



Stapled transanal rectal resection for obstructed defaecation syndrome

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG169.

1 Guidance

- 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

Obstructed defaecation syndrome (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 stapled transanal rectal resection (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.

2.3 Efficacy

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 <u>overview</u>.

2.3.1 A randomised controlled trial (RCT) of 50 patients treated by STARR or STAPL reported a good or excellent clinical outcome (1 to 2 episodes per month or symptom free) in 88% (22 out of 25) and 76% (19 out of 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 out of 54) and 33% (13 out of 39) of patients respectively (p<0.0001).

- 2.3.2 A non-randomised comparative study of 73 patients reported a failure in 17% (6 out of 36) for women treated by STARR and 22% (8 out of 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 2,838 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 2,224 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 out of 2,838) 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.
- The register of 2,838 patients reported 1 case of rectal necrosis requiring a diverting stoma (timing of event not stated).
- 2.4.3 The register of 2,838 patients reported 1 case of rectal necrosis requiring a diverting stoma (timing of event not stated).
- 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 out of 90), 2% (2 out of 85) and 1% (1 out of 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

2,838 patients and case series of 230 patients in 1 patient each.

- 2.4.6 Postoperative faecal incontinence was reported in 8% (3 out of 36) of patients treated by STARR and 3% (1 out of 37) of patients treated by transvaginal repair (follow-up not stated) in the non-randomised comparative study of 73 patients; and in 9% (9 out of 104) of patients at 12-month follow-up in the case series of 104 patients. Dyspareunia was reported in less than 1% (3 out of 2,838) of patients from the register of 2,838.
- Defaecatory urgency was reported in 16% (4 out of 25) and 4% (1 out of 25) of patients treated by STARR or STAPL respectively (within 7 days after surgery). Defecatory urgency continued to occur in 6% (6 out of 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 out of 54), 3% (3 out of 104), 3% (2 out of 68), 4% (1 out of 25), 4% (4 out of 90), 4% (10 out of 230), 5% (143 out of 2,838), 7% (2 out of 29), 12% (10 out of 85) and 19% (7 out of 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

- 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

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.