NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of double stapled transanal rectal resection procedure for obstructed defaecation syndrome

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in August 2005

Procedure name

Double stapled transanal rectal resection procedure (STARR)

Specialty societies

Association of Coloproctology of Great Britain and Ireland

Description

Indications:

STARR is indicated for obstructed defaecation syndrome (ODS). ODS is a complex and multifactorial condition which is often referred to as an 'iceberg syndrome' [1]. Women, particularly multiparious women, are more likely to present with symptoms of obstruction defaecation syndrome.

ODS is characterised by an urge to defecate but an impaired ability to expel the faecal bolus. Symptoms include: unsuccessful faecal evacuation attempts, excessive straining, pain, bleeding after defecation and a sense of incomplete faecal evacuation. Rectocele (herniation of rectum into vagina), internal rectal mucosal prolapse and rectal intssusception may also be associated with ODS. Other lesions may also be present such as genital prolapse, enterocele and non-relaxing puborectalis.

Current treatment and alternatives

Conservative treatment such as diet, biofeedback or pelvic floor retraining improves symptoms in the majority of patients with obstructed defecation. Surgery may be considered in patients for whom conservative treatments have failed and where there is an underlying structural abnormality such as rectocele.

There are various surgical procedures which can be used to correct the underlying condition which use abdominal, vaginal or laparoscopic approaches. However, many of these procedures have high recurrence and complication rates and are often unsuitable for patients who have rectocele with intussusception.

New procedures including single stapled trans-anal prolapsectomy and perineal levatorplasty (STAPL), and double stapled transanal rectal resection procedure (STARR) have been proposed to address structural abnormality associated with ODS.

What the procedure involves:

The STARR procedure is based on the stapled haemorrhoidopexy technique proposed by Longo [2]. Instead of using one circular stapler, the STARR procedure uses two circular staplers to produce a circumferential transanal full-thickness resection of the lower rectum. The combination of the two stapled resections eliminates the structural abnormalities associated with obstructed defaecation syndrome (ODS), namely rectal intussusception, rectocele, and mucosal prolapse.

Prior to undergoing the procedure, patients require a bowel preparation to clean the bowel and intravenous antibiotics.

The procedure is performed under intravenous sedation and general anaesthetic with the patient in the lithotomy position. A circular anal dilator isintroduced into the anal canal and secured with skin sutures. Sutures are placed in the anterior rectal wall at intervals above the anorectal junction in a semi-circumferential manner. Usually a total of 3 to 4 sutures are required. A spatulated retractor is positioned to protect the posterior rectal wall. A circular stapler is then introduced into the rectum and the open head positioned above the level of the most proximal suture. Traction is applied to the sutures to prolapse the redundant rectal wall into the anvil of the stapler. The stapler is closed and the vagina checked to exclude inadvertent incorporation of vagina wall to the stapler. The stapler is fired to perform the anterior rectal resection. The procedure is repeated for the posterior rectal resection. Two or more semi-circumferential sutures are place posteriorly above the anorectal junction. The anterior rectum is protected with a spatulated retractor. The second circular stapler is then introduced into the rectum with the open head positioned above the level of the most proximal suture. Traction is applied to the sutures to prolapse the redundant rectal wall into the anvil of the stapler. The stapler is closed and fired to perform the posterior rectal resection.
The circumferential staple line is checked for bleeding which if present is controlled with interrupted sutures.

Efficacy:

Five studies report on short-term efficacy outcomes following the STARR procedure (follow-up range 2.3 – 20 months)[3] [4,5,6,7]. In all five studies patients reported a reduction in symptoms association with ODS following the procedure. In a study of 50 women with intussusception and rectocele, 25 who had the STARR procedure experienced an improvement in preoperative constipation symptoms at a 20 month follow up. Defecography also demonstrated correction of rectocele and intussusception in all 25 patients [3]. Similar results were found in a study of 54 patients, where the authors noted significant reduction of the rectocele and intussusception in all patients [5]. In a smaller study, reported only as an abstract, anatomy following the STARR procedure was considered good in 72% and fair in 28% of patients [7].

Satisfaction or quality of life following the procedure was assessed in four studies [3 4 6 7]. They all reported either an improvement or excellent or good outcomes in the majority of patients at final follow-up. In one study of 90 patients, excellent or good outcomes (1–2 episodes per month or symptom free) were reported in 80% of patients (81/90) at 12 months; 5.6% (5/90) patients reported fairly good outcomes (more than two episodes per month); and 4.4% (4/90) of patients had unchanged symptoms [4].

The Specialist Advisors noted that there was limited data on this procedure, particularly good quality comparative data and studies reporting on long-term outcomes. They also expressed concern about whether the improvements reported in the literature will be sustained in the longer-term.

Safety:

In one study of 90 patients, early complications included five cases of urinary retention (5.6%), four cases of bleeding requiring readmission (4.4%) and one case of pneumonia (1.1%). Complications at 1 month included 16 cases of faecal urgency (17.8%), eight cases of incontinence to flatus (8.9%), and two cases of stenosis (2.2%). At 12 months there was one case of both faecal urgency and incontinence to flatus (1.1%), with three cases stenosis (3.3%) [4]. In another study that specifically reported on 14 patients experiencing complications following the STARR procedure, severe rectal bleeding was reported in two patients, and there was one case of pelvic sepsis. Persistent anal pain was reported in seven patients, three patients had faecal incontinence, and symptoms of ODS recurred in seven patients [6]. However, patients in this study included those with non-relaxing puborectalis muscle symptoms, which were excluded in other studies. This may account for the high rate of complications. Two cases of rectovaginal fistulae following a STARR procedure have also been reported[1].

The Specialist Advisors noted that there was a risk of recto-vaginal fistula following the procedure. This could arise if the vagina is caught up in the stapling procedure or is there is a bleeding in the recto-vaginal septum. Other complications include bowel perforation, peritonitis and pelvic sepsis.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to double stapled transanal rectal resection. Searches were conducted through MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index, covering the period from their commencement to August 2005. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following table shows the selection criteria that were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts, the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with symptoms of obstructed defecation syndrome in association with rectocele and/or intussusception.
Intervention/test	Double stapled transanal rectal resection
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English language articles were excluded unless they were thought to add substantively to the English language evidence base.

List of studies included in the overview

This overview is based on four published studies (two from the same institution [3] [4]) and two abstracts [6] [7].

One randomised controlled trial is included in the main data extraction table [3]. This study compares two new procedures (single stapled trans-anal prolapsectomy and perineal levatorplasty (STAPL), with double stapled transanal rectal resection (rather than the STARR procedure with an established comparator).

Existing systematic reviews or health technology assessments on this procedure

There were no published reviews identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance.

Interventional Procedures:
The Interventional Procedures Programme has published guidance on circular stapled haemorrhoidectomy.

Technology Appraisals:
Stapled haemorrhoidectomy has been referred to the Technology Appraisal Programme. A draft scope is scheduled to go out for consultation in 2006.

Clinical Guidelines:
None

Public Health:
None

Table 2 Summary of key efficacy and safety findings on double stapled transanal rectal resection

Abbreviations used: STARR – Stapled transanal rectal resection procedure; STAPL – Stapled transanal prolapsectomy associated with perineal levatorplasty; VAS – Visual analogue scale; CSCGS – Constipation scoring and continence grading system

<table>
<tr><th>Study details</th><th>Key efficacy measures</th><th>Key safety measures</th><th>Comments</th></tr>
<tr>
<td>Boccasanta et al (2004) [3]

Italy

Randomised controlled trial (purpose of this review should be analysed as a case series)

October 1999 – October 2001

50 women with outlet obstruction

25 women underwent STARR
Mean age: 54.6 years

25 women underwent STAPL
Mean age: 53.2 years

Mean follow-up: 22.3 months
STARR group
23.4 months in the STAPL group

Patient Characteristics: Women presenting with outlet obstruction who were non-responders (n=67) to medical therapy and biofeedback. All had intussusception and rectocele and symptoms persisting for more than 6 months.

Patients were excluded if presenting with faecal incontinence, enterocele, recurrent rectocele or mega rectum, concomitant genital prolapse or</td>
<td>Outcomes measured: pain (VAS), anorectal manometry changes and symptom resolution rate (CSCGS), operative time, hospital stay and time to return to work (last three outcomes not reported in the below table)

Preoperative scores are in italics.
Postoperative symptoms measured at 20 months.
<table>
<tr><th></th><th>STARR</th><th>STAPL</th></tr>
<tr><td>Feeling of incomplete evacuation</td><td>25 (100%)
4 (16%)</td><td>25 (100%)
5 (20%)</td></tr>
<tr><td>Assistance</td><td>23 (92%)
4 (16%)</td><td>22 (88%)
4 (16%)</td></tr>
<tr><td>Painful evacuation effort</td><td>19 (76%)
4 (16%)</td><td>19 (76%)
5 (20%)</td></tr>
<tr><td>Laxatives</td><td>14 (56%)
3 (12%)</td><td>13 (52%)
3 (12%)</td></tr>
<tr><td>Enema</td><td>9 (36%)
2 (8%)</td><td>10 (40%)
2 (8%)</td></tr>
<tr><td>Abdominal pain</td><td>5 (20%)
2 (8%)</td><td>6 (24%)
3 (12%)</td></tr>
<tr><td>Bleeding</td><td>4 (16%)
1 (4%)</td><td>4 (16%)
1 (4%)</td></tr>
<tr><td>Dyspareunia</td><td>0
0</td><td>0
5 (20%)</td></tr>
</table>
<table>
<tr><th></th><th>STARR</th><th>STAPL</th></tr>
<tr><td>Mean score: Constipation Scoring System</td><td>18.01
5.65</td><td>17.95
6.20</td></tr>
<tr><td>Mean score: Continence Grading Scale</td><td>0.28
0.36</td><td>0.24
0.20</td></tr>
</table>
Authors not that there were no differences between the</td>
<td>Complications:
<table>
<tr><th></th><th>STARR</th><th>STAPL</th></tr>
<tr><td>Early (< 7 days)</td><td></td><td></td></tr>
<tr><td>Urinary retention</td><td>2 (8%)</td><td>2 (8%)</td></tr>
<tr><td>Bleeding</td><td>1 (4%)</td><td>0</td></tr>
<tr><td>Delayed healing of the wound:</td><td>-</td><td>10 (40%)</td></tr>
<tr><td>Late:</td><td></td><td></td></tr>
<tr><td>Urge to defecate</td><td>4 (16%)</td><td>1 (4%)</td></tr>
<tr><td>Incontinence to flatus</td><td>2 (8%)</td><td>1 (4%)</td></tr>
<tr><td>Stenosis</td><td>1 (4%)</td><td>1 (4%)</td></tr>
<tr><td>Dysparenunia</td><td>0</td><td>5 (20%)</td></tr>
</table></td>
<td>Originally 96 patients were recruited for conservative treatment. 67 were non-responders. From those 17 patients were excluded from the study for reasons including genital prolapse or cystocoele (n=5) and faecal incontinence (n=4).

Study powdered at 0.8

Randomisation: Assigned using random permuted blocks. Assignment of the treatment was made by a nurse in the ward before the operation.

Definitions of clinical outcomes:
Excellent: symptom free
Good: 1–2 episodes per month of use of laxatives without digital assistance, use of enema or bleeding.
Fairly good: when they had more than more than 2 episodes per month
Poor: when they were unchanged.</td>
</tr>
</table>

Abbreviations used: STARR – Stapled transanal rectal resection procedure; STAPL – Stapled transanal prolapsectomy associated with perineal levatorplasty; VAS – Visual analogue scale; CSCGS – Constipation scoring and continence grading system

<table>
<tr><th>Study details</th><th>Key efficacy measures</th><th>Key safety measures</th><th>Comments</th></tr>
<tr><td>cystocoele.

Funding source/Conflict of interest: Study was supported by grant (non commercial)</td><td>groups except for the onset of dyspareunia.

Pain
(Absolute figures were not given in the paper).
Pain was significantly higher after STAPL, particularly from the third postoperative day (probably from perineal wound)

Defecography
The descent of anorectal junction was reduced by both operations without statistical differences between the two groups.

7 patients in the STAPL group had a little residual rectocele, while both rectocele and intussusception were corrected in all patients in the STARR group.

Anorectal manometry
Neither operation modified anal pressures

Satisfaction (measured at 20 months)
<table>
<tr><td></td><td>STARR</td><td>STAPL</td></tr>
<tr><td>Excellent</td><td>11 (44%)</td><td>9 (36%)</td></tr>
<tr><td>Good</td><td>11 (44%)</td><td>10 (40%)</td></tr>
<tr><td>Fairly good</td><td>2 (8%)</td><td>4 (16%)</td></tr>
<tr><td>Poor</td><td>1 (4%)</td><td>2 (8%)</td></tr>
</table></td><td></td><td></td></tr>
</table>

Abbreviations used: STARR – Stapled transanal rectal resection procedure; STAPL – Stapled transanal prolapsectomy associated with perineal levatorplasty; VAS – Visual analogue scale; CSCGS – Constipation scoring and continence grading system

<table>
<tr><th>Study details</th><th>Key efficacy measures</th><th>Key safety measures</th><th>Comments</th></tr>
<tr>
<td>Boccasanta et al (2004) [4]

January to October 2001

90 patients

Patient characteristics: All patients had mucosal prolapse, 87 had rectocele and 28 patients haemorrhoids and 1 patients had rectal polyps. 58 patients were multiparous, and 57 patients had a previous episiotomy.

Mean follow-up: 16.3 months (outcomes reported at 12 months)</td>
<td>Outcomes measured: pain (VAS), anorectal manometry changes and symptom resolution rate (CSCGS), operative time, hospital stay and time to return to work

Postoperative symptoms measured at 12 months.
<table>
<tr><th></th><th>Preoperative</th><th>Postoperative</th></tr>
<tr><td>Feeling of incomplete evacuation</td><td>89 (98.9%)</td><td>17 (18.9%)</td></tr>
<tr><td>Assistance</td><td>79 (87.8%)</td><td>4 (4.4%)</td></tr>
<tr><td>Painful evacuation effort</td><td>57 (63.3%)</td><td>18 (20%)</td></tr>
<tr><td>Laxatives</td><td>47 (52.2%)</td><td>9 (10%)</td></tr>
<tr><td>Enema</td><td>40 (44.4%)</td><td>2 (2.2%)</td></tr>
<tr><td>Abdominal pain</td><td>26 (28.8%)</td><td>11 (12.2)</td></tr>
<tr><td>Bleeding</td><td>16 (17.8%)</td><td>2 (2.2%)</td></tr>
<tr><td>Mean score: Constipation Scoring System</td><td>13.02</td><td>4.52</td></tr>
<tr><td>Mean score: Continence Grading Scale</td><td>0.24</td><td>0.39</td></tr>
</table>
Defecography
Both rectocele and intussusception were corrected in all patients in the STARR group.

Anorectal manometry
Anal pressure did not significantly change after procedure.

Satisfaction
<table>
<tr><th></th><th>1 month</th><th>12 months</th></tr>
<tr><td>Excellent</td><td>32 (35.5%)</td><td>48 (53.3%)</td></tr>
<tr><td>Good</td><td>42 (46.7%)</td><td>33 (36.7%)</td></tr>
<tr><td>Fairly good</td><td>11 (12.2%)</td><td>5 (5.6%)</td></tr>
<tr><td>Poor</td><td>5 (5.6%)</td><td>4 (4.4%)</td></tr>
</table>
</td>
<td>Complications:

Early complications (< 7 days)

5 patients (5.6%) urinary retention
4 patients (4.4%) bleeding requiring readmission
1 patient (1.1%) pneumonia

Late complications: (1 month)
16 patients (17.8%) urge to defecate
8 patients (8.9%) incontinence to flatus
2 patients (2.2%) stenosis

Late complications: (12 months)
1 patient (1.1%) urge to defecate
1 patient (1.1%) incontinence to flatus
3 patients (3.3%) stenosis</td>
<td>156 patients with ODS in whom a combination of intussusception and rectocele was found were selected and operated on – 66 patients were excluded for reasons included non relaxing puborectalis muscle (n=27); genital prolapse or cystocoele (n=14) recurrent rectocele and/or enterocele (n=8) and faecal incontinence (n=8)

All surgical teams had previous experience in conventional operations for rectocele, rectal prolapse and stapled anopexy for haemorrhoids (at least 30 operations)

Clinical outcomes as defined above [3]

Control of bleeding after stapling was required anteriorly in 95.5% of patients.</td>
</tr>
</table>

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<table>
<tr><th>Study details</th><th>Key efficacy measures</th><th>Key safety measures</th><th>Comments</th></tr>
<tr>
<td>Grassi et al (2003) [5]
Italy

Case series

January 2001 – June 2003

54 patients
- All had patients had rectocele
- 31 patients had an association between rectocele and intussusception

Mean age: Not reported in study.

Follow-up: 1 and 6 months

Funding source/Conflict of interest: not reported in study</td>
<td>Outcomes measured: symptomology dimension of the rectocele, rectal lumen diameter, distance of the suture line from the anorectal junction, evidence of a suture line, presence of morphologic anomalies, eventual dislocation of the anorectal junction after the procedure (not all outcomes have been reported below)

Authors note significant reduction of the rectocele and intussusception in all patients.

In 45 cases no significant deformity of the rectal ampulla was appreciable; however, in 9 cases a residual anterior rectocele was evident.

Distance from the anorectal junction and the suture line ranged from 3.8 cm – 11.6cm.
Rectal lumen diameter ranged from 4 to 8cm

<table>
<tr><th></th><th>Preoperative</th><th>Postoperative</th></tr>
<tr><td>Excessive straining</td><td>37 (68.5%)</td><td>Appeared to be significantly reduced</td></tr>
<tr><td>Assistance</td><td>43 (79.6%)</td><td>Appeared to be significantly reduced</td></tr>
<tr><td>Painful evacuation effort</td><td>50 (92.5%)</td><td>Appeared to be significantly reduced</td></tr>
<tr><td>Laxatives</td><td>28 (51.8%)</td><td>2 (3.7%)</td></tr>
<tr><td>Enema</td><td>18 (33.3%)</td><td>1 (1.85%)</td></tr>
<tr><td>Faecal incontinence
- gas
- liquid
- solid</td><td>
8 (14.4%)
4 (7.4%)
3 (5.5%)</td><td>
1 (1.85%)
1 (1.85%)
1 (1.85%)</td></tr>
</table>
</td>
<td>Complications:
12 patients (22.2%) urgency in defaecation in the immediate post-operative period – reduced to 1 patient at six months.

2 patients (3.7%) bleeding
2 patients (3.7%) substenosis.</td>
<td>71 patients underwent procedure originally – only those in whom defecogrphay or colpocystodefecography were performed before and after the procedure were include i.e. 54 patients.

It is difficult to tell if these 54 patients are in somehow different to the original 71 patients (i.e. likely to have better outcomes)

Patients classified according to Longos stages of ODS.

Limited information on patient characteristics.

Absolute figures were not given for all outcomes.

Unclear how patient symptoms were measured.

Unclear at what time points some of the outcomes have been measured.

No information given on the experience on the surgeon performing the procedure.</td>
</tr>
</table>

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<table>
<tr><th>Study details</th><th>Key efficacy measures</th><th>Key safety measures</th><th>Comments</th></tr>
<tr>
<td>Dodi et al (2003) [6]
Italy

Case series

14 patients who had presented with severe complications or recurrence of symptoms following the STARR procedure.
(A total of 29 patients had the STARR procedure – those patients who did not experience complications i.e. 15 patients are not reported on in the study)

Age: 36-72 years

Patients characteristics: Women with rectocele and internal mucosal prolapse

Median follow up: 12 months (range 2-24 months)</td>
<td>Outcomes measured: Efficacy was not the aim of the paper</td>
<td>Complications:

1 patient had severe intraoperative bleeding which required multiple layer manual sutures.

2 patients had severe rectal bleeding early after the procedure – one requiring a blood transfusion.

1 patient had pelvic sepsis

7 patients had persistent anal pain

3 patients had faecal incontinence

7 patients had recurrent ODS – further investigations revealed rectocele and or internal mucosal prolapse in six patients.

6 patients had a non-relaxing puborectalis muscle</td>
<td>Aim of the paper: reporting on those patients experiencing complications following the procedure.

Authors note the surgeons were experienced in colorectal surgery and had performed at least 5 (range 5-10) STARR procedures previously.

Authors conclude that parity, spastic floor syndrome and psychoneurosis seem to be the risk factors predisposing to failure of the STARR procedure.</td>
</tr>
<tr>
<td>Nystrom et al (2004) [6]

Case series (4 centres)

36 patients

Mean age: 56 years

Patient characteristics: Women with longstanding symptoms and a proctocoel (97%) and rectal</td>
<td>Outcomes measured: symptoms, hospital stay, quality of life, time to defecation

<table>
<tr><th></th><th>Preoperative</th><th>6 months</th></tr>
<tr><td>Incomplete evacuation</td><td>33</td><td>13</td></tr>
<tr><td>Straining</td><td>23</td><td>4</td></tr>
<tr><td>Assistance</td><td>24</td><td>7</td></tr>
<tr><td>Laxatives</td><td>13</td><td>8</td></tr>
<tr><td>Anal pruritus</td><td>23</td><td>3</td></tr>
<tr><td>Anal bleeding</td><td>12</td><td>1</td></tr>
</table>
</td>
<td>Complications:

Authors note that many patients had some degrees of defecatory urgency in the early postoperative course.

4 patients had a relative stenosis of the staple line

1 patient developed an anastomatic ulcer that healed spontaneously.</td>
<td>Abstract – limited information on patient demographics and how outcomes were assessed.

1 patient was discontinued from the study (no further details given)</td>
</tr>
</table>

Abbreviations used: STARR – Stapled transanal rectal resection procedure; STAPL – Stapled transanal prolapsectomy associated with perineal levatorplasty; VAS – Visual analogue scale; CSCGS – Constipation scoring and continence grading system

<table>
<tr><th>Study details</th><th>Key efficacy measures</th><th>Key safety measures</th><th>Comments</th></tr>
<tr>
<td>intussusception.

Follow-up: 6 months</td>
<td>
<table>
<tr><td>Anorectal pain</td><td>18</td><td>9</td></tr>
<tr><td>Abdominal pain</td><td>20</td><td>6</td></tr>
<tr><td>Gas incontinence</td><td>13</td><td>6</td></tr>
<tr><td>Ability to defecate within 5 mins</td><td>11%</td><td>71%</td></tr>
<tr><td>Patient global assessment of quality of life</td><td>4.7</td><td>7.7</td></tr>
</table>

Authors note that hospital stays varied according to centre where the operation took place (range from 2 – 7 days)
</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regenet et al (2004) [7]

Case series

July 2002 – July 2003

30 patients

Mean age: 59 years

Patient chrematistics: Women complaining of ODS, 73% of patients had a rectocele, with an internal procidentia in 69% of patients.

Follow-up: 68 days</td>
<td>
Outcomes measured: anatomy results, patient satisfaction, presence of symptoms, hospital stay, and operative time.

Anatomy was evaluated as good (72%) and fair (28%) while 30% of patients had rectocoele and 10% internal procidential.

Global satisfaction was evaluated as good (52%), fair (41%) and failed in (7%).

<table>
<tr><td></td><td>Preoperative</td><td>Follow-up</td></tr>
<tr><td>Dyschesia</td><td>76%</td><td>7%</td></tr>
<tr><td>Incomplete evacuation</td><td>54%</td><td>0</td></tr>
<tr><td>Assistance</td><td>64%</td><td>2%</td></tr>
<tr><td>Anal incontinence</td><td>10%</td><td>10%</td></tr>
</table>
</td>
<td>
Complications:

2 patients had bleeding (1 patients requiring reoperation)

1 patient had a stenosis

20% of patients had urgency
</td>
<td>
Abstract – limited information on patient demographics and how outcomes were assessed.

Anatomy results were evaluated by the surgeon in 3 stages (good, fair and failed).

Global satisfaction was evaluated by patients in 3 stages (good, fair, failed)
</td>
</tr>
</table>

Validity and generalisability of the studies

- There is currently limited published evidence on this procedure, particularly in regards to long-term outcomes. It has been noted that similar procedures in comparable populations have required long-term follow up to adequately assess recurrence and complication rates [2].

- The randomised controlled trial in Table 2 is in fact a randomised trial of two novel techniques, rather than one novel technique in comparison to an established procedure. This limits the conclusions that can be drawn with regards to the new procedure.

- The majority of published evidence is from one centre [3 4], and it is difficult to know if these results are generalisable to other centres.

- Obstructive defecation is a complex and poorly understood syndrome [2]. Patients presenting with symptoms may also have one or more underlying anatomical conditions that can contribute to ODS. For the two studies undertaken at the one centre [3 4], both reporting good outcomes, quite specific and select inclusion and exclusion criteria were applied to patients (rectocele is the dominant clinical finding). It appears that such strict criteria were not applied in the other studies. This is likely to have an influence on the reported efficacy and safety outcomes.

- It seems that a learning curve is association with this procedure, however, not all studies reported on the experience of surgeons undertaken the procedure.

- In general, patient characteristics were poorly reported.

- Few studies addressed quality of life or psychological outcomes, which is an important component of patients presenting with symptoms of ODS.

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.
Mr David Bartolo, Mr Graeme Duthie, Professor Ralph John Nicholls,Professor Norman Williams

- Not all patients with obstruction defecation syndrome are suitable for this procedure.

- Surgery for this condition has a long history of early good results and poor long term results.

- There were concerns that this procedure should not be disseminated before it has been proved to be superior to conventional treatment in appropriate trials.

- Long term outcomes are needed.

- Follow-up beyond to 2 years is need to determine successes and failures associated with this procedure.

Issues for consideration by IPAC

There appears to be a significant amount of interest in this procedure, as evidenced by the number of abstracts from recent conferences reporting on outcomes following this procedure.

A prospective audit/registry is currently being devised to be run under the auspices of the Association of Coloproctology of Great Britain and Ireland. The Association hopes to start this audit in 2006.

There also appears to be a European Registry (manufacturer involved).

References

1 Pescatori M, Dodi G, Salafia C et al. (2005) Rectovaginal fistula after double-stapled transanal rectotomy (STARR) for obstructed defaecation [5]. *International Journal of Colorectal Disease* Vol. 20: 85.

2 Jayne DG and Finan PJ. (2005) Stapled transanal rectal resection for obstructed defaecation and evidence-based practice. *British Journal of Surgery* 92: 793-794.

3 Boccasanta P, Venturi M, Salamina G et al. (2004) New trends in the surgical treatment of outlet obstruction: clinical and functional results of two novel transanal stapled techniques from a randomised controlled trial. *International Journal of Colorectal Disease* 19: 359-369.

4 Boccasanta P, Venturi M, Stuto A et al. (2004) Stapled transanal rectal resection for outlet obstruction: a prospective, multicenter trial. *Diseases of the Colon & Rectum* 47: 1285-1296.

5 Grassi R, Romano S, Micera O et al. (2005) Radiographic findings of post-operative double stapled transanal rectal resection (STARR) in patient with obstructed defecation syndrome (ODS). *European Journal of Radiology* 53: 410-416.

6 Dodi G, Pietroletti R, Milito G et al. (2003) Bleeding, incontinence, pain and constipation after STARR transanal double stapling rectotomy for obstructed defecation. *Techniques in Coloproctology* 7: 148-153.

7 Regenet N, Frampas E, Meurette G et al. (2004) Obstruction defecation syndrome: Prospective open study of 30 patients operated by stapled transanal rectal resection. *Diseases of the Colon & Rectum* 47: 615-616.

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Appendix A: Additional papers on double stapled transanal rectal resection not included in the summary tables

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table. It is by no means an exhaustive list of potentially relevant studies or a detailed description of outcomes.

Most of the articles are abstracts presented at presented at the American Society of Colon and Rectal Surgeons (Philadelphia, April 2005), and the World Congress of Coloproctology and Pelvic Disease (Rome, June 2005).

Article title	Number of patients/ follow-up	Reasons for non inclusion	Direction of conclusions
Pescatori M, Dodi G, Salafia C et al. (2005) Rectovaginal fistula after double-stapled transanal rectotomy (STARR) for obstructed defaecation [5]. *International Journal of Colorectal Disease* Vol. 20: 85.	2 patients	Case report – results in efficacy summary section.	Need further trials to assess the complications.
Binda GA, Pescatori M, and Romano G. (2005) The dark side of double-stapled transanal rectal resection.[comment]. *Diseases of the Colon & Rectum.48(9):1830-1; author reply 1831-2*	37 patients 2000-2004 FU: 12 months	Letter – little detail.	Postoperative bleeding occurred in 15% of patients. 11% had faecal incontinence. 33% had recurrence of constipation and rectocele.
Senagore, A., Gallagher, J., Hull, T et al (2005). A short term assessment of the efficacy of the STARR procedure for obstructed defecation syndrome. American Society of Colorectal and Rectal Surgeons April 30 – May 5, Philadelphia.	21 patients FU: 1 month	Conference abstract	All components of the ODS score decreased postoperatively. One significant complication
Lenisa, L., Rusconi, A., Mascheroni, L et al (2005). Stapled Trans-Anal Rectal Resection (STARR) for rectal prolapse and rectocele in women. A two-year experience with > 6 months follow up. American Society of Colorectal and Rectal Surgeons April 30 – May 5, Philadelphia.	24 patients FU: 6 months	Conference abstract	All patients declared an improvement in evacuatory function. No operative mortality or major complications.

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Khader, A., Bianchi, A., Ludovici, M et al (2005). STARR in obstructed defecation syndrome associated with rectocele: our experience in 72 Cases. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	72 patients FU: 12 months	Conference abstract	All constipation symptoms significantly improved. No intraoperative complication was observed.
Angelone, G, Giardiello, C., Prota, C. (2005). STARR: Complications and Follow-up. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	58 patients FU: 12 months	Conference abstract	Major complications: two patients had bleeding, and one late bleeding.
Queralto, M., Cabartot, P.H., Bonnaud, G. (2005). Surgical treatment of symptomatic rectocele. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	110 patients FU: 13 months	Conference abstract – randomised controlled trial of two new procedures.	Decrease in symptoms.
Ceriani, V., Lodi, R., Faleschini, E. et al (2005). Stapled Transanal Rectal Resection (STARR) in the outlet obstructive constipation. Preliminary Experience on 100 Patients. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	100 patients FU: 12 months	Conference abstract	All patients had improvement of symptoms. 3 cases of bleeding
Di Bella, R., Schiano di Viscone, M., Picciano, P. (2005). Obtructed Defecation: a new therapeutic option. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	63 patients FU: 90 days	Conference abstract	Reduction in symptoms 4 cases of bleeding
Toschi, C., Ismail, I., Cavalli, E et al (2005). Stapled Transanal rectal resection for obstructed defecation: the post operative course our experience in 40 cases. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	40 patients FU: unclear	Conference abstract	2 cases of bleeding
Ferulano, G.P., Alabiso, M., Dilillo, S. et al (2005). Evaluation of the obstructed defecation syndrome treated by stapled transanal rectal resection procedure. Single blind prospective study. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	59 patients FU 12 months	Conference abstract	Majority of patients are satisfied, in majority of patients symptoms improved. 1 case of bleeding 3 cases of urgency
Pietrantoni, C., Carducci, G., Favoriti, M et al (2005). Stapled Transanal rectal resection for obstructed defecation syndrome: personal experience and results. World Congress of Coloproctology and Pelvic Disease (Rome June 2005).	54 patients FU: 6 months -3 years	Conference abstract	High satisfaction. Early complications: Pain, urinary retentions, bleeding Late complications: urge to defecate, incontinence to flatus, stenosis.

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Appendix B: Related NICE guidance for double stapled transanal rectal resection

Guidance	Recommendation
Interventional Procedures	Current evidence on the safety and efficacy of circular stapled haemorrhoidectomy appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance. Clinicians wishing to learn circular stapled haemorrhoidectomy should be trained, mentored and monitored, as described in the Association of Coloproctology's consensus document on the procedure (see the association's website: www.acpgbi.org.uk).
Technology Appraisals	Stapled haemorrhoidectomy (in development)
Clinical Guidelines	Not applicable
Public Health	Not applicable

Appendix C: Literature search for double stapled transanal rectal resection

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.
For all other databases a simple search strategy using the key words in the title was employed.

Overview appendix: search history

Procedure number: 328	Procedure Name: Stapled transanal rectal resection	
Databases	**Version searched (if applicable)**	**Date searched**
The Cochrane Library	2005 Issue 3	17.8.2005
CRD	July 2005	16.8.2005
Embase	1980 to 2005 Week 32	15.8.2005
Medline	1966 to August Week 1 2005	15.8.2005
Premedline	August 12, 2005	16.8.2005
CINAHL	1982 to August Week 2 2005	17.8.2005
British Library Inside Conferences (limited to current year only)	Current year	17.8.2005
National Research Register	2005 Issue 3	17.8.2005
Controlled Trials Registry	N/A	17.8.2005

Search strategy used in Medline

1	(trans?anal adj3 stapl$).tw
2	STARR.tw.
3	(double stapl$ procedure$ or DSP).tw.
4	(trans?anal adj2 anteroposterior adj2 proctotomy).tw.
5	(trans?anal adj2 anteroposterior adj2 rectotomy).tw.
6	stapled mucosectomy.tw.
7	Surgical Stapling/
8	or/1-7
9	exp Fecal Incontinence/
10	exp Rectal Prolapse/
11	exp RECTOCELE/
12	exp Intestinal Obstruction/
13	def?ecation disorder$.tw.
14	obstructed def?ecation.tw.
15	pelvic outlet obstruction$.tw.

16	colon inertia.tw.
17	anus prolapse.tw.
18	rectal mucosal prolapse.tw.
19	R-IMP.tw.
20	or/9-19
21	8 and 20
22	Animals/
23	Humans/
24	22 not (22 and 23)
25	21 not 24