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To cite this article: C. A. Leo, P. Campennì, J. D. Hodgkinson, P. Rossitti, F. Digito, G. De Carli, L. D'Ambrosi, P. Carducci, L. Seriau & G. Terrosu (2018) Long-Term Functional Outcome after Internal Delorme's Procedure for Obstructed Defecation Syndrome, and the Role of Postoperative Rehabilitation, *Journal of Investigative Surgery*, 31:3, 256-262, DOI: [10.1080/08941939.2017.1300714](https://doi.org/10.1080/08941939.2017.1300714)

To link to this article: <https://doi.org/10.1080/08941939.2017.1300714>



Published online: 31 Mar 2017.



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ORIGINAL RESEARCH

Long-Term Functional Outcome after Internal Delorme's Procedure for Obstructed Defecation Syndrome, and the Role of Postoperative Rehabilitation

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ABSTRACT

Purpose: To evaluate long-term functional outcomes of Internal Delorme's Procedure (IDP) in patients refractory to conservative treatment for Obstructed Defecation Syndrome (ODS), and to compare those who received postoperative rehabilitation with those who did not. **Materials and methods:** All patients with ODS refractory to nonoperative therapy were identified across three regional pelvic floor referral hospitals, and IDP was performed. Postoperatively selected patients received biofeedback therapy. Functional outcomes were established using the Cleveland Clinic Constipation (CCC) score and obstructed defecation score (OD score) preoperatively at 12 months and at the last available follow-up. Patient satisfaction was assessed with a visual analogue score. **Results:** From October 2006 to September 2013, IDP was performed in 170 patients: 77 received postoperative biofeedback and 93 did not. Mean follow-up was 6.3 years (range 1–8 years). CCC and OD scores improved significantly in both groups after 12 months and at the last follow-up ($p > 0.05$). When comparing two groups while there was no significant difference between CCC and OD scores at 12 months, score was significantly better in the group that received rehabilitation at the last follow-up ($p = 0.001$). Patient satisfaction was higher in the rehabilitation group (67%) compared with those without rehabilitation (55%). Clinical recurrence was recorded in nine patients who did not have postoperative rehabilitation. **Conclusions:** It has been demonstrated that IDP is associated with good long-term functional outcomes. Patients receiving rehabilitation had a better long-term follow-up, a higher overall satisfaction, and lower recurrence rate when compared with the patients who did not receive postoperative rehabilitation.

Keywords: internal Delorme's procedure; obstructed defecation syndrome; biofeedback; proctology; pelvic floor disorders; pelvic floor rehabilitation

INTRODUCTION

Obstructed Defecation Syndrome (ODS) is a well-recognized problem that affects the quality of life of many patients. It is known as a functional and anatomical disorder of the pelvic floor. Rectocele, rectal intussusception, rectal prolapse (also known as procidentia), enterocele, and pelvic dissynergies (including anismus, levator muscle spasm) are all known to be associated with ODS. ODS occurs in approximately 7% of the

population, and nearly 50% of patients with chronic constipation have ODS. Women are more likely to be affected than men are, and the prevalence increases with age. Treatment of ODS is not standardized and many different operative and nonoperative approaches have been described [1–4].

Clinical management can be difficult due to coexistent of anatomical and functional disorders present in patients and because it is not easy to discriminate between cause and consequences. Therapeutic results

Received 13 January 2017; accepted 24 February 2017.

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can also be influenced by the complexity of the disorder and by different operative approaches. Surgical management is usually reserved for patients with severe quality of life impairment. In these cases, the therapeutic aim is resolution/improvement of symptoms and not necessarily completes anatomical restoration [5]. The choice of correct surgical management in ODS is influenced by diagnostic approach and by different surgical approaches. Evaluation of the colon with full colonoscopy and X-ray colonic transit studies are necessary to rule out any obstructive pathology and facilitate optimal conservative management. An accurate examination on the toilet should evaluate all the pelvic structures that can be altered anatomically. A gynecologic examination is mandatory in women.

Intussusception, rectocele, and internal prolapse have their own obstructive mechanism but similar clinical manifestations in ODS. Internal Delorme's Procedure (IDP) is therefore thought to be a good surgical option in patients with a diagnosis of ODS. When considering the best surgical procedure, it is important to reflect how quality of life can be altered by ODS symptoms, particularly in activities of daily living and impairment of social relationships. Quality of life evaluation is a fundamental part of clinical diagnosis of ODS patients [6, 7].

Although these conditions do not usually require surgery, it is often found to be a good treatment option when conservative management fails. The aim of surgical treatment is to restore pelvic organs to their anatomical position. In the last few decades, many different surgical approaches have been described, for example, trans-abdomen, trans-anal, trans-vaginal, and trans-perineal [1, 2]. All these techniques have advantages and disadvantages and no technique yet described is able to give satisfactory results in all patients with ODS [8]. Many authors find the gold standard operation for patients with external prolapse and intussusception resulting in ODS where conservative management has failed is an IDP [9, 10]. Furthermore, we hypothesize that the best functional outcomes can only be reached by offering a tailored approach to

each individual patient, combining surgery (when the conservative treatment fails) with postoperative biofeedback. The primary aim of this study was to evaluate the long-term functional outcomes of IDP for ODS, and secondarily, to evaluate the outcome of the patients who had postoperative biofeedback therapy comparing this with the outcomes of IDP alone.

MATERIAL AND METHODS

In order to evaluate short- and long-term functional results in patients undergone IDP for ODS, we designed a prospective, multi-center study collecting clinical and functional observational data. Three national care centers and all local pelvic floor referral centers were recruited for the study. Data were collected between October 2006 and September 2013. All patients who were presented to the Pelvic Floor Multi Disciplinary Meeting with ODS (diagnosed according to the Rome III criteria [11]) refractory to conservative management and put forward for IDP were included in the study. Patients with neurological pathologies, inflammatory bowel diseases, fecal incontinence, urinary symptoms, sphincter lesions, and patients with any previous surgery for ODS were excluded. Postoperative follow-up was standardized to one week, one month, six months, one year, and annually thereafter. All data for analysis were collected in an anonymized Excel (Microsoft Corporation, Redmont) file. The preoperative evaluation of all patients was standardized, and is detailed in Table 1.

Preoperative demographics, including gender, age, comorbidities, previous surgical operations, nature of symptoms, diagnosis, OD and CCC scores [12], and preoperative biofeedback treatment were recorded. Perioperative data, including type of anesthesia, ASA grade, operative time, and hospital stay, were collected. Intra- and postoperative complications (bleeding, perianal pain, anastomotic stenosis, and anastomotic leak) and recurrence (based on clinical and symptomatic evidence) were evaluated. A satisfactory functional

TABLE 1 The standard preoperative evaluation used to recruit all patients.

-
- Background and assessment
 - ODS-M and CCC score questionnaire preoperatively, at each postoperative follow-up and at the last follow-up
 - Visual Analogue Scale was used to grade satisfaction
 - Clinical examination (abdomen, digital rectal examination, rigid proctoscopy)
 - Full colonoscopy – to rule out any obstructive pathology
 - X-ray colonic transit studies with radiomarkers on the first, second, and fifth day using standard 30 markers; less than 80% of markers were the threshold of the diagnosis of slow transit
 - X-ray cisto-colpo-defecography, at relaxation, contraction, and pushing
 - Ano-rectal physiology studies – resting pressure, squeeze pressure, endurance, anal canal length, recto anal inhibitory reflex, threshold, urge and maximum volumes to distension
 - Endo-anal ultrasound scan to exclude sphincter defects, fistulas, perianal abscesses, and to evaluate muscle morphology
 - Gastroenterologist, urologist, gynecologist opinion when required
 - Pelvic floor multi-disciplinary meeting for discussion and approval prior to the procedure
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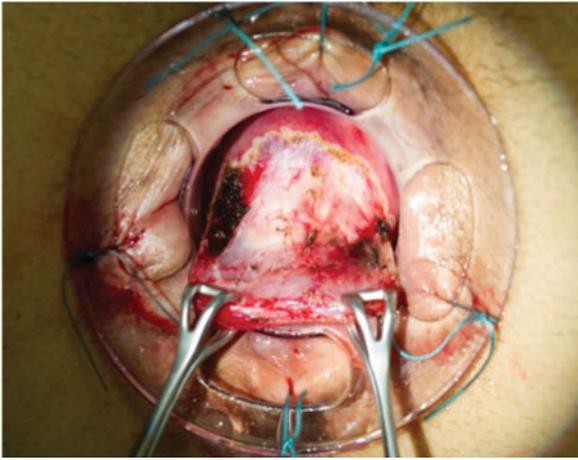


FIGURE 1 A circular incision has normally been made 20 mm above the dentate line after have injected an adrenalin solution.



FIGURE 2 The mucosa dissection performed circumferentially and in a cranio-caudal fashion.

outcome was considered as an improvement of at least 50% in OD and CCC scores at each follow-up time-point; $p < 0.05$ was considered statistically significant. A Visual Analogue Scale was also used to grade patients' satisfaction [13].

Operative Technique

All IDPs were performed in a standardized manner. A phosphate enema was given to all patients 8 to 12 hr before the procedure. Antibiotic prophylaxis was prescribed following local hospital guidelines. Patients received either general or epidural anesthesia depending on medical comorbidity and patient and anesthetist preference. All patients were placed in lithotomy position and draped in a standard fashion.

A PPH proctoscope, 30 mm in length and 29 mm in width (Ethicon, US), was used with four anchoring sutures to the perineum at 3, 6, 9, and 12 o'clock. Adrenalin diluted with normal saline solution (1/200,000) was injected into the submucosal plane. A circular incision was made 20 mm above the dentate line with mono-polar diathermy (Figure 1). The mucosa dissection, 80 to 130 mm in length, was performed circumferentially and in a cranio-caudal fashion (Figure 2). The muscle layer was stitched with eight 2-0 absorbable stitches (Figure 3). The mucosal layer was repaired using interrupted absorbable stitches (Figure 4).

Postoperative Rehabilitation

The postoperative rehabilitation program was available at only one of the three recruited hospitals. All patients from this center were given postoperative rehabilitation. Rehabilitation consisted of evacuatory technique training, biofeedback, electric stimulation,

and volumetric stimulation. The Mann-Whitney U test was used to analyze the medium- and long-term functional data between patients with and without rehabilitation.

RESULTS

Patient Demographics

Between October 2006 and September 2013, 170 patients with a diagnosis of ODS underwent IDP. Male to female ratio was 18:152 (10.59%:89.41%). Median age was 60.41 years (SD: ± 13.27). A predominant pre-operative reported symptom in 165 patients (97%) was feeling of incomplete evacuation. Sixty-three patients (37%) reported incomplete evacuation. Thirty-eight patients (22%) reported digitating via rectum or vagina to aid defecation. Eighty-five patients (50%) had tenesmus. Sixty-seven patients (38%) had a diagnosis of

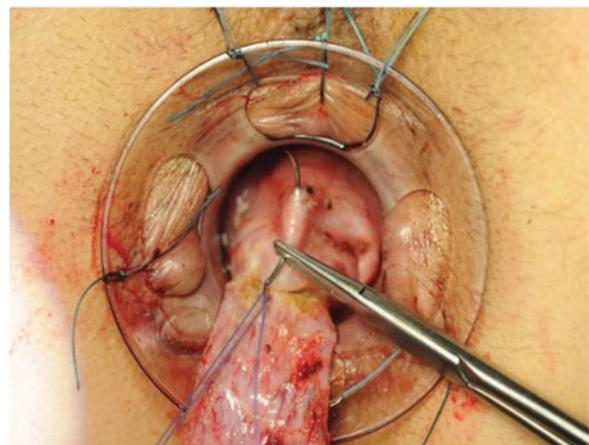


FIGURE 3 The muscle layer has normally been stitched with eight absorbable stitches.

TABLE 2 Results from the 170 patients' cohort.

	Number of patients	Percentage (%)
	Demographics	
Male	18	10.5
Female	152	88.8
Average age (years)	60.41	SD: ± 13.27
	Preoperative reported symptoms	
Incomplete evacuation	63	37
Digitation	38	22
Tenesmus	85	50
	Anorectal manometry studies	
Normal	70	41
Resting pressure reduced	51	30
Volumes tolerated, reduced	49	29
	Diagnosis	
Rectocele with mucosal prolapse	67	38
Mucosal prolapse + rectal intussusception	59	33
Rectocele + mucosa prolapse + intussusception	44	24.8
Descending perineum syndrome	40	23.5

rectocele with mucosal prolapse. Fifty-nine (33%) had mucosal prolapse and rectal intussusception. Rectocele with mucosal prolapse and intussusception was found in 44 patients (24.8%). Of the 170 patients, 23.5% had perineal descent >4 cm. Twenty-six patients (15%) had a previous colorectal surgical procedure (including left/right hemicolectomy, hemorrhoidectomy, and hemorrhoid banding). Seventy patients (41%) had anorectal manometry studies within the normal range values. Fifty-one (30%) patients were found to have a low resting pressure, with normal other manometry pressures. Forty-nine patients (29%) had a significant alteration in rectal volumes tolerated. Results of this cohort are shown in Table 2.

Operative Outcomes

One hundred and forty-five patients (85%) received epidural anesthesia, 25 (15%) had a general anesthesia.

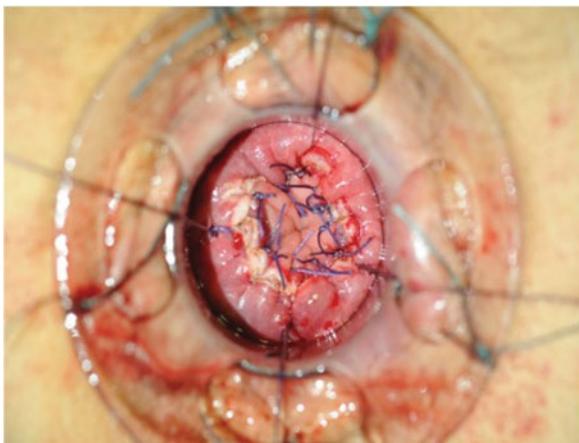


FIGURE 4 The mucosal layer repaired using interrupted absorbable stitches.

General anesthesia was used for the most part for medical reasons but in few cases, it was used for patient's choice. Median operative time was 106 min (SD: ± 30). No major intra-operative complications were reported. Average length of stay was 2.9 days (± 0.93). On average, bowel was opened on the third postoperative day (range 1–4). Thirty patients (17.65%) had a complication in the first 30 days. The most common complication was anastomotic stenosis (20 patients); of these, two patients (10%) required reoperation to correct the defect. The other 18 (90%) patients were prescribed anal dilators for a month with clinically satisfactory results. One of the 20 patients with stenosis also had minor bleeding in the immediate postoperative period. In total, minor bleeding occurred in five patients (16.67%), but return to theatre was never necessary. One patient (3.3%) had a dehiscence of anastomosis, which was conservatively managed. Local postoperative chronic pain occurred in one patient (3.3%) and was treated with simple analgesia with eventual resolution. Some fecal urgency was present initially in both groups that usually disappeared in 3–6 months. At one-year follow-up, 10 patients (6%) continued to suffer from urgency, while at long-term follow-up, urgency was present in only six patients (3.47%). There was no recorded mortality or major systemic complication (including organ failure). Sub-group analysis of postoperative outcomes was performed in patients with perianal descent: there was no significant difference (in numbers) in terms of postoperative outcomes when compared with patients without perianal descent.

Functional Outcomes

Median follow-up was 6.3 years (1–8 years). Five-year follow-up was achieved in 167 patients (98%). Three

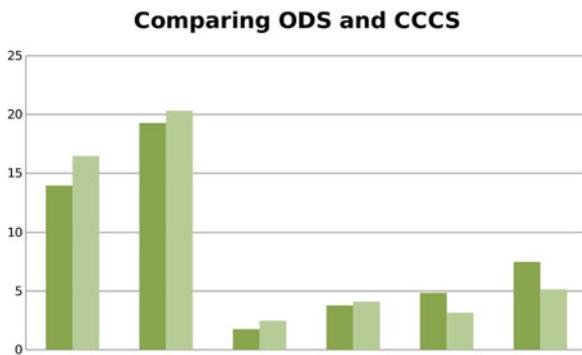


FIGURE 5 Differences between patients who had post-operative biofeedback (in dark green) and patients who had not post-operative biofeedback (in light green) respectively in pre-operative time, 1 year follow-up and five year follow-up.

patients died of other medical conditions not related to the procedure during the follow-up period. Postoperative improvement in clinical symptoms was reported in 156 (92%) patients.

Clinical improvement was seen in 84% of patients with perianal descent syndromes with no statistically significant difference when compared with the patients without perianal descent ($p > .05$). A better outcome was demonstrated when they underwent post-operative rehabilitation.

When considering the cohort as a whole, the visual analogue scale showed a high rate of satisfaction in the majority of cases (84%) at last follow-up: 47 patients (28%) were very satisfied, 94 (56%) were satisfied. Conversely, 15 patients (9%) were not content and 11 (6.6%) were completely unsatisfied. Preoperative OD and CCC scores showed moderate to high levels of chronic constipation, with values of 15.09 (± 3.13) and 19.75 (± 3.36) respectively. At one-year follow-up, all scores improved significantly: median OD and CCC scores were 2.08 ± 2.17 and 3.91 ± 2.77 respectively. At the last follow-up, scores increased slightly compared with one-year follow-up, and still greatly improved when compared with preoperative levels: OD score: 4.07 ± 2.97 and CCC score: 6.41 ± 4.21 ($p > 0.05$). It was observed that patients with a post-operative complication had a higher OD and CCC scores than patients without any complication: OD and CCC scores at the last follow-up were 5.41 and 8.48, respectively, in patients with postoperative complications but not considered statistically significant ($p > .05$).

When comparing patients who received postoperative rehabilitation with those who did not, we did not find any statistically significant difference in ODS-M and CCC scores at one-year follow-up ($p > .05$). At the last follow-up, we found a loss of functional outcome in patients who had not rehabilitation ($p = .001$). The data are depicted in the Figure 5.

Clinical recurrence was seen in 11 patients at the last follow-up (6.58%). There was a higher recurrence rate in non-rehabilitated patients and in patients operated in the first years of this series. All patients with recurrence were managed conservatively and no one was treated with further surgical intervention.

DISCUSSION

In this study, we are able to demonstrate consistent long-term follow-up for functional outcomes from IDP both with and without postoperative rehabilitation. Clinical improvement was observed in 156 patients (92%) with a 50% reduction in OD and CCC scores compared with preoperative symptoms. We observed a higher defecatory frequency with less defecatory discomfort, reduction in anal pain, reduction in incomplete defecation sensation, reduction in incomplete evacuation, and need of digitation or use of enema/suppository. These results were consistent throughout the follow-up period, with minimal deterioration at the last follow-up. Patients who underwent rehabilitation after surgery had a better quality of life than non-rehabilitated patients. A higher recurrence rate in non-rehabilitated patients and in patients operated in the first years of this series is probably due to the important role of rehabilitation, and because of technical improvement in surgical procedure during the study period.

Many authors have suggested the need for rehabilitation after surgery for ODS to improve quality of life and long-term outcomes [14–17]. However, there are so far no validated algorithms published in literature regarding the ideal timing of rehabilitation following surgery. Biofeedback therapy for ODS is well described in literature but there is no international consensus on the best rehabilitation approach, and the evaluation of symptom improvement is not well standardized [18, 19]. Most studies that have compared post-operative rehabilitation for ODS are limited by the fact that they are mostly retrospective, assess small numbers of patients, and report only short-term follow-up. This study is the largest prospectively collected series of IDP for ODS and reports good long-term functional outcomes.

The most frequent complication after IDP in this series was anastomotic stenosis, which is slightly higher at 11.3% than reported in other cohorts. Ohazuru et al. [18] reported a stenosis rate of 8% while Watkins et al. [19] had a stenosis rate at 2%. In our study, 79 patients treated in the last two years were invited to use a 22-mm dilator for three weeks after the surgery, aiming to reduce the rate of stenosis. This decision was based on our experience, although dilators are used worldwide to reduce or improve postoperative stenosis [20].

We had a subgroup of patients with associated perineal descent. This was considered significant when it was >4 cm as described in the literature [21]. Analyzing this group, we found a slightly worse outcome in the results as expected; however, this was not a statistically significant descent ($p > .05$). Rehabilitation seemed to be a key in the management of this sub-cohort of patients. This reflects the success rate shown in the literature [21].

There was no difference in the proportion of other complications compared with other published data. We demonstrate a relatively low proportion of postoperative urgency, which is usually quite frequent after perineal surgery. Using our technique, none of the complications associated with stapled anastomosis was observed, such as recto-vaginal fistula or rectal pocket syndrome. This syndrome represents a sequestered cul-de-sac near the staple line, causing entrapment of fecal material that results in severe proctalgia and soiling. It can be treated by suture line revision, staple removal, and curettage [22, 23]. In their series, Ohazuru et al. describe an 8% rate of stenosis, 16% of flatus incontinence, 16% of liquid and flatus incontinence, and a single case each of faecaloma and urgency [18]. Ganio et al. [24] described a 10% overall rate of complications, mostly fissures in ano (7.2%) and proctalgia (2.4%). In this series, it must be taken into account that biofeedback and postoperative pelvic floor training was not routinely used, and almost half of the patients had a previous surgery [24]. Our symptomatic recurrence rate is similar to other cohorts of IDP reported in literature.

When compared with other surgical options, IDP is favorable for ODS. STARR procedure has a wide range of reported outcomes, likely because of differences in surgeon's experience, different devices used, and variability in technique. In a recent international registry study on STARR, involving 22 European colorectal centers, a total of 100 patients were reported. Complications were reported in 11% of patients, including bleeding and staple line-related complications. The study reporting a low rate of symptom recurrence however describes only 12-month follow-up [25]. Stuto et al. [26] report similar results, with 2171 patients undergoing STARR, with a complication rate of 5% and a significant symptomatic improvement was recorded at 12-month follow-up. In spite of these results, the role of STARR is still controversial and reports of proctalgia, persistent pain, and perianal discomfort are still high even when functionally good results are seen [27, 28]. It has also been demonstrated that poor function outcomes are inevitable when a complication occurs, which requires surgical re-intervention [29].

Abdominal rectopexy is still a valid surgical option with good results in medium and long terms if performed by dedicated surgeons in experienced centers. The downside of this procedure is that it is more

expensive and invasive for patients. Nowadays lateral and posterior rectopexy, and procedures with sigmoid resection, are less frequently performed due to the high risk of possible complications related to rectum-sigmoid mobilization, including iatrogenic injury to the hypo-gastric plexus resulting in worsening constipation [30–32]. D'Hoore's ventral rectopexy does not require mobilization of colon, and has been demonstrated to give good functional results in 84%–88% of patients and has a low recurrence rate (8.2%) at 10 years [33].

It has been demonstrated that IDP is associated with good long-term functional outcomes. There is a trend toward a better long-term outcome when rehabilitation is used in the postoperative period. At 12-month follow-up, good improvement was seen in CCC and OD scores in both groups; however, some of this effect was lost at long-term follow-up. Patients receiving biofeedback had a higher overall satisfaction and a lower recurrence rate compared with the patients who did not receive biofeedback. A standardized and validated guideline is still required for surgeons for the management of ODS that is refractory to conservative treatment.

DECLARATION OF INTEREST

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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