Not stated |
| UK | | Randomised into two treatment arms | Excluded: no informed consent | Gp 2 250 ml normal saline | SSI – Between days 4–17 post op | Study duration: 89 to Jun 92 |
| | | Group 1 = 150 Group 2 = 150 | Baseline characteristics: similar for mean age, sex ratio, diagnosis, surgery types (except anterior resection) | Lavage solutions diluted with a further 250 ml saline, and suction applied after washout. Then a further 250 ml lavage solution applied to abdomen and left for at least 20 minutes. | Gp 1 17/133 Gp 2 17 /134 | |
| | | | | Antibiotic prophylaxis given to both groups | | |
| Buanes 1991 130 | RCT EL = 1- | Total no of participants = 43 | Included: patients with diagnosed perforated appendicitis and generalised peritonitis | Gp 1 Pts received 0.9% saline CPPL (closed postoperative peritoneal lavage) via soft drainage catheter 24 hours post op – 1 litre × 20 for pts > 1 year, 0.5 litre × 20 for pts < 12 years | Infection definition – temp >38.5° C and localised drainage-confirmed accumulation of fluid in the abdominal incision | Study duration: Oct 1984 to 1987 |
| Norway | | Randomised into two treatment arms | Excluded: Age < 6 years, pregnancy, allergy to ampicillin or tinidazole, localised infiltration or abcess around appendix. | Gp 2 No CPPL | SSI – throughout hospitalisation, @ day 14 and @ 6 weeks post-op (pt observation) | Funding: Not stated |
| | | Group 1 = 39 Group 2 = 44 | Baseline characteristics: age, duration of symptoms, length of time to operation and sex ratio similar | CPPL intervention was prematurely discontinued in 10/39 patients | Gp 1 = 9/39 Gp 2 = 2/44 | |
| | | | | Antibiotic prophylaxis and intraoperative saline irrigation given to both groups | | |

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|--|--|---|--|--|
| Cervantes- Sanchez 2000 125 Mexico | RCT EL = 1+ | Total no of participants = 350 Randomised into two treatment arms Group 1 = 175 Group 2 = 175 | Included: adults and children admitted with acute abdomen suggestive of acute appendicitis. Excluded: Age < 5 years, allergy to metronidazole or aminoglycosides, antibiotic therapy within preceding 72 hours, pregnancy, other intraperitoneal bacterial infection, immune deficiency Baseline characteristics: Sex ratio similar, mean age Gp 1 = 20.09 years Gp 2 = 29.1 years, more uncomplicated appendicitis in Gp1 | Gp 1 No wound syringe pressure irrigation Gp 2 Wound syringe pressure irrigation – of subcutaneous fat tissue with 300 ml normal saline applied with 'standard' force Antibiotic prophylaxis given to both groups | Infection definition – a collection of pus or a positive bacteriologic culture from a wound discharge SSI – daily inspection until discharge then at 2 and 4 weeks Gp 1 = 39/156 Gp 2 = 11/127 | Study duration: Jul 1994 – Feb 1995 Funding: Not stated |
| Eklund 1987 126 Sweden | RCT EL = 1+ | Total no of participants = 510 Randomised into two treatment arms Group 1 = 257 Group 2 = 253 | Included: patients over 12 years undergoing acute appendectomy through a grid iron incision Excluded: pts with perforated appendix (surgeon's judgement), antibiotic usage for another condition, appendectomy + other surgery (except simple removal of ovarian cyst) Baseline characteristics: age and sex similar | Gp 1 Standard tinidazole solution for intravenous administration Gp 2 Saline solution After suture of peritoneum, exposed muscles and subcutaneous tissues were washed with 200 ml of test solution | Infection definition – visible discharge of pus either spontaneously or after debridement SSI – reported by wards, outpatient clinic, emergency unit and from patient questionnaire (after 3 weeks) Gp 1 = 13/257 Gp 2 = 5/253 | Study duration: 27 months ending in 1983 Funding: Pfizer AB provided solutions of tinidazole and saline |
| Farnell 1986 127 USA | RCT EL = 1+ | Total no of participants = 3282 Randomised into four treatment arms Group 1 = 803 Group 2 = 836 Group 3 = 828 Group 4 = 815 | Included: Patients undergoing abdominal operations with clean-contaminated, contaminated or dirty wounds 3,282 incisions; Excluded: Clean wounds; allergy to povidone, iodine, neomycin, polymyxin or gentamicin; laparotomy in previous 12 weeks; vascular, urologic or gynaecological procedures Baseline comparability: not stated | Gp 1 Primary closure Gp 2 Subcutaneous catheter and irrigation with saline Gp 3 Subcutaneous catheter and irrigation with DAB Gp 4 Subcutaneous catheter only, no irrigation | Wound infection defined – drainage of purulent material or culture positive SSI – Assessed alternate days until discharge, 6–8 weeks post discharge Assessor: nurse Wound infection: Gp 1 41/803 Gp 2 36/836 Gp 3 39/828 Gp 4 45/815 | Funding: Not stated |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-------------------------------|-------------------------------|---|---|--|--|--|
| Freischlag 1984 131 USA | RCT EL = 1+ | Total no of participants = 88 Randomised into three treatment arms Group 1 = 36 Group 2 = 26 Group 3 = 26 | Included: pts over 18 year undergoing elective biliary operations Excluded: < 18 years, cephalosporin allergy, antimicrobial therapy 72 hours pre study entry, pregnancy, known contamination of the abdominal cavity Baseline characteristics: age, operating time, underlying diseases similar (except cardiovascular/hypertension >in Gp 1 and Crohns > in Gp 1) | Gp 1 Cefamandole nafate 2 g IV pre-op, then 2 g IV every 6 hours post op for four doses Gp 2 Cefamandole nafate 0.4% solution (4 g in 1 litre saline) intra-op: 250 ml irrigate abd wound on opening, 500 ml irrigate sub-hepatic space intra-op, 250 ml to irrigate the wound on closing. Gp 3 Pts received both IV and topical schedules for Gp1 and Gp2 Saline irrigations were used at surgeon's discretion in all groups | Infection definition – spontaneous or surgical drainage of pus SSI – assessment up to 30 days post-op Gp 1 0/36 Gp 2 1/26 Gp 3 1/26 | Study duration: 1979 – 1983 Funding: Eli Lilly |
| Galandiuk 1991 248 USA | RCT EL = 1+ | Total no of participants = 200 Randomised into two treatment arms Group 1 = 106 Group 2 = 94 | Included: Pts undergoing rectal resection for Ca, IBD, diverticulitis, or other. Pts undergoing proctectomy for IBD or Ca Excluded: Pts requiring haemostatic pelvic packs or relaparotomy before removal of sump drains or those participating in antibiotic trials, Baseline characteristics: diagnoses, procedures similar | Gp 1 (135 wounds) Irrigation and drainage Post-op irrigation for at least 24 hours (125 ml saline/hr) or until clear, then drains on low intermittent suction, removed when < 50 ml in 24 hours Gp 2 (118 wounds) Drainage only Drains on low wall suction, removed when < 50 ml in 24 hours <i>Irrigation did not function ideally in 31% of Gp 1</i> Antibiotic prophylaxis given to both groups | Infection definition – not given SSI – perineal and abdominal wound infections, no assessment details Gp 1 12/135 wounds Gp 2 12/118 wounds | Study duration: July 1985 to Aug 1987 Funding: Not stated |
| Grieg 1987 132 UK | RCT EL = 1+ | Total no of participants = 129 Randomised into two treatment arms Group 1 = 65 Group 2 = 64 | Included: pts undergoing elective and emergency colorectal surgery Excluded: not stated Baseline characteristics: similar for mean age, sex, mean weight, diagnosis, cardiovascular or respiratory disease, degree of contamination, elective to emergency procedures | Gp 1 1 litre saline lavage Gp 2 1 litre saline with 1 g cefotetan lavage Antibiotic prophylaxis given to both groups | Infection definition – discharge of pus from the wound SSI – assessed during hospital stay and @ 1 month post-op Gp 1 18/65 Gp 2 15/64 | Study duration: Not stated Funding: Not stated |

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---|-------------------------------|--|--|--|---|---|
| Hargrove 2006 143 UK | RCT EL = 1- | Total no of participants = 356 Randomised into two treatment arms Group 1 = 192 Group 2 = 164 | Included: all patients with a displaced intracapsular fractured neck of femur, due to be treated with a hemiarthroplasty. Excluded: patients assigned to receive pulse lavage treatment but who did not receive it (n = approx 28). Baseline characteristics: Not stated, and an additional potential bias in no description (or separate analysis) being available for the number of patients in each group undergoing 'Austin Moore' type implantation where no pulsed lavage was given, even if assigned. | Group 1 n = 192 2 litres normal saline wash delivered by a jug or a syringe according to the surgeon's preference Group 2 n = 164 2 litres normal saline wash delivered via pulsatile lavage in stages through the procedure except for those patients receiving an 'Austin Moore' uncemented implantation who did not receive pulsed lavage, even if assigned. | Infection definition – an assessor reviewed patient wounds twice weekly until discharge and classified as superficial or deep SSI incidence <i>Overall</i> Group 1 30/192 (10 deep SSIs, 20 superficial SSIs) (15.6% overall infection rate) Group 2 9/164 (3 deep SSIs, 6 superficial SSIs) (5.6% overall infection rate) 15.6% vs 5.6% overall infection rate P = 0.002 <i>Deep infection</i> Group 1 10/192 (5.2%) Group 2 3/164 (1.8%) P = 0.009 | Study duration: Over an 18 month period, dates not given Funding: Not stated |
| Johnson 1985 133 UK | RCT EL = 1+ | Total no of participants = 56 Randomised into two treatment arms Group 1 = 28 Group 2 = 28 | Included: Pts undergoing abdomino-perineal excision of the rectum for Ca Excluded: not stated Baseline characteristics: age, sex similar | Gp 1 Irrigation of the perineal space with 50 ml 1% PVP-I Gp 2 Irrigation of the perineal space with 50 ml sterile normal saline Irrigation in both groups repeated 8 hourly until day 5 post-op No antibiotic prophylaxis given | Infection definition – any wound discharge from which microorganisms were cultured or which appeared to be frankly purulent SSI – no assessment details given Gp 1 10/28 Gp 2 21/28 | Study duration: 1975–1980 Funding: Not stated |
| Kubota 1999 134 Japan | RCT EL = 1- | Total no of participants = 16 Randomised into two treatment arms Group 1 = 8 Group 2 = 8 | Included: children (2–12 years) with perforated appendicitis and generalised peritonitis or nonlocalised abscess Excluded: not stated Baseline characteristics: severity of illness similar | Gp 1 n = 8 Lavage with 100 ml/kg (1.5–4 litres) normal saline Gp 2 n = 8 Lavage with 100 ml/kg (1.5–4 litres) acidic oxidative potential water | Infection definition – not stated SSI – no assessment details given Gp 1 4/8 Gp 2 1/8 | Study duration: Not stated Funding: Not stated |
| Antibiotic prophylaxis given to both groups | | | | | | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|--|--|---|
| Magann 1993 135 | RCT EL = 1+ | Total no of participants = 100 | Included: women undergoing caesarean section | Gp 1 Preop skin prep with povidone-iodine or parachlorometaxylenol and intraop saline irrigation of pelvis and subcutaneous tissue at uterine and fascial closure | Infection definition – subcutaneous infection ; hyperemic skin incision and fluctuant mass when opened contained purulent material SSI – no further assessment details given | Study duration: Not stated |
| USA | | Randomised into two treatment arms Group 1 = 50 Group 2 = 50 | Excluded: presence of chorioamnionitis at caesarean, emergency caesarean for foetal distress with no time for skin prep, patient refusal following consent Baseline characteristics: age, race, gravidity, operative time, caesarean indications, uterine incision type, no of repeat elective caesareans similar | Gp 2 Preop skin prep with povidone-iodine or parachlorometaxylenol and intraop 1 g cefazolin in 500 ml saline solution of pelvis and subcutaneous tissue at uterine and fascial closure | Gp 1 4/50 Gp 2 2/50 | Funding: Not stated |
| Rambo 1972 136 | RCT EL = 1+ | Total no of participants = 94 | Included: Pts whose surgeons believed that irrigation would be helpful for peritoneal cavity cleansing or direct application of an antibiotic to a grossly contaminated peritoneum | Gp 1 Irrigation with 4 litres or 2 litres of cefalotin 4 g/l solution Gp 2 Irrigation with 4 litres or 2 litres of 0.9% saline with multivitamin solution | Infection definition – not given SSI – no assessment details given | Study duration: Oct 1968 to April 1971 |
| USA | | Randomised into two treatment arms Group 1 = 44 Group 2 = 50 | Excluded: not stated Baseline characteristics: diagnosis, age, positive sultures, secondary wound closure, obesity, DM, steroid use, shock, drains, renal failure similar | | Gp 1 11/44 Gp 2 13/50 | Funding: not stated |
| Sauven 1986 137 | RCT EL = 1+ | Total no of participants = 542 | Included: Pts undergoing elective or emergency abdominal operations | Gp 1 1 g latamoxef in 10 ml water IV Gp 2 Peritoneal and parietal irrigation with 1 g tetracycline in 1 litre saline (up to 7 L) | Infection definition – discharge of pus or constitutional disturbance with delayed hospital release SSI – inspected during hospitalisation or at 4 weeks post op (patient assessment) | Study duration: July 1983 to June 1984 |
| UK | | Randomised into two treatment arms Group 1 = 270 Group 2 = 272 | Excluded: < 12 years, elective herniorrhaphy, sensitivity to cephalosporins Baseline characteristics: sex ratio, mean age, obesity, malignancy, emergency and consultant operator similar | Antibiotic prophylaxis given to both groups | Gp 1 17/212 Gp 2 36/219 | Funding: |

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|---|--|--|--------------------------------------|
| Schein 1990 138 | RCT EL = 1+ | Total no of participants = 87 | Included: Patients with confirmed localised or generalised peritonitis | Gp 1 All peritoneal contamination sucked out and cavity swabbed gently with large abdominal swabs | Infection definition – discharge of pus from the wound | Study duration: Jan 1986 to Dec 1987 |
| South Africa | | Randomised into three treatment arms Group 1 = 29 Group 2 = 29 Group 3 = 29 | Excluded: Non ruptured localised abscesses, appendectomy through right iliac fossa incisions, diffuse faecal peritonitis, infected pancreatic necrosis, postop peritonitis Baseline characteristics: sex ratio, mean age, mean hospital stay, mortality, source of peritonitis and APACHE scores similar | Gp 2 All peritoneal contamination sucked out and cavity irrigated with > 5 litres saline soln Gp 3 All peritoneal contamination sucked out and cavity irrigated with > 5 litres saline soln with 2 g chloamphenical added to last litre of soln | SSI – no assessment details given Gp 1 6/29 Gp 2 5/29 Gp 3 5/29 | Funding: Not stated |
| Sherman 1976 139 | RCT EL = 1+ | Total no of participants = 79 | Included: Children (13 months to 16 years) with perforated appendicitis and established peritonitis | Gp 1 Peritoneal cavity and wound irrigated with 0.25% kanamycin soln (up to 0.5 litres), before peritoneum closure | Infection definition – not stated SSI – no assessment details given | Study duration: Apr 1969 to Jul 1974 |
| USA | | Randomised into two treatment arms Group 1 = 36 Group 2 = 43 | Excluded: not stated Baseline characteristics: not stated | Gp 2 Peritoneal cavity and wound irrigated with 0.25% normal saline soln (up to 0.5 litres), before peritoneum closure Antibiotic prophylaxis and peritoneal of wound drainage at discretion of surgeon | Gp 1 5/36 Gp 2 6/43 | Funding: not stated |
| Silverman 1986 140 | RCT EL = 1+ | Total no of participants = 163 | Included: Pts undergoing elective or emergency transperitoneal intestinal surgery (small bowel, colon and rectum) | Gp 1 Peritoneal lavage with 2 litres 0.9% sterile saline with 2 g tetracycline | Infection definition – discharge of pus from the wound | Study duration: 16 months |
| UK | | Randomised into two treatment arms Group 1 = 89 Group 2 = 74 | Excluded: not stated Baseline characteristics: age and sex ratio, diagnosis, procedure and antibiotic prophylaxis similar | Gp 2 Peritoneal lavage with 2 litres 0.9% sterile saline 2 minute lavage and then sump sucker applied Antibiotic prophylaxis given to both groups | SSI – assessment during hospitalisation and at 6 weeks post-op Gp 1 10/85 Gp 2 24/74 | Funding: Not stated |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No of participants | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|--|---|---------------------------------|
| Sindelar 1985 141 | RCT EL = 1+ | Total no of participants = 75 | Included: Patients over 18 undergoing surgical procedures likely to encounter bacterial contamination of the peritoneal cavity (contaminated or dirty) | Gp 1 n = 37 Intraperitoneal irrigation with 10% PVP-I LMW in saline 1 litre x3 intra-op | Infection definition – not given SSI – no assessment details given | Study duration: Not stated |
| USA | | Randomised into two treatment arms Group 1 = 37 Group 2 = 38 | Excluded: iodine sensitivity, thyroid disease, renal insufficiency, surgery involving ischaemic or necrotic tissues Baseline characteristics: no of patients, sex ratio, age, emergency/elective operations, duration of surgery, use of surgical drains, time of post-op hospitalisation and use of peri-op systemic antibiotics similar | Gp 2 n = 38 Intraperitoneal irrigation with saline 1 litre x3 intra-op – 4 protocol violations Suction of irrigant for 30–60 seconds after instillation | Gp 1 1/37 Gp 2 3/38 | Funding: Not stated |
| Sindelar 1979 141 | RCT EL = 1+ | Total no of participants = 500 | Included: patients undergoing general surgery | Gp 1 Subcutaneous tissues irrigated for 60 s with 10% povidone-iodine solution | Infection definition – discharge of any amount of pus | Study duration: Not stated |
| USA | | Randomised into two treatment arms Group 1 = 242 Group 2 = 258 | Excluded: amputations for ischaemic disease, abscess drainage, skin grafting, anorectal procedures Baseline characteristics: Age and sex ratio similar | Gp 2 Subcutaneous tissues irrigated for 60 s with saline Antibiotic prophylaxis given to both groups except for 'clean' category procedures | SSI – examined daily for 7 days then weekly up to 12 weeks Gp 1 7/242 Gp 2 39/258 | Funding: Not stated |
| Toki 1995 142 | RCT EL = 1+ | Total no of participants = 53 | Included: children with perforated appendicitis | Gp 1 Aggressive peritoneal lavage with 1 to 8 litres of saline | Infection definition – none given | Study duration: 1984 to 1993 |
| Japan | | Randomised into two treatment arms Group 1 = 29 Group 2 = 24 | Excluded: moribund dehydration with electrolyte imbalance (pts rehydrated) Baseline characteristics: age, intestinal flora, peritonitis grade, sex ratio similar | Gp 2 Peritoneal drainage with silicon and Penrose drains All wounds irrigated with povidone-iodine | SSI – no assessment details given Gp 1 2/29 Gp 2 6/24 | Funding: Not stated |

6.10 Antiseptic and antimicrobial agents before wound closure

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|---|--------------------------------|--|---|---|--|---|
| Cordtz 1989 ¹⁴⁴ Denmark | Multicentre RCT EL = 1+ | Total no. of patients <i>n</i> = 1340 Randomised in four arms: <i>With re-disinfection and with incise drape n</i> = 325 <i>Without re-disinfection and with incise drape n</i> = 337 <i>With re-disinfection and without incise drape n</i> = 324 <i>Without re-disinfection and without incise drape n</i> = 354 | Post-caesarean patients Exclusion criteria History of sensitivity to iodine | Intervention <i>Iodine re-disinfection</i> (disinfection of the skin around the incision shortly before skin closure with 2.5% iodine in 70% ethanol) Comparison 1 <i>Re-disinfection (incise drape)</i> vs <i>No Re-disinfection (incise drape)</i> Comparison 2 <i>Re-disinfection (no incise drape)</i> vs <i>No Re-disinfection (no incise drape)</i> | Follow-up 14 days Outcome SSI – Localised erythema and/or serous secretion without presence of pus (possibly infected) / presence of pus (infected) Effect size SSI Comparison 1 <i>Re-disinfection (drape) 41/325</i> <i>No Re-disinfection (drape) 58/337</i> Comparison 2 <i>Re-disinfection (no drape) 31/324</i> <i>No Re-disinfection (no drape) 43/354</i> | Funding ns Comments Baseline comparability non reported and allocation concealment unclear |
| Gray 1981 ¹⁴⁶ UK | RCT EL = 1+ | Total no. of participants <i>n</i> = 156 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 71 <u>Control group</u> <i>n</i> = 82 | Adult patients undergoing elective abdominal surgery Exclusion criteria Allergy to iodine Emergency cases | Intervention <i>Iodine application</i> (following closure of the peritoneum wound spraying with povidone-iodine dry powder) Comparison <i>Povidone-iodine application to the wound</i> vs <i>No povidone-iodine application</i> | Follow-up Two weeks Outcome SSI (CDC definition criteria) Effect size SSI <u>Intervention group</u> 7/71 (9.9%) <u>Control group</u> 20/82 (24.4%) | Funding Ns Comments Infection classified as major with copious purulent discharge and minor with scanty discharge of pus (we have considered both) |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|--|---|--|--|--|
| Walsh 1981 ¹⁴⁸ Australia | RCT EL = 1+ | Total no. of participants <i>n</i> = 627 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 308 <u>Control group</u> <i>n</i> = 319 | Adult patients undergoing abdominal surgery Exclusion criteria No details | Intervention <i>Iodine application</i> (following closure of the peritoneum wound spraying with povidone-iodine solution) Comparison <i>Povidone-iodine application to the wound</i> vs <i>No povidone-iodine application</i> | Follow-up One month Outcome SSI (purulent discharge or sero-sanguinous discharge positive on culture) Effect size SSI <u>Intervention group</u> 28/308 (9%) <u>Control group</u> 40/319 (12%) <i>SSI by classification of operation</i> Clean <u>Intervention group</u> 2/59 (3%) <u>Control group</u> 6/63 (10%) Potentially infected <u>Intervention group</u> 21/232 (9%) <u>Control group</u> 25/232 (11%) Dirty <u>Intervention group</u> 5/17 (29%) <u>Control group</u> 9/24 (38%) | Funding FH Faulding and Company Comments |
| Sherlock 1984 ¹⁴⁷ UK | RCT EL = 1+ | Total no. of participants <i>n</i> = 75 Randomised in two arms: Intervention group <i>n</i> = 39 Control group <i>n</i> = 36 | Adult patients with established perforated or gangrenous appendicitis Exclusion criteria ABT prior to hospital admission; pregnant women; persons less than 18 years old | Intervention <i>Iodine application</i> (following closure of the peritoneum wound spraying with povidone-iodine) Comparison <i>Povidone-iodine application to the wound</i> vs <i>No povidone-iodine application</i> | Follow-up four weeks Outcome SSI mild infection = erythema of wound with serious discharge (microscopy confirmed pus cells) + severe infection = purulent discharge or culture of pathologic organisms in any discharge Effect size SSI <u>Treatment group</u> 6/39 <u>Control group</u> 13/36 | Funding Ns Comments The trial had three arms, the two reported and relevant for our study and a third (<i>n</i> = 40) were patients were given im. ABT +povidone-iodine Re-disinfection and was therefore excluded because it considered two variables |

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|---|---|--|---|--|--|--|
| Harihara 2006 ¹⁴⁵ Japan | RCT EL = 1+ | Total no. of participants <i>n</i> = 107 Randomised in two arm: <u>Intervention group</u> <i>n</i> = 71 <u>Control group</u> <i>n</i> = 82 | Adult patients undergoing colorectal and gastric surgery Exclusion criteria No details | Intervention <i>Iodine skin application</i> (povidone-iodine applied to the skin around the incision just before skin closure) Comparison <i>Povidone-iodine skin application</i> vs <i>No povidone-iodine skin application</i> | Follow-up No details Outcome SSI (JNIS definition criteria) Effect size SSI <u>Intervention group</u> 8/54 <u>Control group</u> 8/53 | Funding Ns Comments JNIS system = Japanese modification of the CDC NNIS system |
| Eklund 2005 ¹⁴⁹ Finland | RCT EL = 1+ | Total no. of participants <i>n</i> = 542 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 272 <u>Control group</u> <i>n</i> = 270 | Adult patients undergoing CABG surgery Exclusion criteria Allergy to gentamicin or to multiple drugs, severe renal insufficiency, previous kidney transplant or a redo procedure, foreigners. | Intervention A 10 cm × 10 cm gentamicin-collagen implant (130 mg gentamicine+280 mg collagen) underneath the sternum before wound closure Comparison <i>Gentamicin-collagen implant</i> vs <i>No implant</i> | Follow-up Three months Outcome SSI (CDC definition) Effect size SSI <u>Intervention group</u> 11/272 (4%) <u>Control group</u> 16/270 (5.9%) | Funding Schering Plough Corporation and by Helsinki University Central Hospital Comments Three participants deceased in the gentamicin group and one in the control group; they were included in the analysis |
| Friberg 2005 ¹⁵⁰ Sweden | RCT (conducted in two cardiothoracic centres) EL = 1+ | Total no. of participants <i>n</i> = 1950 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 983 <u>Control group</u> <i>n</i> = 967 | Patients undergoing cardiac surgery through median sternotomy, Exclusion criteria Allergy to gentamicin, pregnancy or breastfeeding, treatment with aminoglycosides during the last two weeks before surgery, expected difficulty in fulfilling the follow-up, no written inform consent | Intervention Two 10 cm × 10 cm gentamicin-collagen implant (130 mg gentamicine+280 mg collagen) underneath the sternum before wound closure Comparison <i>Gentamicine-collagene implant</i> vs <i>No implant</i> | Follow-up Two months Outcome SSI (CDC definition) Effect size SSI <u>Intervention group</u> 42/983 (4.3%) <u>Control group</u> 87/967 (9%) OR 0.47, 95% CI 0.33 to 0.68 <i>P</i> < 0.001 | Funding Schering Plough Corporation and by grants from the Research Committee of Orebro County Council Comments Four infections diagnosed after the two months follow-up and included in the analysis |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|--|--|---|--|--|---|--|
| Moesgaard 1989 ¹⁵¹ Denmark | RCT (conducted in three participating centres) EL = 1+ | Total no. of participants <i>n</i> = 178 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 87 <u>Control group</u> <i>n</i> = 91 | Patients undergoing intra-abdominal operation with generalised or localised peritonitis Exclusion criteria hypersensitivity to cephalosporins or metronidazole, antimicrobial drugs within four days before surgery, pregnancy, immunologic defects, < 13 years old | Intervention Intraincisional A/B prophylaxis (cefotaxime 2 g applied topically to the subcutaneous layer at the time of wound closure) Comparison <i>Intraincisional A/B</i> vs <i>No intraincisional A/B</i> | Follow-up One month Outcome SSI (accumulation of pus, draining spontaneously or after opening the wound) Effect size SSI <u>Intervention group</u> 15/87 (17%) <u>Control group</u> 14/90 (16%) | Funding Schering Plough Corporation and by grants from the Research Committee of Orebro County Council Comments Three patients excluded after randomisation and not included in the analysis, another participant missing in the control group. |

6.11 Closure methods

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--------------------------|----------------------------------|--|--|--|---|----------------------|
| Anderson 2004 197 | Systematic review EL = 1+ | <p>Five trials reported wound infection outcomes (Allaire 2000, Cetin 1997, Chelmow 2002, Magann 2002 and Naumann 1995).</p> <p>Allaire 2000 (USA 1995–97) Included: 76 women undergoing caesarean section and > 2 cm subcutaneous fat (26 closure gp, 50 non closure gp) Wounds assessed prior to discharge and @ 7–10 days post-partum</p> <p>Cetin 1997 (Turkey 1995–97) Included: 164 women undergoing caesarean section (unclear how many women randomised to each treatment gp) Wounds assessed during hospital admission</p> <p>Chelmow 2002 (USA 1995–97) Included: 327 women undergoing caesarean section (162 closure gp, 165 non-closure gp) Wounds assessed 4–8 weeks post-partum</p> <p>Magann 2002 (USA 1998–2001) Included: 590 women eligible – undergoing caesarean section and >2 cm subcutaneous fat – 191 closure gp, 399 non-closure gp Unclear when wounds were assessed</p> <p>Naumann 1995 (USA 1991–93) Included: 245 women undergoing caesarean section and >2 cm subcutaneous fat – 117 closure gp, 128 non-closure gp. Wounds assessec at discharge and at 7–10 days post-partum</p> | <p>Population: Participants were women undergoing caesarean section</p> <p>Five RCTs with 1348 female participants</p> | <p>During caesarean section:</p> <p>Group 1 Sutured closure of subcutaneous fat layer (including Camper's fascia)</p> <p>Group 2 Non-closure of subcutaneous fat layer (including Camper's fascia)</p> | Total RR 1.02, 95% CI 0.69 to 1.50, $P = 0.9$ and $I^2 = 0.0\%$ | Funding = not stated |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------------|-------------------------------|---|--|---|--|---|
| Study: Beresford 1993 179 | RCT EL = 1- | Total no. of participants n = 94 Intervention group n = 48 Control group n = 46 | Inclusion: patients having elective abdominal hysterectomies Exclusion: Other surgical procedure, not low transverse incision, prophylactic antibiotics required | Group 1 Absorbable staples Group 2 Sutures | Wound infection not defined Assessed at: 6 & 18 weeks Assessor: not stated Wound infection: Group 1: 5/48 (11%) Group 2 4/46 (9%) | Centres: Single |
| Setting: Canada | | | | | | |
| Study: Bhatia 2002 167 | RCT EL = 1- | Total no. of participants n = 31 Group 1 n = 13 Group 2 n = 18 | Inclusion: 31 patients having surgery for Dupuytren's contracture, mean age 61 years Exclusion: Not stated Baseline comparability: Not stated Loss to follow-up: none | Group 1 Staples Group 2 Interrupted sutures | Wound infection defined on 1-10 scale, not clearly defined A Assessed at: 7 & 14 days Assessor: not stated Wound infection: Group 1: 0/13 Group 2: 1/18 | Centres: Single Years: 2000- 2001 |
| Setting: UK | | | | | | |
| Buchweitz 2005 156 | RCT EL = 1+ | Total no. of participants n = 104 Group 1 n = 52 Group 2 n = 52 Group 3 n = 23 | Inclusion criteria: Laparoscopic surgery with at least two 5-mm ports in the lower abdomen and lacking previous abdominal operations Exclusion criteria: intraoperative enlargement of port sites for intact specimen extraction Age: Mean 33 ± 6.7 years Loss to follow up: 8/60 Infection recording period: complications noted during hospital stay and afterwards a questionnaire sent before 3 months postoperative appt Baseline comparability: no details given. | Intervention: At least 2 port closures per patient recorded Group 1 Subcutaneous absorbable suture 4-0 polyglactin 910 Group 2 Transcutaneous absorbable suture 4-0 polyglactin 910 Group 3 Where a third trocar wound was made, adhesive paper tape (Steri-Strip) | Outcomes Wound infection 1) 4/52 2) 1/52 3) 1/23 Wound dehiscence 1) 2/52 2) 0/52 3) 1/23 | Study Duration: Oct 2002 – Sep 2003 Funding: Not stated |
| Study Location: Germany | | | | | | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|---|--|---|---|---|
| Cameron 1987 180 Setting: UK | RCT EL = 1+ | Total no. of participants n = 301 Group 1 n = 143 Group 2 n = 141 | Incision: Patients undergoing emergency and elective laparotomy by vertical abdominal incision under the care of three consultants Exclusions: re-operations through same excision excluded Type of wound: gastric = 31.5%, biliary = 48.3%, colonic = 38.6%, other = 35.9% Age: Mean 61 years Baseline comparability: Excess colonic surgery in Prolene group otherwise well balanced | Group 1 No 1 gauge polydioxanone (PDS) (; 69.9% completed) Group 2 No 1 polypropylene (Prolene) (63.8% completed) 17 patents excluded due to death or re-operation within 14 days, group assignment not reported Interrupted mass figure-of-eight suture beginning and ending beneath rectus sheath to bury knots, skin closed with clips or nylon, most patients received subcutaneous heparin, bowel preparation and antibiotic prophylaxis according to surgeon's usual practice. Study duration: Minimum 12 months follow-up, mean 14.7 months | Wound infection defined as: discharge of pus within one month postoperative period Assessed at: up to 1 month post op by 1 registrar blind to method of closure Assessor: House officers Outcomes: SSI rate: Group 1 – 12/143 Group 2 – 21/141 P = 0.11 Wound dehiscence: 1/143 Group A 9/141 Group B No significant difference P=>0.05 | Centres: Single Years: dns |
| Cardosi 2006 162 Study location: USA | RCT EL = 1+ | Total no. of participants n = 225 Group 1 n = 77 Group 2 n = 78 Group 3 n = 67 | Inclusion criteria: patients undergoing elective pelvic surgery through a vertical midline incision with presumed subcutaneous thickness of 3 cm or more Exclusion criteria: patient unable to provide consent, >24 hours preoperative hospitalisation, laparotomy after unsuccessful laparoscopy or vaginal surgery Age: range 28 to 84 years Baseline comparability: details given. Age, height, weight, race, risk factors no statistical significance found. Of seven pre-op diagnoses, two significant differences – uterine ca higher in control gp and benign ovarian neoplasm higher in suture gp. | Interventions Gp 1 = closure of skin only Gp 2 = approximation of Camper's fascia with a running 00 polyglactin suture Gp 3 = closed suction drainage of the subcutaneous space exiting through a separate stab incision All skin closure with staples All participants given antibiotics | Outcomes Infection recording period: postoperatively, observations daily during hospitalisation the at outpatients at 2 and 6 weeks Cellulitis defined as erythema and tenderness requiring antibiotic treatment. Gp 1 = 4/77 Gp 2 = 3/78 Gp 3 = 1/67 Wound disruption defined as an open (spontaneous or iatrogenic) postoperative wound Gp 1 = 9/77 Gp 2 = 6/78 Gp 3 = 10/67 | Study duration: July 2000 to June 2002 Funding: not stated |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|----------------------------|-------------------------------|--|---|--|---|-----------------------------------|
| Study: Carlson 1995 168 | RCT EL = 1+ | Total no. of participants n = 225 Group 1 n = 112 Group 2 n = 113 | Inclusion: Patients undergoing laparotomy through vertical midline incision, elective and emergency procedures (clean and clean-contaminated wounds), Excluded: patients with less than 2 years life expectancy, peritonitis and pre-existing ventral hernia. Type of wound: as above Age: dns Baseline comparability: Procedure status (elective v emergency) wound class and presence or absence of colon procedure not different between groups, no other baseline data reported | Group 1 0-looped nylon (Ethilon) 82% completed Group 2 0-looped polyglyconate (Maxon) 72% completed Running mass closure by Senior or Chief residents incorporating both layers of rectus sheath, technique for skin closure surgeon choice, prophylactic antibiotics for clean-contaminated cases, Study duration: 2 years | Wound infection not defined Assessed at: 2 and 6 weeks, 6 and 12 months, and 2 years, Assessor: Outcomes: Early postoperative wound complications (including infection and dehiscence), dehiscence SSI rate: Group 1: 4/112 Group 2: 2/113 No statistically significant difference Wound dehiscence: Group 1: 3/112 Group 2: 0/113 P=>0.05. | Centres: Single Years: dns |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--------------------------------|-------------------------------|---|--|---|---|----------|
| Chughtai 2000 186 Canada | RCT EL = 1- | Total no. of participants <i>n</i> = 162 Group 1 <i>n</i> = 81 Group 2 <i>n</i> = 81 | Inclusion: patients undergoing coronary artery bypass grafting (elective or emergency) Exclusion: Not stated Baseline comparability: yes except clip group had more women (32.1% vs 17.3%, <i>P</i> = 0.03) and more patients with diabetes (29.6% vs 16.0%, <i>P</i> = 0.04) Loss to follow-up: Not stated | Group 1: Sternal and leg incisions closed with clips Group 2: Sternal and leg incisions closed with subcuticular sutures | Wound infection Sternal wound infection (redness plus discharge or wound required re-opening or patient required antibiotics): Assessed at: not stated Assessor: not stated Sternal wound infection Group 1: 2/81 (2.5%) Group 2: 1 (1.2%) , <i>P</i> = 0.55 Mediastinitis: Group 1: 1/81 (1.2%) Group 2: 1/81 (1.2%) <i>P</i> = 0.99 Leg wound infection (assessed 3–6 weeks post discharge by same surgeon): Group 1: 1/81 (1.2%) Group 2: 2/81 (2.5%) <i>P</i> = 0.58 At follow-up (final denominators not stated): Sternal wound infection: Group 1: 6/81 (7.4%) Group 2: 1 (1.2%) <i>P</i> = 0.05. Sternal wound dehiscence: 4 (4.9%) vs 2 (2.5%), <i>P</i> = 0.39 Mediastinitis: Group 1: 2/81 (2.5%) Group 2 0/81 <i>P</i> = 0.15 Leg wound dehiscence: 7 (8.6%) in A vs 8 (9.9%) in B, <i>P</i> = 0.77 Leg wound infection: Group 1: 9/81 (11.1%) Group 2: 9/81 (11.1%) <i>P</i> = 0.98 | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------------------|-------------------------------|--|--|--|--|------------------------------------|
| Dowson 2006 169 Setting: UK | RCT EL = 1- | Total no. of participants n = 168 Group 1 n = 58 Group 2 n = 61 | Inclusion: All patients undergoing laparoscopic general surgical procedures Exclusion: Diabetes, corticosteroid use, keloid scarring, cyanoacrylate allergy, previous radiation treatment, surgery in last month causing scar 1 cm from intended incision site, >5 cm wound without deep layer sutures, pregnant women or trying to conceive, emergency surgery, ASA score 4/5, mentally incapacitated patients, unable to give consent Baseline comparability: similar for age, sex, procedure, no of incisions, incisional length Sample size = 168 Power calculation – yes Loss to follow up at 4 weeks – 35 | Gp 1 n-butyl-cyanoacrylate tissue adhesive applied to laparoscopy wound avoiding subcutaneous layers, held for 20–30 s. Wound not routinely dressed Gp 2 3/0 interrupted monofilament nylon suture (Ethilon) to close laparoscopy wound and wound routinely dressed | Infection definition: 3 or more of erythema, oedema, tenderness, inflammation, drainage/discharge, malodour. Wound assessment at 4–6 weeks and 3 months postoperatively. Unclear if assessment performed blind. Infection @ 4–6 weeks Gp 1 8/58 Gp2 6/61 P = 0.7 Dehiscence @ 4–6 weeks Gp 1) 2/58 Gp 2) 4/61 | Centre: Single Years:2000 –2002 |
| Eldrup 1981 187 Denmark | RCT EL = 1- | Total no. of participants n = Group 1 n = 69 Group 2 n = 68 | Inclusion: 137 patients undergoing elective abdominal and breast surgery and having a skin incision between 15 and 35 cm long Exclusion: Not stated Baseline comparability: Not stated Loss to follow-up: Not stated | Group 1: Staples Group 2: Suture | Wound infection not defined Assessed at: not stated Assessor: not stated Wound infection: Group 1: 3/69 Group 2: 7/68 NS | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--------------------------------------|--|--|---|----------------------------|
| Ford 2005 | RCT | Total no. of participants n = 151 | Inclusion criteria: paediatric patients scheduled for clean or clean/contaminated surgery | Intervention | Outcomes | Study duration: not stated |
| 152 | EL = 1- | Group 1 n = 91 | Exclusion criteria: contaminated wound sites, retention sutures, inappropriate age, malnutrition, debilitation, conditions impairing wound healing eg AIDS, incision sites prone to stretching, ophthalmic or cardiovascular or neurologic surgical sites, more than one procedure, prior participation, triclosan allergy | Gp 1 – coated polyglactin 910 suture with triclosan | Wound infection – no definition given at day 14 | Funding: Ethicon |
| Study location: USA | | Group 2 n = 44 | | Gp 2 – coated polyglactin 910 suture without triclosan | Gp 1 = 2/91 Gp 2 = 0/44 | |
| | | | Age: mean 9.8 years (1–18 years) | IV Antibiotics given to 65% Gp 1 and 82% Gp 2 | | |
| | | | Infection recording period: postoperatively, observations at 1–2 d, 14 d ± 2 d, 80 d ± 5 d. | | | |
| | | | Baseline comparability: details given. Age, height, weight, race, risk factors no statistical significance found. | | | |
| Study: Gennari 2004 | RCT | Total no. of participants n = 133 | Inclusion: patients having breast surgery for breast cancer or benign mammary lesions | Group 1: 2-octylcyanoacrylate glue (dermabond) | Wound infection not defined | Centres: Years: |
| 183 | EL = 1+ | Group 1 n = 69 | Exclusion: Insulin-dependent diabetes mellitus, blood-clotting disorders, personal or family history of keloid or hypertrophic scar formation, allergy to materials used. | Group 2: Suture | Assessed daily 5–10 days, 6& 12 months post op | Funding: Not stated |
| Setting: Italy | | Group 2 n = 64 | | Assessor: plastic surgeon | Wound infection or dehiscence: None | |
| | | | Baseline comparability: similar | | | |
| | | | Loss to follow-up: 16.5% RCT | | | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|--|--|--|-------------------|
| Gislason 1995 | RCT | Total no. of participants <i>n</i> = 599 | Inclusion: adults having major operations for gastrointestinal conditions | Group 1 Continuous mass polyglyconate (Maxon) double suture with loop | Wound infection - inflammation or discharge or both, confirmed by culture, or abscess [wound requires opening Assessed at: not stated | |
| Norway | EL = 1+ | Group 1 <i>n</i> = 203 Group 2 <i>n</i> = 199 Group 3 <i>n</i> = 197 | Exclusion: Urological, gynaecological and minor general surgical operations; laparotomy in last 3 months Baseline comparability: yes Loss to follow-up: 17.5% Length of follow up: 1 year | Group 2 Continuous mass polyglactin 910 (Vicryl) Group 3 Interrupted polyglactin 910 (layered for transverse and mass for midline incisions) | Assessor: not stated Wound infections]: Group 1: 40/199 (20%) Group 2 and 3 : 44/384 (11.4%) <i>P</i> = 0.015 Burst abdomen (wound dehiscence): 8/197 (4%) in A vs 3 (2%) in B vs 3 (2%) in C, NS | |
| Greene 1999 | RCT | Total no. of participants <i>n</i> = 20 | Inclusion: adult patients requiring bilateral blepharoplasty for functional or aesthetic indications. | Group 1 One upper eye lid with octyl-2-cyanoacrylate (Dermabond®, Ethicon Inc, a Johnson & Johnson company, Somerville, New Jersey, USA) | Wound infection defined as: not defined Assessed at 1,2 &4 weeks post op | |
| 159 | EL = 1- | Group 1 <i>n</i> = 15 | No specific exclusion criteria are described. | Group 2 Other eyelid closed with 6.0 suture (10 fast-absorbing gut or 10 polypropylene, Prolene, Ethicon Inc, a Johnson & Johnson company, Somerville, New Jersey, USA). | Assessor: physician Dehiscence, infection, patient satisfaction, surgeon satisfaction and cosmetic appearance at 1, 2, and 4 weeks. | |
| USA | | Group 2 <i>n</i> = 5 | split-body design study – a blepharoplasty model with identical skin sites on the same patient and each patient acting as his or her own control. No patients lost to follow-up. | Blepharoplasties were closed on the tissue adhesive side by using Castroviejo forceps to approximate the skin edges in 15 patients and by using 3–4 sutures as handles to facilitate apposition and eversion of edges in 5 patients. | | |
| Study: Grgić 2002 | RCT | Total no. of participants <i>n</i> = | Incision: consecutive patients with head & neck tumours requiring surgical resection. | Group 1 Skin Staples (Proximate Plus MD35 Wide) | Wound Infection not defined Assessed at: not stated | Centres: Single |
| 192 | EL = 1- | Group 1 <i>n</i> = 25 | Exclusion: not stated | Group 2 Interrupted Sutures (3–0 monofilament nylon- Ethicon) | Assessor: not stated | Years: no details |
| Setting: Croatia | | Group 2 <i>n</i> = | Type of wound: head & neck Age: not stated | Staples & sutures removed at 7 days post op. | SSI: none Wound dehiscence: none | |
| | | | Baseline comparability: no details | Study duration: not stated. | | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|---|--|--|--|--|
| Study: Gys 1989 195 Setting: Belgium | RCT EL = 1+ | Total no. of participants n = 167 Group 1 n = 65 Group 2 n = 67 | Population: Consecutive patients undergoing elective or emergency laparotomy Type of wound: Colo-rectal = 33.3%, pancreaticobiliary = 30.3%, gastric = 21.2%, vascular = 4.5%, other = 10.6% Baseline comparability: States balanced groups but slightly higher proportion of patients with risk factors in PA group (malignancy, obesity, shock and dirty wounds), only reported for evaluable population | Group 1 Polyglyconate (Maxon) absorbable synthetic monofilament Group 2 Polyamide (Ethilon) a non-absorbable synthetic monofilament Numbers per group only reported for patients evaluated (79% of randomised sample) Continuous layered closure technique of closing peritoneum with No 0, and musculo-aponeurotic layer with No 1, skin closed with 2/0 vertical mattress sutures except if contaminated, when skin closed partially to enable secondary healing | Wound Infection defined as: purulent discharge confirmed by bacteriological growth Assessed at: observed daily as inpatient, reviewed at 1,6 & 12 months Assessor: not stated SSI rate: Group 1: 14/67 Group 2: 10/65 No statistically significant difference. Wound dehiscence: 2/67 PA, 1/65 PG | Centres: Single Years: May 1986 to January 1987 Study duration: 1 year |
| Harvey 1986 160 Ireland | RCT EL = 1- | Total no. of participants n = 20 Group 1 n = 10 pts 20 infections Group 2 n = 10 pts 20 infections | Inclusion: 20 patients with bilateral varicose veins Exclusion: Not stated Baseline comparability: each patient own control Loss to follow-up: Not stated Length of follow up: 1 month | Group 1: 1 limb closed with staples Group 2: 1 limb closed with sutures | Wound infection defined as: redness, necrosis & infection score(0=absent, 1=present) Assessed at: 2-5 days post op & at out patient follow up, time not stated Assessor: not stated Infection: 1/20 in each group | |
| Jallali 2004 170 Setting: UK | RCT EL = 1+ | Total no. of participants n = 25 Group 1 n = 13, 51 wounds Group 2 n = 12, 48 wounds | Inclusion: consecutive patients requiring laparoscopic cholecystectomy. Exclusion: Baseline comparability: Baseline characteristics were comparable. Patients in the tissue adhesive group were younger than suture group | Group 1 Subcuticular 3/0 polydioxanone (Vicryl) (n = 13- 51 wounds) Group 2 2-octylcyanoacrylate (Dermabond) All patients received 2/0 polybutylate coated polyester(Ethibond) to close the linea alba under the epigastric & umbilical ports. | Wound Infection not defined Assessed at: 6-8 weeks post op. Assessor: plastic surgeon blind to closure method SSI: none | Centres: Single Years: October 2002 - March 2004 |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|----------------------------|-------------------------------|--|---|---|--|----------|
| Johnson 1997 161 USA | RCT EL = 1- | Total no. of participants <i>n</i> = 242 Group 1 <i>n</i> = Group 2 <i>n</i> = | Inclusion: patients with sternal and saphenous vein harvest wounds for clean incisions for coronary artery bypass operations had half of each wound (upper or lower) closed by each method; mean age 64.7 years Exclusion: Emergency operations Baseline comparability: similar Loss to follow-up: 17 patients (9 died, 2 not closed according to protocol, 6 did not return for follow up) Length of follow up: 3–4 weeks | Group 1: Staples Group 2: Intradermal sutures | Wound infection defined – purulent drainage, antibiotic therapy or debridement Assessed at: discharge, 1 week post discharge & 3 weeks post op. Assessor: 1 of 3 doctors blind to closure technique.); Leg wounds: Group 1: 46/ (8.9%) Group 2: 48 (9.3%) <i>P</i> = 0.99 Sternal wounds: Group 1: 12 (2.5%) Group 2: 2 (0.4%) <i>P</i> stated to be 0.061 in table and 0.128 in abstract | |
| Keng 1989 193 UK | RCT EL = 1- | Total no. of participants <i>n</i> = 43 pts, 46 incisions Group 1 <i>n</i> = Group 2 <i>n</i> = | Inclusion: patients requiring 46 groin incisions (inguinal hernia, femoral hernia, sapheno ligations, testicular operations and lymph-node biopsies). Exclusion criteria were not stated. Seven-month follow-up. Three patients lost to follow-up: one from the suture group and two from the tissue adhesive group. | Group 1 Skin incisions were closed with either Histoacryl tissue adhesive Group 2 dexon subcuticular suture. In the three bilateral operations the left side was closed with Histoacryl and the right with dexon. Dexon suture on straight needle using anchoring knot both ends or opposing the wound with forceps and Histoacryl | Wound infection defined as: pus &/or open wound Assessed at 7 days & 1 month post op Assessor: not stated | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--------------------------------------|-------------------------------|--|--|--|--|--|
| Krukowski 1987 171 Setting: UK | RCT EL = 1+ | Total no. of participants n = 757 Group 1 n = 374 Group 2 n = 383 | Inclusion: All patients undergoing elective or emergency laparotomy through a midline vertical incision under the care of two consultants Exclusion: patients undergoing incisional hernia repair excluded. Type of wound: as above Age: 49% < 60 years Baseline comparability: balanced for age, sex, type of operation and degree of contamination | Group 1 Polydioxanone (PDX) 4-metric 76.2% completed Group 2 Polypropylene (PPL) 4-metric 77.0% completed Abdominal wall sutured with tension-free continuous mass closure technique using 50 mm reverse cutting needle, knots buried deep to linea alba. Skin closure with interrupted monofilament polyamide mattress sutures removed day 10, | Wound Infection Wound infection defined as discharge of pus from wound or growth of a pathogenic organism from serous or sanguineous discharge, or any reported discharge from the wound, assessed at 4–6 weeks after discharge from hospital. Assessed at 4–6 weeks post discharge Assessor: not stated SSI rate: Group 1: 13/374 Group 2: 27/383 P < 0.05 Wound dehiscence: 1 in each group | Centres: Presumed single Study duration: 1 year |
| Leaper 1985a 157 Setting: UK | RCT EL = 1– | Total no. of participants n = 95 patients with 111 wounds Group 1 n = 54 Group 2 n = 57 | Inclusion: Patients undergoing elective inguinal surgery (hernia or sapheno-femoral ligation) under care of one surgeon Type of wound: hernia = 48.6%, veins = 51.4% Age: Mean 47 years Baseline comparability: no imbalances reported | Group 1 Subcuticular 2/0 polypropylene Prolene 88.8% completed Polydioxanone (PDX) Group 2 85.9% completed Suture ends loosely tied over wound after insertion, same skin preparation used throughout, subcutaneous fat layer closed with 3/0 continuous chromic catgut, each wound covered with Op-site, wounds left undisturbed until 7th day, then prolene removed but PDX clipped flush with skin Study duration: 6 months | Wound infection defined as: persistent superficial cellulitis or induration lasting beyond 7th post-op day, meaningful if antibiotics prescribed, spontaneous discharge of pus or wound required to be opened Assessed: 7 days, 6 weeks & 6 months post op Assessor: not stated, included GP & patient recall. Wound infection; wound appearance at 6 weeks and 6 months SSI rate: Group 1: 9/54 Group 2: 10/57 No significant difference. | Centres: Presumed single Years: dns |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--------------------------------------|-------------------------------|---|--|---|--|--|
| Leaper 1985b 196 Setting: UK | RCT EL = 1+ | Total no. of participants <i>n</i> = 233 Group 1 <i>n</i> = 97 Group 2 <i>n</i> = 107 | Inclusion: Patients with major laparotomy wounds, midline or transverse Type of wound: gastric = 16.1%, pancreatico-biliary = 45%, small bowel = 4.4%, colon = 25.5%, other = 8.8% Age: Mean 57.7 years Baseline comparability: demographic details only available for study completers | Group 1 No 1 (BPC) polyamide (nylon) Group 2 Polydioxanone (PDX) 87.6% of randomised sample completed overall Continuous mass technique to close abdominal wall, midline and transverse incisions but not through scar tissue, skin closed with continuous subcuticular 00 polypropylene suture, wound covered with Op-site dressing, antibiotic prophylaxis if required | Wound infection defined as: purulent discharge, systemic symptoms causing delayed discharge Assessed at: daily during inpatient period up to 14 days, 6 week & 6 months at out patient Assessor: not stated Outcomes: SSI rate: Group 1: 9 /97 (7 minor, 2 major) Group 2: 18 /107 (14 minor, 4 major) Not statistically significant. Authors suggest trend towards increased infection with synthetic sutures which are absorbed more slowly. | Centres: Two centres Years: dns |
| Maartense 2002 163 Netherlands | RCT EL = 1+ | Total no. of participants <i>n</i> = 140 Group 1 <i>n</i> = 48 Group 2 <i>n</i> = 42 Group 3 <i>n</i> = 50 | Inclusion: adult patients requiring elective laparoscopic surgery. Exclusion: Patients who had undergone previous laparotomy or were pregnant. The study was undertaken at two centres, Sixteen-month follow-up There were no withdrawals, however seven patients treated with paper tape and three with tissue adhesive were converted to the suture group. | Group 1 Octylcyanoacrylate (Dermabond®, Johnson & Johnson, Amersfoot, The Netherlands) tissue adhesive Group 2 76 mm × 6 mm adhesive paper tape (SteriStrip® Bioplasty/Uroplasty, Geleen, The Netherlands) Group 3 intracutaneous polyglactone (Monocryl®) 4/0, Johnson & Johnson) interrupted sutures | Wound infection defined as: pus requiring surgical or spontaneous drainage Assessed at 10–14 days & 3 months Assessor: surgical house officers. Notes – There were 43 patients and 46 wounds included. The wounds were treated as independent data which strictly is incorrect, however as there were only three patients with more than one wound it will make little difference to the conclusions so the study and data is included. | Centres: 2 |
| Magann 2002 164 Australia | RCT EL = 1+ | Total no. of participants <i>n</i> = Group 1 <i>n</i> = Group 2 <i>n</i> = | Inclusion: 964 women having Caesarean section with ≥2 cm subcutaneous tissue Exclusion: Emergency operation Baseline comparability: yes Loss to follow-up: 26.4% RCT Length of follow up: 6 weeks | All skin closure with clips Subcutaneous closure with: A: Not closed (<i>n</i> = 205) B: Running suture of polyglycolic suture (<i>n</i> = 191) C: 7-mm closed drainage system (<i>n</i> = 146) | Wound infection defined as: induration, erythema, purulent material Assessed at: 14 & 42 days post op Assessor: not stated Wound infection: 14 in A vs 16 in B vs 14 in C, NS | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|--|---|--|---|--|
| Mullen 1999 165 USA | RCT EL = 1- | Total no. of participants n = 80 Group 1 n = 20 Group 2 n = 20 Group 3 n = 19 Group 4 n = 18 | Inclusion: patients (3 later excluded) undergoing elective coronary artery bypass surgery Exclusion: Insertion of a drain, intra-aortic balloon pump in index limb, or inability to complete follow up Baseline comparability: similar Loss to follow-up: 3.75% Length of follow up: 6-8 weeks | Group 1: Staples, close immediately Group 2: Staples, close after protamine administration Group 3: Subcuticular sutures, close immediately Group 4: Subcuticular sutures, close after protamine administration | Minor leg wound infection rate (erythema+ one of: fever 38.5° C, raised WBC >12 × 10 ⁹ /litre: or purulent discharge): Group 1: 3/20 (15%) Group 2: 3/20 (15%) Group 3: 1/19 (5.3%) Group 4: 0/18 Major leg wound infection rate (infection requiring i.v. antibiotics or surgical therapy, prolonging hospital stay or requiring readmission): Group 1: 0/20 Group 2: 0/20 Group 3: 0/19 Group 4: 2/18 (10.5%) Assessed daily during inpatient stay by phone & 6-8 weeks post discharge Assessor: not stated | |
| Murphy 1995 158 Setting: Ireland | RCT EL = 1- | Total no. of participants n = 114, 173 wounds Group 1 n = 41 wounds Group 2 n = 38 wounds Group 3 n = 45 wounds Group 4 n = 49 wounds | Inclusion: Patients undergoing bypass surgery with a groin incision Type of wound: Aorto-femoral bypass = 25% femorodistal bypass = 75% Age: Mean 67 years Baseline comparability: no imbalances noted | Group 1 Subcuticular Maxon Group 2 Continuous nylon over and over technique Group 3 Interrupted nylon Group 4 Clips Subcutaneous tissues closed with 3/0 Maxon in two layers to leave skin edges to be closed by four interventions Study duration: 14 days | Wound infection defined as positive cultures. Assessed at: alternate days up to 14 days post op Assessor: not stated Outcomes: Infection confirmed by bacteriological culture, dehiscence, cost of suture material SSI rate: Group 1: 1/41 Group 2: 1/38 Group 3 : 2/45 Group 4 : 1/49 No significant difference between groups. 13 wounds showed local signs of infection but had negative cultures | Centres: Presumed single Years: dns |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-------------------------|-------------------------------|---|--|---|--|----------|
| Murphy 2004 191 | RCT EL = 1- | Total no. of participants <i>n</i> = 60 Group 1 <i>n</i> = 31 Group 2 <i>n</i> = 29 | Inclusion: patients undergoing routine clean orthopaedic procedures Exclusion: Not stated Baseline comparability: Not stated Loss to follow-up: Not stated Length of follow up: 13 days | Group 1: Clips Group 2: Sutures | Wound infection (erythema plus discharge, wound required opening or antibiotics): Group 1: 1/31 (3.2%) Group 2: 1/29 (3.4%) NS Dehiscence: 1 (3.2%) in A vs 1 (3.4%) in B, NS Assessed at 13 days, further assessment not stated Assessor: surgeon | |
| Nasir 2001 188 | RCT EL = 1+ | Total no. of participants <i>n</i> = 100 Group 1 <i>n</i> = 50 Group 2 <i>n</i> = 50 | Inclusion: patients having laparotomy through midline incision Exclusion: not stated Baseline comparability: Unclear – patients having emergency operations were more likely to be in group 2 (54% vs 46% in 1, not clear how significant this is; not adjusted for in analysis) Loss to follow-up: none | Group 1: Continuous double loop closure Group 2: Continuous mass closure (<i>n</i> = 50) Both arms used polypropylene | Wound infection not defined Assessed at: 5–7, 21 & 42 days post op Assessor: not stated Infection: Group 1: 6/50 (12%) Group 2: 9/50 (18%) Wound dehiscence: None in A vs 4 (8%) in B | |
| Niggebrugge 1999 172 | RCT EL = 1+ | Total no. of participants <i>n</i> = 390 Group 1 <i>n</i> = 204 Group 2 <i>n</i> = 186 | Inclusion: Patients undergoing midline-laparotomy wound closure Exclusion: Age 15 or less; laparotomy in previous 3 months Baseline comparability: similar except 23% emergency in Group 1 vs 33% in Group 2 <i>P</i> = 0.02; accounted for by separate analyses for elective and emergency Loss to follow-up: none | Group 1: Continuous Running Suture (CRS) Group 2: Continuous double-loop closure (CDLC) | Wound infection (purulent discharge or positive cultures): Group 1: 13/204 (6.4%) Group 2: 17/184 (9.1%) NS Wound dehiscence: 4 (2.0%) in A vs 7 (3.8%) in B, NS | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------|-------------------------------|---|--|--|---|--|
| Ong 2002 153 | RCT EL = 1+ | Total no. of participants <i>n</i> = 59 Group 1 <i>n</i> = 26 Group 2 <i>n</i> = 33 | Inclusion: children having herniotomies (mean age 4.5 years) Exclusion: Neonates or children allergic to glue Baseline comparability: similar Length of follow up: 2–3 weeks; originally planned to review at 3 months but only 9/59 patients returned Blinding of outcome assessors: yes | Group 1: 2-octylcyanoacrylate glue Group 2: Sutures | Wound infection defined: not stated Assessed at 14–21 days & 3 months Assessor: independent nurse observer. Wound dehiscence: none in either group Wound infection: none in either group | Funding: Ethicon |
| Study: Orr 2003 249 | RCT EL = 1+ | Total no. of participants <i>n</i> = 203 Group 1 <i>n</i> = 104 Group 2 <i>n</i> = 97 | Inclusion: High risk factors for poor wound outcome with abdominal incisions, age at least 18 years, evidence of compromised wound healing due to at least 1 of following: age > 70 years, obesity, cancer, diabetes, COPD, chronic steroid use, altered nutritional status, ascites, renal insufficiency, jaundice, prior radiation to surgical site, prior transverse incision crossing study incision Type of wound: abdominal malignancy = 70%, others = 30% Age: Mean 55 years; range 21–87 years | Group 1: No 1 long-term absorbable multifilament suture poly(L-lactide/glycolide) (PLG) Group 2: Permanent monofilament (No 1) polypropylene (<i>n</i> = 97) Overall 99% completed Continuous fascial closure for both with strict per-operative management protocol | Wound infection: not defined Assessed at: It is unclear when infections were measured, but complications were recorded in the immediate postoperative period as well as at scheduled visits (4–6 weeks, 6 months). Assessor: not stated SSI rates: Group 1: 8/104 Group 2: 6/97 <i>P</i> = 0.75) Dehiscence: 4/104 PLG 10/97 No1ppp No significant difference(<i>P</i> = 0.09). | Centres: 9 Years: May 1999 to June 2000 |
| Orr 1990 173 | RCT EL = 1+ | Total no. of participants <i>n</i> = 402 Group 1 <i>n</i> = 201 Group 2 <i>n</i> = 201 | Inclusion: low risk women having abdominal gynaecological procedures Exclusion: High risk (e.g. active infection plus cancer plus previous radiation); vaginal operation Baseline comparability: similar Loss to follow-up: None RCT Length of follow up: 6 months Blinding of outcome assessors: not stated Power calculation: not stated | Group 1: Continuous closure of fascia Group 2: Interrupted closure of fascia | Wound infection not defined Assessed at: daily as inpatient, 4 & 24 weeks post discharge Assessor: Doctor Infection or seroma: Group 1: 9/201 (4.5%) Group 2: 4/201 (2.0%) | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|--|--|--|
| Osther 1995 | RCT | Total no. of participants <i>n</i> = 204 | Inclusion: People with suspected impaired wound healing undergoing elective or emergency laparotomy, Impaired wound healing included one or more of following criteria: age > 70 years, COPD for at least 10 years, intra-abdominal malignancy or diffuse peritonitis, | Group 1 Early absorbable multifilament polyglycolic acid sutures (Dexon 0/0) for fascial closure (84% completed 3 months, 70% 12 months) | Wound infection defined as purulent discharge leading to surgical drainage | Centres: Presumed single |
| Setting: Denmark | EL = 1+ | Group 1 <i>n</i> = 100 Group 2 <i>n</i> = 104 | Excluded: incisions through previous scar Type of wound: dns Age: Median 75 years (Dexon) and 77 years (Maxon) Baseline comparability: balanced for age, sex, type of incision and operation, risk factors, presence of malignancy or corticosteroid use | Group 2 Late absorbable monofilament polyglyconate sutures (Maxon) (74% completed 3 months, 64.4% completed 12 months) Fascial closure following abdominal surgery, sutures placed 1.5 cm from fascial margins with 1 cm between each stitch as a simple interrupted suture, subcutaneous tissues not closed, skin closed with interrupted nylon 3/0. | Assessed at: the time of measurement was not stated, but is described as 'early complications' Assessor: not stated SSI incidence: Group 1: 16% Group 2: 7% (<i>P</i> = 0.04). | Years: March 1990 to December 1991 |
| Ozturan 2001 | RCT | Total no. of participants <i>n</i> = 101 | Inclusion: patients requiring rhinoplasty or septorhinoplasty were entered to the study. | Group 1: Butylcyanoacrylate (LiquiBand. MedLogic Global Ltd, Plymouth, Devon, UK) tissue adhesive | Wound infection defined as: not stated | |
| 175 | EL = 1+ | Group 1 <i>n</i> = 34 Group 2 <i>n</i> = 67 | Exclusion: Patients who had a history of peripheral vascular disease, diabetes mellitus, clotting disorder, keloid or hypertrophy, or allergy to cyanoacrylate or formaldehyde. | Group 2 6.0 polypropylene sutures for columellar skin closure after the majority of the tension had been taken up using 5.0 chromic catgut. | Assessed: weekly for 1st 4 weeks post op, then at 8 & 12 weeks. | |
| Turkey | | | There were no withdrawals. | | Assessor: surgeons Dehiscence and infection at one week. | Notes – The authors were contacted to clarify the numbers in each group randomised by coin toss and received confirmation that the numbers were correct. We also received clarification that the standard deviations were presented after the means in the results section of the paper. |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|---|---|---|--|
| Paral 2007 176 | RCT EL = 1+ | Total no. of participants n = 415 Group 1A n = 101 Group 1B n = 109 Group 2A n = 109 Group 2B n = 105 | Population: Participants were patients undergoing elective abdominal surgery and were split into two groups according to wound contamination – clean (n = 201) and clean-contaminated (n = 214) Age: 18–88 years Exclusion criteria: long term anticoagulative therapy, haematological disease or haemocoagulation disorders Infection recording period: days 3, 7, 10 and 30 postoperatively Baseline comparability: details given. Age, BMI, subcutaneous fat thickness and risk factors all similar except sex (Gp A1 and A2 considerably fewer females) and nicotine usage. | Intervention: 1) Sutured closure of subcutaneous fat 2) No closure of subcutaneous fat layer 4 Groups: 1A: Clean wound with sutured subcutaneous fat 1B: Clean wound with no closure of subcutaneous fat (n = 100) 2A: Clean-contaminated wound with sutured subcutaneous fat (n = 109) 2B: Clean-contaminated wound with no closure of subcutaneous fat (n = 105) | Outcomes Wound infection (Superficial and Deep) at Day 30 1A – 3% 1B – 2% 2A – 6.4% 2B – 5.8% Wound Dehiscence (Partial – no total dehiscence observed) at Day 30 1A – 2% 1B – 2% 2A – 4.6% 2B – 1.9% | Study duration: not stated Funding: Ministry of Defence and University of Defense of the Czech Republic |
| Ranaboldo 1992 184 | RCT EL = 1– | Total no. of participants n = Group 1 n = 22 Group 2 n = 26 | Inclusion: 48 patients with midline abdominal wounds, mean age 65 years Exclusion: Not stated Power calculation: no – underpowered Baseline comparability: yes Loss to follow-up: Not stated | Group 1: Staples Group 2: Sutures | Wound infection not defined Assessed at: 1 month Assessor: not stated Wound infection with discharge of pus: Group 1: 1/22 Group 2: 1/26 | |
| Sadick 1994 185 | RCT EL = 1– | Total no. of participants n = 100 Group 1 n = 50 Group 2 n = 50 | Inclusion: Patients having excision of benign pigmented lesions of upper back Exclusion: not stated Baseline comparability: not stated Loss to follow-up: not stated | Group 1: Conventional bi-layered technique Group 2: Buried vertical mattress technique (n = 50) | Infection: Group 1: 3/50 (6%) Group 2: 2/50 (4%) iNS | |
| Australia | | | | | | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---------------------------------|-------------------------------|---|---|--|--|------------------|
| Sebesta 2003 194 USA | RCT EL = 1- | Total no. of participants n = 59 Group 1 n = 30, 118 incisions Group 2 n = 29, 110 incisions | Inclusion: 59 patients in whom 228 laparoscopic trocar scars were closed Exclusion: Wounds in both groups that did not closely approximate received interrupted subcutaneous sutures Baseline comparability: Not stated Loss to follow-up: Not stated | Group 1: 2-octylcyanoacrylate glue (dermabond) Group 2: Sutures | Wound infection defined as: not stated Assessed: 14 days post op. Assessor: not stated Wound infection: Group 1: 1/30 Group 2: 0/29 | Funding: Ethicon |
| Shamiyeh 2001 166 Austria | RCT EL = 1+ | Total no. of participants n = 79 Group 1 n = 26 Group 2 n = 28 Group 3 n = 25 | Inclusion: adult patients requiring varicose vein surgery on the leg. Exclusion: Patients with a history of chronic venous insufficiency with dermatosclerosis, previous phlebectomies, or allergy to plaster or octylcyanoacrylate. Nine-month follow-up randomised, parallel group study. Two patients were lost to follow-up from the suture group due to failure to attend and could not be traced by mail or phone. | Mullerian phlebectomy creating average wound length of five mm. Used 5 minutes wound compression followed by skin closure with Group 1: octylcyanoacrylate tissue adhesive Group 2: 5.0 monofilament suture or tape. Group 3: A small plaster was placed over each wound. | Wound infection defined as: not stated Assessed: 10 days & 2 weeks post op. Assessor: not stated Wound dehiscence, infection, at 10 days Notes – The authors were approached to clarify the reason that two patients were lost to follow up and also to clarify how many patients in each group had dehiscence and infection at 10 days. We received the clarification required to enable us to use the data in this review. | |
| Sinha 2001 182 UK. | RCT EL = 1+ | Total no. of participants n = 44 Group 1 n = 20 Group 2 n = 24 | Inclusion: adult patients requiring hand or wrist surgery (carpal tunnel syndrome, trigger finger, De Quervain's tenosynovitis, ganglions of wrist and hand, and cysts of fingers). Exclusion: Patients requiring surgery for Dupuytren's contracture, repeat surgery or had a history of skin allergy, keloid formation, diabetes, or corticosteroid use. | Skin approximating with skin hooks and applying Group 1: n-butyl 2-cyanoacrylate adhesive (Indermil) Group 2: suturing with 4.0 monofilament. All cases have local anaesthetic infiltration with or without general anaesthesia. | Wound infection: Assessed: 7–10 days, 6, 12 weeks Assessor: Tissue viability nurse blind to closure method Dehiscence, infection, pain on movement, cosmetic appearance at 10 days, 2 weeks and 6 weeks. | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---------------------------|-------------------------------|---|--|---|--|-----------------------------|
| Stenvik 2006 | RCT | Total no. of participants <i>n</i> = 239 | Inclusion criteria: patients undergoing CABG saphenectomy | Intervention | Outcomes | Study duration: during 2003 |
| 189 | EL = 1+ | Group 1 <i>n</i> = 119 | Exclusion criteria: unclear. | Gp 1A – intracutaneous closure only using Ethicon Monocryl 3–0 absorbable suture (<i>n</i> = 59) | Definition SSI: symptoms of rubor, calor and dolor requiring wound drainage or antibiotic treatment | Funding: not stated |
| Study location: Norway | | Group 2 <i>n</i> = 120 | Gp 1 (<i>n</i> = 119) were further randomised to ic only Gp 1A(<i>n</i> = 59) or in and sc closure Gp 1B (<i>n</i> = 60). Gp B were matched controls – not reported here Age: not stated Baseline comparability: details given. Diabetes, BMI sex, operation time, unstable angina all similar, no statistical significance found. | Gp 1B – intracutaneous continuous closure using Ethicon Monocryl 3–0 absorbable suture and subcutaneous continuous closure using Ethicon Vicryl 3–0 absorbable suture Antibiotic treatment given | Infection recording period: unclear – local patients seen in outpatients and others contacted by phone, time not specified Gp A1 – 2/59 Gp A2 – 4/60 | |
| Toriumi 1998 | RCT | Total no. of participants <i>n</i> = 111 | Inclusion: patients of 1 year of age and over requiring elective surgery for benign skin lesions predominantly in face and neck. | Incisions with and without subcutaneous sutures and then randomised for closure with | Wound infection defined as: not stated | |
| 154 | EL = 1– | Group 1 <i>n</i> = | Exclusion: Patients were excluded if there was a history of significant trauma, peripheral vascular disease, diabetes mellitus, and blood clotting disorder, keloid or hypertrophy, known allergy to cyanoacrylate or formaldehyde. | Group 1: octyl-2-cyanoacrylate suture | Assessed: Dehiscence and infection were noted at 5–7 days. | |
| USA | | Group 2 <i>n</i> = | 11 patients were lost to follow-up: reason for withdrawal not stated by group. | Group 2: 5.0 or 6.0 nylon suture. | Assessor: not stated | |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|---|-------------------------------|---|--|--|--|---------------------|
| Van den Ende 2004 155 Netherlands | RCT EL = 1+ | Total no. of participants <i>n</i> = Group 1 <i>n</i> = 50 Group 2 <i>n</i> = 50 | Inclusion: 100 children having herniotomies or orchidopexy Exclusion: Not stated Baseline comparability: similar Loss to follow-up: None stated | Group 1: N-butylcyanoacrylate glue; mean age 2.5 years Group 2: Sutures mean age 3.0 years | Wound infection defined as: not stated Assessed: 10 days & 6 weeks post op. Assessor: not stated Wound dehiscence: Group 1: 13/50 (26%) Group 2 ; 0/50 (<i>P</i> < 0.001) Wound infection: Group 1: 4/50 Group 2 ; 2/50 (NS) | Funding: Not stated |
| Velmahos 2002 177 USA | RCT EL = 1+ | Total no. of participants <i>n</i> = 48 Group 1 <i>n</i> = 26 Group 2 <i>n</i> = 22 | Inclusion: 48 patients having operations for colon injuries at a trauma centre Exclusion: Aged under 18 years, pregnant, operated on >6 hours after admission or damage control procedures with abdomen left open Baseline comparability: yes Loss to follow-up: 3 (6%) re-operated within 2 days and left with open abdomen | Group 1: Primary skin closure Group 2: Delayed skin closure | Wound infection (pus, positive wound cultures and, if wound closed, need for opening for drainage): Group 1: 17/26 (65%) Group 2: 8 /22 (36%) <i>P</i> = 0.04 Wound dehiscence (separation of fascia): Group 1: 8/26 (31%) Group 2: 3/22 (14%) NS | |
| Wolterbeek 2002 178 Netherlands | RCT EL = 1+ | Total no. of participants <i>n</i> = 170 Group 1 <i>n</i> = 86 Group 2 <i>n</i> = 84 | Inclusion: 170 patients with femoro- popliteal or femoro-tibial bypass Exclusion: Baseline comparability: similar Loss to follow-up: 10 (6%) | Group 1: Staples but 2 had 2nd procedure and 1 died within 2 weeks Group 2: Sutures but 5 had 2nd procedure and 2 died within 2 weeks | Superficial infections (erythema + serous leak): Group 1: 2/86 (2%) Group 2: 6/84 (8%) NS Deep infections: Group 1:1/86 (1%) Group 2:1/84 (1%) NS | |

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|------------------------|-------------------------------|--------------------------------------|--|--|--|---|
| Yigit 2005 | RCT | Total no. of participants n = 152 | Population: Participants were male patients with chronic pilonidal sinus undergoing excision and primary closure | Intervention | Outcomes | Study duration: May 2003 to May 2004 |
| ¹⁹⁰ | EL = 1+ | Group 1 n = 74 | | Gp 1 – intracutaneous closure only using Ethicon Monocryl 3–0 absorbable suture | Wound infection – no definition given Infection recording period: early complication @ 10 days, late complication during subsequent 6 weeks | Funding: not stated |
| Study location: Turkey | | Group 2 n = 78 | Age: median 22 years (range 15–64) | Gp 2 – intracutaneous continuous closure using Ethicon Monocryl 3–0 absorbable suture and subcutaneous continuous closure using Ethicon Vicryl 3–0 absorbable suture | Early Gp 1 1/74 deep infection (1.35%) 5/74 superficial infection (6.7%) | |
| | | | Inclusion criteria: male patients with chronic pilonidal sinus undergoing excision and primary closure | Antibiotic treatment given | Gp2 1/78 deep infection (1.3%) 2/78 superficial infection (2.6%) | |
| | | | Exclusion criteria: patients with active infection | | Late Gp 1 None observed | |
| | | | Baseline comparability: details given. Age, mean lateral distance from midline similar, no statistical significance found. Length of operation significantly higher in Gp 1. | | Gp 2 1/78 wound dehiscence (1.3%) on day 20 P.o. | |

6.12 Wound dressings

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|----------------------------------|-------------------------------|--|---|--|---|--|
| Chrintz (1989) 209 Denmark | Quasi-RCT EL = 1- | Total no. of patients n = 1325 Randomised in two arms <u>Group1</u> n = 569 <u>Group2</u> n = 633 | Post-surgical patients with clean or clean-contaminated wounds exclusion criteria: < 3 years old, patients with casts or any other type of immobilising bandage, no informed consent. | <u>Group 1</u> sterile dressing applied at the end of the operation and left for 24 h, then removed and the area left uncovered (wound exposed) <u>Group 2</u> sterile dressing applied at the end of the operation and left until the sutures were removed (wound dressed) *Patients in both groups allowed to shower from first post-op day Comparison Wound exposed vs wound dressed | Follow-up Until sutures removal Outcome Surgical site infection (secretion of pus from the cicatrix, suture canals, or subcutaneous abscess) Effect size SSI <u>Group 1</u> 27 out of 569 (4.7%) <u>Group 2</u> 31 out of 633 (4.9%) | Funding N.S. Comments |
| Cosker (2005) 205 UK | RCT EL = 1+ | Total no. of patients n = 300 Randomised in three arms Group1 n = 100 Group2 n = 100 Group3 n = 100 | Patients undergoing hip or knee surgery (elective or emergency) Exclusion criteria No consent, dressing allergies, closed fracture with existing blisters | <u>Group1</u> Primapore (absorbent dressing) <u>Group2</u> Tegaderm with pad <u>Group3</u> Op-site Post-op (hydro-active dressing) | Follow-up Not stated (likely to correspond to the patients' hospital stay) Outcome Surgical Site Infection (no definition given) Effect size SSI <u>Group1</u> 5 out of 100 <u>Group2</u> 5 out of 100 <u>Group3</u> 4 out of 100 | Funding not mentioned Comments Loss to follow-up not stated Figures for baseline comparability not given; the study reported that patients in group3 (opsite) were significantly older than those in the other groups. |

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|---------------------------------|-------------------------------|--|---|---|---|--|
| Heal (2006) 208 Australia | RCT EL = 1+ | Total no. of patients n = 857 Randomised in two groups <u>Group1</u> n = 442 <u>Group2</u> n = 415 | Patients undergoing a minor skin excision in a GP setting Exclusion criteria Skin excision on face, oral antibiotics, clinical indication for post-op antibiotics, immunosuppressive therapy, lacerations, presenting a flap or 2 layer procedure, sebaceous cyst, no written consent | <u>Group 1</u> Dressing in place and dry for 12 hours, than wound undressed until sutures removal <u>Group 2</u> Dressing in place and dry for 48 hours, than wound undressed until sutures removal Comparison 12 hours dressing ('wet' group) vs 48 hours dressing ('dry' group) | Follow-up Until sutures removal (when the assessment of the wound took place or sooner if the patient re-presented with a perceived infection) Outcome Surgical Site Infection (from CDC definition criteria) Effect size SSI rate <u>Group 1</u> 84% <u>Group 2</u> 8.9% | Funding From the primary healthcare research and development fund |
| Phan (1993) 202 Belgium | RCT EL = 1+ | Total no. of patients n = 207 Group1 n = 93 Group2 n = 86 | Patients undergoing extensive surgery for head and neck cancer (stage II, III and IV or recurrent). Exclusion criteria Patients with simple laryngectomy, partial glossectomy or pharyngoplasty | <u>Group1</u> Pure vaseline ointment without gauze dressing <u>Group2</u> Standard gauze dressing Comparison Vaseline ointment without dressing vs Gauze dressing | Follow-up 20 days Outcome Surgical Site Infection (clinically documented infection of the site with purulent discharge and severe inflammatory reaction/or mucocutaneous fistula) Effect size SSI rate <u>Group1</u> 29/93) <u>Group2</u> 21/86 | Funding n.s. Comments Other outcomes reported were: bacteraemia, pulmonary infection, need to administer systemic A/B. All patients were given A/B prophylaxis |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|--|--|---|--|
| Segers (2007) 250 | Quasi-RCT EL = 1- | Total no. of patients n = 1185 <u>Group1</u> n = 615 <u>Group2</u> n = 570 | Adult patients undergoing sternotomy for cardiothoracic surgery accepted only if pt related risk factors could be successfully managed or if their clinical situation left no option Exclusion criteria emergency procedures and pts with previous cardiac surgical interventions. | <u>Group1</u> A sterile transparent film (Opsite) was applied over a dry gauze pad and left for 48 hours. It was then changed in 'non-touch' conditions. After 72 hours the site was left uncovered <u>Group2</u> A water and air-permeable absorbent dressing (Hansapore) was applied to the surgical wound. It was then changed daily in 'clean' conditions. After 72 hours following the intervention the surgical site was left uncovered. Comparison Opsite dressing vs Hansapore | Follow-up unclear Outcome Surgical site infection (CDC definition criteria) Effect size <i>SSI rate</i> <u>Group1</u> 16 out of 615 (2.6%) <u>Group2</u> 19 out of 551 (3.3%) | Funding n.s. Comments All patients received A/B prophylaxis Randomisation according to birth year (odd/even) |
| Vogt (2007) 204 | RCT EL = 1+ | Total no. of patients n = 136 Randomised in two arms <u>Group1</u> n = 70 <u>Group2</u> n = 66 | Patients (>18 years) undergoing elective vascular surgery with an expected hospitalisation of at least 4 days exclusion criteria emergency procedures and patients with previous cardiac surgical interventions | <u>Group 1</u> Aquacel dressing <u>Group 2</u> Mepore dressing Comparison Wound exposed vs wound dressed | Follow-up 6 weeks Outcome Surgical site infection: (redness, tenderness, swelling or exudates) Effect size <i>SSI</i> <u>Group 1</u> 9 out of 70 (13%) <u>Group 2</u> 7 out of 60 (11%) | Funding N.S. Comments Initially 160 patients randomised, 24 patients lost to follow-up, not included in the analysis Other outcomes considered were Number of dressing changes, length of hospital and patient comfort |

| Bibliographic details | Study type and evidence level | No. of patients | Patient characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|---|---|---|--|
| Wikblad (1995) 207 | RCT EL = 1- | Total no. of patients n = 250 Randomised in three arms Group1 n = 92 Group2 n = 77 Group3 n = 81 | Patients undergoing elective coronary by-pass surgery Exclusion criteria | <u>Group1</u> Absorbent dressing <u>Group2</u> Hydrocolloid dressing (Duoderm) <u>Group3</u> Hydroactive dressing (Cutinova hydro) * Dressings applied after operation, examined daily and changed only if there was a exudates leakage; dressings left in place for 5 days and then removed. Comparison Absorbent dressing vs Hydroactive and hydrocolloid dressing | Follow-up 4 weeks Outcome Surgical Site Infection (no definition given) Effect size SSI <u>Group1</u> 5 out of 92 <u>Group2 and 3</u> 2 out of 158 | Funding not mentioned Comments Surgical site infections were only reported for group 1 and for group 2 and 3 (together). Other outcomes reported: ease of dressing removal, pain at removal, redness and wound healing |
| Wynne (2004) 203 | RCT EL = 1+ | Total no. of patients n = 737 Randomised in two groups <u>Group1</u> n = 243 <u>Group2</u> n = 267 <u>Group3</u> n = 227 | Patients undergoing cardiac surgery and who required a median sternotomy incision. Exclusion criteria patients unable to provide written consent, or were immunosuppressed or under care of surgeon who did not want patient to participate. | <u>Group 1</u> Dry absorbent dressing (Primapore) <u>Group 2</u> Hydrocolloid dressing (Duoderm Thin) <u>Group3</u> Hydroactive dressing (Opsite) Comparison C1 Hydrocolloid vs Absorbent C2 Hydroactive vs Absorbent C3 Hydrocolloid vs Hydroactive | Follow-up Outcome Surgical Site Infection (from CDC definition criteria) Effect size SSI rate <u>Group 1</u> 6 out of 243 (2.5%) <u>Group 2</u> 6 out of 267 (2.2%) <u>Group 3</u> 9 out of 227 (4%) | Funding n.s. Comments Other outcomes reported: patient comfort, wound healing, cost. |

7 Postoperative phase

7.1 Changing dressings

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|--|---|--|--|--|
| Stotts (1997) 211 | Pilot Study, RCT | Total number of participants $n = 30$ | Patients underwent abdominal surgical procedures. | <u>Group1</u> Sterile dressing and sterile dressing change technique. | Outcome Measures Wound healing Wound infection | Funding Collaborative Research Project, Univ. of California Medical Center, Univ. of California, San Francisco |
| USA | EL = 1- | Randomised in two arms <u>Group1</u> ($n = 16$) <u>Group2</u> ($n = 14$) | Exclusion criteria ns | <u>Group2</u> Clean dressing and clean dressing change technique | Follow-up Average follow-up of 4.2 days (range 3 to 9 days, SD 1.58) | Comments Unclear reporting of the methodology and conduction of the trial. |
| | | | | Comparison Group1 vs group2 | Effect Size SSI One subject in each treatment group acquired infection. No statistically significant. | One subject in the sterile treatment group had wound dehiscence and therefore not followed-up. |
| | | | | | <i>Wound healing</i> There was no difference in rate of wound healing (measured by wound volume) between the clean and sterile groups ($U = 89.0, P < 0.49$) at the end of the study. | Short follow-up |

7.2 Postoperative cleansing

| Bibliographic details | Study type and evidence level | Study details | Patient characteristics | Intervention and comparisons | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|---|--|---|--|
| Fernandez 2004 | Systematic review | 2 out of 14 RCTs included in review relevant | Riederer 1997 | Riederer 1997 | Riederer 1997 | Applicable to UK |
| 212 | EL = 1+ | Riederer 1997 <i>n</i> = 121 Group 1: <i>n</i> = 49 Group 2: <i>n</i> = 52 | Patients who had undergone surgery for inguinal hernia | Group 1 Patients showered on day 1 Group 2 Patients who kept wounds dry for 14 days | Results: No wound infections in either group. Voorhees 1982 Group 1: 2/39; Group 2: 4/43 | Funding: The New South Wales Centre for Evidence Based Health Care (update) |
| Australia | | Voorhees 1982 <i>n</i> = 82 Group 1: 39 Group 2: 43 | Patients who had undergone surgery with or without drains | Voorhees 1982 Group 1: Showered on 2nd postoperative day Group 2: Not showered | | South-western Sydney Area Director of Nursing and Clinical Services |

7.3 Topical antimicrobial agents for wound healing by primary intention

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|--|---|---|---|---|
| Kamath 2005 ²¹⁴ UK | RCT EL = 1+ | Total no. of participants <i>n</i> = 92 Randomised in two arms: <u>Intervention group</u> <i>n</i> = 47 <u>Control group</u> <i>n</i> = 45 | Patients undergoing orthopaedic surgery for fracture neck of femur Exclusion criteria: Undisplaced intracapsular neck of femur fractures | <u>Intervention group</u> Topical chloramphenicol ointment applied at the surgical site at the end of the procedure and 3rd day postoperatively <u>Control group</u> No ointment applied at the surgical site Comparison topical chloramphenicol ointment vs non ointment | Follow-up 30 days Outcome Superficial SSI (criteria based on the Scottish Centre for Infection and Environmental Health, SCIEH, guidelines for SSI surveillance) Effect size <u>Intervention group</u> 4 SSI out of 47 <u>Control group</u> 8 SSI out of 45 | Funding N.S. Comments Initially 100 patients included in the study. Baseline comparability of the two groups under study was not reported. |

7.4 Dressings for wound healing by secondary intention

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|-------------------------------------|-------------------------------|---|--|---|---|--|
| Cannavo 1998 215 Australia | RCT EL = 1- | Total no. of patients $n = 36$ Randomised in three arms: <u>Group 1</u> $n = 13$ <u>Group 2</u> $n = 10$ <u>Group 3</u> $n = 13$ | Adult patients with surgical abdominal wound Exclusion criteria: Less than 18 years old, known allergies to the dressings agents and no inform consent. | <u>Group1</u> Alginate dressing <u>Group2</u> Gauze dressing with sodium hypochlorite (0.05%) then normal saline (0.09%) when wound granulating, plus a combine dressing pad <u>Group3</u> A combine dressing pad (cotton wool and gauze) Comparisons C1 Alginate dressing vs gauze dressing with sodium hypochlorite C2 Combine dressing pad vs gauze dressing with sodium hypochlorite | Follow-up Until healing end-point (up to 38 days) Outcome Healing rate= wound size reduction per day (mean in surface: cm^2/day and volume: cm^3/day) Effect size <i>Wound reduction</i> <u>Group1</u> 0.55 cm^2/day <u>Group2</u> 0.57 cm^3/day <u>Group2</u> 0.51 cm^2/day 0.50 cm^3/day <u>Group3</u> 0.79 cm^2/day 0.90 cm^3/day <i>Difference Group 2 from Group 1 (cm^2/day and cm^3/day)</i> -0.03, 95% CI -0.81 to 0.41 $P = 0.08$ -0.07, 95% CI -0.53 to 0.38 $P = 0.32$ <i>Difference Group 2 from Group 3 (cm^2/day and cm^3/day)</i> -0.04, 95% CI -0.17 to 0.09 $P = 0.53$ -0.07, 95% CI -0.20 to 0. $P = 0.30$ | Funding Division of Surgery, St George Hospital, Kogarah Comments 39 patients recruited for the trial but three withdraw before the start. Six further withdrawals before the end of the study. |

Surgical site infection: evidence tables

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|--|-------------------------------|---|--|--|---|--|
| Macfie 1980 ²¹⁶ UK | RCT EL = 1- | Total no. of patients <i>n</i> = 50 Randomised in two arms: <u>group1</u> <i>n</i> = 25 <u>group2</u> <i>n</i> = 25 | Patients with open perineal wounds after abdominal perineal excision of the rectum Exclusion criteria: n.s. | <u>group1</u> Silicone foam elastomer +catalyst <u>Group2</u> Ribbon gauze soaked in mercuric chloride antiseptic solution Comparison Silicone foam vs gauze with mercuric antiseptic solution | Follow-up Until complete healing Outcome Healing (time to complete epithelialisation days and time to a dry dressing, mean ±) Effect size <i>Time to FE</i> <u>group1</u> 60.3 ± 3.0 <u>group2</u> 69.5 ± 7.3 (<i>P</i> < 0.05) <i>Time to a DD</i> <u>group1</u> 47.5 ± 3.1 <u>group2</u> 62.6 ± 6.3 (<i>P</i> < 0.05) | Funding Foam dressings supplied by Dow Corning Ltd Comments Unclear if patients who died before complete healing (3 in each group) or those whose wounds failed to heal (2 in each group) were included in the analysis. When no cavity remained a dry dressing was applied as the sole dressing in both groups. |
| Dawson 1992 ²¹⁸ UK | RCT EL = 1- | Total no. of patients <i>n</i> = 34 randomised in two arms: <u>group1</u> <i>n</i> = 18 <u>group2</u> <i>n</i> = 16 | Patients over 16 y.o. with incision and drainage of abscess Exclusion criteria: n.s. | <u>group1</u> Gauze soaked in saline <u>Group2</u> Calcium alginate dressing Comparison Gauze with saline vs alginate dressing | Follow-up Outcomes assessed at 2 weeks. If wound not healed final follow-up at 4 weeks Outcome Complete healing at 2 weeks Effect size <i>Complete healing</i> <u>group1</u> 12 out of 16 (75%) <u>group2</u> 13 out of 18 (72%) <i>P</i> > 0.05 | Funding BritCair UK provided Alginate dressings Comments No sufficient baseline details reported |

| Bibliographic details | Study type and evidence level | No. of participants | Participants characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|---------------------------------|-------------------------------|--|--|---|---|---|
| Meyer 1997 217 Germany | RCT EL = 1- | Total no. of patients <i>n</i> = 43 randomised in two arms: <u>group1</u> <i>n</i> = 22 <u>group2</u> <i>n</i> = 21 | Patients with a secondary healing wound after laparotomy or surgical incision of an abscess Exclusion criteria: Allergic reactions to the products used, diabetes, immunodeficiency, steroids, radiotherapy, chemotherapy or wounds consisting of a big subcutaneous cavity | <u>group1</u> Moist cotton gauze <u>group2</u> Polyurethane foam with active particles Comparison Moist gauze vs foam | Follow-up 4 weeks Outcome Wound size reduction Number of wounds completely healed at week 4 Effect size <i>Wound size reduction</i> <u>group1</u> 50.1% <u>group2</u> 75.6% <i>Number of wounds healed</i> <u>group1</u> 4 out of 22 <u>group2</u> 10 out of 21 | Funding n.s. Comments The statistical used to analysed the data was not reported |

7.6 Debridement

| Bibliographic details | Study type and evidence level | No. of participants | Participant characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|-----------------------------------|-------------------------------|---|--|---|--|---|
| Goode 1979 219 UK | RCT EL = 1- | Total no. of patients <i>n</i> = 20 Randomised in two arms: <u>Group1</u> <i>n</i> = 10 <u>Group2</u> <i>n</i> = 10 | Patients with wound infection after bowel surgery (wounds heavily contaminated at surgery and left open for delayed closure or closed wounds that had required opening and drainage following infection) Exclusion criteria: Non stated | <u>Group1</u> The open wound instilled twice-daily with Dextranomer polysaccharide beads (Debrisan) <u>Group2</u> Twice daily dressings of Eusol and paraffin soaked ribbon gauze Comparison Dextranomer beads vs Eusol gauze | Follow-up Unclear; until time to clean wound Outcome Mean time to a clean wound and secondary closure: time taken to secondary skin closure. Clean wound when resolution of erythema and oedema, absence of pus, slough at the base, formation of granulation tissue. Effect size Mean time in days to wound closure by secondary suture <u>Group1</u> 8.1 (5–28) <u>Group2</u> 11.6 (6–22) <i>P</i> < 0.05 | Funding Not stated Comments All patients were given antibiotics cover prior to surgery and for 48–72 hours postoperatively One patient in each group was left to heal by granulation but the time to healing was not reported |
| Michiels (1990) 220 Belgium | RCT EL = 1- | Total no. of patients <i>n</i> = 40 Randomised in two arms <u>Group1</u> <i>n</i> = 20 <u>Group2</u> <i>n</i> = 20 | Patients with post surgically infected wounds, covered with pus and debris Exclusion criteria: Patients with diabetes, vascular insufficiency, severe anaemia and serum albumin < 30 g/l | <u>Group1</u> Application of a 3 mm layer of dextranomer paste covered with a compress and bandaged. Dressing changed daily <u>Group2</u> Gauze dressing soaked in 10% polyvinylpyrrolidone in aqueous solution covered with a dry dressing and bandaged. Dressings changed daily. Comparison Dextranomer paste vs polyvinylpyrrolidone 10% | Follow-up 12 days Outcome Time to a clean wound bed Effect size <i>Mean time to clean wound</i> <u>Group1</u> 6.5 days <u>Group2</u> 5.2 days <i>Mean time to complete healing</i> not reported | Funding n.s. Comments 1 wound in the intervention group and 2 in the control group did not presented granulation tissue at the end of the trial and were removed from the study |

| Bibliographic details | Study type and evidence level | No. of participants | Participant characteristics | Intervention and comparison | Outcome measures, follow-up and effect size | Comments |
|-----------------------|-------------------------------|---|--|---|--|---|
| Poulsen (1983) 221 | RCT EL = 1- | Total no. of participants $n = 18$ Randomised in two arms <u>group1</u> $n = 7$ <u>group2</u> $n = 11$ | Patients who underwent laparotomy and had their surgical wounds infected (minimum length 7 cm and maximum depth 7 cm); requiring opening and drainage. Exclusion criteria: Burst abdomen, stoma or fistula close to the wound | <u>Group1</u> Twice daily dressing soaked in 20 ml Streptodornase/ streptokinase (Varidase) solution <u>Group2</u> Twice daily dressing soaked in 20 ml saline solution Comparison Enzymatic dressing (streptodornase/ streptokinase) vs saline soaked dressing | Follow-up Time required for a secondary suture of a clean wound Outcome Healing time (mean time to a clean wound in days) Effect size <u>Group1</u> Mean time 5.00 ± 2.16 <u>Group2</u> Mean time 13.45 ± 6.77 $P < 0.05$ | Funding n.s. Comments 3 withdraws/ dropouts not included in the analysis |
| Young (1982) 222 | RCT EL = 1- | Total no. of participants $n = 50$ Randomised in two arms <u>group1</u> $n = 25$ <u>group2</u> $n = 25$ | Patients who underwent an appendectomy for a gangrenous or perforated appendix with free peritoneal pus Exclusion criteria: n.s. | <u>Group1</u> Dextranomer polysaccharide beads (Debrisan) changed twice daily initially and then once daily when reduction in discharge permitted <u>Group2</u> Silicone foam elastomer (Silastic); foam dressing was removed and cleaned twice daily initially, and then once daily when the discharge decreased; new foam stents were made weekly Comparison Dextranomer beads vs foam | Follow-up Until complete healing; wounds were reviewed on day 0,3 and 7 after breakdown, and thereafter weekly Outcome Mean time to complete healing (healing measures: length, breadth and depth) Effect size <i>Mean \pm SD</i> <u>Group1</u> 40.92 ± 3.98 days <u>group2</u> 36.90 ± 3.18 days $P < 0.05$ | Funding Pharmacia Comments Patient satisfaction also reported as secondary outcome |

Health economics

5.1 Preoperative showering

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
|--|--|--|---|---|
| Lynch W <i>et al.</i> 1992 ³⁶ | Patients attending elective surgery Cost minimisation analysis. | Intervention Three showers (on admission to hospital, before going to bed, morning of the operation) with a 4% chlorhexidine detergent solution ($n = 1,744$). Comparator Three showers with placebo detergent ($n = 1738$) | Outcomes <i>Outcomes</i> Bacterial count after 3rd shower, and surgical wound infection <i>Costing</i> Undertaken prospectively. Costs included: drugs, length of stay, dressings, and visits to GP and district nurses. The authors reported that the costs of the placebo and chlorhexidine detergent were not included. Price year not reported. Costs & quantities not reported separately | Results <i>Effectiveness</i> Mean bacterial score: Chlorhexidine: 8.6 Placebo: 12.6 ($P < 0.0001$) <i>Wound infection rates:</i> Chlorhexidine: 250/1744 (14.33%) Placebo: 263/1738 (15.33%, P not significant) <i>Costing</i> Chlorhexidine: £963 per patient Placebo: £897 per patient <i>Synthesis of costs & benefits</i> Not relevant, as both antiseptics were found equally effective and placebo was cheaper Comments The possible effects of confounding (such as type of surgery performed) were controlled in the study as patients were matched for age, sex, surgeon, and type of operation. The authors however, did not include the costs of chlorhexidine or placebo detergents in the analysis. In the costing analysis, the authors only included dressing and outpatient costs for the last 2,000 patients randomised to the study. It is unclear if the differences in mean costs between the two patient groups are statistically significant. |

5.10 Antibiotic prophylaxis

| Bibliographic details | Background | Intervention and cost data | Outcomes |
|--|---|--|---|
| Fonseca SNS, <i>et al.</i> 2006 ⁹¹ Country: Brazil | Surgery performed on 6140 consecutive patients from February 2002 to October 2002, and December 2002 to August 2003. 12 299 surgeries including orthopaedic, gastrointestinal, urology, vascular, lung, head and neck, heart, gynaecologic, oncology, colon, neurologic, and paediatric surgeries. <i>Study design</i> cost minimisation | 24 hour prophylactic antibiotic regimen compared with 1 dose antibiotic prophylaxis. Cost data: cost per month of cephazolin vials <i>Source</i> not reported <i>Discounting</i> : not applied | 6140 surgeries in period 1, and 6159 in period 2. Significantly more patients were successfully followed-up in period 2. 99% compliance of 1 dose antibiotic prophylaxis. The rate of SSI did not change, 2% and 2.1%, respectively, $P = 0.67$ Cephazolin vials purchased per month (n ; cost) Period 1: 1259; \$3147 Period 2: 467; \$1167 |
| Blair EA, <i>et al.</i> 1995 ⁸⁹ Country: USA | Retrospective review of all patients who underwent neck dissections from 1977 to 1989. Infection was defined as purulent drainage, with or without cellulitis of fistula, requiring antibiotics. Wound dehiscence and ischemic necrosis of the edges requiring local care were not included as wound infections. Erythema, induration, edema, and increased warmth of the wound were also not considered infections. <i>Study design</i> cost analysis | Perioperative prophylaxis – antibiotic therapy started perioperatively and continued postoperatively for 24 hours or longer. vs No antibiotic prophylaxis <i>Cost data</i> Hospital bills from 9 randomly selected charts were used to establish a per diem charge (US \$ 1992). The cost of infection was compared with the theoretical cost of several commonly used prophylactic antibiotics. <i>Source</i> 1992 pharmacy charges <i>Discounting</i> not applied | 93 patients received prophylaxis antibiotics and 99 patients did not. The most commonly used prophylactic regimen was first-generation cephalosporins (62%), followed by clindamycin (14%) and penicillins (9%). Wound infection developed in 10% of the patients who did not receive prophylactic antibiotics, and 3.3% of those who did. The difference was not statistically significant ($P = 0.09$) Postoperative hospitalisation averaged 8 days in patients healed without wound infection, and 23 days in patients who developed infections. Average cost of hospitalisation was \$2402 per day. |
| Bold RJ, <i>et al.</i> 1998 ⁹⁰ Country: USA | Prospective study including all patients undergoing axillary lymph node dissection (alone or in combination with a segmental mastectomy, total mastectomy, or wide local excision). Exclusion criteria were set to assure a population at low risk for postoperative infections. An infection was defined as erythema and induration of the surgical wound that required the initiation of antibiotics, purulent drainage from the incision, or systemic symptoms of an infection (i.e. fever with malaise or anorexia) in the absence of any other site of infection. When an infection was identified, patients were given antibiotics to appropriately treat the suspected microorganism. If the infection was deemed severe (associated with signs or symptoms of sepsis) by the staff surgeon, the patients was admitted to the hospital for administration of IV antibiotics, and open drainage of the surgical site was performed as necessary. | Cefonicid (1 g) IV vs Placebo within 60 minutes prior to the initiation of the surgical procedure. IV infusion was initiated in the preoperative area and completed prior to the initiation of the surgical procedure. <i>Cost data</i> cost of treatment, charge for outpatient treatment, charge for hospitalisation. <i>Source</i> not reported | Placebo group, $n = 90$, 13% suffered a postoperative infectious wound complication Cefonicid group, $n = 88$, 6% were treated for a wound infection. ($P = 0.08$) 7 of the 90 placebo patients were hospitalised for severe wound infection. 1 of the 88 in cefonicid group required hospitalisation ($P = 0.033$) Charge for a single IV dose of cefonicid was \$28.75 Cost of outpatient treatment was for a 7-day course of an oral antibiotic (either dicloxacillin or cephalosporin) The cefonicid treated patients had a shorter length of stay in the hospital when admission was required (3 days vs 5.9 days). |

Surgical site infection: evidence tables

| Bibliographic details | Background | Intervention and cost data | Outcomes |
|--|---------------------------------------|---|--|
| <p>Gomez-Alonso A <i>et al.</i> Prospective study, 122 appendicectomies and 66 colorectal operations. 1984 ⁸⁸ Spain</p> | <p><i>Discounting</i> not applied</p> | <p>80 mg Gentamicin 2 hours prior to the operation and 500 mg of Metronidazole over 20 minutes, and postoperatively every 8 hours for 24 hours following appendicectomy and 72 hours in colorectal surgery.</p> <p>vs</p> <p>No antibiotics pre- or postoperatively</p> <p><i>Cost data:</i> Antibiotic costs: Appendicectomies – \$70 per patient, Colorectal surgery – \$170 per patient Cost per day in hospital – \$120</p> | <p>Appendicectomies – 4.9% of patients developed infections in the antibiotic group compared with 34.4% in the control group ($P < 0.001$).</p> <p>Colorectal surgery – 17.1% of patients developed an infection in the antibiotic group, compared with 48.4% in the control group ($P < 0.05$)</p> <p>Postoperative hospitalisation was significantly reduced in the antibiotic group (results shown in diagram).</p> |

6.1 Hand decontamination

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
|----------------------------|--|--|---|---|
| Tavolacci MP 2006 94 | No patient characteristics were reported. <i>Study Design:</i> Cost-minimisation analysis | Surgical hand scrubbing vs Surgical hand rubbing <i>Cost data:</i> Secondary | No statistically significant difference in SSI rate by hand decontamination strategy. Lowest cost option. | Results SHR was equivalent to SHS in preventing SSI after clean and clean-contaminated surgery. SHR reduced the cost of hand disinfection by 67%. |
| Country: France | | <i>Source:</i> A review of published studies was carried out, the quality of the studies was not reported. No meta-analysis was undertaken. <i>Discounting:</i> not stated <i>Details of costs:</i> (taxes not included in costs) Antiseptic soap Hibiscrub (500 ml) €3.40 Betadine scrub (500 ml) €3.15 Nail brush €0.28 Sterile towel (2 sheets) €0.70 Antibacterial water filters Pall Aquasafe '7 days' €27.00 Phagofiltre C500 €54.00 Unmedicated soap Aniosoft (1 litre) €3.20 Non-sterile towel (98 sheets) €0.52 Alcohol-based hand rubs Manurub (500 ml) €2.28 Sterillium Gel (475 ml) €2.90 | | Comments Cost of healthcare worker time was not included. SHR saves about 1–2 minutes. Very specific amounts of soap were used which is unlikely to happen in real practice, and a sensitivity analysis of the costs would have been useful. |

6.12 Wound dressings

| Bibliographic details | Methods | Population | Interventions | Results | Conclusions | Comments |
|--------------------------------|---|--|---|---|--|---|
| Terrill 2000 210 | Cost-consequence analysis. <i>Clinical effectiveness</i> Randomised controlled trial (n = 108). Outcomes studied: surgical wound infections and inflammation, appearance of the wound, pain experienced by patient at removal and ease of removal. <i>Costing</i> Undertaken prospectively. Costs included: unit costs of dressings. | Patients undergoing either elective or emergency hand surgery. | 1) Jelonet: paraffin-impregnated gauze dressings (n = 36) 2) Adaptic: cellulose acetate fibre dressing coated with a petrolatum emulsion (n = 35) 3) Mepited: polyamide net dressing impregnated with silicone gel (n = 37) | <i>Effectiveness</i> Condition of the wound: Jelonet: 26% inflammation, 5% infection; Adaptic: 6% inflammation, 0% infection (P = 0.052 compared with Jelonet); Mepitel: 6% inflammation, 3% infection (P = 0.25 compared with Jelonet) No pain at removal: Jelonet: 51%; Adaptic: 75% (P < 0.01 compared with Jelonet); Mepitel: 56% (P > 0.05 compared with Jelonet). Dressing removal reported as very easy: Jelonet: 57%; Adaptic: 88% (P < 0.05 compared with Jelonet); Mepitel: 84% (P > 0.05 compared with Jelonet). <i>Costing (costs of dressing per sheet)</i> Jelonet (10 × 10 cm): AU\$0.48; Adaptic (7.6 × 7.6 cm): AU\$0.48; Mepitel (5 × 7.5 cm): AU\$5.87. <i>Synthesis of costs and benefits</i> Not applicable. | The authors recommended that Adaptic should be used routinely as the non-adherent dressing for incisions or traumatic wound on the hand. | The study appeared to be underpowered to detect statistically significant differences in terms of wound infection and inflammation. The costing exercise only took into account the unit cost of the dressing, and did not include the frequency of dressing changes nor the labour costs associated with dressing change. These important omissions could have biased the authors' results. |
| Wikblad & Anderson 1995 207 | Cost-consequence analysis. <i>Clinical effectiveness</i> Randomised controlled trial (n = 250). Outcomes studied: wound healing as rated in a three point scale; positive cultures; possibility of inspecting the incision through dressing; ease and pain of drain removal; number of dressing changes; and patient ratings. <i>Costing</i> | Patients undergoing elective coronary bypass or replacement surgery. | 1) Absorbent dressings (n = 92) 2) Hydroactive wound dressings (Cutinova Hydro; Beiersdorf – n = 81) 3) Hydrocolloid occlusive wound dressings (Duoderm; ConvaTec – n = 77) | <i>Effectiveness</i> Wound healing: hydroactive dressings had significantly poorer wound healing (27% well and 25% partially healed) compared with absorbent dressings (57% well and 33% partially healed; P < 0.0001), and with the hydrocolloid dressings (50% well healed and 27% partially healed; P < 0.02). Nurses found it significantly easier to remove absorbent dressings than hydrocolloid and hydroactive dressings. Hydroactive and hydrocolloid dressings were significantly more painful at removal than the absorbent dressings. Absorbent dressings required the highest number of changes (1.7 per patient) than the hydrocolloid (1.2 per patient) and hydroactive dressings (1.2 per patient) (P < 0.001). Four weeks after surgery a total of 8 wounds were found to be infected, 6 of which belonged to the absorbent dressing group. | The authors concluded that absorbent dressings were safe and comfortable and gave satisfactory wound healing. | It is unclear if groups were comparable at analysis in terms of preoperative and operative characteristics. The authors did not explicitly take into account the time costs associated with dressing changes. However the authors reported it took approximately 3 minutes of nursing time to change an absorbent dressing at a cost of \$0.50. Net of these costs, the authors concluded that absorbent dressings were still the cheapest. |

| Bibliographic details | Methods | Population | Interventions | Results | Conclusions | Comments |
|---------------------------------|--|--|---|---|---|---|
| | Undertaken prospectively. Costs included: costs of dressings. | | | <i>Costing</i> Mean cost per patient: absorbent dressings \$0.73; hydrocolloid dressings \$3.60 and hydroactive dressings \$3.34. <i>Synthesis of costs and benefits</i> Not applicable. | | |
| Wynne <i>et al.</i> 2004 203 | Cost-consequence analysis. <i>Clinical effectiveness</i> Randomised controlled trial ($n = 737$). Outcomes studied: surgical wound infections, patient comfort as rated by the visual analogue scale, exuding wounds, frequency of dressing and rate of wound healing. <i>Costing</i> Undertaken prospectively. Costs included: costs of dressings. | Patients undergoing cardiac surgery who required a medium sternotomy incision in a major metropolitan teaching hospital. | 1) Dry absorbent dressings (Primapore; Smith & Nephew – $n = 243$) 2) Hydroactive dressings (Opsite; Smith & Nephew – $n = 227$) 3) Hydrocolloid dressings (Douderm Thin; ConvaTec – 267) | <i>Effectiveness</i> No significant differences in terms of incidence of surgical wound infections and wound healing between groups. Exuding wounds: dry absorbent 6.9%, hydrocolloid 21.3% and hydroactive 13.8% ($P = 0.0001$). Patients receiving dry absorbent dressings had significantly less movement limitation ($P = 0.002$), discomfort with removal ($0 = 0.05$) and dissatisfaction ($P = 0.008$). Significantly more patients in the dry absorbent group (90%) required a single dressing than in the hydrocolloid (50%) and hydroactive (71.7%) groups ($P < 0.0001$) <i>Costing</i> Dry absorbent dressings: median cost AU\$0.52 (IQR: \$0.52 to \$0.52). Hydrocolloid dressings: median cost AU\$3.93 (IQR: \$3.93 to \$7.86). Hydroactive dressings: median cost AU\$1.59 (IQR: \$1.59 to \$3.18). <i>Synthesis of costs and benefits</i> Not applicable. | The authors concluded that in the context of no additional benefit for the prevention of wound healing for any of the three dressings, dry absorbent dressings were the most comfortable and cost-effective products for sternotomy wounds following cardiac surgery. | Groups were shown to be comparable in virtually all preoperative and operative characteristics. Data were only collected for the first 5 postoperative days. However, it would have been useful to continue data collection until and beyond patient discharge. To make the costing exercise more complete the authors should have also examined the time costs associated with dressing changes and other resource use (e.g. doctor and nurse visits). |

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
|-------------------------|--|---|------------------------|---|
| Vogt KC; 2007 204 | Patients, 18 years or older, planned for vascular surgery with an expected postoperative hospitalisation time of at least 4 days. Patients who were known to be hypersensitive to either Meopore or Aquacel, had dementia, knew insufficient Danish, or were pregnant were excluded. | Aquacel – modern type of occlusive dressing vs Meopore, a self-adhesive dressing with a wound pad made of viscose Cost data: Primary Discounting not stated Details of costs: An Aquacel dressing cost between 20.3€ and 48.7€ depending on the number of surgical wounds while a Meopore dressing cost from 0.34€ to 0.92€. The nursing time needed for a change was on average 9.5 minutes, corresponding to a cost of 2.84€ in wages. The expenses on other materials (gloves, saline, etc.) were 1.68€. | least cost alternative | Results: Patients using Meopore dressings, who needed 2 changes, had an average cost between 10€ and 11.8€, whereas the patients using Aquacel, where the majority of patients did not need new dressings had a cost between 20.3€ and 48.7€. Comments: Advantages of Aquacel were found to be; fewer changes required, patients could shower earlier, and it's absorbent ability. No difference was found in hospital stay or reduction in the number of infections in the RCT. In the group of patients in this study the standard care of Meopore dressing was significantly cheaper than Aquacel. |
| Country: Denmark | Study Design: Cost-minimisation analysis Sources of Data: RCT – 160 patients randomised, 24 excluded. Per protocol analysis. The relevant dressing was applied after wound closure after 4 days no dressing was applied if the wound was dry. | | | |

7.2 Postoperative cleansing

| Bibliographic details | Background | Intervention and cost data | Outcomes | Results and comments |
|---|--|--|--|--|
| Griffiths RD <i>et al.</i> 2001 213 Country: Australia | Double blind randomised controlled study of patients with acute or chronic non-sutured wounds for a 6 week period. | Irrigation of wounds with normal saline (0.9%) vs Tap water <i>Cost data:</i> 30 ml sachet of normal saline – 13 cents Dressing pack -51 cents 30ml syringe – 21 cents and a cannula – 18 cents | There was no statistically significant difference between the healing and infection rates in the wounds cleansed with tap water or normal saline. 3 wounds became infected during the study, all were in the control group. 8 wounds in the experimental and 16 in the control group healed completely within the 6-week period. | <p>Results</p> <p>The cost per wound irrigating using a normal saline – \$1.16 per wound.</p> <p>Tap water can be used as part of routine showering. Materials such as syringes, catheters and dressing packs.</p> <p>As no significant difference was reported for clinical outcomes, using tap water would be cost-saving.</p> <p>Comments</p> <p>The authors report that a major limitation of the study was the small sample size.</p> |

Appendix D Cost-effectiveness of hair removal

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and Comments |
|--|---|---|---|---|
| Alexander <i>et al.</i> 1983 ³⁹ | Patients scheduled to receive elective, major operations. Cost-consequence analysis. <i>Clinical effectiveness</i> Randomised controlled trial (<i>n</i> = 1,013). | Interventions 1) Routine shaving the night before the operation. 2) Routine shaving the morning of the operation. 3) Clipping of hair the night before the operation. 4) Clipping of hair the morning of the operation | Outcomes <i>Outcomes</i> Rate of surgical wound infections at hospital discharge and at 30 days follow-up. <i>Costing</i> Undertaken prospectively. Costs included: costs of treating SSIs. Length of stay and total costs were compared for infected patients and their matched controls. Costs and quantities were reported separately. | Results <i>Effectiveness</i> Surgical wound infection rate, at discharge (at 30 day follow-up): Shaving day before: 5.2% (8.8%) Shaving morning: 6.4% (10%) Clipper day before: 4.0% (7.5%) Clipper morning: 1.8%, <i>P</i> = 0.27 (3.2%, <i>P</i> = 0.006) <i>Costing</i> 655.8 days of hospitalisation per 1,000 patients treated would have been avoided if clipping hair in the morning of the operation would have been used exclusively. This generated cost savings of \$274,780 per 1,000 patients treated. <i>Synthesis of costs and benefits</i> Not applicable. Comments The costing study did not include the costs of preoperative hair removal. However, it is unlikely that inclusion of these costs would have altered the authors' conclusions. In the analysis of effectiveness surgical wound infection at 30 days was reported by the patient. It is unclear if these reports were verified by the research staff in the study. |
| Court-Brown CM 1981 ⁴⁰ | Patients undergoing Abdominal surgery. Cost-consequence analysis. <i>Clinical effectiveness</i> Randomised controlled trial (<i>n</i> = 406). | Interventions 1) No hair removal (<i>n</i> = 141) 2) Hair removal with depilatory cream (<i>n</i> = 126) 3) Hair removal with disposable razor (<i>n</i> = 137) | Outcomes <i>Outcomes</i> Outcomes studied: rate of surgical wound infections and acceptability to patients. The authors stratified results by clean, clean-contaminated, contaminated and dirty surgery. <i>Costing</i> Undertaken prospectively. Costs included: costs of hair removal materials. Costs and quantities were not reported separately. | Results <i>Effectiveness</i> Surgical wound infection rate: Razor 12.4% (17/137) Cream 7.9% (10/126) No preparation 7.8% (11/141; <i>P</i> >0.05) However, there was a significant increase in the number of wound infections in the clean and clean-contaminated surgery groups of the razor group (<i>P</i> < 0.05). <i>Costing</i> Costs of hair removal (per 100 patients) Razor: £14 Cream: £22 <i>Synthesis of costs and benefits</i> Not undertaken. Comments The costing study did not include staff time costs, which are important as the time spent by the healthcare professional removing hair from the patient will vary between the different preoperative hair removal interventions |

Surgical site infection: evidence tables

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and Comments |
|--------------------------------------|--|---|--|---|
| De Geest <i>et al.</i> 1996 41 | <p>Patients undergoing coronary artery bypass graft (CABG) surgery.</p> <p>Cost-consequence analysis. <i>Clinical effectiveness</i> Descriptive pilot study ($n = 82$).</p> | <p>Interventions</p> <p>1) Hair removal with depilatory cream ($n = 19$) 2) Hair removal with electric clipper ($n = 29$) 3) Hair removal with disposable razor ($n = 34$)</p> | <p><i>Outcomes</i></p> <p>rate of macroscopic skin lesions standardised by hair growth.</p> <p><i>Costing</i></p> <p>Undertaken prospectively. Costs included: costs of hair removal materials, and staff time costs. Costs and quantities were reported separately.</p> | <p>Results</p> <p>The rate of macroscopic lesions was: Cream 0% Clipper 13.8% Razor 20.6%</p> <p><i>Costing</i></p> <p>Median Costs of hair removal per patient: Clipper: \$9.84 Razor: \$6.13 Cream: \$8.16</p> <p><i>Synthesis of costs and benefits</i></p> <p>Not undertaken.</p> <p>Comments</p> <p>The study design was based on a series of case studies. However, the authors did standardise their costs and effectiveness results by hair growth. The costing study was complete and comprehensive, as it included all relevant costs likely to vary between interventions.</p> |
| Hamilton <i>et al.</i> 1977 42 | <p>Patients undergoing surgery.</p> <p>Cost-consequence analysis. <i>Clinical effectiveness</i> Prospective cohort study ($n = 160$).</p> | <p>Interventions</p> <p>1) No hair removal ($n = 41$) 2) Hair removal with depilatory cream ($n = 32$) 3) Hair removal with electric clipper ($n = 31$) 4) Hair removal with disposable razor ($n = 56$)</p> | <p><i>Outcomes</i></p> <p>Outcomes studied: number of wound infections and degree of erythema.</p> <p><i>Costing</i></p> <p>Undertaken prospectively. Costs included: costs of hair removal materials. Costs and quantities were not reported separately..</p> | <p>Results</p> <p><i>Effectiveness</i></p> <p>Number of superficial wound infections: no removal 2, depilatory 2, clipper 3 and razor 4. Number of deep wound infections: no removal 1, depilatory 0, clipper 0 and razor 2.</p> <p><i>Costing</i></p> <p>Costs of hair removal (/m²/1000 patients/year): Clipper: \$4.95 Razor: \$11.40 Cream: \$56.70</p> <p><i>Synthesis of costs and benefits</i></p> <p>Not undertaken.</p> <p>Comments</p> <p>It is unclear what study design was used by the authors to compare the different interventions. The costing study did not include staff time costs, which are important as the time spent by the healthcare professional removing hair from the patient will vary between the different preoperative hair removal interventions.</p> |

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and Comments |
|-----------------------------------|--|--|---|---|
| Powis <i>et al.</i> 1976 43 | Patients undergoing Surgery that required removal of hair from the operative site. Cost-consequence analysis. <i>Clinical effectiveness</i> Randomised controlled trial ($n = 92$). | Interventions 1) Conventional shaving ($n = 46$) 2) Hair removal with depilatory cream ($n = 46$) | <i>Outcomes</i> Outcomes studied: wound infection rates, colony counts, wound swab results, and patient acceptability. <i>Costing</i> Undertaken prospectively. Costs included: costs of hair removal materials and staff costs. Costs and quantities were not reported separately.. | Results <i>Effectiveness</i> The incidence of wound infection was similar between the two groups. The number of <i>Staph aureus</i> colony counts was significantly lower in the depilation group than in the shaved group ($P < 0.05$). <i>Costing</i> Costs of hair removal: Depilatory cream: £0.25 Shaving: £0.80 <i>Synthesis of costs and benefits</i> Not undertaken. Comments surgical wound infection was defined in the study. The authors included all the relevant costs in their economic analysis. However, the authors did not report separately estimates of resource use such as time needed for hair removal in each of the two interventions. |

Appendix E Cost-effectiveness of nasal decontamination

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
|---|--|--|--|--|
| VandenBergh MF and Kluytmans JA 1996 50 Country: The Netherlands | <p>Patients undergoing cardiothoracic surgery</p> <p><i>Study Design:</i> Cost-effectiveness analysis</p> <p><i>Sources of Data:</i> Cohort study – 1,796 patients</p> <p>Historical control Control 1989–1991 Intervention 1991–1992</p> | <p>Mupirocin calcium ointment (Bactroban) vs no preventative treatment</p> <p><i>Cost data:</i> Primary</p> <p><i>Costs discount:</i> N/A</p> <p><i>Details of costs:</i> Postoperative length of stay – number of postoperative hospital days including day of surgery and day of discharge or death, and periods of readmission – \$265 for medium-care unit to \$930 for postoperative intensive-care unit. 5 day course of nasal mupirocin \$11 The initial surgical procedure was not included as it would not be influenced by application of mupirocin No costs occurred due to adverse events or development of mupirocin resistance in the study so these were not included in the model The hospital accounting system was used for hospital days and lab procedures. For radiographic and invasive procedures the Dutch tariff system could be used as a close approximation of unit costs. (US\$1 = 1.8 Dutch guilder)</p> | <p>cost per SSI prevented</p> | <p>Results</p> <p>Incidence of SSIs 7.3% in historical control, 2.8% in the intervention. Mupirocin led to a 62% reduction in SSIs which was calculated to prevent 45 SSIs per 1000 patients undergoing surgery. The mean SSI-attributable costs were \$16,878 per patient. Treating 1000 surgical patients with mupirocin would lead to a cost saving of \$747,969 (45 SSIs prevented with associated hospitalisation costs saved minus cost of mupirocin application for 1000 patients) \$16,633 saved per SSI prevented.</p> <p><i>Sensitivity analyses</i> incidence of SSIs were varied from 1% to 100%, effectiveness of mupirocin 1% to 100%, SSI-attributable costs 0% to 200%, mupirocin treatment \$0 to \$1000. Mupirocin treatment remained cost-saving except when SSI-attributable costs dropped below \$245 per patient with an SSI.</p> <p>Comments</p> <p>The study on which this analysis was based used historical controls which may bias results.</p> <p>No staff costs were included for the application of mupirocin.</p> <p>These results may not be generalisable to the UK setting as infection rates and costs will differ.</p> |
| Young LS 2006 51 Country: USA | <p>Men and women, mean age 54 years, with multiple coexisting illness who underwent nonemergent cardiothoracic, neurologic, general and gynecologic surgery.</p> <p>The model should not be applied to orthopaedic patients or patients with few comorbidities undergoing low-risk procedures.</p> <p><i>Study Design:</i> Cost-effective analysis</p> <p><i>Sources of Data:</i> One large RCT for mupirocin effectiveness (3,864 surgical patients). Only prospective studies available for infection-attributable mortality</p> | <p>Screen patients for <i>S. aureus</i> colonisation with nasal culture and given carriers mupirocin</p> <p>vs</p> <p>Screen no patients and give all mupirocin</p> <p>vs</p> <p>No screening and no treatment with mupirocin</p> <p><i>Cost data</i> Secondary</p> <p><i>Source</i> various studies and reports</p> <p><i>Costs discount:</i> N/A</p> <p><i>Benefits used:</i> N/A</p> | <p>cost per life saved</p> <p>cost per infection prevented</p> | <p>Results</p> <p>Base case Both mupirocin strategies were cost-saving, \$102 per patient undergoing surgery in the screen and treat strategy, and \$88 per patient in the treat-all strategy. If mupirocin efficacy was less than 16.1% effective then the screen and treat strategy was no longer cost saving. If <i>S. aureus</i> carriage rate was greater than 42.7% then the treat all strategy was more cost-effective. The results did not change if only the hospital perspective was used.</p> <p>Comments</p> <p>Minor side effects such as nasal itching or irritation from topical mupirocin treatment was reported infrequently in the literature and so were not modelled. No serious complications were identified by the authors.</p> |

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
|-----------------------|------------|--|----------|---|
| | | <p><i>Details of costs</i></p> <p>Mupirocin calcium nasal ointment \$48.36</p> <p>Nasal bacterial culture without drug-susceptibility testing \$11.62</p> <p>Hourly total compensation for registered nursing \$35.77</p> <p>Hourly patient opportunity costs \$24.30</p> <p>Excess Hospitalisation costs</p> <p>Healthcare-associated bloodstream infection \$25,127.62</p> <p>Healthcare-associated pneumonia \$18,365.71</p> <p>Surgical site infection \$16,255.58</p> <p>Home healthcare services and durable equipment \$2,237.92</p> <p>Model assumed no future healthcare costs associated with complications of the intervention.</p> | | <p>Resistance was considered to be more of an issue in haemodialysis patients repeatedly receiving mupirocin. The effect of mupirocin resistance was tested in the model by applying a low mupirocin efficacy rate.</p> <p>Reported limitations</p> <p>Assumed 100% sensitivity of swabs.</p> <p>There may be a decrease in incidence of nosocomial spread and subsequent infection among patients not colonised at admission due to eradication of <i>S. aureus</i> nasal colonisation with mupirocin. This was not tested in the model.</p> <p>These results may not be generalisable to the UK setting as infection rates and costs may differ.</p> |

Appendix F Cost-effectiveness of closure methods

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
|--|--|--|---|---|
| Gennari <i>et al.</i> 2004 198 | <p>Patients with benign mammary lesions and operable breast cancer.</p> <p>Cost-consequences analysis. <i>Clinical effectiveness</i> Randomised controlled trial ($n = 133$).</p> | <p>Interventions</p> <p>1) Skin closure with tissue adhesive (2-octylcyanoacrylate ($n = 69$)).</p> <p>2) Standard wound closure; running subcuticular 4-0 or 5-0 monofilament ($n = 64$).</p> | <p><i>Outcomes</i></p> <p>Duration of wound closure, cosmetic outcome, complication rates, patient satisfaction and application time.</p> <p><i>Costing</i></p> <p>Application of the skin closure, and physician and nurse services. Price year not reported.</p> | <p>Results</p> <p><i>Effectiveness</i></p> <p>Mean duration of wound closure: tissue adhesive 19.9 seconds, suturing 2 minutes 25 seconds ($P < 0.001$).</p> <p><i>Early follow-up:</i></p> <p>At 5–10 days after operation there were no signs of infection, and the wounds healed without sequelae in both groups.</p> <p>There were no differences in cosmetic outcomes as rated by patients or surgeon.</p> <p>Patients' satisfaction was higher for tissue adhesives than for suturing (9.5 vs 7.45, respectively; $P < 0.001$)</p> <p><i>Six- and 12-month follow-up:</i></p> <p>There were similar outcomes between groups on the wound cosmetic evaluation by both plastic surgeons and patients.</p> <p><i>Costing</i></p> <p>The total mean cost per patient was €20.3 ± 0.8 for the tissue adhesive group and €29.3 ± 1.4 in the suturing group ($P < 0.001$).</p> <p><i>Synthesis of costs and benefits:</i> Not applicable.</p> <p>Comments</p> <p>The analysis of the clinical study would appear to have been conducted on treatment completers only. Groups were shown to be comparable. Doctors were blinded when assessing. The method of randomisation was not reported. All differences in outcomes and costs were tested for statistical significance.</p> |
| Maartense <i>et al.</i> 2002 163 | <p>Patients scheduled for an elective laparoscopic procedure aged 18 years or above.</p> <p>Cost-consequences analysis. <i>Clinical effectiveness</i> Randomised controlled trial ($n = 140$)</p> | <p>Interventions</p> <p>1) OCA – octylcyanoacrylate (Dermabond) tissue adhesive ($n = 48$)</p> <p>2) Adhesive paper tape slips (Steristrips – $n = 42$)</p> <p>3) Intracutaneous closure with poliglecaprone (monocryl 4/0) interrupted sutures ($n = 50$)</p> | <p><i>Outcomes</i></p> <p>duration of wound closure, cosmetic results as scored by patients and doctors, and wound infections.</p> <p><i>Costing</i></p> <p>Costs included: costs of materials used, including those used as a result of failures and materials used for wound dressing; and costs for use of an operating room and medical personnel. Price year not reported.</p> | <p>Results</p> <p><i>Effectiveness</i></p> <p><i>Median time to close wound:</i></p> <p>OCA 33 seconds; poliglecaprone 65 seconds; and paper tape 26 seconds ($P < 0.001$).</p> <p><i>Wound infections:</i></p> <p>OCA 5 patients; poliglecaprone 3 patients; and papertape 2 patients (P=non-significant).</p> <p>Cosmetic results, as scored by patients, were not significantly different. However, there were significant differences in cosmetic results, as scored by surgeons, with wounds in the OCA group having the best cosmetic appearance (9.3 in the VAS scale) and those in the paper tape group the worst (6.9; $P < 0.05$).</p> <p><i>Costing</i></p> <p>The median (range) cost per patient was:</p> <p>OCA: €34.01 (15.33 to 61.99);</p> <p>Poliglecaprone: €17.82 (3.32 to 63.46); and</p> <p>Adhesive paper tape: €8.68 (2.64 to 43.60; $P < 0.001$).</p> <p><i>Synthesis of costs and benefits</i></p> <p>Not applicable.</p> |

| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
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| | | | | <p>Comments</p> <p>The authors omitted some relevant costs such as those relating to treatment of complications. However, the authors did include all the costs of the interventions themselves (i.e. unit costs of consumables and time to closure). It is unclear which outcome measure was the primary outcome of the study.</p> |
| <p>Matin <i>et al.</i> 2003 199</p> | <p>Adult patients scheduled for elective laparoscopic surgery by three surgical specialties (general surgery, gynaecology and urology).</p> <p>Cost-consequences analysis. <i>Clinical effectiveness</i> Randomised controlled trial ($n = 92$).</p> | <p>Interventions</p> <p>1) Closure of laparoscopic portsite incisions using octylcyanoacrylate (OCA – Dermabond) tissue adhesives ($n = 50$)</p> <p>2) Closure of laparoscopic portsite incisions using traditional subcuticular suturing ($n = 42$)</p> | <p>Outcomes studied: duration of wound closure, wound morbidity, and patient satisfaction.</p> <p><i>Costing</i></p> <p>Costs included: costs of sutures and time costs associated with the operating room. Price year not reported</p> | <p>Results</p> <p><i>Wound infection defined as: not stated</i> <i>Assessed: 2–3 weeks post op.</i> <i>Assessor: not stated</i> <i>Effectiveness</i> <i>Median time to close wound:</i> OCA 2.5 minutes vs 6 minutes suturing ($P < 0.001$) Patient acceptance and assessment of scars was not significantly different. At a mean follow-up of 17 days, wound infections occurred in 5 and 3 patients in the OCA and suturing group ($P = 0.99$). <i>Costing</i> Although the price of OCA was more expensive, savings associated with less time in operation room outweighed the initial costs. The authors reported that savings of approximately \$65 to \$85 per patient could be generated depending on the amount of OCA used. <i>Synthesis of costs and benefits</i> Not applicable.</p> <p>Comments</p> <p>The authors did not reach the targeted sample size, determined at 150 patients, to detect a 2.1 minutes difference in closing time. Despite this the difference in time to wound closure was such that the difference was still significant. The authors did not perform appropriate statistical analyses to test if differences in cost between the two groups were statistically significant.</p> |
| <p>Sebesta & Bishoff 2003 194</p> | <p>Patients undergoing laparoscopic surgery and needing trocar sites to be closed.</p> <p>Wounds less than or equal to 1 cm were evaluated.</p> <p>Cost-consequences analysis. <i>Clinical effectiveness</i> Randomised controlled trial ($n = 59$).</p> | <p>Interventions</p> <p>1) OCA – octylcyanoacrylate (Dermabond), long chain cyanocrylate tissue adhesive ($n = 30$)</p> <p>2) Subcuticular suture using either 4–0 vicryl or 4–0 monocryl ($n = 29$).</p> | <p><i>Outcomes</i></p> <p>duration of skin closure, evidence of infection, dehiscence, seroma, and general cosmetic appearance of the wound.</p> <p><i>Costing</i></p> <p>Costs included: sutures and costs. Price year not reported</p> | <p>Results</p> <p><i>Effectiveness</i> <i>Mean (range) closure time:</i> OCA 3 minutes 42 seconds (2.41 to 5) and 14 minutes 5 seconds (8.27 to 24.43) in the suture group ($P < 0.001$). Wound complications consisted of subcuticular seroma (5 in OCA group and 2 in suturing group). <i>Costing</i> The mean cost per patient (range) was: OCA: \$193.32 (130–365) Suturing: \$497 (295–835; $P < 0.005$) <i>Synthesis of costs and benefits</i> Not applicable.</p> <p>Comments</p> <p>Patient groups were not shown to be comparable at baseline. The authors did not discuss the</p> |

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| Bibliographic details | Background | Interventions and cost data | Outcomes | Results and comments |
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| Shamiyeh <i>et al.</i> 2001 ¹⁶⁶ | Patients requiring varicose vein surgery. Cost-consequences analysis. <i>Clinical effectiveness</i> Randomised controlled trial (<i>n</i> = 79). | Interventions 1) 5–0 monofilament sutures (<i>n</i> = 28) 2) OCA – octylcyanoacrylate tissue adhesive (<i>n</i> = 26) 3) Tape placed crosswise (<i>n</i> = 25) | <i>Outcomes</i> wound dehiscence and infection, optical satisfaction of patient and dermatologist. <i>Costing:</i> Only unit costs of wound closure consumables were included in the study. The price year was not reported. | higher complication rate in the OCA group. Results <i>Effectiveness</i> 10 days postoperatively there were no significant differences between the three groups in wound infections and dehiscences (<i>P</i> >0.05). There were no significant differences in terms of optical satisfaction with wound of patient and dermatologist after one year (<i>P</i> >0.05). <i>Mean closure time (S.D.)</i> OCA 1.14 minutes (0.24), sutures 0.64 minutes (0.23) and tape 0.58 (0.27; <i>P</i> >0.05) <i>Costing</i> The median cost of closure of one incision was \$3.24 with OCA, \$0.08 with tape, and \$0.23 with sutures. <i>Synthesis of costs and benefits</i> Not applicable. Comments Only unit costs of wound closure consumables appeared to have been included in the study. The study appeared to have been underpowered to detect any statistically significant differences between the two groups. |
| Singh B 2006 ²⁰⁰ UK | Patients with fracture neck of femur, admitted to an ortho-geriatric unit. Study design: Cost analysis Sources of data: Prospective study carried out from September 2001 to March 2002. Not randomised, small study. | Clips (<i>n</i> = 41) vs subcuticular vicryl sutures (<i>n</i> = 30) | Infection and wound healing, inflammation. Cost of wound closure | Dressing changes were needed less frequently in the sutures group, mean of 5 compared with 3 changes for clips. 3 cases of infections were identified all in patients where clips were used. The number was too small to test for any statistical significance. Costs for clips: £6 for application, £6.10 for remover, £6 for dressings on average. TOTAL: £18.10 Costs for sutures: £1.40 for application, £0 for remover, £3.60 for dressings on average. TOTAL: £5 No unit costs reported, or resources required, for instance nurses' time. |

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- Antenatal care: routine care for the healthy pregnant woman
- Fertility: assessment and treatment for people with fertility problems
- Caesarean section
- Type 1 diabetes: diagnosis and management of type 1 diabetes in children and young people
- Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception
- Urinary incontinence: the management of urinary incontinence in women
- Heavy menstrual bleeding
- Feverish illness in children: assessment and initial management in children younger than 5 years
- Urinary tract infection in children: diagnosis, treatment and long-term management
- Intrapartum care: care of healthy women and their babies during childbirth
- Atopic eczema in children: management of atopic eczema in children from birth up to the age of 12 years
- Surgical management of otitis media with effusion in children
- Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period
- Induction of labour

Guidelines in production include:

- Diarrhoea and vomiting in children under 5
- When to suspect child maltreatment
- Hypertensive disorders in pregnancy
- Neonatal jaundice
- Constipation in children
- Bacterial meningitis and meningococcal septicaemia in children
- Pregnant women with complex social factors
- Autism in children and adolescents
- Multiple pregnancy

Enquiries regarding the above guidelines can be addressed to:

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A version of this guideline for patients, carers and the public is available from the NICE website (www.nice.org.uk/CG074) or from NICE publications on 0845 003 7783; quote reference number N1702.

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