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Impact of Transversus Abdominis Release (TAR) with Botulinum Toxin (BTX) Injection versus TAR without BTX Injection on Quality of Life and Postoperative Pain in Large Ventral Hernia Repair: A Comparative Study

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ABSTRACT

Background: Large ventral hernias pose significant challenges due to high recurrence rates and financial burdens. Transversus abdominis release (TAR) improves surgical outcomes by reducing abdominal wall tension.

Objectives: This study aimed to compare the outcomes of TAR with BTX injection versus without BTX injection in terms of their impact on quality of life and postoperative pain. **Methods:** We conducted a prospective cohort study of 97 patients undergoing TAR for large ventral hernia repair at Mansoura University Hospital (April 2019–June 2023). Patients were divided into TAR+BTX (n = 55) and TAR-only (n = 42) groups. Outcomes assessed over 12 months included quality of life (HerQLes), intra-abdominal pressure (IAP), postoperative pain (VAS) and recurrence rates. Statistical analysis identified predictors and threshold values for optimizing surgical results.

Results: The TAR+BTX group had significantly higher Sabbagh's indices (13.9% vs. 12.3%, P=0.004) and larger defects (14 cm vs. 12 cm, P<0.001). They also showed greater HerQLes score improvement (107% vs. 91.5%, P=0.006), lower postoperative IAP (5 mmHg vs. 6 mmHg, P<0.001), earlier mobilization (5 vs. 6 hours, P=0.002), and reduced patient-controlled analgesia (PCA) use (23.6% vs. 64.3%, P<0.001). Multivariate analysis identified defect width, preoperative HerQLes scores, and postoperative IAP as key predictors of quality-of-life outcomes. The cutoff analysis determined that defect widths of 13 cm, when used as a standalone criterion, was the optimal threshold for considering BTX injection, with Sabbagh's index playing a less significant role. **Conclusion:** BTX is a valuable adjunct to TAR resulted in improving quality of life, comparatively lowering IAP, and accelerating recovery in large ventral hernia repairs.

Keywords: Large ventral hernia, Intra-abdominal pressure, Quality of life, Defect width, Sabbagh's index, Pain management.

INTRODUCTION

Large ventral hernias represent a significant clinical challenge due to their high recurrence rates and associated economic burden. These hernias often result in complex surgical repairs, prolonged recovery, and a substantial impact on patients' quality of life. The recurrence rate of large ventral hernias remains a major concern, despite advances in surgical techniques, and has led to a growing need for more effective solutions [1, 2]. Various repair techniques for large ventral hernias have been proposed, including open, laparoscopic, and robotic approaches. Traditional methods, such as mesh implants, have proven effective in many cases, but they still carry recurrence risks and complications. In response to these challenges, the transversus abdominis release (TAR) technique, among other techniques, has emerged as an innovative solution, offering improved abdominal wall tension release and reduced recurrence rates in complex hernia repairs [3, 4].

In recent years, the adjunctive use of Botulinum Toxin (BTX) has gained attention for its potential to enhance the outcomes of hernia repair. Further, BTX has been shown to temporarily reduce muscle tone, thereby improving abdominal wall compliance and potentially decreasing postoperative pain and recurrence. This additive effect of BTX may offer significant advantages in improving the overall surgical outcome [5, 6].

This study aimed to compare the outcomes of TAR with BTX injection versus without BTX injection in terms of their impact on quality of life and postoperative pain. By evaluating these factors, we seek to better understand the role of BTX as an adjunctive therapy in enhancing the results of TAR for large ventral hernia repairs.

PATIENTS AND METHODS

Study design and setting: This prospective cohort study investigated patients with large ventral hernias who underwent abdominal wall reconstruction using the TAR technique, with or without adjunctive BTX injection, at the General Surgery Department of Mansoura University Hospital in collaboration with Mansoura Center for Colorectal Surgery, Egypt, between April 2019 and June 2023.

Eligibility criteria: Patients of both sexes, aged 18 years or older, who presented with uncomplicated large ventral hernia, (either primary or recurrent) and were eligible for open abdominal wall reconstruction using the TAR technique.

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Exclusion criteria: Patients with an American Society of Anesthesiologists classification greater than class II, those with severely compromised pulmonary functions, and individuals with impaired wound healing attributed to uncontrolled diabetes, connective tissue disorders, or long-term steroid or chemotherapy use. Pregnant women or those planning for pregnancy within 12 months post-procedure, patients with immunodeficiency, individuals with psychiatric disorders precluding surgical intervention and those who declined to participate in the study.

Preoperative assessment: Patients underwent a thorough history-taking and clinical examination. The history focused on symptoms such as pain or discomfort during physical activity or when increasing intra-abdominal pressure (IAP), as well as the progression of the hernia. Important factors included comorbidities, prior abdominal surgeries or hernia repairs, and risk factors such as obesity, smoking, chronic lung disease, connective tissue disorders and symptoms that could suggest a complicated hernia requiring urgent intervention. The clinical examination included the assessment of hernia's size, location and reducibility while focusing on potential complications such as tenderness, strangulation or bowel obstruction. The examination also included evaluation for signs of previous abdominal surgeries, defect width, prior incisions or stomas and any presence of draining sinuses, exposed mesh, or skin issues such as thinning, ulceration, or cellulitis. Additionally, reviewing old operative reports is crucial to identify previously attempted repairs, the type of mesh used (if any) and the plane in which it was placed. Preoperative impact on quality of life was conducted using the Hernia-related Quality of Life Survey (HerQLes) questionnaire. This tool consists of 12 items, each scored using a Likert scale from 1 to 6, where 1 indicates a minimal impact on quality of life and 6 indicates the maximum impact. The total score is calculated as **Score = 120 - (mean score × 20)** [7, 8].

Pulmonary function tests (PFTs) were routinely performed in patients with a history of chronic pulmonary disease, respiratory symptoms or suspected reduced lung capacity based on clinical or radiological evaluation. Patients with a severe reduction in forced vital capacity (FVC) or total lung capacity (TLC) (< 50% of predicted values) were excluded from the study. Those with mild to moderate reductions (50–80% of predicted values) were considered amenable to preoperative optimization.

Routine laboratory investigations included complete blood count, liver and kidney function tests, prothrombin time and fasting blood glucose. Non-contrast CT scans were routinely performed alongside ultrasound assessments to evaluate the hernia's defect width, location and the condition of the surrounding abdominal musculature. The defect width was measured as the transverse diameter. For multiple adjacent defects, the overall width was determined by summing their diameters, taking into account the presence or absence of a tissue bridge. In cases of stacked defects, only the largest defect was considered. For Swiss cheese-type defects, the overall width was represented by the diameter of an imaginary circle encompassing all defects. A large ventral hernia was defined as a defect width of ≥10 cm on CT, with an additional assessment of loss of domain using Sabbagh's index. This index calculates the ratio of the hernia sac volume to the total volume of the abdominal cavity plus the hernia sac. Loss of domain was diagnosed when Sabbagh's index was ≥ 20% [9, 10]. Patients with ascites or intra-abdominal masses were excluded from the study.

Botulinum toxin injection: Since TAR is generally indicated for hernia defect widths >10 cm [11], and BTX injection is commonly used for defects >10 cm as well [12], we established a criterion in this study to utilize BTX as an adjunct to TAR specifically for defect sizes >12 cm. Other criteria included a Sabbagh's index ≥ 20%, or mild to moderate reduction in PFTs. A modified technique, based on the previous work of **Whitehead-Clarke and Windsor** [13], was adopted for this study. These modifications involved administering 200 units of Botulinum Neurotoxin Type-A (Botox®, Allergan, Irvine, CA, USA) per patient (100 units per side) diluted in 24 ml of 0.9% saline (8.3 units/ml), for ultrasound-guided injections into the lateral abdominal wall, administered about four weeks before the surgery at the outpatient clinic. The total 24 ml solution was divided into eight equal doses, with each dose containing approximately 3 ml. Injection sites were marked by dividing the lateral abdominal muscles on each side into four quadrants, with the medial limit set 5 cm from the hernia defect margin. After administering local anesthesia with 1% lignocaine, a 25-gauge spinal needle was used to inject 3 ml of the diluted BTX into the muscle bellies of the transversus abdominis, internal oblique and external oblique muscles at each of the four marked sites. This procedure was repeated on the opposite side. Patients were monitored for 30 minutes before being allowed to resume normal activities until the time of surgery. All BTX injections were performed by a senior consultant in anesthesia, intensive care, and pain management (EME) with more than 20 years of experience in the field. The use of BTX in this context represents an off-label application that is not currently approved by the US Food and Drug Administration (FDA), however its use is supported by clinical practice and evidence in the literature.

Operative setting: Prophylactic antibiotics were provided to all patients. All procedures were performed with the patient in the supine position under general anesthesia. Preoperative IAP was estimated using modified Kron's method to measure the bladder pressure, which involves the insertion of an indwelling urinary catheter into the bladder through the urethra, followed by the injection of 20 ml of 0.9% saline. A pressure transducer was then used to monitor the pressure within the bladder. To minimize the influence of respiratory cycles on the measurement, pressure readings were taken at the end of a respiratory cycle [14].

Surgical technique: We adopted the technique described by **Novitsky *et al.*** [4]. Various skin incisions were utilized, including scarectomy, elliptical, midline, or abdominal crease incisions, followed by excision of redundant skin. The abdominal cavity was accessed via the linea alba to avoid bowel injury. Adhesions were lysed to enable complete hernia content reduction and optimize abdominal wall mobility. Careful dissection prevented injury to the peritoneum and transversalis fascia. Any foreign material, including old mesh or sutures, was removed. An incision was made in the posterior rectus sheath, 0.5-1 cm lateral to its medial border using electrocautery. This dissection extended along the rectus muscle length **(Figure 1)**. Medial-to-lateral dissection preserved epigastric vessels and continued into the retroxyphoid, retrosternal, and Retzius spaces. TAR was achieved by incising the posterior sheath 0.5-1 cm medial to the linea semilunaris, exposing and dividing the transversus abdominis muscle, while preserving the transversalis fascia. The avascular retromuscular plane was developed to the diaphragm, myopectineal orifice and psoas muscle **(Figure 2)**. The posterior rectus sheath was re-approximated using running 2-0 polyglycolic acid sutures. Any defects were closed to prevent bowel contact with the mesh, aided by native tissue such as omentum or appendices epiploicae if needed **(Figure 3)**. Hemostasis was ensured before mesh placement.

A 30 x 30 cm^2 light-weight macroporous mesh (Bard® Soft Mesh, Bard Medical, Covington, GA, USA) was shaped into a diamond configuration and anchored superiorly and inferiorly using two transfascial stitches of slow-absorbing 0 monofilament polydioxanone suture as shown in figure (4a). Once the mesh was secured, the linea alba was re-created by suturing the anterior rectus sheaths together using running stitches of 0 PDS loop as shown in figure (4b). No suction drains were placed over the mesh, though drains were inserted into the subcutaneous space if needed. The skin and subcutaneous tissues were then closed.

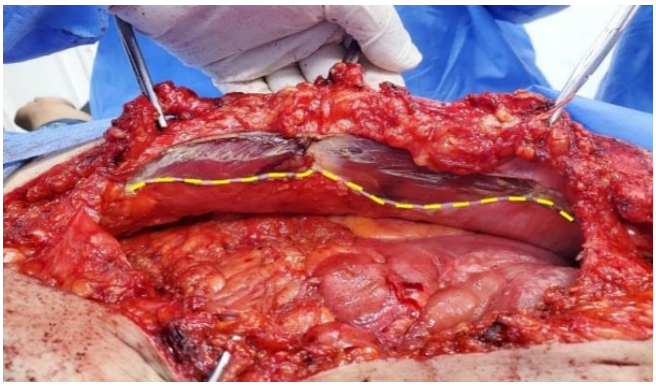

Figure (1): Incision of posterior rectus sheath 0.5-1 cm away from the linea alba

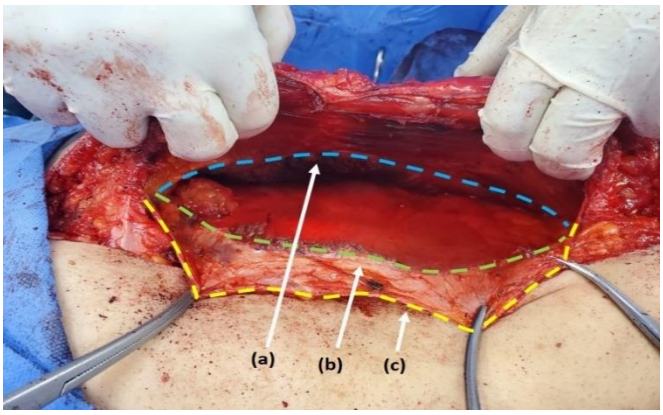

Figure (2): Transversus abdominis release; **a)** released belly of transversus abdominis muscle, **b)** released attachment of transversus abdominis muscle at linea semilunaris, and **c)** incised posterior rectus sheath near the linea alba.

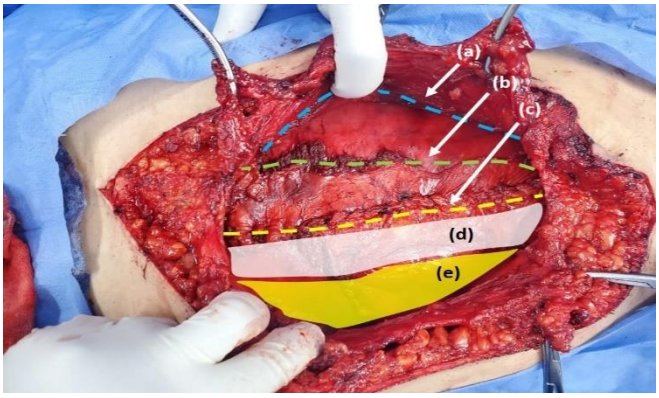

Figure (3): Closure of posterior rectus sheath;
a) released belly of transversus abdominis muscle,
b) released attachment of transversus abdominis muscle at linea semilunaris, **c)** closed posterior rectus sheath at the midline, **d)** posterior rectus sheath with only fascia transversalis below the linea semicircularis, and **e)** fascia transversalis/parietal peritoneum.

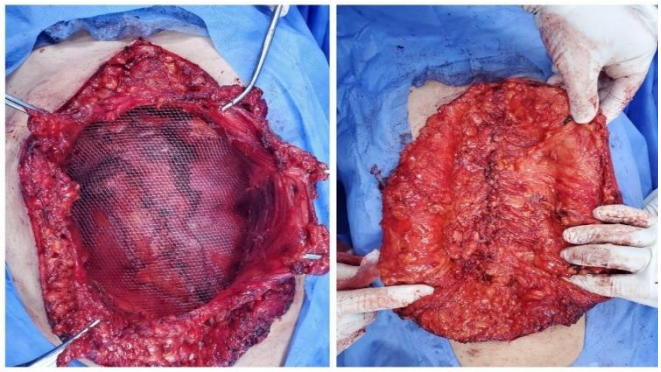

Figure (4): a) Large prosthesis 30 x 30 cm^2 applied diagonally, occupying the entire dissected transversus abdominis and retrorectus planes and **b)** closure of both recti muscles and anterior rectus sheath to recreate linea alba at the midline.

The surgical procedures were performed by a team led by the primary surgeon (M.A.) with over 20 years of experience, supported by one or more surgeons (M.B., M.A., M.F.) each having between 9 and 14 years of experience in the field.

Postoperative care: Postoperative IAP was measured at the conclusion of the procedure, before the patient recovered from anesthesia, using the modified Kron's method previously described. Patients were managed in a standard ward setting and allowed to resume oral intake on the same operative day. Postoperative antibiotic prophylaxis was maintained for 24 hours.

The pain was assessed 12 hours postoperatively using the Visual Analogue Scale (VAS). Pain management was tailored to the patient's needs, utilizing either a combination of non-steroidal anti-inflammatory drugs (NSAIDs) with acetaminophen or patient-controlled analgesia (PCA). The time to the first mobilization was recorded to assess recovery. Patients were routinely discharged after 24 hours unless additional monitoring or intervention was required.

Follow-up and outcomes: Patients were routinely followed up in the outpatient clinic at 1, 2, and 4 weeks postoperatively, then monthly during the second and third months, and finally at 6 and 12 months postoperatively. During these visits, patients were examined for complications, including surgical site occurrence and surgical site infection. Pain was reassessed using the VAS at 1, 2, and 4 weeks. Quality of life was reevaluated using the HerQLes questionnaire at 12 months postoperatively. Recurrence was defined as the reappearance of symptoms or a bulge at or near the site of the hernia, identified 6 months after the repair. Timeframes shorter than 6 months were considered more indicative of a failure of the repair rather than a recurrence. **The primary outcome** of the study was the percent change in the HerQLes score at 12 months postoperatively. **Secondary outcomes** included postoperative IAP, pain VAS score, operative time, hospital stay, follow-up duration, incidence of respiratory complications and recurrence rate.

Sample size calculation: Based on previous experience with a small series of patients undergoing the TAR procedure, it is estimated that the percent change in the HerQLes score after TAR is approximately 90%. The adjunct application of BTX is estimated to contribute an additional 15%, with a pooled standard deviation (SD) of 27.3. Using these data, the calculated effect size was 0.55, with an alpha error of 0.05 and a beta error of 0.8. G*Power software, version 3.1.9.4 (Heinrich Heine University, Düsseldorf, Germany) calculations indicated that the estimated sample size required for the study was 84 patients. To account for potential patient loss to follow-up, an additional 10% was added, resulting in a final sample size of 95 patients.

Ethical approval: The study protocol was approved by the Institutional Review Board (IRB) of Mansoura University (R/19.03.451) and registered at ClinicalTrials.gov (NCT04419844). Written informed consent was obtained from each participant to participate and for publication after they were fully informed about the study's objectives and potential risks. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Statistical analysis

The statistical analysis of the data was performed using SPSS™ software, version 23 (IBM Corp., Chicago, IL). Unpaired parametric continuous data (mean ± SD) were analyzed using an independent sample t-test to compare differences between groups. Independent non-parametric continuous data (median and range) were analyzed using the Mann-Whitney U test. Paired non-parametric continuous data (median and range) were evaluated using the Wilcoxon signed-rank test. Categorical data were analyzed using the Chi-square test. The correlation between variables was assessed using Spearman's Rank, Kendall's tau, the Point-Biserial, or Chi-square tests, depending on the nature of the data. Multivariate analysis was conducted using linear regression, while the Receiver Operating Characteristic (ROC) curve analysis was used to determine cut-off values for diagnostic purposes. A p-value of ≤ 0.05 was considered statistically significant for all tests.

RESULTS

This prospective cohort study evaluated outcomes in patients with large ventral hernias undergoing TAR, comparing those who received adjunctive BTX injections (TAR+BTX group) with those undergoing TAR alone (TAR-only group) from April 2019 to June 2023. Of the

209 initially identified patients, 97 were analyzed (55 in TAR+BTX, 42 in TAR-only). Screening, eligibility, exclusions, and data completeness are summarized in the flow diagram as shown in figure (5).

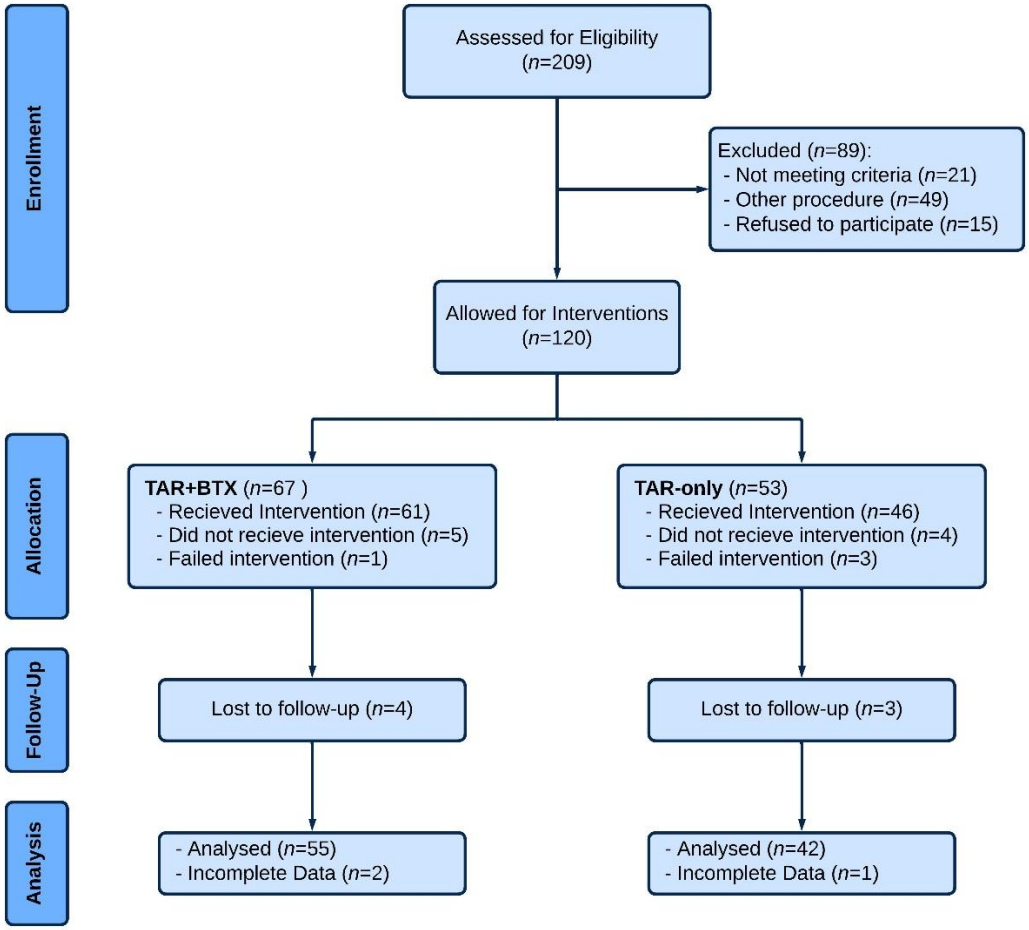

Figure (5): Flow diagram illustrating study progression

The mean age of the entire cohort was 53.4 ± 9.9 years (range 34-78), with female preponderance (78.4%). Nearly half of the cohort had comorbidities (47.4%), including type 2 diabetes mellitus, hypertension, chronic kidney disease, and chronic obstructive pulmonary disease (COPD), all were optimized before surgery. Baseline characteristics were comparable between groups with no significant differences in age, sex, or comorbidities as shown in table (1).

Table (1): Demographics and preoperative information

Variable	TAR+BTX (*n*=55)	TAR-only (*n*=42)	P value
Age in years, mean ± SD	54.8 ± 10.1	51.7 ± 9.4	P=0.123
Sex (*n*, %) • **Male** • **Female**	 12 (21.8) 43 (78.2)	 9 (21.4) 33 (78.6)	P=0.963
Comorbidities (*n*, %)	27 (49.1)	19 (45.2)	P=0.707

TAR: transversus abdominis release, **BTX:** botulinum toxin, **SD:** standard deviation, ***n*:** number. Independent parametric continuous data (mean ± SD) were tested using Independent Samples'-test and categorical data (proportion & percentage) were tested using Chi-Square test. P-value <0.05 is considered statistically significant.

Regarding hernia characteristics, the TAR+BTX group had a significantly higher prevalence of loss of domain (21.8% vs. 0%, P=0.001), a greater median Sabbagh's index (13.9% vs. 12.3%, P=0.004), and larger defect widths (median 14 cm vs. 12 cm, P<0.001). No significant differences were observed between the groups in hernia presentation, preoperative IAP, or preoperative HerQLes scores as shown in table (2).

Table (2): Hernia characteristics

Variable	TAR+BTX (*n*=55)	TAR-only (*n*=42)	P value
Hernia presentation (*n*, %) • **Primary** • **Recurrent**	 41 (74.5) 14 (25.5)	 36 (85.7) 6 (14.3)	P=0.178
Loss of domain (*n*, %)	12 (21.8)	0 (0)	P=0.001
Sabbagh's Index, median (range)	13.9 (7-27.9)	12.3 (6.9-16.2)	P=0.004
Defect width in cm, median (range)	14 (10.5-18)	12 (10-12)	P<0.001
Preoperative IAP in mmHg, median (range)	5 (3-6)	4 (3-5)	P=0.581
Preop. HerQLes score, median (range)	43.3 (28.3-56.7)	43.3 (31.7-53.3)	P=0.677

TAR: transversus abdominis release, **BTX:** botulinum toxin, ***n*:** number, **IAP:** intra-abdominal pressure, **HerQLes:** hernia-related quality of life survey. Independent non-parametric continuous data (median & range) were tested using Mann-Whitney U test and categorical data (proportion & percentage) were tested using Chi-Square test. P-value <0.05 is considered statistically significant.

The correlations between preoperative IAP and defect width (ρ=0.165) and Sabbagh's index (ρ=0.166) were weak. Similarly, the correlations between the preoperative HerQLes score and defect width (ρ=0.106) and Sabbagh's index (ρ=-0.139) were weak. The decision of adjunctive BTX injection in the TAR+BTX group was primarily based on defect width >12 cm in 74.5% of cases, one case (1.8%) due to Sabbagh's index ≥ 20%, 18.2% meeting both criteria, and 5.5% due to COPD. Two cases experienced exertional dyspnea following BTX injection, and one case developed a skin allergy, all were effectively managed with conservative measures. The median operative time was significantly longer in the TAR+BTX group compared to the TAR-only group (140 minutes vs. 120 minutes, P<0.001) as shown in table (3). Predictors of prolonged operative time were identified as sabbagh's index (P=0.036) and recurrent cases (P=0.005). On the other hand, defect width, BTX injection, and preoperative IAP did not show statistically significant associations.

The TAR+BTX group showed consistently lower pain scores at all-time points in comparison to the TAR-only group. Generally, the TAR+BTX group demonstrated a more rapid and sustained reduction in pain, with tighter interquartile ranges, indicating less variability in pain experience. Meanwhile, the TAR-only group experiences a slower reduction in pain with greater variability over time as shown in figure (6). Analgesic requirements showed that 23.6% of the TAR+BTX group used PCA, while 64.3% of the TAR-only group required it (P<0.001). The TAR+BTX group had a faster median time to first mobilization (5 hours vs. 6 hours, P<0.001), as shown in table (3).

Table (3): Operative and postoperative information

Variable	TAR+BTX (*n*=55)	TAR-only (*n*=42)	P value
Operative time in min., median (range)	140 (100-200)	120 (100-200)	P<0.001
Analgesic requirement (*n*, %) • **PCA** • **NSAIDs + Paracetamol**	 13 (23.6) 42 (76.4)	 27 (64.3) 15 (35.7)	P<0.001
Time to 1st mobilization in hours, median (range)	5 (3-9)	6 (4-12)	P=0.002

TAR: transversus abdominis release, **BTX:** botulinum toxin, ***n*:** number, **PCA:** patient-controlled anesthesia, **NSAIDs:** non-steroidal anti-inflammatory drugs. Independent non-parametric continuous data (median & range) were tested using Mann-Whitney U test and categorical data (proportion & percentage) were tested using Chi-Square test. P-value <0.05 is considered statistically significant.

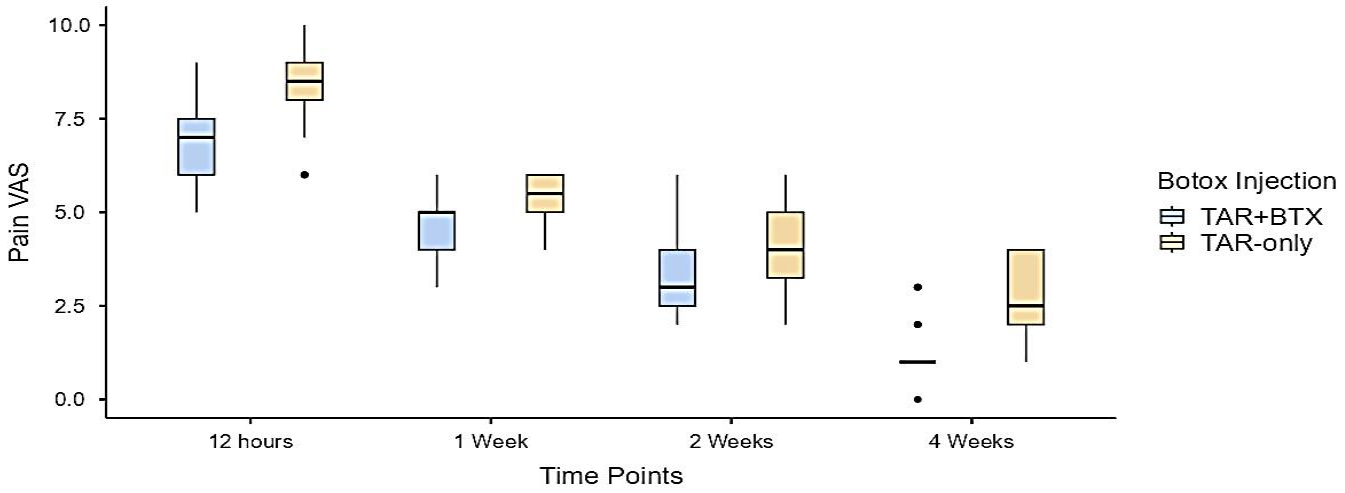

Figure (6): Postoperative pain assessment using Visual Analogue Scale (VAS); **a)** TAR+BTX group and **b)** TAR-only group

There was a noticeable moderate to strong inverse relationship between BTX injection and postoperative pain scores at various time points (τ ranging from -0.249 to -0.692). A moderate inverse correlation was also seen between BTX injection and postoperative IAP (r_{pb} =-0.519). In addition, a moderate inverse correlation (χ^2 = 16.2, Phi coefficient=0.41) was found between BTX injection and postoperative PCA use. Both groups demonstrated a statistically significant but mild increase in IAP that was not sufficient to result in any clinical consequences (P<0.001). Additionally, both groups showed a significant improvement in HerQLes scores at postoperative 12 months (P<0.001). The TAR+BTX group demonstrated significantly lower postoperative IAP compared to the TAR-only group (5 mmHg vs. 6 mmHg, P<0.001). Postoperative HerQLes scores were significantly higher in the TAR+BTX group (median 90 vs. 82.5, P<0.001), with a greater percentage change in HerQLes score (median 107% vs. 91.5%, P=0.006). The TAR+BTX group showed a significantly higher percentage of patients with adequate improvement compared to the TAR-only group (78.2% vs. 47.6%, P=0.002). The cutoff for adequate improvement was determined by ROC curve analysis to be >91.7% as shown in figure (7). Hospital stay and follow-up durations were comparable between both groups. Recurrence rates and respiratory complications were lower in the TAR+BTX group compared to the TAR-only group (P=0.073 and P=0.044, respectively) as shown in table (4).

Table (4): Postoperative outcomes

Variable	TAR+BTX (*n*=55)	TAR-only (*n*=42)	P value
Postoperative IAP in mmHg, median (range)	5 (3-6)	6 (5-7)	P<0.001
Postoperative HerQLes score, median (range)	90 (81.7-95)	82.5 (65-93.3)	P<0.001
Percentage change of HerQLes score, median (range)	107 (59.4-218)	91.5 (46.4-136)	P=0.006
Improvement (*n*, %) • **Adequate** • **Inadequate**	 43 (78.2) 12 (21.8)	 20 (47.6) 22 (52.4)	P=0.002
Hospital stay in hours, median (range)	24 (12-48)	24 (12-96)	P=0.958
Follow-up in months, median (range)	36 (18-60)	36 (12-48)	P=0.343
Recurrence (*n*, %)	1 (1.8)	4 (9.5)	P=0.089
Respiratory complications (*n*, %)	0 (0)	3 (7.1)	P=0.044

TAR: transversus abdominis release, **BTX:** botulinum toxin, ***n*:** number, **IAP:** intra-abdominal pressure, **HerQLes:** hernia-related quality of life survey. Independent non-parametric continuous data (median & range) were tested using Mann-Whitney U test and categorical data (proportion & percentage) were tested using Chi-Square test. P-value <0.05 is considered statistically significant.

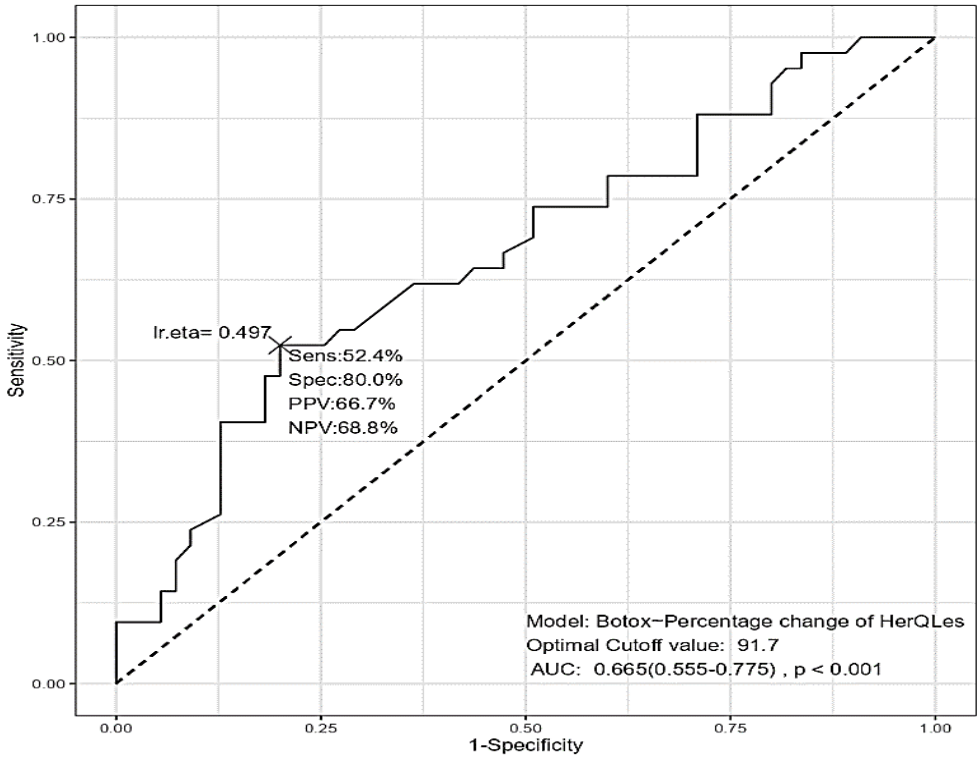

Figure (7): Receiver Operating Characteristic (ROC) curve determining the cutoff value for adequate improvement based percent change in HerQLes score.

In the TAR + BTX group, there were 5 cases of seroma, 2 cases of hematoma, and 2 cases of wound infection. In the TAR-only group, there were 4 cases of seroma, 1 case of wound ischemia, and 3 cases of wound infection. There were no significant differences between the two groups regarding SSO (12.7% vs 11.9%, P = 1) or SSI (3.6% vs 7.1%, P = 0.649). All SSO cases were managed conservatively, except for the wound ischemia, which required debridement and primary closure under anesthesia. All surgical site infection (SSI) cases were treated with systemic antibiotics, guided by culture and sensitivity testing.

Multivariate analysis: None of the predictors, including BTX injection, Sabbagh's index, defect width, operative time, early postoperative pain score, or postoperative IAP, were significant for respiratory complications. Hernia presentation (recurrent vs. primary) was the only significant predictor of recurrence (P=0.026), while factors such as BTX injection, age, sex, comorbidities, defect width, Sabbagh's index, or postoperative respiratory complications showed no significant association with recurrence.

Defect width, preoperative HerQLes score and postoperative IAP were identified as significant predictors of postoperative HerQLes scores (P=0.001, P=0.013 and P=0.012 respectively), while age, sex, hernia presentation, Sabbagh's index, and preoperative IAP were not significant. For postoperative IAP, significant predictors were BTX injection and preoperative IAP (P<0.001 for both), while age, sex, hernia presentation, Sabbagh's index, defect width, and preoperative HerQLes score were not significant.

Determination of cutoff values: The cutoff value for defect width alone to achieve adequate improvement in HerQLes scores was determined to be 13 cm (AUC=0.661, sensitivity=75.8%, specificity=62.5%, PPV=51%, and NPV=83.3%). For Sabbagh's index, the cutoff was 10.8% (AUC=0.553, sensitivity=45.5%, specificity=71%, PPV=45.5%, and NPV=71.9%.

DISCUSSION

This prospective cohort study aimed to evaluate the effects of adjunctive BTX injection in patients undergoing abdominal wall reconstruction using the TAR technique. The study specifically compared postoperative outcomes, such as pain reduction, IAP, quality of life, and recurrence rates, between two groups: those receiving adjunctive BTX (TAR+BTX) and those undergoing TAR alone (TAR-only). By focusing on these critical outcomes, the study sought to assess whether BTX could enhance recovery and improve clinical results in large ventral hernia repairs. Objective measures, such as IAP and CT imaging, provided a solid foundation for assessing BTX's impact on abdominal wall function. Additionally, subjective outcomes, including pain scores and HerQLes quality of life assessments, allowed for a

more comprehensive understanding of the patient experience.

The TAR technique provided superior access to the posterior components of the abdominal wall, facilitating effective reconstruction with reduced tension, an essential factor in lowering the risk of recurrence [15]. This approach enabled a durable repair, enhancing long-term outcomes and strengthening the abdominal wall [16]. Moreover, TAR restored the natural anatomy of the abdominal wall, leading to improved core stability, reduced chronic pain, enhanced mobility and better postoperative function [11, 17]. As a result, patients often experience faster recovery and a significantly improved quality of life [16].

The TAR technique can be performed using a less invasive open approach, minimizing tissue trauma by avoiding the creation of large skin flaps commonly associated with traditional methods. This refined approach results in reduced postoperative pain and quicker recovery times [18]. Additionally, TAR is versatile and can be adapted for laparoscopic or robotic-assisted surgery, further minimizing complications, reducing postoperative discomfort, and shortening hospital stays. These advancements contribute to a more efficient recovery process and improved patient outcomes [19, 20].

Incorporating BTX into the TAR procedure is driven by its potential to enhance recovery and improve outcomes, particularly in complex abdominal wall reconstructions [5]. BTX's muscle-relaxing properties effectively alleviate muscle spasms, a significant source of postoperative pain. This reduction in pain is critical for decreasing opioid reliance, facilitating early mobilization, and improving patient satisfaction [13]. Furthermore, BTX has been shown in animal studies to reduce muscle tension and IAP, effects that may lead to faster recovery and fewer complications in humans [21]. By decreasing mechanical tension on the reconstructed abdominal wall, BTX injections may aid in restoring normal function and provide a stable, functional repair, thereby reducing the likelihood of hernia recurrence [22].

Clearly defining the criteria for BTX injection ensures a consistent and objective decision-making process, which is essential for minimizing bias and enhancing the reliability of the study results. Previous studies have employed various defect width ranges, often alongside a consistent criterion for loss of domain (≥20%), as a defining factor for BTX injection [13]. In this study, we utilized predefined criteria such as a hernia defect width >12 cm, a Sabbagh's index (indicating loss of domain) ≥ 20%, or mild to moderate reductions in pulmonary function. These criteria help eliminate subjective judgment in selecting patients for BTX injections, ensuring a more standardized approach to patient selection.

In this study, the mean age (53.4 ± 9.9 years) was slightly lower than the 57 years that was reported by **Wegdam *et al*.** [23] but near the mean age (55 ± 13.4 years) that was reported by **Chaves *et al*.** [11] Additionally, our cohort had a marked female predominance, with 78.4% of patients being female, compared to a male predominance of 64% in the **Chaves *et al*.** [11] cohort. Furthermore, our study had a higher prevalence of comorbidities, including type 2 diabetes, hypertension, chronic kidney disease, and COPD (47.4%), compared to **Wegdam *et al*.** [23] who reported lower rates of diabetes (21%) and COPD (12%), and **Chaves *et al*.** [11] where 36.1% had hypertension and a smaller proportion had diabetes**.**

In terms of hernia characteristics, our study reported a pooled mean defect width of 13.3 ± 2 cm, which is slightly larger than the 10.8 cm reported by **Punjani *et al***. [24] but nearly half the width reported by **Montelione *et al*.** [25]and **Alkhatib *et al*.** [7] who documented mean defect widths of 25 cm and 26 cm respectively. Additionally, the prevalence of loss of domain in our study was approximately 12.4%, which was lower compared to 19% in **Punjani *et al***. [24]. Regarding baseline quality of life, as assessed by the HerQLes questionnaire, our study reported a pooled median score of 43.3, nearly double that reported by **Montelione *et al*.** [25] (21.7) and **Alkhatib *et al*.** [7]. The higher preoperative HerQLes scores observed in our cohort could be attributed to the substantially smaller defect widths, despite the weak correlation between defect width and preoperative HerQLes scores (ρ=0.106).

Approximately 93% of the TAR+BTX group received BTX based on the primary criterion of defect width > 12 cm. This high prevalence is supported by the ROC curve analysis, which demonstrated that defect width has moderate discriminatory ability as a predictor of BTX need. In contrast, around 19% of the group received BTX based on a Sabbagh's index ≥ 20%. This lower prevalence aligns with the ROC curve analysis, which showed that Sabbagh's index has weak discriminatory ability as a predictor.

The significantly lower postoperative IAP in the TAR+BTX group (5 mmHg vs. 6 mmHg, P<0.001) highlighted the possible role of adjunctive BTX in improving abdominal wall compliance and reducing tension. This finding is consistent with the results of the multivariate analysis, which identified both BTX injection (beta coefficient=1.44) followed by preoperative IAP (beta coefficient=0.39) as predictors of decreased postoperative IAP. While lower IAP may contribute to improved outcomes as identified as a predictor of improvement of postoperative HerQLes score (P = 0.012). The clinical significance of the observed difference between the two groups remains small despite the statistical significance. Further research is needed to determine its true impact on postoperative outcomes. Postoperative HerQLes median score of 82.5 (65-93.3) in the TAR-only group was slightly higher than 73.3 (41.7–

86.7) reported by **Montlione *et al*.** [25]. The significantly higher postoperative HerQLes score in the TAR+BTX group (median 90 vs. 82.5, P<0.001) along with a greater percentage change in HerQLes score of up to 107%, could be attributed to the improved postoperative IAP. In the multivariate analysis, postoperative IAP was identified as the second most significant predictor for postoperative HerQLes scores (beta coefficient=-0.27), following defect width (beta coefficient=0.41), and preceding preoperative HerQLes score (beta coefficient=0.2).

The results indicated that the TAR+BTX group consistently experienced lower pain scores at all-time points compared to the TAR-only group, with a more rapid and sustained reduction in pain. This suggests that the addition of BTX significantly improves pain management following the procedure. The moderate to strong correlation between preoperative BTX injection and pain scores, along with the moderate inverse correlation between BTX injection and postoperative PCA use, further supports this finding. Additionally, the inverse relationship between BTX and postoperative IAP may contribute to the improved pain scores observed in the TAR+BTX group. This novel correlation between BTX injection and lower pain scores warrants further investigation in future studies to confirm its significance and underlying mechanisms.

Regarding complications from BTX injection, only three patients experienced minor issues, all of which were resolved by the time of surgery. This low complication rate of 5.5% corresponds to that of **Deerenberg *et al*.** [26] who reported minor complications in less than 5% of patients. Our study reported a 9.5% recurrence rate following TAR, which is comparable to the 9.94% recurrence rate observed by **Oprea *et al*.** [27] but significantly higher than the 1.6% recurrence rate reported in the systematic review by **Vasavada and Patel** [28] and more than double the 4% recurrence rate reported in the systematic review by **Wegdam *et al***. [23] This discrepancy may be attributed to differences in patient characteristics, defect size, surgical techniques, and follow-up duration among studies. Notably, the adjunctive use of BTX in our study contributed to a lower recurrence rate, reducing it to 1.8% in the TAR+BTX group compared to 9.5% in the TAR-only group, though this difference was not statistically significant. Further research is needed to validate this finding and assess the precise impact of BTX on recurrence prevention.

This study demonstrated lower rates of both surgical site occurrence (SSO) and SSI compared to the pooled results reported by a recent systematic review and meta-analysis by **Vasavada and Patel** [28] with our TAR+BTX and TAR-only groups showing SSO rates of 12.7% and 11.9% versus a pooled SSO rate of 21.72%, and SSI rates of 3.6% and 7.1% compared to 9.13%. These differences may be explained by variations in patient selection, surgical technique and perioperative management protocols

We recommend using a defect width threshold of 13 cm as a reliable predictor for the necessity of BTX injections to enhance postoperative outcomes when considered as a single factor. Further research using larger sample sizes and longer follow-up durations are needed to precisely determine a standard cutoff value for defect width. Although Sabbagh's index shows some predictive value, its smaller coefficient suggests a less significant role compared to defect width. Further research is necessary to refine predictive models, considering other clinical factors, to better guide decision-making and optimize patient outcomes in complex ventral hernia repairs.

LIMITATIONS

A key limitation of this study was the absence of randomization, which may introduce selection bias. Future randomized controlled trials are necessary to confirm the observed benefits of BTX and refine its indications in TAR procedures. Further limitations include its single-center design, relatively small sample size, reliance on subjective measures, and the absence of long-term follow-up for assessing quality of life.

CONCLUSION

This study supported the role of BTX as an adjunct in TAR in the management of large ventral hernias, showing improvements in postoperative pain, quality of life and IAP. However, further large-scale, randomized trials are necessary to validate these findings, to assess long-term outcomes and to determine cost-effectiveness before widespread clinical adoption.

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