

Stapled Trans-Anal Rectal Resection (STARR) for Obstructive Defecation Syndrome—Functional Outcome and Quality of Life after Two Years

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Received 15 February 2016; accepted 14 March 2016; published 17 March 2016

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Abstract

Background: Stapled transanal rectal resection (STARR) has been shown to improve patients' functional and quality of life outcomes in several studies. Although it is a safe and effective treatment for obstructive defecation syndrome, still data on long-term follow-up are missing. **Methods:** From January 2010 to July 2014, 46 consecutive patients undergoing STARR using the CONTOUR® TRANSTAR™ device, shortly named TRANSTAR (transanal stapler assisted resection), were prospectively followed. Recurrence rate, quality of life (Patient Assessment of Constipation-Quality of Life (PAC-QoL)) and complication were documented at baseline, 12 and 24 months after operation. Two subgroups of patients were compared to assess the impact of resection length on outcome. **Results:** We included 46 patients (89% female) in the study. The mean age was 65 ± 16 years and the duration of the operation was 48 ± 4 min. Total PAC-QoL score improved from 2.0 (SD 0.3) to 0.9 (1.4) after 12 months, but deteriorated to 1.2 (0.3) after 24 months ($p < 0.001$ for both comparisons). Complications were noted in 7% of the patients: Urinary retention (2 patients), post-operative bleeding (1 patient). No major complications or mortality were seen. After one year, we had one prolapse recurrence and after 24 month we had another. There was no significant relation between the length of the specimen and the improvement of life quality. **Conclusions:** The STARR procedure seems to be a safe and fast therapeutic option for patients with ODS and/or rectal prolapse. It is a tailored transanal full-thickness rectal resection improving the patients' quality of life still two years after the operation.

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Keywords

STARR, Obstructive Defecation Syndrome, External Rectal Prolapse, Transanal Approach, Constipation

1. Introduction

Constipation is described in international studies with a prevalence in the general population ranging from 1.9% to 27.2% [1] [2]. The wide range is mainly caused by different definitions of constipation making accurate collection of epidemiological data difficult [3] [4]. Often, constipation is a multifactorial problem. Broadly constipation can be divided into three categories: Slow transit, normal transit and defecatory disorders [4]. Defecatory disorders can be a result of functional or anatomical pelvic floor alterations [1]. Surgical options play a minor role in functional causes like anismus. They should be treated mainly conservative. On the other side symptomatic rectocele or internal prolapse of the rectum are generally considered to be an underlying anatomical cause. Obstructed defecation syndrome (ODS) is a type of constipation characterised by fragmented stools, need for straining at defecation, sense of incomplete evacuation, tenesmus, urgency, pelvic heaviness and self-dilatation [5]-[9]. Most of the patients are females. The major pathomorphological determinants of ODS are the internal or external prolapse of the rectum. Internal rectal prolapse can also cause fecal incontinence in 50 percent.

It is very important to choose the right treatment and the right approach for surgical treatment following the functional outcome of surgery [1] [5]-[9]. Numerous surgical procedures have been used to correct the underlying conditions of ODS [1] [8]. Stapled trans-anal rectal resection (STARR) allows a tailored circumferential correction of the internal rectal prolapse [8]. The used device, called CONTOUR[®] TRANSTAR[™], is a curved cutter-stapler (Ethicon, Norderstedt, Germany). It is also used to treat the external prolapse [8]. The TRANSTAR[™] Registry Study group published the one-year data of 100 patients having a stapled transanal resection with the CONTOUR[®]TRANSTAR[™] device because of ODS. They concluded that STARR is safe and effective improving patient functional and life quality outcomes at one year postoperatively [8], but they demanded long-term follow-up data to prove the sustainability of results.

Our study documents the data in long-term follow-up focussing on life quality, complications and recurrence rate.

2. Materials and Methods

2.1. Study Design and Patients

This prospective, observational trial was initiated at a single institution, a community teaching hospital. The aim of the study was to analyse the long-term results of transanal rectum-resection with patients suffering from ODS. The one-year results of patients' function and quality life were compared with baseline and two-year results. The study was conducted in accordance with the Declaration of Helsinki and all its amendments.

The 46 consecutive patients were selected for surgical procedure on the basis of recognized clinical symptoms of ODS: frequent visits to the toilet with unsuccessful evacuation attempts, prolonged straining, anorectal discomfort or pain, a sensation of incomplete evacuation and the need for manual assistance [8]. These symptoms were associated with the evidence of rectocele and/or internal or external rectal prolapse. All patients were examined digitally and received a recto- and a proctoscopy. Finally they all received a defecography.

Patients were excluded from surgery when there were inflammatory or septic conditions of the rectum or reasons for impossible data collection in the follow up because mental reduction.

2.2. Anaesthesia and Surgery

The majority of operations (41) were done in general anaesthesia and five received a spinal anaesthesia. Three of these patients with spinal anaesthesia preferred it and two had cardiopulmonary risk factors for general anaesthesia. The general anaesthesia started with premedication (midazolam 7.5 mg orally) and followed a standard protocol. For induction of total intravenous anaesthesia, propofol (4 mg/kg bodyweight) and fentanyl (0.1 to 0.2 mg/kg bodyweight) were administered intravenously. If necessary, anaesthesia was prolonged using ram-

ifentanal. Patients reporting pain in the postoperative recovery unit received morphine (5 to 15 mg IV) and metamizole (1 to 2.5 g IV).

The spinal injection was given under local anaesthesia in the skin. The needle position was between lumbar vertebrae 2 - 4. Hyperbaric mepivacain 4% was used.

All patients were treated with a preoperative enema, received an antibiotic prophylaxis (500 mg metronidazole and 1.5 g cefuroxime intravenously) and routine prophylaxis for deep vein thrombosis. The intraoperative placement was in lithotomy position in Trendelenburg. Surgery was performed in standardised procedure: only two experienced surgeons did the operations. The circular anal dilator (CAD) was gently introduced and fixed to the perianal skin with four cardinal sutures. A swab was inserted and pulled outward to visualize the apex of the intussusception. Then 6 sutures (2.0 Polypropylene, Ethicon, Norderstedt, Germany) were placed in parachute-technique. The prolapse was completely pulled out and divided at 3 and 9 o'clock with a linear stapler (Ethicon, Norderstedt, Germany) into an anterior and posterior portion. Then the complete prolapse resection was started anteriorly at 3 o'clock and 9 o'clock posteriorly via continuous, counter clockwise transections using the curved CONTOUR®TRANSTAR™ stapler (Ethicon, Endo-Surgery, Norderstedt, Germany). The stapler was positioned parallel to the dentate line. After the resection was completed, the neo-rectum and anal mucosa relocated spontaneously. Absorbable monofilament sutures were placed to achieve haemostasis.

The anterior and posterior specimens were opened at the sutures and sent to the histo-pathological examination.

2.3. Analgesia and Perioperative Care

After surgery, all patients received the same analgesic drug regimen, which consisted of diclofenac 50 mg orally three times a day and metamizol 500 mg orally four times a day. Furthermore, 5% lidocaine ointment was applied locally. This medication was discontinued if the patient was discharged from the hospital or was pain-free. In addition to this regular baseline analgesia, the following rescue analgesics could be applied if a patient reported strong pain and requested additional therapy: oxycodone (10 to 20 mg orally, depending on body weight) or piritramide (15 mg intravenously as a slow infusion over 30 min). From the first day after the resection to the end of hospitalization an easily digestible diet was recommended. The thrombotic prophylaxis was given until discharge from the hospital.

2.4. Outcomes

We used the disease-specific PAC-QoL (Patient Assessment of Constipation-Quality of Life) score to assess quality-of-life. Scores were raised in a personal interview in the clinic. The PAC-QoL is composed of 28 items and has been validated in several languages [10]. PAC-QoL items and subscale scores range from 0 (no problems) to 4 (most severe problems).

Length of hospital stay included both pre- and postoperative stay. Complications, recurrence rates and personal data of the patients were documented in a standardized questionnaire.

2.5. Statistical Analysis

Differences between time points were compared by applying Student's t test for paired observations. The sample was then subdivided into two subgroups according to the median length of specimen. The two groups were compared by Student's t test for independent observations. Significance was defined as a p-value of <0.05. Due to the explorative character of the study, no adjustment for multiple statistical testing was employed. Data are presented as means \pm standard deviations unless stated differently.

3. Results

The majority of the patients were female (91%), mean age 66 ± 17 years with a mean body mass index (BMI) of 28 ± 4 kg/m². As comorbidities 13 patients had a hypertension, 4 a diabetes mellitus type II, 4 suffered from COPD, one had a morbus Parkinson and suffered from depression (see **Table 1**). The day when the patients came in the hospital all received a defecography. In 80% we found an anterior rectocele and all these patients suffered from ODS. In 85% a rectum prolapse stadium II could be seen in the defecography and in 15% an external prolapse (stadium III) could be documented. 5 patients described a fecal incontinence stadium III and 3 had fecal incontinence stadium II. Only 2 female patients described also an urinary incontinence.

Table 1. Baseline and operative data of 46 patients with ODS.

Patient	Gender	Age [years]	Symptoms	Comorbidities	Intussusception [grade]	Time of operation [min]	Length x of specimen [cm]	Hospital stay [days]	Complications
1	m	80	Incontinence III.	Hypertony	III.	65	7	8	No
2	w	80	Incontinence III.	Cirrhosis, ascites	III.	45	4	7	No
3	m	42	ODS	No	II.	60	6	8	No
4	w	65	ODS	No	II.	45	7.5	7	No
5	w	80	ODS	Hypertony, diabetesmelitus	II.	45	5	7	No
6	w	80	ODS	Hypertony	II.	50	8.5	10	No
7	w	72	Incontinence III.	No	III.	48	7	12	No
8	w	70	ODS	Hypertony	II.	50	6	9	No
9	w	83	Incontinence III.	Diabetesmelitus	II.	45	4.5	10	No
10	w	64	ODS	Depression	II.	48	5.5	9	No
11	w	86	ODS	Hypertony	II.	52	7	8	No
12	w	83	ODS	COPD, hypertony, diabetesmelitus	III.	42	4	12	No
13	w	46	ODS	No	II.	45	6	8	No
14	w	49	ODS	Hypothyreose/COPD	II.	42	5	8	No
15	m	31	ODS	No	III.	48	4.4	8	No
16	w	67	Incontinence III.	No	II.	45	4.2	22	Urinaryret.
17	w	58	ODS	Hypertony	II.	52	3.5	8	No
18	w	42	ODS	No	II.	42	4.5	9	Bleeding
19	w	76	ODS	No	II.	58	4	7	No
20	w	79	ODS	No	II.	45	6	7	No
21	w	29	ODS	No	II.	48	6	7	No
22	w	78	ODS	Morbusparkinson	III.	45	13	10	No
23	w	88	ODS	Coronarsclerosis	III.	48	7.5	7	No
24	m	68	ODS	No	II.	52	10.5	8	No
25	w	67	ODS	Hypertony	II.	50	6	7	No
26	w	80	ODS	Chronicpainsyndrom, hypertony	II.	49	5	8	No
27	w	37	Incontinence II.	No.	II.	52	6	6	No
28	w	20	ODS	Deficientweight	III.	46	6	8	No
29	w	67	ODS	No	II.	53	5	6	No
30	w	72	ODS	Spinal stenosis	II.	48	5	6	No
31	w	81	ODS	Hypertony	III.	47	8.7	11	No
32	w	38	ODS	No	II.	52	5	7	No
33	w	84	ODS	Hypertony, diverticulosis	II.	50	4.8	6	No
34	w	78	ODS	Anal polyp	II.	55	4.7	9	No
35	w	46	ODS	Hypothyreose, COPD	II.	48	8.5	8	No
36	w	86	ODS	COPD	II.	53	6	10	No
37	w	84	ODS	No	II.	50	8	7	No
38	w	60	Incontinence II.	Anal polyp	II.	47	6	9	No
39	m	70	Incontinence II.	Hypertony	II.	48	5	7	No
40	w	67	ODS	Keine	II.	45	9	8	No
41	w	62	ODS	No	II.	48	3.9	8	No
42	w	69	ODS	Hypertony, diabetesmelitus	II.	48	9	8	No
43	w	72	ODS	No	II.	53	8	6	No
44	w	63	ODS	Hypothyreose, COPD	II.	50	6	7	No
45	w	72	ODS	Gastritis	II.	48	5	9	Urinaryret.
46	w	56	ODS	Colonicpolyposis	II.	47	6	7	No

The mean PAC-QoL score at baseline was increased (see **Table 2**). Overall, PAC-QoL scores improved considerably after surgery. Two years after surgery the mean scores were still significantly decrease to baseline ($p < 0.001$) and were not significantly increased in comparison to the one year results. But an increased tendency could be stated. After subdividing the cohort into patients with longer and shorter specimen length, these two subgroups were compared, but no significant difference was found. The 26 patients with a specimen length of 6 cm or more had a preoperative PAC-QoL score of 2.0 (SD 0.3), whereas the 20 patients with a resected specimen shorter than 6 cm had a score of 1.9 (0.3). This baseline variable revealed no significance ($p = 0.42$). Postoperative PAC-QoL scores are shown in **Figure 1**, but again both subgroups showed very similar courses ($p = 0.62$ after 12 months, $p = 0.84$ after 24 months). Furthermore, length of hospital stay was similar in both groups: 8.1 (1.5) versus 8.7 (3.5) in patients with more and less extended resection ($p = 0.48$).

Postoperative morbidity was low: 3 patients with urinary retention and one with postoperative bleeding from the staple line. 2 patients (4%) had a recurrence prolapse stadium II after the second year. The 5 patients with fecal incontinence stadium III were complete continent and also the patients suffering from fecal incontinence stadium II before the operation improved. Defecatory urgency has been seen with 8 patients one year after operation and still four patients after two years. Patients with additional mental disorders like depression did not have an advantage of the surgical procedure.

4. Discussion

The role of surgery in ODS is discussed very different in international literature [9] [11]-[14]. Careful patient's selection is crucial to achieve optimal functional results. The indication for operation fits not to every patient. Of

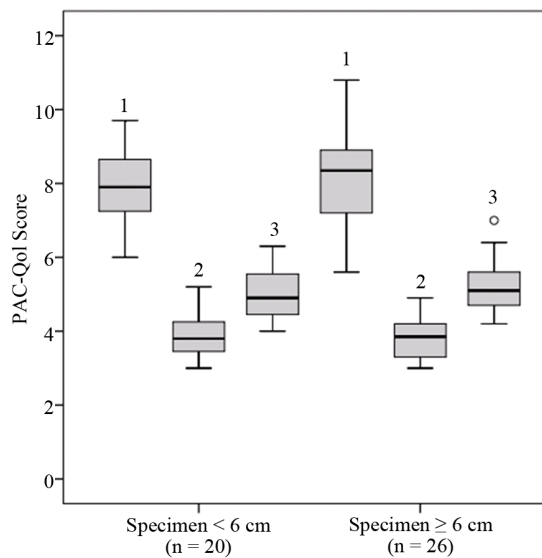


Figure 1. PAC-QoL results over time in patients with longer or shorter length of rectum resection; (1: baseline, 2: 12 months postoperative, 3: 24 months postoperative).

Table 2. Change of PAC-QoL results over time. Results are means (standard deviations). All 15 comparisons between timepoints were highly significant ($p < 0.001$).

PAC-QoL subscale	Baseline (n = 46)	After 12 months (n = 46)	After 24 months (n = 46)
Total score	2.0 (0.3)	0.9 (1.4)	1.2 (0.3)
Physical discomfort	1.9 (0.5)	0.9 (0.3)	1.1 (0.3)
Psychosocial discomfort	1.5 (0.5)	0.8 (0.3)	1.1 (0.3)
Worries	1.9 (0.5)	0.9 (0.2)	1.3 (0.3)
Satisfaction	2.8 (0.4)	1.2 (0.3)	1.6 (0.3)

course conservative management should be offered before planning operative treatment. Still the diagnostic tools are very important to find the tailored therapy for the individual patient. A profound anamnesis and clinical investigation are building the fundamental starting point. In our study every patient got a defecography. It is essential to have a functional defecography in which you can reproduce the defecation process [15] [16]. With this tool the defecation disorders can be seen (rectocele, intussusception, enterocele) and the level of the pelvic floor. It needs some experience to interpret it in the right way and to correlate the findings of the clinical examination with the radiological findings [15]. One central critical point in the multicentre study of Ribaric *et al.* [8] [17] was the missing standardisation of diagnostic imaging. Of course ventral rectocele and intussusception without providing symptoms on evacuatory function has been diagnosed radiologically [15] [17] and emphasizes the description of the patients' symptoms and the clinical examination. The significant improvements documented with the PAC-Qol score in our study are also described in the study of Ribaric *et al.* [8]. The scores are nearly the same. So this shows good reproducible results with this operative method. Fecal incontinence we described preoperatively in 5 patients having an intussusception grade III. All this patients were healed from the incontinence at one year after operation and even at the second year. This is confirmed by Jayne *et al.* [11] reporting a significant improvement in the Cleveland Clinic Fecal score at 12-month follow-up as compared with baseline. At the study of Wolf *et al.* [18] also 6 months after TRANSTAR all preoperatively incontinent patients were continent. The authors of other studies describe the phenomenon that patients developing fecal incontinence after TRANSTAR procedure tended to be those with pre-existing asymptomatic incontinence [18]. In the different international literature defecatory urgency has been described 6 months after TRANSTAR in 17% - 18% [19] [20] of the patients or one year after operation in 26.8% [8]. We found one year postoperatively 20% of patients complaining about fecal urgency and after two years still 10%. Postoperative morbidity in our results was low in comparison to international literature: 2% urinary retention and 0.5% postoperative bleeding from the staple line. In recent studies [18] [21] urinary retention varies from 1.2% to 10.3%. Postoperative bleeding from the staple line occurs in 1.5% to 7% in other studies.

In our cohort we found 7 patients with external rectal prolapse. Two years after TRANSTAR two of them had a re-prolapse. Tschuor *et al.* [22] examined 9 consecutive patients with external rectal prolapse undergoing TRANSTAR. With a median follow-up of 40 months (range 14 - 58 months) the prolapse recurrence rate was described with 44% (4 patients of 9). The Rehn-Delorme operation and Altemeier procedure are associated with high recurrence rates up to 32% [14] [23]. It is difficult to compare our findings with this data because of the different range of median follow-up. The authors of the other studies explain the poor results in long-term follow-up because of the missing of lavatory plastic. On the other hand they explain their high recurrence rate with a learning curve. Re-prolapses are discussed to be caused by a growing weakness of the pelvic floor and an extended colon. Prolonged anorectal pain was not seen in our cohort as Ribaric *et al.* had it in their study [8]. We had no major complications in our study. In the international literature rectal perforations [21], large hematomas [24] and rectovaginal fistulas [25] are described.

The median length of the specimen in our study (6.1 ± 1.2 cm) was shorter than the prolapse documented by Tschuor *et al.* (7.5 cm) [22]. This difference may be caused by the fact that they included just patients with an external rectal prolapse. The majority of our patients showed an intussusception of grade II. We did not find a significant relation between the length of the specimen and the improvement of life quality.

A limitation of our study could be seen in the fact that we used just one scoring system. The results of the TRANSTAR procedure should be compared randomised with the other operative therapies, for example Altemeiers' procedure in long-term follow up.

5. Conclusion

In conclusion our data show that the TRANSTAR procedure seems to be a safe and effective therapy of patients suffering from ODS. The long-term recurrence rate of 4% is quite low. The length of the specimen does not influence the improvement of life quality.

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