Impact on Quality of Life of Laparoscopic Nerve-sparing Radical Treatment of Parametrial Deep Infiltrating Endometriosis (Postoperative Pain Assessment and Functional Outcomes)

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Research Article

Keywords: Parametrial endometriosis, laparoscopy, deep endometriosis, outcomes, nerve-sparing, quality of life

Posted Date: January 3rd, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1021436/v1

Abstract

Objective: Complete eradication of parametrial nodules of Deep Infiltrating Endometriosis (DIE) is associated with a high risk of iatrogenic nerves damage and pelvic organs dysfunction. The aim of this study is to evaluate via validated questionnaires the effect of laparoscopic excision of parametrial DIE on quality of life as first outcome and on pain symptoms and post- operative voiding function (bladder and rectal) as secondary outcome.

Study design: All patients undergoing laparoscopic excision of posterior or lateral parametrial DIE by a single expert surgeon between January 2013 and March 2017 were included in the study. A nerve-sparing approach was adopted in all patients. Quality of life (QoL) and Functional outcomes were evaluated using validated questionnaires (EHP-30 for the health profile, NBD score for intestinal function, ICIQ-FLUTS for urinary function), administered preoperatively and after surgery. Pain scores were collected before and after surgery using Visual Analogue Scale (VAS).

Results: During the study period a total of fifty-nine patients met the inclusion criteria. Fifty-one patients agreed to fill out questionnaires for post-operative outcomes. EHP-30 scores had a significant improvement in all the domains analyzed even in the relationship with children and fertility module despite to the small number of patients answering those questions. No differences were found in terms of urinary function between pre and post-operative questionnaires (ICIQ-FLUTS). Bowel function improved in patients' subjective perception. The NBD score showed that intestinal dysfunction related only to constipation and was reported as very minor by 76.4% of patients, minor by 11.8%, moderate by 5.9% by and severe by 5.95% of patients. Pain symptoms (VAS score) decreased significantly after surgery with the exception of chronic pelvic pain. (p value < 0,05).

Conclusions: Laparoscopic nerve-sparing radical excision of parametrial DIE is safe and effective when performed by an expert surgical equipe. This approach can favorably impact on patients QoL. Moreover, it has proved to result in pain score and voiding function improvements.

1. Introduction

Endometriosis is a chronic inflammatory disease, characterized by ectopic proliferation of endometrial glands and stroma. It is estimated that it can affect up to 2-10 % of reproductive age women, 20-50% of infertile women and 30-80% of women with chronic pelvic pain. (1)(2)(3)(4)(5)

In its deeply infiltrating form (DIE) the disease affects up to 34% of women with pelvic endometriosis. The DIE is a specific clinical entity characterized by an extension of the disease more than 5 mm under the peritoneal surface, retroperitoneal fibrosis and neural tropism with distortion of the regular pelvic anatomy. (6)(7)(8)(9) DIE affects most frequently uterosacral ligaments (69.2%), rectovaginal septum (14.5%), bowel (9.9%) and bladder (4.2%). (10)

In a retrospective study, Fauconnier et al. (11) demonstrate that different types of chronic pelvic pain are related to the anatomic location of DIE. In recent years a growing attention was pointed out on parametrial localization of deep infiltrating nodules with studies investigating diagnosis, treatment and clinical outcomes. (12)(13)(14)(15)

The parametrium has been described as the supporting system of the uterus that anchors the organ to the lateral pelvic wall and has both supply-drainage and fascial functions (16). All the three components (anterior, posterior, lateral) in which the parametrium is normally classified can be infiltrated by DIE. More often DIE lesions are at the level of the posterior and lateral part of the parametrium associated to retrocervical, bowel and ureteral nodules(17)(18). This pattern of lesions distribution can be associated with ureteral and bowel function impairment and often with chronic pelvic pain symptoms expressed as dyspareunia and dyschezia (14)(11). Due to these symptoms, endometriosis may have a profound impact on quality of life and mental health of the patients affected. In 2004 Abbot et al. (19) demonstrated that surgical excision of endometriosis determines a symptomatic improvement significantly more than placebo.

The lateral parametrium has a ventral component called *pars vasculosa* and a dorsal part defined as *pars nervosa* because it contains the nerve branches of autonomic pelvic organs innervation, therefore the complete eradication of the disease is associated with the risk of serious impairment of rectal, bladder and sexual function due to the iatrogenic disruption of inferior hypogastric plexus.

Different authors have described the nerve-sparing approach in case of DIE nodules (20)(21)(22). In 2012, a prospective cohort study compared the laparoscopic nerve-sparing approach to the classical laparoscopic procedure demonstrating the feasibility of radical removal of fibrotic infiltrating endometriosis tissue from parametrial structures avoiding disruption of autonomic pelvic organs innervation.(23)

There has been a growing interest in recent years on analyzing QoL after laparoscopic surgery for endometriosis. However, despite the large amount of literature on surgical techniques and diagnostic assessment of parametrial endometriosis, only a few studies have specifically addressed data on functional outcomes, and, to the best of our knowledge, no one was published investigating patient's QoL with validated questionnaires. (24) (25)

The aim of this study is to use validated questionnaires to evaluate patients' response to laparoscopic nerve-sparing excision of parametrial DIE in terms of self-perceived well-being, pain relief and voiding function.

2. Materials And Methods

This study was approved by the local Ethics Committee (protocol number 0024582/19), and all patients expressed their informed consent to anonymous data collection. All patients that underwent laparoscopic surgery for endometriosis in the period between January 2013 and March 2017 at Obstetrics and

Gynecology Division of the Sassuolo Civil Hospital and at the Endometriosis tertiary level referral center of the University Hospital of Modena were enrolled. All surgeries were performed by the same surgeon with high expertise in laparoscopic treatment of endometriosis (C.A.) and patients with histologically confirmed laparoscopic resection of posterior and lateral parametrium were selected. Exclusion criteria were age < 18, preoperative diagnosis of neurogenic bladder and bowel inflammatory disease and absence of sexual activity.

All patients underwent speculum examination, pelvic bimanual vagino-rectal evaluation and transvaginal ultrasound performed by an expert sonographer expert in endometriosis diagnosis. A transabdominal ultrasound scan of the kidneys was also routinely performed to rule out hydroureteronephrosis (an indirect marker for parametrial nodules). (19)

Eventually, they underwent pelvic magnetic resonance with rectal injection of 10-50 ml of sterile gel to confirm dimension and depth of infiltration of the bowel lesions (if any) and to define the parametrial/ureteral involvement.

All patients signed a specific informed consent before surgery, specifying the preoperatively diagnosed localization of lesions, all surgical procedures necessary for their complete excision and the potential risks (vascular, neurologic, urologic and intestinal) related to the type of surgery.

Patients were hospitalized the same day of the intervention. A nerve-sparing laparoscopic surgical technique was implemented for all the surgeries (23).

In case of bowel lesions infiltrating the muscularis interna and causing a stenosis of more than 50% of the lumen in patients symptomatic for bowel dysfunction, a segmental resection with Knight-Griffen technique and end-to-end anastomosis was performed by an equipe of general surgeons.(27) A protective ileostomy was routinely done in case of ultra-low rectal segmental resection (resection margin < 5 cm from the dental line). Antibiotics were administered for 48 hours postoperatively. The data on patient age, parity, body mass index, previous abdominopelvic surgery, operating time, amount of blood loss, use of hormonal therapy, length of hospital stay were recorded, while intraoperative, early and late postoperative complications were analysed according to the Clavien-Dindo classification system.(28) Pain symptoms were investigated using the visual analogue scale (VAS) and the different need of analgesic drugs was evaluated at the preoperative visit (range 10-45 day before surgery) and at the follow up evaluation after three months. For the comparative analysis of dysmenorrhea with VAS scale, patients underwent hysterectomy and patients with post-operative continuous hormonal therapy were excluded.

Quality of life and functional and status outcomes were collected using the italian validated version of three questionnaires (29), administered in paper form, one month before surgery and three months after the intervention. The Endometriosis Health Profile-30 Questionnaire (EHP-30) was used to evaluate the global health profile of the patients (30)(31)(32) as primary outcome of our study. The EHP-30 consists of 30 questions about pain, control and powerlessness, emotional well-being, social support and self-image. Currently is the only questionnaire that evaluates QoL specifically in patients with endometriosis.

For bowel function the Neurogenic Bowel Dysfunction (NBD) score was used (33), whereas the urinary function was evaluated using the International Consultation on Incontinence-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) (34,35).

2.1 Statistical analysis

Data were expressed as mean±standard deviation for numerical variables and as numbers (percentages) for categorical variables. The Wilcoxon test was used to compare changes in variables between before and after the surgical treatment. P value of <0.05 denoted statistical significance. All statistical analyses were performed using SPSS software (version 21, SPSS, Inc., Chicago, IL, USA).

3. Results

During the study period a total of sixty-five patients underwent nerve-sparing surgery for parametrial deep infiltrating endometriosis. Fifty-nine patients met the inclusion criteria and were included and fifty-one of these agreed to fill out questionnaires for postoperative outcomes evaluation.

Median age was 36 ± 6.2 years. The majority of these patients were married or a common-law wife (72.5%) and employed (88.2%) at the time of surgery. Demographic characteristics of patients are provided in Table 1.

Eight patients had had previous surgery for endometriosis (15.6%) and twenty-seven were nulliparous (53%).

Diagnosis of parametrial endometriosis was confirmed by histological examination in all patients included. Laparoscopic approach was used in all cases, no conversion to open surgery occurred. Laparoscopic segmental bowel resection was performed in fifteen patients, while discoid resection was performed in only one. Three patients needed protective ileostomy for ultra-low rectal anastomosis. Operative details and procedures are summarized in Table 3. The mean operating time was 239 +/- 111 minutes, the mean estimated blood loss during surgery was 165 +|- 59.9 mL (range 50-1020 mL) and the mean hospital stay was 6 days (range 3-12 days). The average length of the removed intestinal segments was 12.5 cm (+/- 5,7).

In thirty-seven patients (62,7%) parametrial endometriosis was unilateral, in 22% of cases both posterior and lateral parametrium were involved and in 15.3% of cases posterior and lateral parametria were involved bilaterally.

Right posterior parametrium was involved in 38% of cases (19/50), while the left one was involved in 40% of cases (20/50). Right lateral parametrium was involved by endometriosis in 59.1% of cases (13/22), the left one was involved in 31.8% of cases (7/22), and lateral parametria were involved bilaterally in 9.1% of cases (2/22). The average size of parametrial nodules was 2 +/- 0.5 cm. No cases of intrinsic ureteral endometriosis were found.

Endometriosis of the anterior compartment was detected in 41.2% of patients with three cases of DIE of the bladder (5.9%). Others DIE localizations are shown in Table 2. Posterior compartment was most frequently involved by DIE than the anterior with the presence of nodules of the rectosigmoid colon in 69.5 % of the cases. Ovarian endometriosis was detected in 74.5% of patients. Pre-operative pain symptoms, evaluated with VAS score, are reported on Table 5. Dysmenorrhea was the most frequent symptom (84.3%), followed by dyspareunia (74.5%), ovulatory pain (70,6%), dyschezia (51%), chronic pelvic pain (35.3%) and stranguria (27.5%).

Intraoperative complications occurred in five patients. Four patients had monolateral hypogastric nerve involvement and in two of the four patients neuroablation was necessary due to the need for radical resection of nodules. In one patient sigmoid lesion occurred during the shaving procedure and required the intervention of the general surgeon for the suture. A total of three postoperative complications were registered: one hemoperitoneum (class IIIb) that required a second surgery, one rectovaginal fistula requiring three operations for complete resolution (class IIIb) and we had one case of stenosis of colorectal anastomosis requiring endoscopic balloon dilation (class IIIa).(36)

Twenty-seven patients (52.9%) were undertaking estroprogestins at the post-operative follow up visit (3 months).

Pain symptoms (expressed in VAS score) were significantly decreased after the operation (p value < 0,05) as shown in figure 1. Post-operative use of analgesic drugs also decreased from 37.5% (19/51) to 5.9% (3/51).

The EHP-30 score variation is shown in Table 4. The comparison of pre-operative and post-operative scores showed that surgery improved significantly QoL in many of the domains analyzed such as pain, control and powerlessness, emotional well-being, social support, self-image, satisfaction of treatment, sexual life. It was not possible to evaluate the “infertility” and “relationship with children” modules because respectively 21 (41.2%) and 31 (60.8%) patients did not answer the questions respectively. Limited to the small sample analyzed, however, even in these two modules a statistically significant improvement was observed.

No differences were found in terms of urinary function between pre and post-operative questionnaires (ICIQ-FLUTS). The correlation between resected parametrium and urinary symptoms was examined: of the seven patients undergoing lateral parametrium resection, four had no symptoms (57.1%), three had mild difficulties in bladder filling (33.3%) and one complained of mild incontinence; of the thirty-six patients undergoing posterior parametrium resection, twentyfour (66.7%) had no symptoms, while twelve (33.3%) complained of mild incontinence. Six of the eight patients undergoing resection of both parametria developed difficulties in bladder filling, one was asymptomatic and one developed mild incontinence.

Bowel function has improved in patients' subjective perception, although the results are controversial: while the surgery was resolutive for diarrhea and alternating alvus, there was no improvement in

constipation. In fact the NBD score showed that intestinal dysfunction in the whole group was related to constipation. Most of the patients showed mild dysfunction (76.4%), while only three patients had severe dysfunction (5.9%).

NBD scores of patients undergoing recto-sigmoid shaving was compared with that of patients undergoing bowel resection: data are shown in figure 2.

4. Discussion

Surgical eradication of DIE represents the treatment of choice in symptomatic patients unresponsive to medical treatment. The preservation of the pelvic autonomic system may be challenging in case of large nodules and surgical treatment of deep infiltrating endometriosis needs adequate surgical skills and expertise to minimize the risk of surgical complication; in fact only a few series, with limited sample size, have demonstrated the feasibility of nerve-sparing surgery in case of parametrial DIE (37)(38–41)

Many studies showed that laparoscopic excision of endometriosis is associated with improvement in pelvic pain, but only few of this provides data on QoL using validated questionnaires. (25)(42)(43)(44) To the best of our knowledge this study is the first to analyzed the impact of nerve-sparing laparoscopic surgery for parametrial deep infiltrating endometriosis on quality of life with EHP-30 questionnaire.

Preservation of pelvic innervation system entails better functional outcomes.

Patients reported a subjective improvement in bowel function, excepted for constipation. This evidence is in accordance with a retrospective study by Abo et al. (45) on 371 women undergoing surgery for colorectal endometriosis and divided into three arms depending on the surgical technique used (segmental resection, discoid resection or shaving). Authors did not observe postoperative improvement in constipation in all three groups but an improvement in diarrhea only.

The results of the ICIQ-FLUTS questionnaire on urinary function show that incontinence was more frequent in patients undergoing posterior parametrial resection than those undergoing lateral or resection of both parametria. However, a final conclusion can’t be achieved because of size discrepancy between the three groups (36/51 patients underwent resection of the posterior parametrium, 7/51 of the lateral parametrium and 8/51 of both parametria). The main bias of our study is related to the lack of pre-operative data on urinary function due to the preponderance of intestinal symptoms. Many authors have studied the incidence of urinary symptoms in patients with endometriosis. Fauconnier et al.(11) related specific symptoms to anatomical locations of DIE, but did not evaluate the correlation between urinary symptoms and posterior DIE; Darai et al.(46) reported an high incidence of urinary symptoms in patients with deep infiltrating endometriosis, but without being able to correlate the presence of symptoms with well-defined anatomical lesions.

The EHP-30 score shows that nerve-sparing surgery improves quality of life of patients and reduces all the painful symptoms, except for chronic pelvic pain. This evidence suggests that a “symptom guided

approach” and a radical surgery are associated with better postoperative outcomes. The main post-operative improvement in term of quality of life relates to domains affecting social and relationship life. This represents an important goal considering that the average age of the patients enrolled is 36 years, with a percentage of working and married women being respectively 88.2% and 72.5%, and that 47% of them are engaged in the management of children. Furthermore, the eventuality of surgical complications associated with this technique was low.

Among the possible limitations of this study, we mention the small sample size, the lack of a comparison arm of patients not receiving nerve-sparing approach and the short follow up.

On the other hand our study provides the first analysis of the impact of nerve-sparing surgery on quality of life, using validated questionnaires and it gives good and promising results for the systematic use of this type of approach.

5. Conclusion

In conclusion, the use of nerve sparing technique by expert surgeons warrants good results in term of improvement of QoL and pain control and provides good functional outcomes. The development of surgical skills based on anatomical knowledge can lead to a more extensive use of the nerve-sparing technique with a persistent improvement in the quality of life of the patients with parametrial localization of DIE.

Declarations

AUTHOR CONTRIBUTION

C. Alboni : protocol development

V. Sampogna: manuscript writing

M. Airoud: data management

S. Malmusi: data collection

G. Colucci: data collection

A. Farulla: data analysis

L. Camacho Mattos: manuscript editing

A. Pecchi: data collection

A. La Marca: project development

Disclosure

The authors declare no conflict of interest. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Tables

Table 1. Demographic characteristics of patients. Values are given in mean +/- standard deviation.

AGE	36 +/- 6,2
WEIGHT	62.1 Kg +/- 12,9
BMI	22.7 Kg/m ^{2} +/- 3,9
NATIONALITY	
• Italian	76.5%
• Foreign	23.5%
MARITAL STATUS	
• Married	72.5%
• Divorced	11.8%
• Nubile	13.7%
• Widow	2%
EDUCATION	
• Secondary school	21.6%
• High-school	56.8%
• Degree	21.6%
OCCUPATION	
• Employed	88.2%
• Unemployed	9.8%
• Students	2%
MEDICAL HISTORY	
• No prior history	33.3% (17/51)
• Hypothyroidism	19.6% (10/51)
• Mood disorder	15.6% (8/51)
• Allergic asthma	11.7% (6/51)
• Migraines with aura	3.9% (2/51)
• Chronic Hypertension	3.9% (2/51)
• Epilepsy	2% (1/51)
• Myasthenia gravis	2% (1/51)
• Ulcerative colitis	2% (1/51)

Table 2. Localization of deep infiltrating endometriosis nodules

LOCALIZATION OF DIE	%
Uterosacral ligaments	91.5% (54/59)
Rectum, rectosigmoid junction and sigmoid	69.5% (41/59)
Retrocervical area	32.2% (19/59)
Bladder	8.5% (5/59)
Endometrioma	74.5% (44/59)

Table 3. Detail of operative procedures

OPERATIVE PROCEDURES	
cyst enucleation	60.8%
monolateral adnexectomy	15.7%
removal of peritoneum of ovarian fossa	49%
Total hysterectomy	10%
Parametrectomy	100%
Shaving of rectum and sigmoid	29.4%
bowel resection	29.4%
discoid resection	2%
protective stomy	5.9%

Table 4. EHP-30 scores before and after surgery

EHP-30 questionnaire	BEFORE SURGERY (mean +/- SD)	AFTER SURGERY (mean +/- SD)	p Value
- Pain	47.2 (+/- 25.3)	10.1 (+/- 14.8)	< .00001
control and powerlessness	56.3 (+/- 25.7)	13.2 (+/- 15.6)	< .00001
- Emotion	53.4 (+/- 24)	23.3 (+/- 20.7)	< .00001
- Social support	38.8 (+/- 26.5)	22.2 (+/- 21.5)	< .00001
- Self image	30.7 (+/- 23.9)	19.7 (+/- 22.5)	< .00001
- work module	38.8 (+/- 28.3)	9.3 (+/- 16.7)	< .00001
relationship with children	20 (+/- 26.1)	6 (+/- 12.9)	0.0022
sexual intercourse	49.2 (+/- 27.8)	20.6 (+/- 22.6)	< .00001
medical profession	21 (+/- 26.7)	3.9 (+/- 8.7)	< .00001
treatment module	38.3 (+/- 29.1)	15.5 (+/- 21.9)	< .00001
infertility module	48.8 (+/- 27.8)	30.2 (+/- 30.0)	0.0065

Table 5 is not available with this version.

Figures

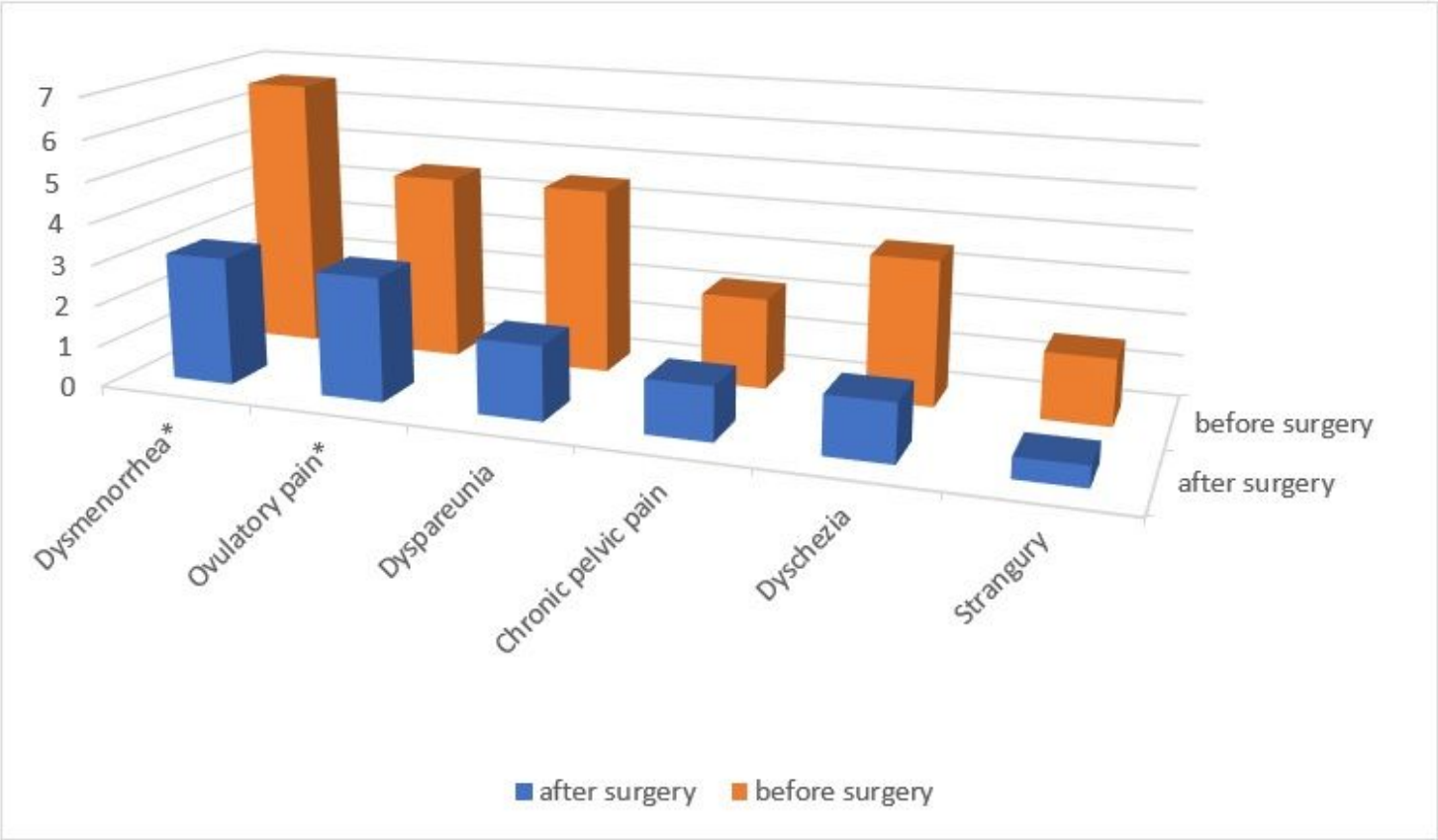

Figure 1

VAS score before and after surgery, values are given in mean +/- standard deviation. *no oral contraceptives

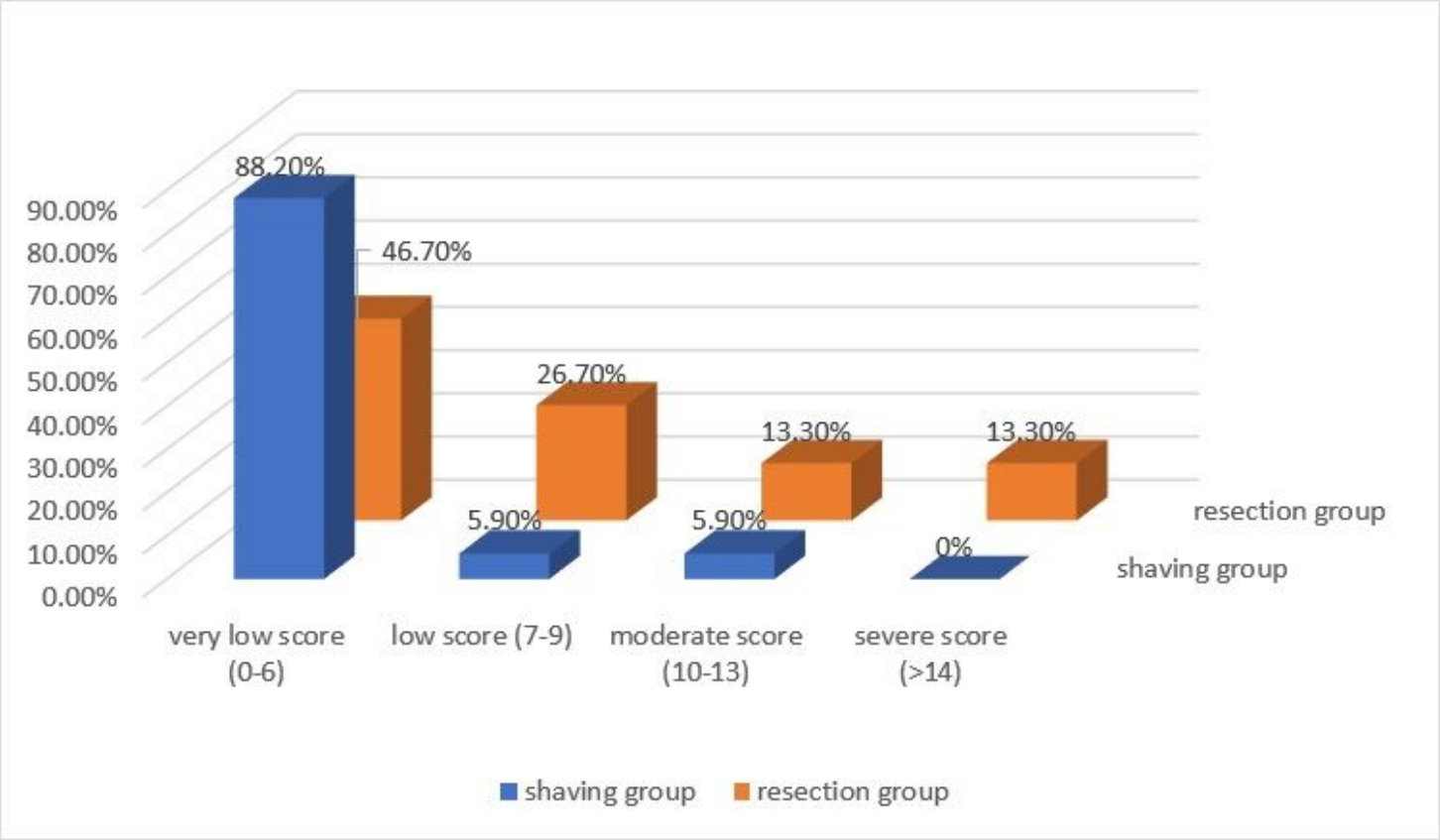

Figure 2

comparison of NBD scores between patients undergoing shaving and patients undergoing segmental resection.