

Decision-making Algorithm for the STARR procedure in Obstructed Defecation Syndrome: Position statement of the group of STARR Pioneers

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Internal rectal prolapse (rectal intussusception) and rectocele are frequent clinical findings in patients suffering from refractory constipation that may be best characterized as obstructive defecation syndrome. However, there is still no clear evidence whether the stapled transanal rectal resection (STARR) procedure provides a safe and effective surgical option for symptom resolution in patients with obstructive defecation syndrome, as evidence-based guidelines and functional long-term results are still missing. On the basis of the need for objective evaluation, a European group of experts was founded (Stapled Transanal Rectal Resection Pioneers). Derived from 2 meetings (October

26-28, 2006, Gouvieux, France and November 28-29, 2007, St Gallen, Switzerland) a concept for treatment options in patients suffering from obstructive defecation syndrome was developed, including a clear decision-making algorithm specifically focusing on the role of the stapled transanal rectal resection procedure based on clinical symptoms and dynamic imaging and inclusion and exclusion criteria for the stapled transanal rectal resection procedure.

Keywords: STARR; obstructive defecation syndrome, rectocele; internal rectal prolapse; algorithm

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Internal rectal prolapse (rectal intussusception) and rectocele are frequent clinical findings in patients suffering from refractory constipation that may be best characterized as obstructive defecation syndrome (ODS). Derived from stapled hemorrhoidopexy introduced by Longo, the STARR Pioneers rectal resection procedure (STARR) has been included as a treatment option for ODS in many European centers (Figure 1). In the meantime, the safety and promising results related to symptom resolution of the STARR procedure for ODS caused by internal rectal prolapse and anterior rectocele has been shown in various studies.¹⁻⁴ Conversely, some case reports on serious major complications following STARR have caused a certain scepticism.^{5,6} Derived from these conflicting results, there is still no clear evidence whether the STARR

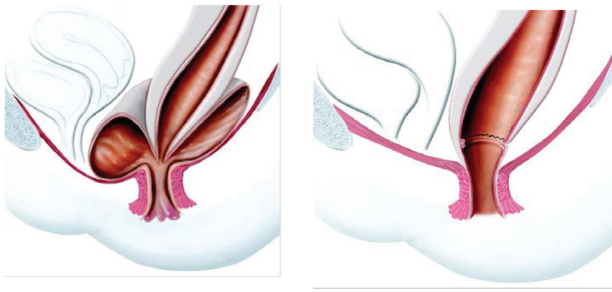


Figure 1. Stapled transanal rectal resection (STARR).

procedure provides a safe and effective surgical option for symptom resolution in patients with ODS. Following a consensus conference and based on a need for evidence-based conclusions,^{7,8} the STARR pioneers were established in October 2006. At the time of a kick-off meeting in Gouvieux, France, from October 26-28, 2006, a consensus position statement on inclusion and exclusion criteria, as well as an algorithm, specifically focusing on the role of the STARR procedure was created. Furthermore, a position statement on the use of the different devices (PPH01 vs Contour Transtar, Ethicon-EndoSurgery) was developed during the St Gallen meeting, November 28-29, 2007.

Role of the STARR Pioneers

As there is still no common understanding of the disease itself, the adequate indication for surgery, and the definite role of the STARR procedure, it was the aim to set up a running round table forum of European experts to develop consensus on various topics related to ODS and the procedure, as well as to create a European network, to discuss the STARR procedure as a treatment option for patients suffering from ODS. In contrast to the international working party, which firstly published their results on the role of the STARR procedure,⁷ the purpose of creating the STARR pioneers is much wider and primary goals are to

- develop a consensus on ODS symptoms, inclusion and exclusion criteria for STARR,
- develop a common definition of ODS,
- set up a standardized preoperative diagnostic assessment,
- propose an algorithm for STARR,

- define clear indications and contraindications for STARR,
- share and discuss complications following STARR,
- provide education and consultancy regarding optimal training,
- assess the quality of STARR for ODS and the standardization of the procedure, and
- plan and perform prospective studies in addition the European STARR registry.

The current suggestions are derived from the kick-off meeting of the STARR Pioneers from October 26-28, 2006 (Gouvieux, France) and the last meeting from November 28-29, 2007 (St Gallen, Switzerland).

Definition of ODS and ODS Symptoms

Obstructed defecation syndrome is defined as the normal desire to defecate, but an impaired ability to satisfactorily evacuate the rectum. Additionally, ODS is a complex and multifactorial disease, more common in women. Typical symptoms of ODS includes

- evacuation by prolonged or repeated straining,
- frequent calls to defecate prior to or following evacuation,
- use of digital means to effect evacuation,
- sense of incomplete evacuation,
- laxative or enema use required to defecate,
- excessive time spent on the toilet during defecation, and
- pelvic pressure, rectal discomfort, and perineal pain.

Frequently, in these patients, an internal rectal prolapse or rectocele are found during clinical examination. Patients with the combination of the above symptoms and these anatomical findings may be candidates for further assessment and possible surgical treatment.

Diagnostic Assessment in ODS

As symptoms, morphological findings, and potential treatment options are wide range in patients with ODS, a careful diagnostic assessment has to be recommended. It is a prerequisite to exclude colorectal malignancy and inflammatory bowel disease by colonoscopy. As conservative treatment, such as diet, stool regulation including enemas and laxatives, pelvic floor retraining, and biofeedback, improves constipation symptoms in a considerable

S.T.A.R.R. Algorithm

Written and agreed upon by the group of S.T.A.R.R. Pioneers Oct. 26-28, 2006.

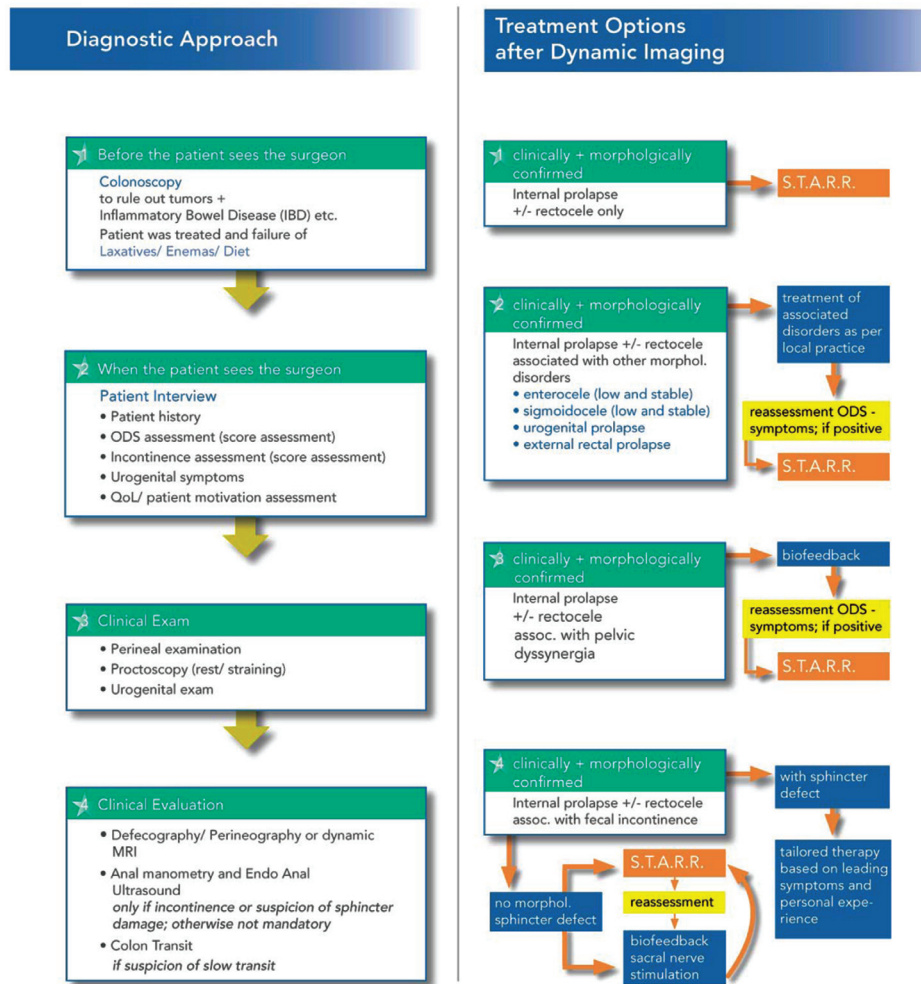


Figure 2. Diagnostic approach and decision-making algorithm in obstructive defecation syndrome.

proportion of patients, surgery (including the STARR procedure) may be considered in patients for whom conservative treatment options have failed, where there is an underlying morphologic abnormality, such as internal rectal prolapse or rectocele. Radiologic dynamic imaging either provided by defecography or by dynamic magnetic resonance imaging of the pelvic floor should be recommended in all patients, whereas anal manometry and endoanal ultrasound is not primarily mandatory in all patients. However, particularly manometry should not only be performed in patients with fecal incontinence but also in patients with pelvic dyssynergia (eg, anismus, paradoxical puborectalis syndrome). The proposed diagnostic assessment is outlined in Figure 2.

Treatment Options After Dynamic Imaging With Special Reference to the STARR Procedure

It is a crucial issue that patient selection is the key for successful therapeutic implications in patients with ODS. Following diagnostic assessment, those patients who may be considered as suitable candidates for the STARR procedure should have failed prior conservative treatment.

To provide a standardized decision-making algorithm, treatment options after dynamic imaging were differentiated in relation to the most common clinical findings (internal rectal prolapse ± rectocele) in patients suffering from ODS.

If internal rectal prolapse and rectocele are confirmed clinically and morphologically, and diagnostic assessment can rule out significant additional pathologies, the STARR procedure can be recommended as first option.

However, if internal rectal prolapse and rectocele are combined with other pelvic floor disease, such as enterocele, sigmoidocele, or urogenital prolapse, a treatment of these associated disorders (per local practice) should be recommended first. Specifically focusing on enterocele, enterocele should be treated prior to the STARR procedure, but can also be combined with the STARR procedure in experienced pelvic floor centers. In terms of external rectal prolapse, transabdominal or perineal procedures have to be recommended.

If clinically and morphologically confirmed internal prolapse and rectocele are associated with pelvic dyssynergy, the primary treatment option should be conservative (eg, biofeedback).

If fecal incontinence is associated with internal rectal prolapse and rectocele, a tailored therapy with special reference to sphincter function should be initiated. Particularly, patients with fecal incontinence related to a morphologic sphincter defect assessed by endoanal ultrasound are no candidates for STARR.

The proposed decision-making algorithm with special reference to the STARR procedure is shown in Figure 2.

In general, it has to be clearly stated that patients with rectocele without any symptoms of ODS or internal rectal prolapse are no candidates for a STARR procedure. Accordingly, patients with pelvic dyssynergy or anismus should not be treated surgically.

Exclusion Criteria for the STARR Procedure

Precise exclusion criteria have been developed by the STARR pioneers on the background of technical aspects and with special reference to prevent septic complications.

Absolute exclusion criteria for STARR are

- active anorectal infection,
- concurrent severe anorectal pathology (including anal stenosis),
- proctitis (inflammatory bowel disease, radiation-induced),
- enterocele at rest (low, stable, fixed),
- chronic diarrhea, and
- previous anterior resection with rectal anastomosis

Relative exclusion criteria includes

- presence of foreign material adjacent to the rectum (ie, mesh),
- previous transanal surgery (ie, rectal anastomosis), and
- concurrent psychiatric disorder.

As symptoms of ODS cannot be strictly differentiated from symptoms in patients suffering from irritable bowel syndrome (IBS), a careful assessment of symptoms has to be performed prior to appropriate treatment. Therefore, a standardized assessment of IBS symptoms using the Rome II or III criteria is mandatory prior to STARR to prevent poor functional outcome postoperatively.⁹

Additionally, as psychiatric comorbidity is observed in a considerable percentage of patients suffering from obstructed defecation, a careful assessment of symptoms, patient motivation, and psychiatric history has to be maintained.¹⁰

In terms of concurrent severe pathology of the pelvic floor, including genital prolapse or external rectal prolapse, the STARR procedure is not an appropriate surgical option of choice, as surgical correction of a single component in combined complex pathologies does not lead to satisfactory functional results.

Position Statement Related to the Device

Actually, the STARR procedure can be performed by 2 devices: PPH01 and Contour Transtar Curved cutter stapler (Ethicon Endo-Surgery, Norderstedt, Germany).

The Contour Curved Cutter stapler device seems to ensure more tailored therapy based on the concept of the STARR procedure including a circumferential full thickness resection with the potential of removing more tissue. However, it is technically demanding and must be performed by dedicated and fully trained colorectal surgeons.

To date, it is unclear whether transanal resection of more tissue using the Contour Transtar device leads to improved functional outcome, and this needs further evaluation. Therefore, prospective data collection is ongoing.

The strategy of device selection should be tailored to the size of the prolapse. On the basis of personal experience of the group, the use of a STARR procedure using 2 PPH01 may be best suited for small internal rectal prolapse or male patients.

Position Declaration

It was the objective of the STARR pioneers to present a decision-making algorithm specifically focusing on the role of the STARR procedure for ODS. This recommended algorithm on diagnostic and therapeutic implications was strictly based on the experience of 11 specialists in coloproctology and pelvic floor disease, and it was concluded after a 100% consensus within the group. To date, this is the first algorithm on treatment options in patients with ODS specifically focusing on the role of the STARR procedure. However, this proposal does not represent a fixed or dogmatic position, as knowledge and evidence on ODS and STARR are dynamically increasing. The STARR pioneers have the objective to participate and elucidate this process in the future.

As the current proposals are derived from a consensus of the personal experience of the group, no levels of evidence and grade recommendations are given.

Acknowledgment

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