

Musculoskeletal

Interventional Procedures Guidance

- Artificial metacarpophalangeal and interphalangeal joint replacement for end-stage arthritis 752 **NEW**
- Artificial trapeziometacarpal joint replacement for end-stage osteoarthritis 752 **NEW**
- Balloon kyphoplasty for vertebral compression fractures 754
- Computed tomography-guided thermocoagulation of osteoid osteoma 757
- Endoscopic division of epidural adhesions 759
- Endoscopic laser foraminoplasty 760
- Extracorporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder 761
- Laser lumbar discectomy 763
- Mini-incision surgery for total knee replacement 765 **NEW**
- Minimally invasive placement of pectus bar 766
- Minimally invasive two-incision surgery for total hip replacement 766 **NEW**
- Needle fasciotomy for Dupuytren's contracture 767
- Percutaneous endoscopic laser thoracic discectomy 767
- Percutaneous intradiscal electrothermal therapy for lower back pain 768
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain 769
- Percutaneous vertebroplasty 769
- Prosthetic intervertebral disc replacement 770 **NEW**

Technology Appraisals

- Anakinra for rheumatoid arthritis 752

- Autologous chondrocyte implantation for the treatment of cartilage defects in knee joints (review) 753 **NEW**
- Bisphosphonates (alendronate, etidronate, risedronate), selective oestrogen receptor modulators (raloxifene) and parathyroid hormone (teriparatide) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women 755 **NEW**
- Cyclo-oxygenase (Cox) II selective inhibitors, celcoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis 758
- Etanercept and infliximab for rheumatoid arthritis 761
- Etanercept for juvenile idiopathic arthritis 762
- Metal on metal hip resurfacing arthroplasty 764
- Selection of hip prostheses for primary total hip replacement 771

TECHNOLOGY APPRAISAL

Anakinra for rheumatoid arthritis**Issue date** – November 2003 **Review date** – June 2006

On the balance of its clinical benefits and cost effectiveness, anakinra is not recommended for the treatment of rheumatoid arthritis, except in the context of a controlled, long-term clinical study.

Patients currently receiving anakinra for rheumatoid arthritis may suffer loss of well-being if their treatment were discontinued at a time they did not anticipate. Therefore, patients should continue therapy with anakinra until they and their consultant consider it is appropriate to stop.

INTERVENTIONAL PROCEDURE GUIDANCE

Artificial metacarpophalangeal and interphalangeal joint replacement for end-stage arthritis

NEW

Issue date – February 2005

Current evidence on the safety and efficacy of artificial metacarpophalangeal (MCP) and interphalangeal (IP) joint replacement of the hand for end-stage arthritis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

Most of the evidence was based on a single type of joint prosthesis. The range of prostheses used is continually changing and clinicians are encouraged to submit their results to the appropriate joint-replacement registry for evaluation of long-term outcomes of different types of prosthesis.

INTERVENTIONAL PROCEDURE GUIDANCE

Artificial trapeziometacarpal joint replacement for end-stage osteoarthritis

NEW

Issue date – February 2005

Current evidence on the safety and efficacy of artificial

trapeziometacarpal (TMC) joint replacement for end-stage osteoarthritis appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

Most of the evidence was based on a single type of joint prosthesis. The range of prostheses used is continually changing and clinicians are encouraged to submit their results to the appropriate joint replacement registry for evaluation of long-term outcomes of different types of prosthesis.

TECHNOLOGY APPRAISAL

Autologous chondrocyte implantation for the treatment of cartilage defects in knee joints (review)

NEW

Issue date – May 2005 **Review date** – May 2008

NOTE: This guidance replaces Technology Appraisal Guidance No. 16 issued in December 2000.

The Institute reviews each piece of guidance it issues.

The review and re-appraisal of the use of autologous chondrocyte implantation (ACI) for the treatment of cartilage defects in knee joints has resulted in modifications to the guidance. Specifically:

- the recommendation that ACI should not be used for routine primary treatment has been expanded to include all treatment levels
- the recommendation on the use of ACI in clinical trials has been revised to recommend that all patients receiving ACI should be enrolled in ongoing or new clinical studies
- a recommendation has been made that patients should be fully informed of the uncertainties about the long-term effectiveness and the potential adverse effects of this procedure.

Autologous chondrocyte implantation (ACI) is not recommended for the treatment of articular cartilage defects of the knee joint except in the context of ongoing or new

clinical studies that are designed to generate robust and relevant outcome data, including the measurement of health-related quality of life and long-term follow-up. Patients should be fully informed of the uncertainties about the long-term effectiveness and the potential adverse effects of this procedure.

INTERVENTIONAL PROCEDURE GUIDANCE

Balloon kyphoplasty for vertebral compression fractures

Issue date – November 2003

Current evidence on the safety and efficacy of balloon kyphoplasty for vertebral compression fractures does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Although the benefits and risks of this procedure appear similar to those for percutaneous vertebroplasty in the first few months after the procedure is carried out (NICE issued guidance on percutaneous vertebroplasty in September 2003), there is insufficient long-term evidence to substantiate this at present. Clinicians wishing to undertake balloon kyphoplasty for vertebral compression fractures should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

The following are recommended:

- This procedure should only be undertaken when there are arrangements for good access to a spinal surgery service, and with prior discussion between a specialist multidisciplinary team that includes a radiologist and a spinal surgeon.

- Clinicians should receive training to reach an appropriate level of expertise before carrying out this procedure. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of embolisation.
- The procedure should be limited to patients whose pain is refractory to more conservative treatment.

TECHNOLOGY APPRAISAL

Bisphosphonates (alendronate, etidronate, risedronate), selective oestrogen receptor modulators (raloxifene) and parathyroid hormone (teriparatide) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women

NEW

Issue date – January 2005 **Review date** – October 2007

This guidance covers the secondary prevention of osteoporotic fragility fractures in postmenopausal women who have sustained a clinically apparent osteoporotic fracture.

This guidance covers the treatment of postmenopausal women who have normal calcium levels and/or vitamin D levels. Unless clinicians are confident that women who receive osteoporosis treatment have an adequate calcium intake and are vitamin D replete, calcium and/or vitamin D supplementation should be provided.

This guidance does not cover the treatment of corticosteroid-induced osteoporosis.

Bisphosphonates (alendronate, etidronate and risedronate) are recommended as treatment options for the secondary prevention of osteoporotic fragility fractures:

- in women aged 75 years and older, without the need for prior dual energy X-ray absorptiometry (DEXA) scanning
- in women aged between 65 and 74 years if the presence of osteoporosis is confirmed by DEXA scanning, and
- in postmenopausal women younger than 65 years of age, if they have a very low bone mineral density (BMD, that is

with a T-score of approximately -3 SD or below*, established by a DEXA scan), or if they have confirmed osteoporosis plus one, or more, additional age-independent risk factor: low body mass index (< 19 kg/m²); family history of maternal hip fracture before the age of 75 years; untreated premature menopause; certain medical disorders independently associated with bone loss (such as chronic inflammatory bowel disease, rheumatoid arthritis, hyperthyroidism or coeliac disease); conditions associated with prolonged immobility.

In their choice of bisphosphonate, clinicians and patients need to balance the drug's overall proven effectiveness profile against tolerability and adverse effects in individual patients.

Raloxifene is recommended as an alternative treatment option, under the circumstances specified above, in women:

- for whom bisphosphonates are contraindicated (see Summaries of Product Characteristics), **or**
- who are physically unable to comply with the special recommendations for use of bisphosphonates, **or**
- who have had an unsatisfactory response to bisphosphonates (as defined below), **or**
- who are intolerant of bisphosphonates (as defined below).

Teriparatide is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures in women aged 65 years and older who have had an unsatisfactory response to bisphosphonates or intolerance to bisphosphonates (as defined below), **and**:

* The World Health Organization (WHO) classification of osteoporosis has been widely adopted and is based on the measurement of BMD, with reference to the number of SDs from the BMD in an average 25-year-old woman (T score):

- normal: T-score of -1 SD or more
- osteopenia: T-score between -1 and -2.5 SD
- osteoporosis: T-score below -2.5 SD
- established osteoporosis: T-score below -2.5 SD, with one or more associated fragility fractures.

BMD T-scores can vary by site and method of measurement. Reference standards have been published for the different measurement sites. The prediction of fracture risk is usually based on BMD measurements at the femoral neck.

- who have an extremely low BMD (with a T-score of approximately -4 SD or below), or
- who have a very low BMD (with a T-score of approximately -3 SD or below) plus multiple fractures (that is, more than two) plus one, or more, additional age-independent risk factor: low body mass index (< 19 kg/m²); family history of maternal hip fracture before the age of 75 years; untreated premature menopause; conditions associated with prolonged immobility.

For the purpose of this guidance, an unsatisfactory response occurs when a woman has another fragility fracture despite adhering fully to treatment for 1 year and there is also evidence of a decline in BMD below her pre-treatment baseline.

For the purpose of this guidance, intolerance of bisphosphonates is defined as oesophageal ulceration, erosion or stricture, or severe lower gastrointestinal symptoms, any of which warrants discontinuation of treatment with a bisphosphonate.

INTERVENTIONAL PROCEDURE GUIDANCE

Computed tomography-guided thermocoagulation of osteoid osteoma

Issue date – March 2004

Current evidence on the safety and efficacy of computed tomography (CT)-guided thermocoagulation of osteoid osteoma appears adequate to support its use, provided that the normal arrangements are in place for consent, audit and clinical governance.

TECHNOLOGY APPRAISAL

Cyclo-oxygenase (Cox) II selective inhibitors, celecoxib, rofecoxib, meloxicam and etodolac for osteoarthritis and rheumatoid arthritis

Issue date – July 2001 **Review date** – May 2004

Please note that following the voluntary worldwide withdrawal of rofecoxib (Vioxx) by Merck Sharp & Dohme (MSD) on 30 September 2004, rofecoxib is no longer available for prescription. The NICE guidance therefore no longer applies to rofecoxib but continues to apply to the other Cox II inhibitors.

On the 17 February 2005 the MHRA issued advice to healthcare professionals giving advice on prescribing selective Cox-2 inhibitors. Information can be found on the MHRA website www.mhra.gov.uk/

NICE will be reviewing how this advice impacts on its current guidance on the use of Cox II selective inhibitors for osteoarthritis and rheumatoid arthritis issued in July 2001 and the subsequent review of this guidance, which is currently suspended.

Cox II selective inhibitors and other non-steroidal anti-inflammatory drugs (NSAIDs) are indicated for pain and stiffness in inflammatory rheumatoid arthritis and for the short-term management of pain in osteoarthritis. All NSAIDs are associated with adverse events and should only be prescribed when there is a demonstrable clinical need and in accordance with their summary of product characteristics. Long-term use should be avoided without appropriate monitoring and re-evaluation of the clinical need.

Of particular concern is the propensity of NSAIDs, including the Cox II selective agents, to cause gastrointestinal adverse events, which can include life threatening gastrointestinal perforations, ulcers or bleeds. These agents should therefore only be prescribed after careful consideration of their risks and benefits, especially in patients who may be at increased risk of such adverse events.

Cox II selective inhibitors are not recommended for routine use in patients with rheumatoid arthritis (RA) or osteoarthritis (OA). They should be used in preference to standard NSAIDs, when clearly indicated as part of the management of RA or OA, only in patients who may be at 'high risk' of developing serious gastrointestinal adverse effects.

Patients at 'high risk' of developing serious gastrointestinal adverse events include those of 65 years of age and over, those using concomitant medications known to increase the likelihood of upper gastrointestinal adverse events, those with serious comorbidity or those requiring the prolonged use of maximum recommended doses of standard NSAIDs. The risk of NSAID-induced complications is particularly increased in patients with a previous clinical history of gastroduodenal ulcer, gastrointestinal bleeding or gastroduodenal perforation. The use of even a Cox II selective agent should therefore be considered especially carefully in this situation.

In all patients with cardiovascular disease, there remains uncertainty over the use of Cox II selective inhibitors and they should not therefore be prescribed routinely in preference to standard NSAIDs where these are indicated in this group of patients. Furthermore, many patients with cardiovascular disease receive low dose aspirin and this carries an increased risk of gastrointestinal events. In patients who are taking low dose aspirin, the benefit of using Cox II selective agents (to decrease gastrointestinal toxicity) is reduced. Prescribing Cox II selective agents preferentially over standard NSAIDs in this situation is therefore not justified on current evidence.

There is no evidence to justify the simultaneous prescription of gastro-protective agents with Cox II selective inhibitors as a means of further reducing potential gastrointestinal adverse events.

INTERVENTIONAL PROCEDURE GUIDANCE

Endoscopic division of epidural adhesions

Issue date – September 2004

Current evidence on the safety and efficacy of endoscopic

division of epidural adhesions does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

Clinicians wishing to undertake endoscopic division of epidural adhesions should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having endoscopic division of epidural adhesions.

Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

INTERVENTIONAL PROCEDURE GUIDANCE

Endoscopic laser foraminoplasty

Issue date – December 2003

Current evidence of the safety and efficacy of endoscopic laser foraminoplasty does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake endoscopic laser foraminoplasty should inform the clinical governance leads in their Trusts. They should ensure that patients offered the procedure understand the uncertainty about its safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Further research into safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE is not undertaking further investigation at present.

INTERVENTIONAL PROCEDURE GUIDANCE

Extracorporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder

Issue date – November 2003

Current evidence on the safety and efficacy of extracorporeal shockwave lithotripsy for calcific tendonitis of the shoulder appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

TECHNOLOGY APPRAISAL

Etanercept and infliximab for rheumatoid arthritis

Issue date – March 2002 **Review date** – April 2005

Etanercept and infliximab (infliximab only in combination with methotrexate) are recommended as options for the treatment of adults who have continuing clinically active rheumatoid arthritis that has not responded adequately to at least two disease-modifying anti-rheumatic drugs, including methotrexate (unless contraindicated).

Both etanercept and infliximab should be prescribed in accordance with relevant sections of the British Society for Rheumatology (BSR) guidelines, April 2001, which set out criteria for eligibility, definitions of failure of standard therapy, exclusion criteria and criteria for withdrawal of therapy. In particular, treatment should be withdrawn in the event of severe drug-related toxicity or because of lack of response at 3 months.

Prescription of these agents and follow-up of treatment response and adverse events should be undertaken only by a consultant rheumatologist specialising in their use. The choice of which of the two agents is used should be determined by consultation between the patient and the clinician responsible, taking into account differences in treatment schedules and patient preferences.

Maintenance therapy with these agents in those who respond

to treatment initially should be at the lowest licensed dose compatible with continuing clinical response.

All clinicians prescribing etanercept or infliximab should (with the patient's consent) register the patient with the Biologics Registry established by the BSR and forward information on dosage, outcome and toxicity on a 6-monthly basis.*

There is currently no evidence to support treatment beyond 4 years. A decision to continue therapy should therefore be contingent on ongoing monitoring of disease activity and clinical effectiveness in individual cases. Outcomes from the BSR Biologics Registry will help inform such decisions.

There is no evidence for the consecutive use of these agents, and therefore this is not recommended.

TECHNOLOGY APPRAISAL

Etanercept for juvenile idiopathic arthritis

Issue date – March 2002 **Review date** – January 2005

Etanercept is recommended for children aged 4 to 17 years with active polyarticular-course juvenile idiopathic arthritis whose condition has not responded adequately to, or who have proved intolerant of, methotrexate.

Etanercept should be prescribed in accordance with relevant sections of the British Paediatric Rheumatology Group (BPRG) protocol which sets out criteria for eligibility, definitions of failure of standard therapy, exclusion criteria and criteria for withdrawal of therapy. In particular, treatment should be

* May 2005: The Biologics Registry is no longer registering new etanercept patients because the planned number of patients has been reached. The registry will continue to recruit new patients treated with other biologic therapies. The collection of follow-up data will continue for all recruited patients.

In light of this, NICE no longer recommends that clinicians prescribing etanercept register their patients with the BSR Biologics Registry. All other recommendations remain the same. The BSR suggest the use of local computerised records to register and track new patients whilst on treatment.

Data from the register will be used to inform the review of this guidance, which began in March 2005.

withdrawn in the event of severe drug-related toxicity or because of lack of response at 6 months.

Initiation of etanercept therapy should only be undertaken by a consultant who regularly sees children and young people with juvenile idiopathic arthritis and who runs specialised paediatric rheumatology clinics. In addition, the prescribing centre should have a nurse specialist or an appropriately trained nurse who is able to teach children and parents injection techniques and who does this regularly. Follow-up of treatment response and adverse events may be on a shared-care basis depending on local circumstances.

It is strongly recommended that all clinicians prescribing etanercept should (with the permission of the child and/or parent) register the child with the Biologics Registry established by the BPRG and forward information on dosage, outcome and toxicity on a quarterly basis.

There is currently no evidence to support treatment beyond 2 years and continuation of therapy is therefore contingent upon ongoing monitoring of disease activity and clinical effectiveness in individual cases.

INTERVENTIONAL PROCEDURE GUIDANCE

Laser lumbar discectomy

Issue date – December 2003

Current evidence on the safety and efficacy of laser lumbar discectomy does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians wishing to undertake laser lumbar discectomy should inform the clinical governance leads in their Trusts. They should ensure that patients offered it understand the uncertainty about the procedure's safety and efficacy and should provide them with clear written information. Use of the Institute's *Information for the Public* is recommended. Clinicians should ensure that appropriate arrangements are in place for audit or research. Publication of safety and efficacy outcomes will be useful in reducing the

current uncertainty. NICE is not undertaking further investigation at present.

TECHNOLOGY APPRAISAL**Metal on metal hip resurfacing arthroplasty**

Issue date – June 2002 **Review date** – February 2005

Metal on metal (MoM) hip resurfacing arthroplasty is recommended as one option for people with advanced hip disease who would otherwise receive and are likely to outlive a conventional primary total hip replacement. In considering hip resurfacing arthroplasty, it is recommended that surgeons take into account activity levels of potential recipients and bear in mind that the current evidence for the clinical and cost effectiveness of MoM hip resurfacing arthroplasty is principally in individuals less than 65 years of age.

When MoM hip resurfacing arthroplasty is considered appropriate, the procedure should be performed only in the context of the ongoing collection of data on both the clinical effectiveness and cost effectiveness of this technology. Ideally, this data collection should form part of a UK national joint registry.

This guidance should be read in conjunction with the Institute's guidance on devices for total hip replacement (Guidance on the selection of prostheses for primary total hip replacement: *NICE Technology Appraisal Guidance No 2*. April 2000 also in this section). In that guidance, the Institute recommended that the best prostheses (using long-term viability as the determinant) should demonstrate a 'benchmark' revision rate (the rate at which they need to be replaced) of 10% or less at 10 years or, as a minimum, a 3 year revision rate consistent with this 10-year benchmark. Establishing and confirming similar benchmarking criteria will be necessary for MoM hip resurfacing arthroplasty and will be facilitated by a UK national joint registry. In the interim, the 3 year minimum benchmark should apply to MoM hip resurfacing devices.

MoM hip resurfacing arthroplasty should be performed only by

surgeons who have received training specifically in this technique.

Surgeons should ensure that patients considering MoM hip resurfacing arthroplasty understand that less is known about the medium- to long-term safety and reliability of these devices or the likely outcome of revision surgery than for conventional total hip replacements. This additional uncertainty should be weighed against the potential benefits claimed for MoM devices.

INTERVENTIONAL PROCEDURE GUIDANCE

Mini-incision surgery for total knee replacement NEW

Issue date – March 2005

Current evidence on the safety and efficacy of mini-incision surgery for total knee replacement does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research. More evidence is required on the long-term safety and efficacy of this procedure and clinicians should submit data to the National Joint Registry (www.njrcentre.org.uk).

Clinicians wishing to undertake mini-incision surgery for total knee replacement should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended.

Clinicians undertaking this procedure should have adequate training before performing this technique.

Further research will be useful. Clinicians are encouraged to enter patients in well-defined trials and to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

INTERVENTIONAL PROCEDURE GUIDANCE

Minimally invasive placement of pectus bar**Issue date** – July 2003*This procedure is also known as the Nuss procedure*

The evidence of the safety and efficacy of minimally invasive placement of pectus bar reviewed by the Interventional Procedures Advisory Committee was not adequate to support the use of this procedure without special arrangements for consent and for audit or research. Clinicians should ensure that the uncertainty about the procedure's safety and efficacy is understood by the parent or carer and where possible the child, and involve the child appropriately in arrangements for informed consent. The clinician should provide them with clear written information. Use of the information for the public, produced by NICE, is recommended. Clinicians should inform the clinical governance leads in their Trusts and ensure that appropriate arrangements are in place for clinical audit or research.

All those who have the procedure should be entered, subject to their consent, onto the Registry maintained at the Wessex Regional Centre for Paediatric Surgery, Southampton General Hospital. The Registry's Surgical Codirectors are Mr Robert Wheeler and Mr David Weeden.

It is recommended that minimally invasive placement of pectus bar be referred to the Institute's Review Body, which should liaise with the Registry and prepare an analysis of its results for the Committee to consider. Further guidance will then be issued by the Institute.

INTERVENTIONAL PROCEDURE GUIDANCE

Minimally invasive two-incision surgery for total hip replacement

NEW

Issue date – February 2005

Current evidence on the safety and efficacy of minimally invasive two-incision surgery for total hip replacement does not appear adequate for this procedure to be used without special

arrangements for consent and for audit or research. More evidence is required on the long-term safety and efficacy of this procedure and clinicians should submit data to the National Joint Registry (www.njrcentre.org.uk).

Clinicians wishing to undertake minimally invasive two-incision surgery for total hip replacement should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the public* is recommended.

Clinicians should have adequate training before performing this procedure. The British Hip Society has agreed to produce standards for training.

Further research will be useful. Clinicians are encouraged to enter patients into well-designed randomised controlled trials and to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

INTERVENTIONAL PROCEDURE GUIDANCE

Needle fasciotomy for Dupuytren's contracture

Issue date – February 2004

Current evidence on the safety and efficacy of needle fasciotomy for Dupuytren's contracture appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

INTERVENTIONAL PROCEDURE GUIDANCE

Percutaneous endoscopic laser thoracic discectomy

Issue date – May 2004

Current evidence on the safety and efficacy of percutaneous endoscopic laser thoracic discectomy does not appear adequate

for this procedure to be used without special arrangements for consent and for audit or research.

Clinicians wishing to undertake percutaneous endoscopic laser thoracic discectomy should take the following action.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having percutaneous endoscopic laser thoracic discectomy.

Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

INTERVENTIONAL PROCEDURE GUIDANCE

Percutaneous intradiscal electrothermal therapy for lower back pain

Issue date – August 2004

Current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.

Clinicians wishing to undertake percutaneous intradiscal electrothermal therapy for lower back pain should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for lower back pain.

Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

INTERVENTIONAL PROCEDURE GUIDANCE

Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain

Issue date – August 2004

Current evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research.

Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation for lower back pain should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's *Information for the Public* is recommended.
- Audit and review clinical outcomes of all patients having percutaneous intradiscal radiofrequency thermocoagulation for lower back pain.

Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.

INTERVENTIONAL PROCEDURE GUIDANCE

Percutaneous vertebroplasty

Issue date – September 2003

Current evidence on the safety and efficacy of percutaneous vertebroplasty appears adequate to support the use of the

procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

The following are recommended.

- This procedure should only be undertaken when there are arrangements for good access to a spinal surgery service, and with prior discussion between a specialist multidisciplinary team that includes a radiologist and a spinal surgeon.
- Clinicians should receive training to reach an appropriate level of expertise before carrying out this procedure. In particular, they must follow the manufacturer's instructions for making the cement, to reduce the risk of embolisation.
- The procedure should be limited to patients whose pain is refractory to more conservative treatment.

INTERVENTIONAL PROCEDURE GUIDANCE

Prosthetic intervertebral disc replacement

NEW

Issue date – November 2004

Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure. However, there is little evidence on outcomes beyond 2–3 years and collection of long-term data is therefore particularly important.

Clinicians wishing to undertake prosthetic intervertebral disc replacement should take the following actions.

- Ensure that patients understand the uncertainty about the procedure's long-term efficacy and provide them with clear written information. Use of the Institute's Information for the Public is recommended.
- Audit and review clinical outcomes of all patients having prosthetic intervertebral disc replacement.

Publication of longer-term efficacy outcomes will be useful in reducing the current uncertainty. The Institute may review the procedure upon publication of further evidence.

TECHNOLOGY APPRAISAL

Selection of hip prostheses for primary total hip replacement

Issue date – April 2000 **Review date** – April 2003

Using the most recent available evidence of clinical effectiveness, the best prostheses (using long term viability as the determinant) demonstrate a revision rate (the rate at which they need to be replaced) of 10% or less at 10 years. This should be regarded as the current 'benchmark' in the selection of prostheses for primary total hip replacement (THR).

The evidence used in support of any prosthesis, to establish whether or not it achieves this benchmark, should relate to data on 10 or more years follow-up from a number of centres, obtained via adequately sized, well conducted observational studies (preferably with consecutive patients from non-selected populations) or randomised controlled trials. Such evidence should have been published or be available for peer review.

The Institute also considers it reasonable to recommend consideration of prostheses with a minimum of 3 years revision rate experience (collected as described above) if their performance is consistent with the benchmark of a 10% revision rate at 10 years. Prostheses that achieve this 'entry benchmark' would then need to be subject to annual review (up to 10 years) to ensure that the revision rate remains consistent with the 10 year benchmark.

Prostheses (cemented, uncemented, and hybrid) that have not been shown to achieve either of these benchmarks, should be the subject of comparative clinical evaluation before they can be recommended for routine use in the NHS.

There is currently more evidence of the long-term viability of cemented prostheses, which, in many cases, occupy the lower end of the range of prostheses cost, than there is for uncemented and hybrid prosthesis.

NHS net users access hip database – www.pasa.nhs.uk/Inice