



THE EFFECT OF COMBINING BOTULINUM TOXIN INJECTION INTO THE ANAL SPHINCTER COMPLEX WITH TRANSVAGINAL REPAIR IN THE MANAGEMENT OF OBSTRUCTED DEFECATION SYNDROME DUE TO ANTERIOR RECTOCELE

Abdallah Alqasaby¹, Haitham Elkaffas², W M Thabet^{1,2}, Wael Khafagy^{1,2}, Mostafa Shalaby^{1,2}

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Background: Transvaginal repair (TVR) is a well-established approach for the repair of the anterior rectocele and exhibits good results regarding recurrence rates and symptomatology. A previous study suggested that the injection of botulinum toxin (BTX) into the anal sphincter complex successfully managed rectocele due to obstructed defecation syndrome (ODS). This study aimed to study the effect of simultaneous BTX injection with TVR of rectocele on the incidence of recurrence.

Methods: Data from female patients who had transvaginal repair of anterior rectocele and botulinum toxin injection in puborectalis muscle (TVR + BTX) were retrospectively collected. The incidence of recurrence was recorded in addition to the assessment of clinical symptoms, defecatory function, sexual function, and quality of life (QOL).

Results: Data from 20 female patients (mean age = 43.9 ± 12.8) were included. In a 12-month follow-up, no cases reported recurrence of symptoms. Also, at postoperative 12 months, patients showed better constipation score (from 14.5 ± 1.7 to 6.3 ± 2.6 , $P < 0.0001$) and sexual function score (from 28.6 ± 2.2 to 39.9 ± 2.5 , $P < 0.0001$). Moreover, the patients showed better results regarding the symptoms and the quality of life scores. Median pain score remained ≥ 3 up to the first week of follow-up, then no significant pain was reported in the following follow-up dates.

Conclusion: The application of TVR + BTX resulted in zero incidence of recurrence and the addition of BTX injection to TVR probably resulted in better defecatory function, sexual function and QOL.

Keywords: Transvaginal repair, botulinum toxin, defecatory functions, sexual functions, quality of life.

¹ General Surgery Department, Faculty of Medicine, Mansoura University, Egypt.

² Colorectal Surgery Unit, Faculty of Medicine, Mansoura University, Egypt.

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INTRODUCTION

A rectocele a type of pelvic organ prolapse where the anterior wall of the rectum herniates through a defect in the rectovaginal septum into the vaginal lumen resulting in a vaginal bulge (Mustain, 2016). It is considered an anatomic disorder, but its functional burden is challenging to be determined and does not exhibit strong correlation with the size and/or the level of rectocele (Lefevre and Davila, 2008).

Rectoceles affect about two-thirds of parous females in varying degrees which may be symptomatic or not (Ladd and Tuma, 2020) and it has been recently suggested that there is a significant correlation between vaginal delivery and occurrence of rectocele and its depth with the highest effect after the 1st vaginal delivery (Dietz et

al., 2018). Nevertheless, about 12% of nulligravida women might acquire rectoceles because of congenital defects (Dietz and Clarke, 2005).

Several factors affect the loss of the rectovaginal septum integrity. Non-modifiable risk factors include old age and genetics. On the other hand, modifiable risk factors include higher parity, vaginal delivery, pelvic surgeries, obesity, educational level, constipation, and chronic increase in the intra-abdominal pressure e.g. COPD or chronic cough (Glazener et al., 2013 & Nygaard et al., 2004).

Rectoceles are associated with manifestations of obstructed defecation syndrome. About 30-70% of cases have difficult rectal evacuation, excessive straining, local pelvic manifestations, and they need additional aids for facilitating rectal emptying

(**Farid et al., 2010**). Coexisting causes of constipation are often observed. These associated conditions could be predictors of a worse outcome after management of rectoceles, because the defect could be a secondary condition (**Beck and Allen, 2010**).

Treatment of rectoceles often starts with conservative measures which include high-fiber diet, increase in water drinking, and use laxative agents. A patient with rectocele can benefit from Kegel exercises and a pelvic floor physiotherapy specialist (**Tso et al., 2018**).

Various surgical techniques are available for the management of rectoceles to achieve anatomic correction and to relieve symptoms (**Maher et al., 2006**). The surgical repair of the rectoceles can be accomplished through the perineal approach including transvaginal, transperineal, or transanal repairs and the transabdominal approach in the form of ventral mesh rectopexy (**Leanza et al., 2013 & Wong et al., 2011**).

Recently, rectocele can be managed through resection and anastomosis of the herniated rectal wall, a technique known as Stapled transanal rectal resection (STARR). Using STARR in managing anterior rectocele showed a success rate of up to 96% and excellent patient satisfaction at postoperative 12 months in 86% of the patients (**Giarratano et al., 2019**).

Transvaginal repair of the rectocele is a well-known effective technique for the repair of the rectocele and exhibits good results regarding recurrence rates and symptomatology compared to transperineal repair (**Zimmermann et al., 2017**). Also, we have a good experience with this approach with excellent results and a low incidence of complications in Mansoura University's colorectal surgery unit (**Balata et al., 2020, Youssef et al., 2017, & Farid et al., 2010**).

The study by Maria et al. suggested that the use of BTX injection in puborectalis muscle and external anal sphincter alone was successful in the management of rectocele due to ODS with only one case reported to develop a transient fecal incontinence to flatus for 15 days after the use of a rescue dose (**Maria et al., 2001**).

A systematic review showed that BTX injection was successful in managing ODS due to anismus with only 5.8% of patients developing minor transient fecal incontinence (**Emile et al., 2016**).

This study aimed to study the safety and the effectiveness of BTX injection into the anal

sphincter complex with the transvaginal repair of rectocele in improving symptoms of ODS because of anterior rectocele and in addition to the improvement in the sexual functions and the effect on QOL.

Patients and methods

Study design, setting, and approval

This is a single-center, retrospective case series of women with ODS because of anterior rectoceles. The study was conducted at Mansoura University Hospital, General Surgery Department, Colorectal Unit, Egypt. The retrieved data included the patients during the period from January 2021 through January 2023. The study was approved by the Institutional Review Board, Faculty of Medicine, Mansoura University.

Eligibility Criteria

We retrieved the data of females with symptomatic rectoceles who failed conservative therapy, for at least 6 months. The inclusion criteria included those with anterior rectoceles > 3 cm using fluoroscopic defecography, in addition to one or more of the following symptoms: excessive straining, sense of partial emptying, the necessity for digital manipulation while defecating, or dyspareunia.

We excluded data of patients who had significant anterior compartment symptoms, recurrent rectoceles, previous anal surgeries, anal hypertonia, systemic steroids use, connective tissue diseases, and slow-transit constipation, faecal incontinence (FI), abnormal thyroid profile, or those who failed to complete the follow-up.

Preoperative data

Retrieved data included functional evaluation of each patient using the Cleveland Clinic Constipation Score (CCCS) (**Agachan et al., 1996**) and the short form of Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12) (**Rogers et al., 2003**). Also, faecal incontinence was assessed using Wexner Incontinence Score (WIS) (**Jorge and Wexner, 1993**).

The Pelvic Floor Impact Questionnaire (PFIQ-7) was used to assess the effect of rectocele on QoL (**Barber et al., 2005**) and the Patient Assessment of Constipation Quality of Life (PAC-QoL) questionnaire for constipation symptoms (**Marquis et al., 2005**).

A colon-transit study, fluoroscopic defecography, and ano-rectal manometry were performed for each patient.

At time of surgery, antibiotic prophylaxis (third-generation cephalosporin and metronidazole) was administered on induction of anesthesia.

Operative technique

All patients were subjected to TVR (posterior colporrhaphy) followed by BTX injection into anal sphincter complex. Regarding TVR, we adopted the technique previously described in literature (**Balata et al., 2020 and Shalaby et al., 2018**).

Botulinum toxin injection

We adopted a modification of the technique previously described by Maria and coworkers (**Maria et al., 2001**). Prior to the injection, a vial containing 100 units of lyophilized type-A BTX were diluted in saline to 50 U/mL. A total of 30 units of type-A BTX was injected using a 22 Gauge needle evenly divided into 3 sites, 2 on either side of the puborectalis muscle (at III and IX O'clock) and the third posteriorly (at XII O'clock) in the external anal sphincter.

Follow-up data

Data from follow-up records included weekly postoperative outpatient clinic visits in the first 4 weeks, every two weeks in the 2nd month, then using phone calls at the 3rd month, the 6th month, and the 12th month.

In every follow-up visit, the patient was assessed for any complication and also the wound condition was assessed in terms of healing, disruption, collection, haematoma, and surgical site infection (SSI). The continence was evaluated using WIS. Any complication was recorded and managed accordingly.

At the postoperative 12th month, improvements in defecating and sexual functions were assessed with CCCS and PISQ-12 while QoL changes were evaluated with PAC-QoL and PFIQ-7.

Pain was assessed at 8 hrs postoperatively with a visual analog scale (VAS) from 0-10 where 0 is the least pain and 10 is the highest pain. Then it was assessed at one week, 1, 3, and 6 months postoperatively. Fluoroscopic defecography was reperformed at the postoperative 6th month to confirm the anatomic correction of the rectocele and to assess the function.

Study outcomes

The primary outcome is the incidence of recurrence. Secondary outcomes include functional improvement (changes in CCCS & PISQ-12), improvement in QOL (changes in PAC-QoL & PFIQ-7), post-operative pain, changes in anatomical

parameters (detected by fluoroscopic defecography), operation time, time to healing, as well as post-operative complications.

Statistical analysis

Data were analyzed by SPSS™ software, v 23 (Bristol, UK). For quantitative variables, continuous variables were represented as means \pm standard deviations (SDs) and discrete variables as medians and ranges. Categorical variables were represented as frequencies and percents. Student t-test for paired samples was utilized to compare between the means of continuous variables, Mann-Whitney U test was utilized to detect differences in the medians of discrete variables or non-parametric continuous variable, and Fisher exact test or Chi-square test were utilized for processing categorical variables. *P* value <0.05 was considered significant.

RESULTS

This is a retrospective case series in which prospectively collected data from 55 females with ODS due to anterior rectoceles were retrospectively retrieved from the records. Thirty females did not fit the inclusion criteria, five females failed to complete the follow-up. So, data of 20 females were ultimately included and were analyzed.

The mean age was 43.9 ± 12.8 years. The mean depth of rectocele assessed using fluoroscopic defecography was 5.1 ± 1.1 cm with 90% of the patients showing barium trapping. Data regarding preoperative constipation score, sexual function, and QOL were reported in **Table 1**.

At postoperative 12 months, significant differences were found regarding CCCS (from 14.5 ± 1.7 to 6.3 ± 2.6 , $P < 0.0001$), PISQ-12 (from 28.6 ± 2.2 to 39.9 ± 2.5 , $P < 0.0001$), overall PFIQ-7 (from 88.6 ± 7.1 to 14.9 ± 5.6 , $P < 0.0001$), and PAC-QoL (Dissatisfaction Index from 66 ± 4.1 to 23.4 ± 6.4 and Satisfaction Index from 0.7 ± 0.8 to 10.2 ± 1.6 , $P < 0.0001$) as shown in **Tables 2 & 3**.

The median pain score remained ≥ 3 up to the first postoperative week. Then the pain declined and no significant pain scores were detected up to the sixth postoperative month as shown in **Table 4**.

No recurrent cases were reported up to the end of follow-up. Only three patients showed minor complications in the form of postoperative bleeding (5%), surgical site infection (5%), and wound dehiscence (15%) as shown in **Table 4**. Those patients were successfully managed by conservative measures.

Table (1): Preoperative primary data.

| Item | TVR+BTX n=20 |
|--|-----------------|
| Age in years, mean ± SD | 43.9 ± 12.8 |
| Parity, median (range) | 2 (1-4) |
| Preoperative CCCS, mean ± SD | 14.5 ± 1.7 |
| Preoperative PISQ-12, mean ± SD | 28.6 ± 2.2 |
| Preoperative PFIQ-7, mean ± SD | |
| • UIQ | 4.1 ± 2.1 |
| • POPIQ | 25.9 ± 4.9 |
| • CRAIQ | 58.6 ± 6.3 |
| • Overall | 88.6 ± 7.1 |
| Preoperative PAC-QoL, mean ± SD | |
| • Dissatisfaction Index (1-24) | 65.9 ± 3.9 |
| • Satisfaction Index (25-28) | 0.7 ± 0.9 |
| Preoperative Fluoroscopic Defecography | |
| • Rectocele Depth in cm, mean ± SD | 5.1 ± 1.1 |
| • Barium Trapping, n (%) | 18 (90) |

TVR: transvaginal repair, BTX: botulinum toxin, n: number, SD: standard deviation, CCCS: Cleveland Clinic Constipation score, PFIQ-7: Pelvic Floor Impact Questionnaire - Short Form 7, UIQ: Urinary Impact Questionnaire, POPIQ: Pelvic Organ Prolapse Impact Questionnaire, CRAIQ: Colorectal-Anal Impact Questionnaire, PISQ-12: The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire - Short Form 12, PAC-QoL: Patient Assessment of Constipation – Quality of Life, cm: centimeter.

Table (2): Functional and anatomical outcomes at postoperative 12 months.

| Outcome | Preoperative n=20 | Postoperative n=20 | P value |
|------------------------------------|----------------------|-----------------------|---------|
| CCCS, mean ± SD | 14.5 ± 1.7 | 6.3 ± 2.6 | <0.0001 |
| PISQ-12, mean ± SD | 28.6 ± 2.2 | 39.9 ± 2.5 | <0.0001 |
| Fluoroscopic Defecography | | | |
| • Rectocele Depth in cm, mean ± SD | 5.1 ± 1.1 | 1.8 ± 0.4 | <0.0001 |
| • Barium Trapping: n (%) | 18 (90) | 1 (5) | <0.0001 |

n: number, SD: standard deviation, CCCS: Cleveland Clinic Constipation score, PISQ-12: The Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire - Short Form 12.

Any P-value colored in red is considered significant (≤ 0.05)

Table (3): Quality of life assessment at postoperative 12 months.

| Outcome | Preoperative n=20 | Postoperative n=20 | P value |
|--------------------------------|----------------------|-----------------------|---------|
| PFIQ-7, mean ± SD | | | |
| • UIQ | 4.1 ± 2.1 | 1.1 ± 1.5 | <0.0001 |
| • POPIQ | 25.9 ± 4.9 | 6.2 ± 3.2 | <0.0001 |
| • CRAIQ | 58.6 ± 6.3 | 7.6 ± 4 | <0.0001 |
| • Overall | 88.6 ± 7.1 | 14.9 ± 5.6 | <0.0001 |
| PAC-QoL, mean ± SD | | | |
| • Dissatisfaction Index (1-24) | 66 ± 4.1 | 23.4 ± 6.4 | <0.0001 |
| • Satisfaction Index (25-28) | 0.7 ± 0.8 | 10.2 ± 1.6 | <0.0001 |

n: number, SD: standard deviation, PFIQ-7: Pelvic Floor Impact Questionnaire - Short Form 7, UIQ: Urinary Impact Questionnaire, POPIQ: Pelvic Organ Prolapse Impact Questionnaire, CRAIQ: Colorectal-Anal Impact Questionnaire, PAC-QoL: Patient Assessment of Constipation – Quality of Life.

Any P-value colored in red is considered significant (≤ 0.05)

Table (4): Additional data.

| Outcome | TVR+BTX n=20 |
|--|-----------------|
| Pain assessment using VAS, median (range) | |
| • 12 hours | 7.5 (6-9) |
| • 1 week | 3 (3-5) |
| • 1 month | 1 (0-3) |
| • 3 month | 0 (0-2) |
| • 6 m month | 0 (0-2) |
| Operative time in min, mean ± SD | 40.5 ± 8.3 |
| Healing Time in days, mean ± SD | 16.1 ± 4 |
| Complications, n (%) | |
| • Recurrence | 0 (0) |
| • Bleeding | 1 (5) |
| • SSI | 1 (5) |
| • Wound dehiscence | 3 (15) |

TVR: transvaginal repair, BTX: botulinum toxin, n: number, VAS: Visual Analogue Scale, hr: hour, wk: week, m: month, SD: standard deviation, SSI: surgical site infection.

DISCUSSION

Rectocele is frequently asymptomatic. Vaginal delivery represents the major risk factor for rectocele, possibly due to localized laceration in the rectovaginal fascia. Clinical examination and defecography are considered the cornerstone for diagnosing rectoceles (Lopez et al., 2001).

Patient selection for surgical repair is still challenging and debatable. The success rates of the repair of rectoceles range from 70% to 90%. It is not clear why in many cases, constipation does not resolve, even anatomical correction is achieved (Sloots et al., 2003).

The concept behind the adopted technique is that the use of BTX injection improves the symptoms of ODS and temporarily lowers the pressure distal to the rectocele repair giving a chance for earlier symptoms improvement, better healing, and more sustained results.

In our study, the mean age is younger compared to that reported in earlier studies (Eustice et al., 2018 & Hagen et al., 2014) but was close to that reported in studies based in our community (Balata et al., 2020 & Youssef et al., 2017).

At postoperative 12 months, functional outcomes showed a significant improvement regarding both defecatory and sexual functions. This could be attributed to the effect of reduction in rectocele depth and the decline in the prevalence of barium trapping. This long-term improvement can be achieved only after complete healing. So, the use of BTX injection was justified as a bridge therapy to improve the ODS symptoms until complete healing of rectocele repair is achieved.

Maria and coworkers used BTX injection alone in the management of anterior rectocele and reported a significant decrease in rectocele depth from 4.3 ± 0.6 to 1.8 ± 0.5 cm (Maria et al., 2001). Although we performed BTX injection in addition to TVR, we reported a similar decline from 5.1 ± 1.1 to 1.8 ± 0.4 cm.

Moreover, the improvement of defecatory and sexual functions resulted in similar improvements in the quality of life. This could be noticed especially in the CRAIQ and overall components of PFIQ-7 in addition to both indices of PAC-QoL scores.

Although pain scores ranged from medium to high in the first 12 hours, BTX injection might be responsible for the rapid decline of pain scores to mild pain by the end of the first postoperative week, possibly due to the improvement of ODS symptoms. No recurrent cases were reported by the end of the follow-up. Because of the nature of this study, these results cannot be attributed to the surgical technique or the added effect of the BTX injection. However, long-term follow-up and/or a larger sample size may result in the appearance of such cases.

Only three patients showed complications. All of them were mild in nature and were managed successfully by conservative measures with no reported negative impacts on the QOL.

Unfortunately, the lack of a control arm (TVR only) made it difficult to calculate the added effect of BTX injection. Hence, further studies are required to assess this factor. Also, a specific ODS score and anorectal manometry are required for a better assessment of ODS symptoms and assessment of

the effect of BTX injection on the anorectal sphincter complex.

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