

Rectocele Repair With or Without Internal Sphincter Botulinum Toxin Injection: A Prospective Randomized Trial

BY

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INTRODUCTION

Many surgical procedures were described for the management of symptomatic rectoceles aiming at the anatomical correction of rectocele and relief of symptoms.

(Maher et al., 2006)

Overall, surgical repair of rectocele can be achieved through a transvaginal, transperineal, transanal, or transabdominal approach.

(Leanza et al., 2013 & Wong et al., 2011)

Transvaginal rectocele repair is a promising approach for rectocele repair and exhibits better results regarding recurrence rates and symptomatology compared to transperineal repair.

(Zimmermann et al., 2017)

Although TVR showed promising results, some patients still suffer from dyspareunia after TVR and others who do not experience complete sexual satisfaction.

(Balata et al., 2020, Youssef et al., 2017, & Farid et al., 2010)

This could be attributed to the high-pressure zone distal to the site of repair. This high-pressure zone could delay or prevent the complete healing of the repair and result in persistent bulging and redundancy of the posterior vaginal wall leading to unsatisfactory defecatory and sexual functions.

Maria and coworkers successfully used BTX injection in the EAS and puborectalis muscles without surgical repair in the management of ODS symptoms in the anterior rectocele.

(Maria et al., 2001)

However, the technique of Botox injection in the IAS is much easier than in the external anal sphincter and puborectalis muscles and does not require ultrasound guidance.

(Brisinda et al., 2004)

So, we chose this technique as an adjuvant to the classic TVR.

A recent systematic review showed that the use of botulinum toxin injection was successful in the management of ODS with only 5.8% of patients developing minor transient fecal incontinence.

(Emile et al., 2016)

As shown by a recent systematic review, most studies injected BTX at both sides of the anal fissure then the third dose at an anterior or posterior position. Neither the dose (ranging between 10 and 100 IU) nor the type of botox injected has been found to alter healing rates.

(Nelson et al., 2012)

Hence, in this study, we chose the lowest dose (10 IU in each location).

Regarding the recurrence rate after transvaginal repair, previous studies showed that the recurrence rate reaches up to 7%.

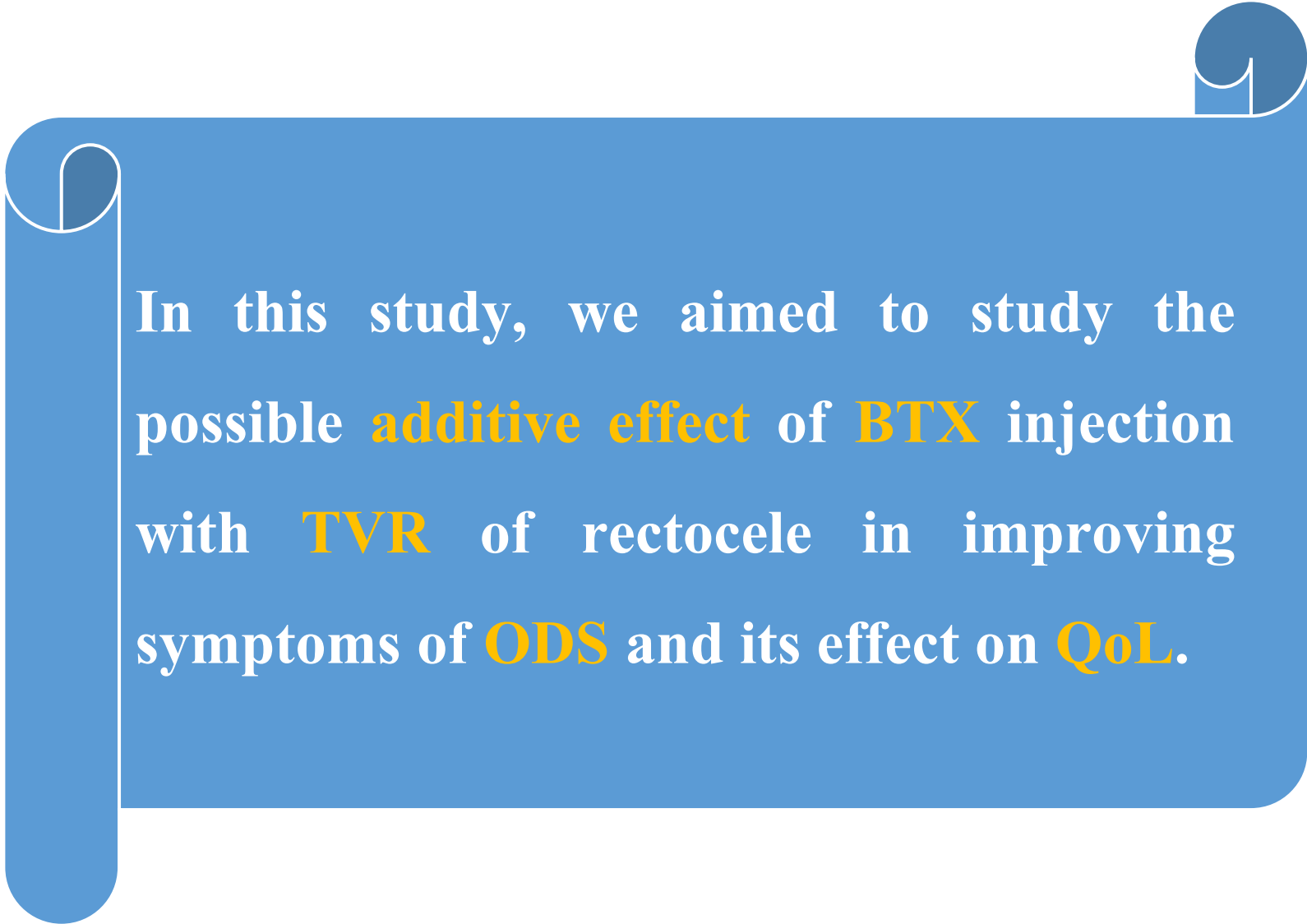
(Abramov et al., 2005;
Nieminen et al., 2004)

Also, the use of botox injection alone showed anatomical recurrence in 28.6% with no obvious ODS symptoms.

(Maria et al., 2001)

AIM OF THE WORK





In this study, we aimed to study the possible **additive effect** of **BTX** injection with **TVR** of rectocele in improving symptoms of **ODS** and its effect on **QoL**.

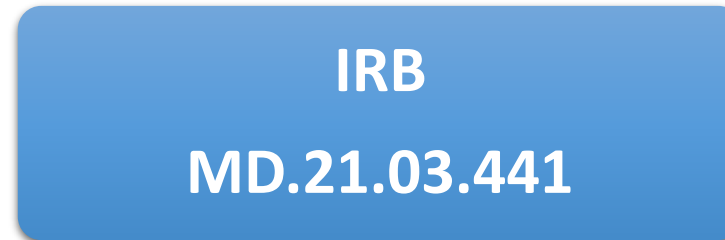
PATIENTS AND METHODS



Study Type:



Study Approval:



Study Population:

Patients

- Female patients with anterior rectocele associated with ODS

Setting

- General Surgery Department, Colorectal Unit
- Mansoura University Hospital

Duration

- From July 2021
- Until September 2023

Eligibility Criteria:

Inclusion

Female patients with symptomatic rectocele who failed conservative treatments for at least 3 months

Radiological

- Anterior rectocele >3 cm in size in defecogram.
- Retention of the contrast in the rectocele on defecography

Clinically

The following manifestations: are excessive straining, a sense of incomplete evacuation, the need for digital manipulation during defecation, or dyspareunia.

Eligibility Criteria:

Exclusion

Significant urinary manifestations due to anterior vaginal wall prolapse

Recurrent rectocele

Slow-transit constipation

Fecal incontinence

Abnormal thyroid functions

Systemic steroid treatment or connective tissue disease

ASA classification >3

Preop. Assessment:

History

- Detailed Hx of the complaint
- Associated medical conditions
- Bowel habits
- defecation symptoms
- Obesity parameters
- Previous treatments
- Previous anal or pelvic surgeries



Defecatory functions

were assessed using the
Cleveland Clinic
Constipation Score (CCCS)

Frequency of bowel movements		Time: minutes in lavatory per attempt	
0	1-2 times per 1-2 days	0	Less than 5
1	2 times per week	1	5-10
2	Once per week	2	10-20
3	Less than once per week	3	20-30
4	Less than once per month	4	More than 30
Difficulty: painful evacuation effort		Assistance: type of assistance	
0	Never	0	Without assistance
1	Rarely	1	Stimulative laxatives
2	Sometimes	2	Digital assistance or enema
3	Usually		
4	Always		
Completeness: feeling incomplete evacuation		Failure: unsuccessful attempts for evacuation per 24 hours	
0	Never	0	Never
1	Rarely	1	1-3
2	Sometimes	2	3-6
3	Usually	3	6-9
4	Always	4	More than 9
Pain: abdominal pain		History: duration of constipation (yr)	
0	Never	1	0
1	Rarely	2	1-5
2	Sometimes	3	5-10
3	Usually	4	10-20
4	Always	5	More than 20
		Total score: _____ (range, 0-30)	

POP symptoms

were assessed using the
Pelvic Floor Impact
Questionnaire (PFIQ-7)

How do symptoms or conditions in the following usually affect your	(UIQ) Bladder or urine	(POPIQ) Vagina or pelvis	(CRAIQ) Bowel or rectum
1. Ability to do household chores (cooking, laundry, housecleaning)?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
2. Ability to do physical activities such as walking, swimming, or other exercise?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
3. Entertainment activities such as going to a movie or concert?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
4. Ability to travel by car or bus for a distance greater than 30 minutes away from home?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
5. Participating in social activities outside your home?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
6. Emotional health (nervousness, depression, etc)?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
7. Feeling frustrated?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit

Sexual functions

were assessed using the
short form of Pelvic Organ
Prolapse/Urinary
Incontinence Sexual
Questionnaire (PISQ-12)

1. How frequently do you feel sexual desire? This feeling may include wanting to have sex, planning to have sex, feeling frustrated due to lack of sex, etc.				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
2. Do you climax (have an orgasm) when having sexual intercourse with your partner?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
3. Do you feel sexually excited (turned on) when having sexual activity with your partner?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
4. How satisfied are you with the variety of sexual activities in your sex life?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
5. Do you feel pain during sexual intercourse?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
6. Are you incontinent (leak urine) with sexual activity?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
7. Does fear of incontinence (either stool or urine) restrict your sexual activity?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
8. Do you avoid sexual intercourse because of bulging in the vagina (either bladder, rectum, or vagina falling out)?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
9. When you have sex with your partner, do you have negative emotional reactions such as fear, disgust, shame, or guilt?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
10. Does your partner have a problem with erections that affects your sexual activity?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
11. Does your partner have a problem with premature ejaculation that affects your sexual activity?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)
12. Compared to orgasms you have had in the past, how intense are the orgasms you have had in the past six months?				
Always (4)	Usually (3)	Sometimes (2)	Seldom (1)	Never (0)

Impact on QoL

was assessed using the Patient Assessment of Constipation
Quality of Life (PAC-QoL) questionnaire

	Not at all (0)	A little bit (1)	Moderately (2)	Quite a bit (3)	Extremely (4)
The following questions ask about your symptoms related to constipation. During the past 2 weeks, to what extent or intensity have you...					
1. felt bloated to the point of bursting?	☐	☐	☐	☐	☐
2. felt heavy because of your constipation?	☐	☐	☐	☐	☐
The next few questions ask about how constipation affects your daily life. During the past 2 weeks, how much of the time have you...					
3. felt any physical discomfort?	☐	☐	☐	☐	☐
4. felt the need to have a bowel movement but not been able to?	☐	☐	☐	☐	☐
5. been embarrassed to be with other people?	☐	☐	☐	☐	☐
6. been eating less and less because of not being able to have bowel movements?	☐	☐	☐	☐	☐
The next few questions ask about how constipation affects your daily life. During the past 2 weeks, to what extent or intensity have you...					
7. had to be careful about what you eat?	☐	☐	☐	☐	☐
8. had a decreased appetite?	☐	☐	☐	☐	☐
9. been worried about not being able to choose what you eat (for example, at a friend's house)?	☐	☐	☐	☐	☐
10. been embarrassed about staying in the bathroom for so long when you were away from home?	☐	☐	☐	☐	☐
11. been embarrassed about having to go to the bathroom so often when you were away from home?	☐	☐	☐	☐	☐
12. been worried about having to change your daily routine (for example, traveling, being away from home)?	☐	☐	☐	☐	☐
The next few questions ask about your feelings related to constipation. During the past 2 weeks, how much of the time have you...					
13. felt irritable because of your condition?	☐	☐	☐	☐	☐
14. been upset by your condition?	☐	☐	☐	☐	☐
15. felt obsessed by your condition?	☐	☐	☐	☐	☐
16. felt stressed by your condition?	☐	☐	☐	☐	☐
17. felt less self-confident because of your condition?	☐	☐	☐	☐	☐
18. felt in control of your situation?	☐	☐	☐	☐	☐
The next questions ask about your feelings related to constipation. During the past 2 weeks, to what extent or intensity have you...					
19. been worried about not knowing when you are going to be able to have a bowel movement?	☐	☐	☐	☐	☐
20. been worried about not being able to have a bowel movement?	☐	☐	☐	☐	☐
21. been more and more bothered by not being able to have a bowel movement?	☐	☐	☐	☐	☐
The next questions ask about your life with constipation. During the past 2 weeks, how much of the time have you...					
22. been worried that your condition will get worse?	☐	☐	☐	☐	☐
23. felt that your body was not working properly?	☐	☐	☐	☐	☐
24. had fewer bowel movements than you would like?	☐	☐	☐	☐	☐
The next questions ask about your degree of satisfaction related to constipation. During the past 2 weeks, to what extent or intensity have you been...					
25. satisfied with how often you have a bowel movement?	☐	☐	☐	☐	☐
26. satisfied with the regularity of your bowel movements?	☐	☐	☐	☐	☐
27. satisfied with the time it takes for food to pass through the intestines?	☐	☐	☐	☐	☐
28. satisfied with your treatment?	☐	☐	☐	☐	☐

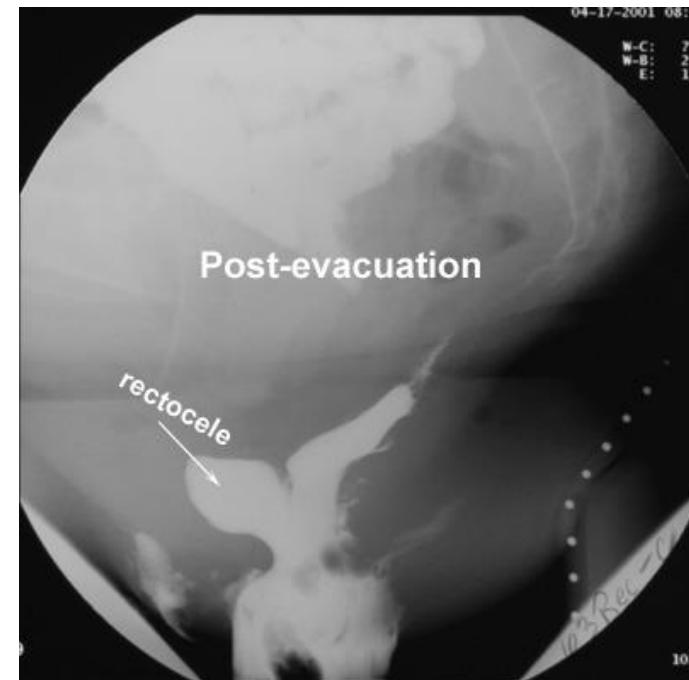
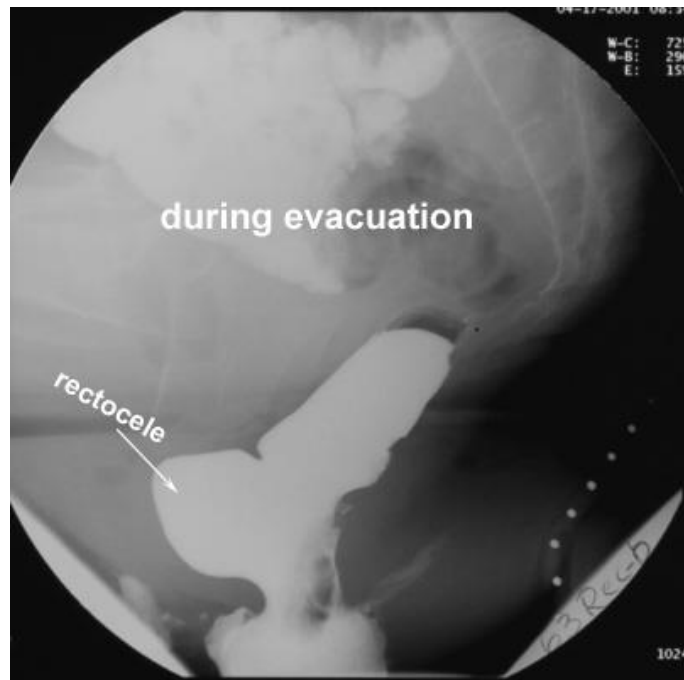
Preop. Assessment (Continued):

Physical Exam.

- to exclude patients with other causes of constipation
- to assess the perineum carefully for any abnormalities or scars of previous surgeries
- DRE was done to detect any stricture, spasm, tenderness, mass, or retained fecal matter.

Preop. Assessment (Continued):

Investigations



Fluoroscopic Defecography

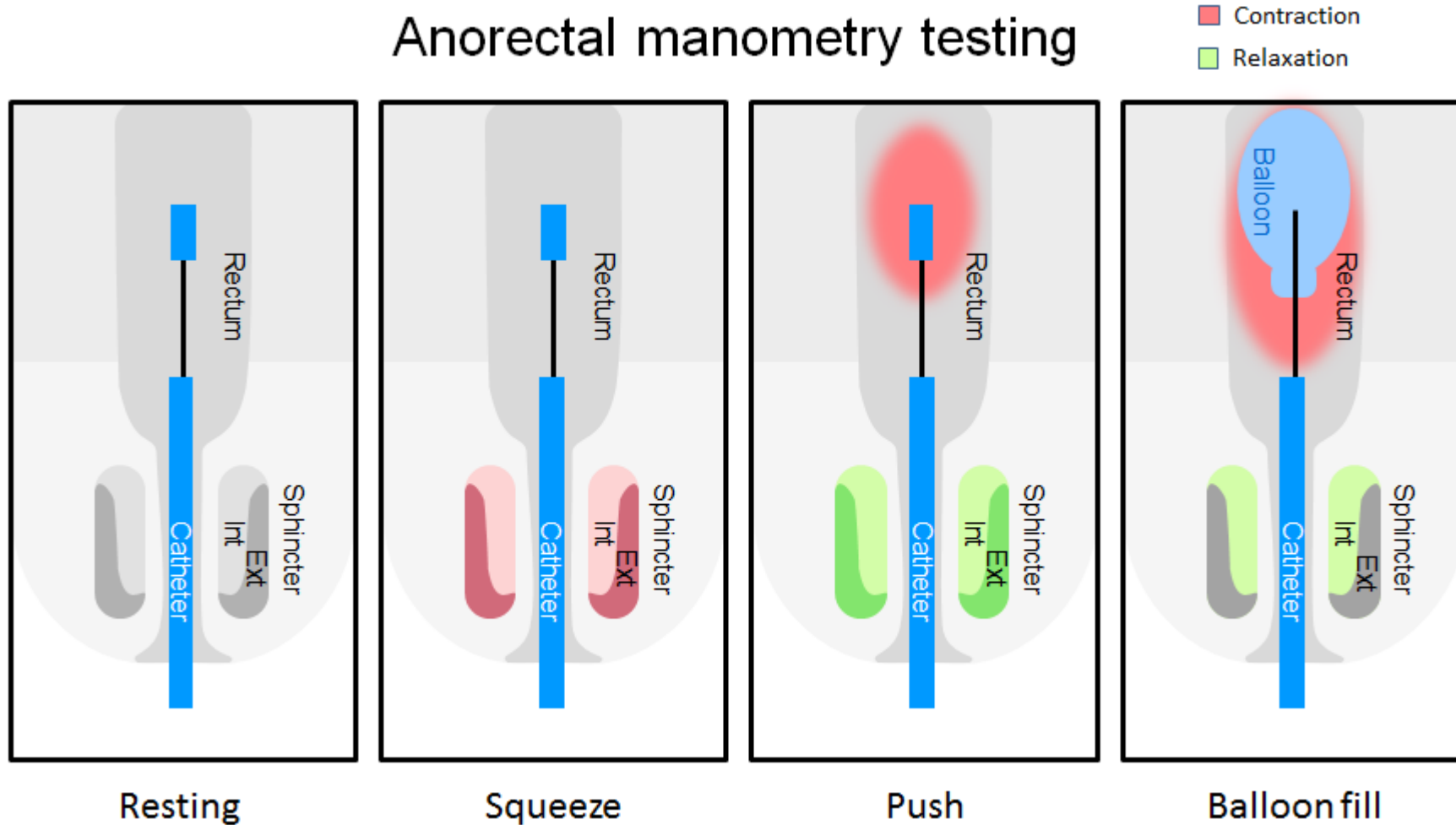
Preop. Assessment (Continued):



Colon-Transit Study

Preop. Assessment (Continued):

Anorectal manometry testing



Conventional Anorectal Manometry

Preop. preparation:

Preoperative medication

- Antibiotic as 3rd generation cephalosporins and metronidazole
- Thromboembolic prophylaxis with BMI > 40



Surgical Procedure:

Anesthesia

- All procedures were done under **Spinal** anesthesia in the lithotomy position



Surgical Procedure:

TVR (Posterior Colporrhaphy)

An intraoperative photograph showing a surgical repair of a rectovaginal fistula. The surgical field is illuminated, and the rectum and vagina are visible. A gloved hand is on the left, and another is on the right, both holding the tissue. The fistula is a small, reddish, oval opening between the rectum and vagina. The text "The size and the extent of the rectovaginal fistula before the repair." is overlaid on the image.

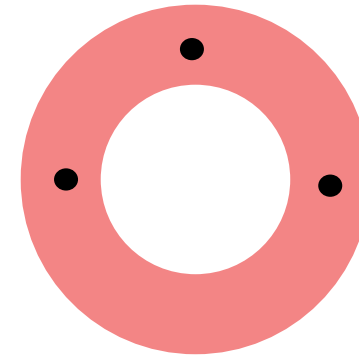
The size and the extent of the rectovaginal fistula before the repair.

BTX Injection:

In TVR+BTX group: vials containing 100 units of lyophilized type-A botulinum toxin were diluted in saline to 50 U/mL before the injections.



A total of 30 units of type-A botulinum toxin was injected with a 22-G needle evenly divided in 3 sites



In Control group: BTX was substituted with distilled water.

Postop. Care:

Setting

- Regular ward

Oral Feeding

- Same operative day

Medications

- Multimodal analgesia

Pain Assessment using VAS

- 12 hours after surgery (0-10)

Discharge

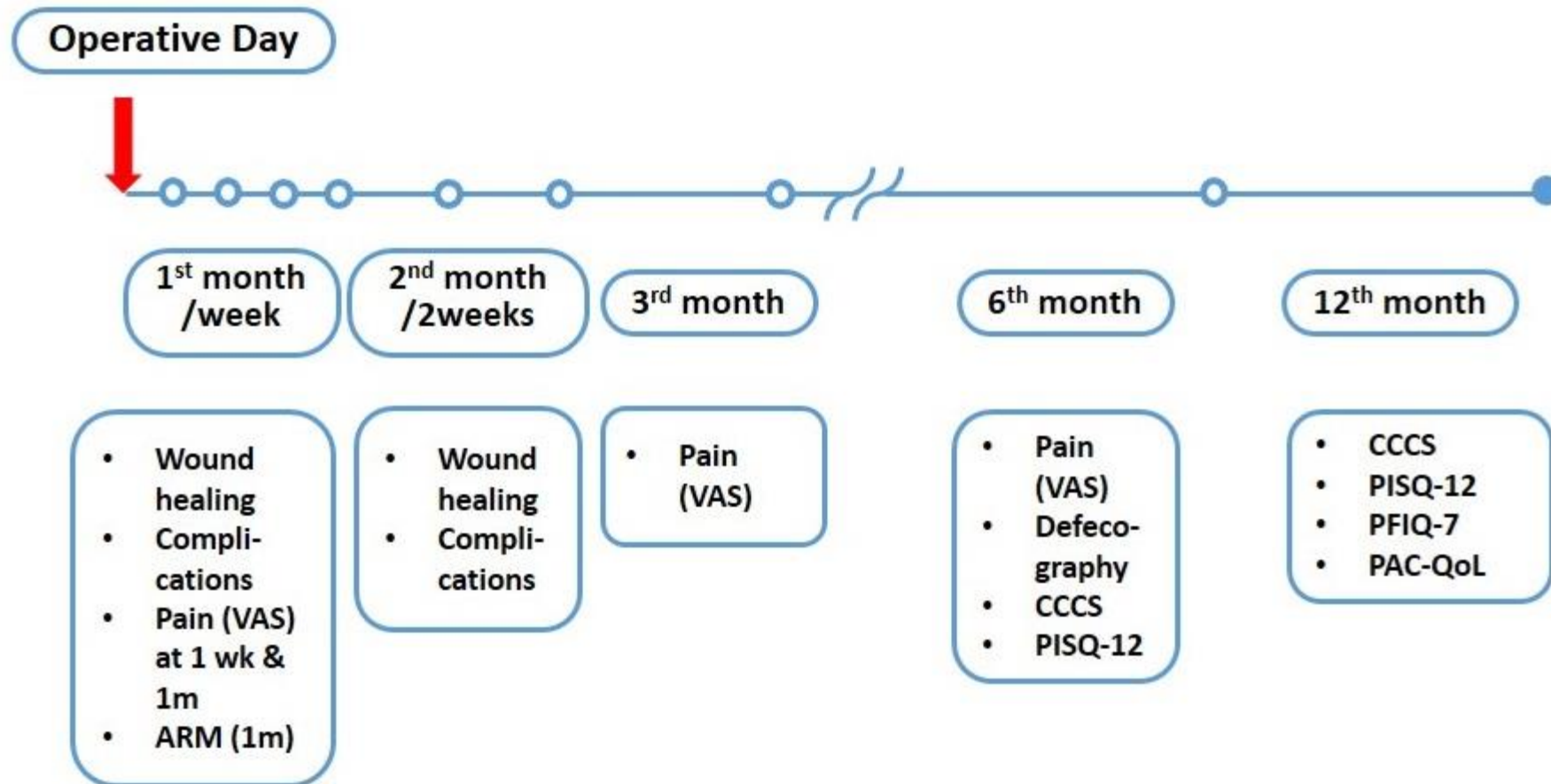
- 1st POD

Home Instructions:

Patients were advised to:

- **Increase fluid intake and dietary fibers**
- **Use laxatives for the first two weeks**
- **Avoid excessive straining**
- **Maintain local perineal hygiene.**

Follow-up schedule:



Primary Outcome Measure:



Incidence of Recurrence

Secondary Outcome Measures:

Defecatory Functions

- Improvement assessment using CCCS

Sexual Functions

- Improvement assessment using PISQ-12

POP Symptoms

- Improvement using PFIQ-7

QoL

- Improvement using PAC-QoL

Other

- Postoperative pain
- Changes in anatomic parameters (assessed with fluoroscopic defecography)
- Operative time
- Healing time
- Postoperative complications

RESULTS & DISCUSSION

Preop. Basic Data:

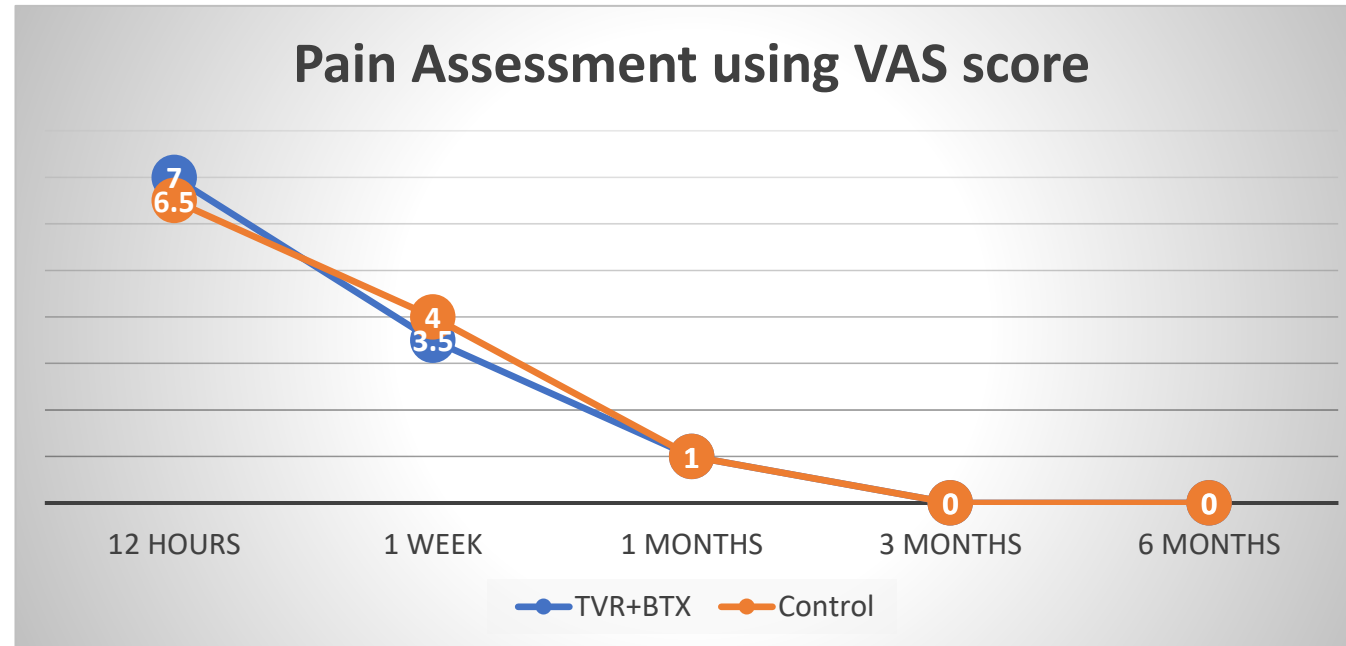
- There were **no significant differences** between the two groups regarding age, Parity, Defecatory and sexual functions, POP symptoms, QoL, anatomical assessment, and anorectal manometry results.
- This ensured a **minimal risk of selection bias**.

Outcome	TVR+BTX <i>n</i> =30	Control <i>n</i> =30	<i>P</i> value
Age in years, mean $\pm$ SD	43.4 $\pm$ 11.9	43.9 $\pm$ 11.3	0.87
Parity, median (range)	2 (1-4)	2 (1-4)	0.49
Preoperative CCCS, mean $\pm$ SD	14.9 $\pm$ 1.7	14.3 $\pm$ 1.6	0.16
Preoperative PFIQ-7, mean $\pm$ SD			
• UIQ	3.9 $\pm$ 1.9	3.9 $\pm$ 2.1	1
• POPIQ	25.1 $\pm$ 4.9	26.6 $\pm$ 5.2	0.25
• CRAIQ	58.9 $\pm$ 5.6	58.5 $\pm$ 6.3	0.8
• Overall	87.8 $\pm$ 7.7	89.1 $\pm$ 8.3	0.53
Preoperative PISQ-12, mean $\pm$ SD	26.2 $\pm$ 2.8	25.6 $\pm$ 2.2	0.36
Preoperative PAC-QoL, mean $\pm$ SD			
• Dissatisfaction Index (1-24)	65.7 $\pm$ 4	65.4 $\pm$ 5	0.8
• Satisfaction Index (25-28)	0.7 $\pm$ 0.8	0.6 $\pm$ 0.8	0.63
Preoperative Fluoroscopic Defecography			
• Rectocele Depth in cm, mean $\pm$ SD	5.1 $\pm$ 1.1	5.3 $\pm$ 1.3	0.52
• Barium Trapping, n (%)	27 (90)	27 (90)	1
Anorectal Manometry in mmHg, mean $\pm$ SD			
• MRP	64.9 $\pm$ 8.4	64.6 $\pm$ 8.6	0.9
• MSP	137.3 $\pm$ 20.7	136.4 $\pm$ 14.6	0.85

Recurrence Rate:

- TVR+BTX and control groups showed **comparable** results regarding recurrence rate (0% and 6.7%, $P=0.49$).
- The recurrence rate in the control group was similar to a previous study which reported a recurrence rate of 7%. **(Nieminen et al., 2004)**
- Recurrent cases were successfully managed using **BTX injection** (as in the TVR+BTX group) and **biofeedback therapy**.

Pain Assessment:



- VAS score showed that there were no significant differences between both groups.
- Among the entire cohort, the pain was severe on the same operative day, tended to be moderate by the end of the first postoperative week, and then the pain was mild by the end of the first postoperative month.

Postop. Manometry:

Outcome	TVR+BTX <i>n</i> =20	Control <i>n</i> =18	<i>P</i> value*
Preoperative MRP	65.2 ± 9.8	65.4 ± 7.6	0.94
Postoperative MRP	51.4 ± 8.7	66.8 ± 8.3	<0.0001
<i>P</i> value**	<0.0001	0.6	
Preoperative MSP	133.3 ± 18.8	137.4 ± 13.1	0.45
Postoperative MSP	128.4 ± 20.2	138.8 ± 14.1	0.08
<i>P</i> value**	0.43	0.8	

- There was a significant decline in postoperative **MRP at 1 month** in the **TVR+BTX group** with significant difference between both groups
- The results were comparable between preoperative and postoperative MSP at 1 month between both groups

Postop. Scores & Defecography:

There **were significant differences** between the two groups regarding defecatory and sexual functions, POP symptoms, QoL, and anatomical assessment in favor of TVR+BTX group.

Outcome	TVR+BTX <i>n</i> =30	Control <i>n</i> =30	<i>P</i> value
Postoperative CCCS, mean $\pm$ SD			
• 6 m	7.7 $\pm$ 1.9	10.3 $\pm$ 1	<0.0001
• 12 m	5.7 $\pm$ 2.5	9.6 $\pm$ 1.1	<0.0001
Postoperative PFIQ-7 at 12 m, mean $\pm$ SD			
• UIQ	1 $\pm$ 1.4	1.9 $\pm$ 1.7	0.03
• POPIQ	4.8 $\pm$ 3.4	11.2 $\pm$ 1.4	<0.0001
• CRAIQ	6.1 $\pm$ 3.6	8.2 $\pm$ 4.3	0.04
• Overall	11.8 $\pm$ 6.1	21.3 $\pm$ 5	<0.0001
Postoperative PISQ-12, mean $\pm$ SD			
• Score at 6 m	12.7 $\pm$ 2.6	14.1 $\pm$ 2.5	0.038
• Score at 12 m	11.7 $\pm$ 3.1	13.2 $\pm$ 1.9	0.028
Postoperative PAC-QoL at 12 m, mean $\pm$ SD			
• Dissatisfaction Index (1-24)	24.3 $\pm$ 6.1	44.1 $\pm$ 5.7	<0.0001
• Satisfaction Index (25-28)	10.4 $\pm$ 1.6	7.1 $\pm$ 0.9	<0.0001
Postoperative Fluoroscopic Defecography at 6m			
• Rectocele Depth in cm, mean $\pm$ SD	1.8 $\pm$ 0.6	2.2 $\pm$ 0.7	0.02
• Barium Trapping: n (%)	3 (10)	14 (46.7)	0.0034

Other Data:

Outcome	TVR+BTX <i>n</i> =30	Control <i>n</i> =30	<i>P</i> value
Operative time in min, mean ± SD	42.3 ± 8.6	46.8 ± 10.5	0.07
Healing Time in days, mean ± SD	16.8 ± 4.7	16.3 ± 4.2	0.67
Complications, <i>n</i> (%)			
• Bleeding	3 (10)	5 (16.7)	0.71
• SSI	2 (6.7)	4 (13.3)	0.67
• Wound dehiscence	6 (20)	13 (43.3)	0.09

- There were **no significant differences** between the two groups regarding operative time, healing time, and postoperative complications.

Limitations:

Include

Single-center study

Small sample size (Pilot)

Relatively short follow-up

Future studies may investigate the effect of timing, BTX injection sites, injection doses in the IAS, and/or injection in the EAS with puborectalis muscle.

CONCLUSION

Conclusion:

TVR with BTX injection in IAS was a successful procedure for treatment of anterior rectocele with improvement in symptoms, function, anatomic parameters, and QoL when compared to TVR alone.

Postoperative complication and recurrence rates were comparable in both groups

Thank You