Stapled transanal rectal resection for obstructed defaecation syndrome

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg351

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful
discrimination, advance equality of opportunity, and foster good relations. Nothing in this
guidance should be interpreted in a way that would be inconsistent with compliance with
those duties. Providers should ensure that governance structures are in place to review,
authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally
sustainable health and care system and should assess and reduce the environmental
impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG169.

1  Guidance

This document replaces previous guidance on stapled transanal rectal resection for
obstructed defaecation syndrome (interventional procedure guidance 169).

1.1  Current evidence on the safety and efficacy of stapled transanal rectal
resection (STARR) for obstructed defaecation syndrome (ODS) is
adequate in the context of this condition, which can significantly affect
quality of life. The procedure may therefore be used with normal
arrangements for clinical governance, consent and audit.

1.2  Stapled transanal rectal resection for ODS should be carried out only in
units specialising in the investigation and management of pelvic floor
disorders. Patient selection and management should involve a
multidisciplinary team including a urogynaecologist or urologist and a
colorectal surgeon experienced in this procedure.

2  The procedure

2.1  Indications and current treatments

2.1.1  ODS is a complex and multifactorial condition, characterised by an urge
to defaecate but an impaired ability to expel the faecal bolus. Symptoms
include unsuccessful faecal evacuation attempts, excessive straining, pain, bleeding after defaecation and a sense of incomplete faecal evacuation. ODS is often associated with structural defects in the rectum such as rectocele, internal rectal prolapse and perineal descent. Women, particularly multiparous women, are more likely to present with symptoms of ODS than men.

2.1.2 Conservative treatments include diet, biofeedback, laxatives and pelvic floor retraining. In patients refractory to conservative treatment, and/or if a structural abnormality is present, surgery may be considered including stapled transanal prolapsectomy and perineal levatorplasty (STAPL) and laparoscopic ventral mesh sacrocolporectopexy.

2.2 **Outline of the procedure**

2.2.1 Patients having STARR usually receive bowel preparation and prophylactic antibiotics before surgery. With the patient under spinal or general anaesthesia, a circular anal dilator is introduced into the anal canal and secured with skin sutures. Resection of the redundant parts of the anterior and posterior rectal walls is done sequentially. Traction sutures are inserted (with an anoscope to aid visualisation) above the anorectal junction to prolapse the redundant rectal wall into the anvil of a stapler, which is then fired to produce a full thickness resection. The opposite posterior or anterior wall is protected with a spatula. Any bleeding at the circumferential staple line is controlled with interrupted sutures.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3 **Efficacy**

2.3.1 A randomised controlled trial (RCT) of 50 patients treated by STARR or STAPL reported a good or excellent clinical outcome (1–2 episodes per month or symptom free) in 88% (22/25) and 76% (19/25) of patients
respectively at 20-month follow-up. An RCT of 119 patients treated by STARR or biofeedback reported treatment success (defined as a decrease in ODS score of at least 50% at 1 year) in 82% (44/54) and 33% (13/39) of patients respectively (p < 0.0001).

2.3.2 A non-randomised comparative study of 73 patients reported a failure in 17% (6/36) for women treated by STARR and 22% (8/37) for women treated by transvaginal repair at mean follow-ups of 8 months and 14 months respectively (p = 0.80).

2.3.3 Register data on 2838 patients reported a mean baseline ODS score (higher score indicates more severe symptoms) of 17.8 (95% confidence interval [CI] 15.5 to 16.0). This reduced to 5.8 (95% CI 5.3 to 6.4) at 12-month follow-up among 2224 patients treated by STARR (p < 0.001).

2.3.4 The Specialist Advisers listed an additional key efficacy outcome as improvement in quality of life.

2.4 Safety

2.4.1 Septic events (not otherwise described) were reported in 4% (124/2838) of patients in a register. In a case series of 38 patients, 1 patient developed septic shock and died as a result of necrotising pelvic fasciitis.

2.4.2 The register of 2838 patients reported 1 case of rectal necrosis requiring a diverting stoma (timing of event not stated).

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2.4.4 Early stenosis was reported in 1 patient in each treatment group in the RCT of STARR (25 patients) versus STAPL (25 patients), and in 2% (2/90), 2% (2/85) and 1% (1/104) in case series of 90, 85 and 104 patients respectively. A 3% incidence of stenosis was reported after 1 month in the case series of 90 patients.

2.4.5 Rectovaginal fistula (timing of event not stated) was reported in the
register of 2838 patients and case series of 230 patients in 1 patient each.

2.4.6 Postoperative faecal incontinence was reported in 8% (3/36) of patients treated by STARR and 3% (1/37) of patients treated by transvaginal repair (follow-up not stated) in the non-randomised comparative study of 73 patients; and in 9% (9/104) of patients at 12-month follow-up in the case series of 104 patients. Dyspareunia was reported in less than 1% (3/2838) of patients from the register of 2838.

2.4.7 Defaecatory urgency was reported in 16% (4/25) and 4% (1/25) of patients treated by STARR or STAPL respectively (within 7 days after surgery). Defaecatory urgency continued to occur in 6% (6/104) of patients in the case series of 104 patients at 12-month follow-up. Instances of bleeding were reported in 10 studies with rates of 2% (1/54), 3% (3/104), 3% (2/68), 4% (1/25), 4% (4/90), 4% (10/230), 5% (143/2838), 7% (2/29), 12% (10/85) and 19% (7/36). In 6 of these studies, at least 1 patient required further hospital intervention.

2.4.8 The Specialist Advisers considered theoretical adverse events to include pain, staple line complications, rectal wall perforation or haematoma.

2.5 Other comments

2.5.1 The Committee noted that the procedure may sometimes be followed by defaecation urgency and incontinence. However, it remains unclear whether these sequelae are caused by the procedure or whether they are the results of pre-existing abnormalities.

2.5.2 NICE received 9 completed questionnaires from patients treated by the procedure. Five of the patient commentators reported substantial improvements in quality of life after the procedure.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk
Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

www.nice.org.uk/accreditation