



Use of Botox in abdominal wall hernia surgery

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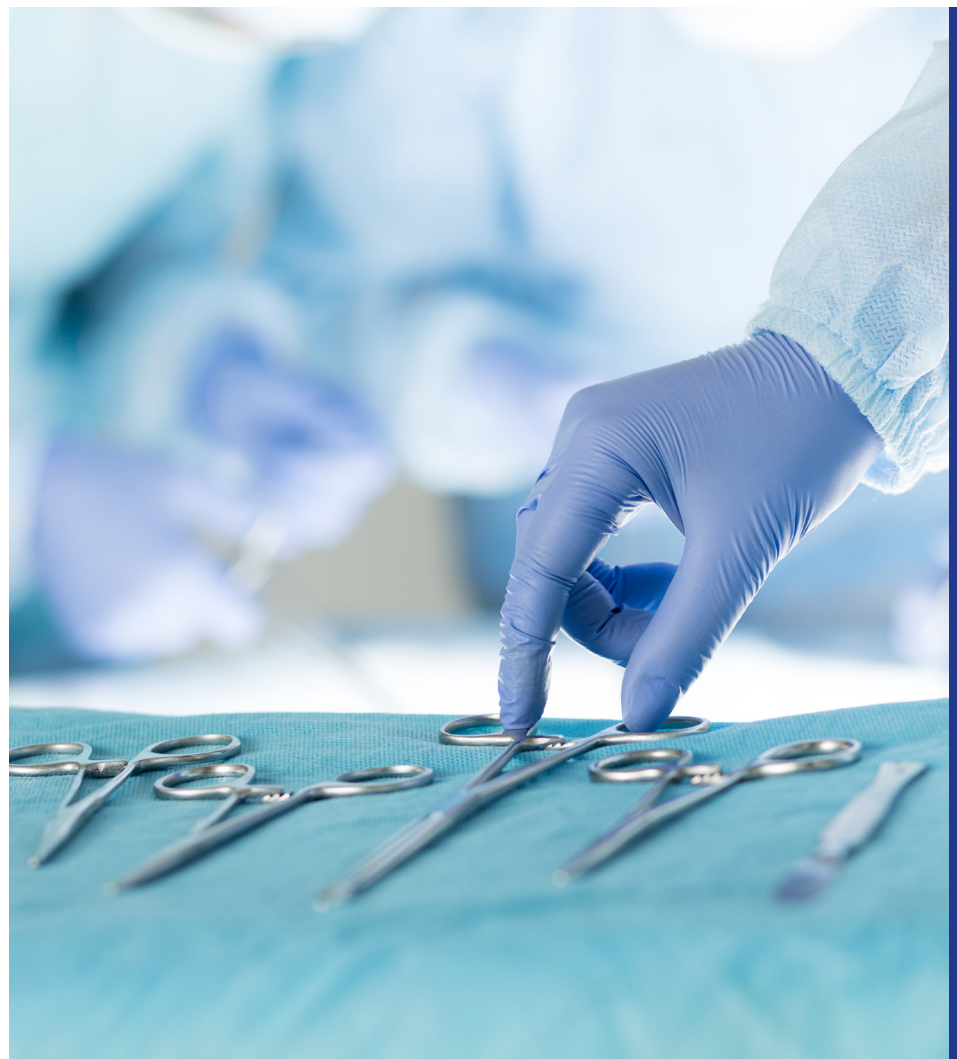


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Editorial: Use of Botox in Abdominal Wall Hernia Surgery

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Keywords: abdominal wall surgery, botulinum toxin A (BTA), prehabilitation, progressive pneumoperitoneum, secondary effects of BTA

Editorial on the Special Issue

Use of Botox in abdominal wall hernia surgery

Since the first publication in 2009 describing the use of Botulinum Toxin A (BTA) in abdominal wall reconstruction, its use as an adjunct to the prehabilitation strategy for patients with abdominal wall hernias has increased worldwide. Evidence suggests that BTA may help closing the fascial defects and thereby avoid bridging with mesh, and may even reduce the need for component separation techniques (CST), which are associated with significant morbidity, and most important, diminish the risk of abdominal compartment syndrome. Furthermore, the adverse effects of BTA appear to be minimal and uncommon.

However, after more than 15 years of widespread use, the optimal dose, the number of injections per side of the abdominal wall, the appropriate muscular plane for injection and many other important questions remain to be answered. In addition, indications for BTA as a prehabilitation tool vary across different clinical settings. The most common indication is midline hernias with wide defects (≥ 10 cm, W3 according to the EHS classification) and/or in patients with loss of domain. Favourable outcomes in this patient population have encouraged its use in smaller transverse defects, circular defects that are traditionally difficult to close, hernias out of the midline, giant inguinoscrotal hernias, open abdomen management, and other complex scenarios.

This Special Issue addresses and describes the multiple aspects of BTA use in abdominal wall reconstruction. BTA is frequently combined with other prehabilitation strategies, such as preoperative progressive pneumoperitoneum (PPP) and intraoperative fascial traction (IFT) and most specialized centers managing complex hernias have developed structured algorithms for patient management.

Marques-Antunes et al. propose a preoperative planning strategy based on CT findings for complex midline hernias. BTA was indicated 4–6 weeks prior to surgery when the defect width was ≥ 8 cm, lateral muscle thickness ≥ 1 cm, or loss of domain (LOD) was present (Tanaka index > 0.20). PPP was added in cases with LOD. In W3 hernias with significant lateral muscle retraction, IFT was recommended. Using this algorithm, CST was avoided in 61.4% of patients.

Taking this approach one step further, Nip et al. describe the establishment of a dedicated BTA service in a tertiary hernia center in the United Kingdom. A multidisciplinary team developed an algorithm recommending BTA injection for transverse defects measuring 5–10 cm when associated with additional risk factors, and for all defects > 10 cm. Only 51% of patients required CST, and fascial closure was achieved in 91% of cases.

Conversely, Girieasen et al. applied a different algorithm, reserving BTA (combined with PPP) for cases with a Tanaka index > 0.35 . All patients managed under this protocol ultimately required CST, possibly reflecting its use exclusively in highly complex cases.

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Bustamante-Recuenco et al. describe the use of BTA combined with a novel IFT device in a patient with a large 8-cm umbilical hernia associated with rectus diastasis. A preperitoneal enhanced-view totally extraperitoneal (Pe-TEP) approach was performed using this new traction system, achieving successful defect closure.

Sánchez-Moreno et al. report an unusual indication for BTA: three cases of severe diaphragmatic paralysis in which a substantial volume of abdominal contents had migrated into the left hemithorax, resulting in significant respiratory impairment. Four weeks after BTA injection, patients underwent diaphragmatic plication with mesh reinforcement. This strategy prevented the development of postoperative abdominal compartment syndrome. Recovery was uneventful, and all patients experienced improved quality of life.

Most publications report few complications related to BTA administration, aside from occasional injection-site hematomas. While the anatomical and muscular benefits of BTA as a prehabilitation tool are well documented, its potential effects on pulmonary function remain insufficiently studied, despite the role of lateral abdominal muscles in respiration. Smietanski et al. evaluated the impact of BTA on respiratory function using spirometry in 37 patients to determine whether observed changes represented true physiological improvement, mechanical compensation, or possible impairment. The authors conclude that BTA appears safe from a respiratory standpoint, as core spirometric parameters were not adversely affected. However, conventional spirometry may not fully capture BTA-induced functional changes, highlighting the need for further investigation.

There is, however, limited information regarding patients' perspectives and experiences with BTA. Klein et al. report the results of a questionnaire administered to 22 patients with complex hernias treated with preoperative BTA prior to abdominal wall reconstruction. Injection-related pain was infrequent; three patients reported no pain at all. Eight patients noticed changes in abdominal contour, two described altered trunk function, one experienced mild dyspnea, and another reported constipation. Overall, 59% of patients described positive memories and good tolerance of the procedure. These findings are consistent with the first international survey on patient-reported outcomes following preoperative BTA administration, recently published.

Although this Special Issue does not address all unresolved questions regarding BTA use in abdominal wall reconstruction, it provides a comprehensive overview of its global application, primarily within structured management algorithms for complex hernias. Patient-reported outcomes further support the notion that BTA is generally well tolerated, with few

adverse effects. Nevertheless, many questions remain unanswered.

We hope this special issue will be both engaging and informative, contributing to a deeper understanding of the diverse applications and effects within this field, while also encouraging further research and scientific publications in the future.

AUTHOR CONTRIBUTIONS

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

CONFLICT OF INTEREST

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Complex Abdominal Wall Hernias: Structured Use of Adjuvant Therapies

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Purpose: Repairing complex abdominal wall hernias is challenging, often requiring component separation techniques (CST) for tension-free closure. Adjuvant therapies, such as botulinum toxin type A (BTA), preoperative progressive pneumoperitoneum (PPP), and intraoperative fascial traction (IFT), may reduce the need for CST by improving abdominal wall compliance and reduce the complexity of the hernia. There is limited knowledge about the effects of their combined use. Our aim is to evaluate the rate of CST in abdominal wall reconstruction for complex midline hernias after adjuvant therapies.

Methods: A cross-sectional study was conducted on patients who underwent surgery for correction of midline complex abdominal hernias between June 2020 and June 2024. Patients submitted to BTA, PPP, or/and IFT were included. Exclusion criteria were non-midline hernias, non elective surgeries and less than 3 months of follow-up.

Results: Among the 44 patients studied, 61.4% underwent abdominal wall reconstruction without requiring CST. Traditional predictors like component separation index and rectus/defect ratio were not associated with a higher rate of CST after adjuvant therapies. 45.5% of patients underwent a combination of adjuvant techniques (BTA + PPP or BTA + IFT). The early and late complication rates were 20.5% and 9.1%. A recurrence rate of 4.5% was reported after a median follow-up of 13 months.

Conclusion: This study suggests that adjuvant therapies may influence the surgical approach to abdominal wall reconstruction. The synchronous application of adjuvant therapies, both preoperatively and intraoperatively, could enhance their effect and contribute to the use of less disruptive techniques.

Keywords: abdominal wall reconstruction, preoperative progressive pneumoperitoneum, intraoperative fascial traction, botulinum toxin type A, complex hernia

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INTRODUCTION

Repair of complex abdominal wall hernias entails a significant challenge for surgeons. The abdominal wall dysfunction is not only due to the hernia itself but also to the intrinsic muscle impairment [1]. Chronic muscle retraction typically reduces abdominal cavity volume. The reconstruction of the linea alba resembles to reverse the lateral retraction and fibrosis of the musculature [2, 3]. Restore the anatomy and function of the abdominal wall through a tension-free, mesh-reinforced, midline fascial closure is the main goal of surgery.

Rives-Stoppa retrorectus repair allows reconstruction of the abdominal wall by placing the mesh in a vascularized space, which promotes incorporation on the tissue and avoids subcutaneous dissection [4]. In some cases, achieving primary and tension-free myofascial closure is impossible with this technique, and component separation techniques (CST), such as transversus abdominis release (TAR), are required [5]. CST are more challenging to perform and can lead to irreversible disruption of the abdominal wall anatomy, as well as an increased risk of perioperative complications [6]. Alternatively, adjuvant therapies, such as injection of botulinum toxin type A (BTA), progressive pneumoperitoneum (PPP) or intraoperative dynamic fascial traction (IFT) can be used to increase abdominal wall compliance, avoiding CST [7–9].

BTA induces temporary paralysis of the lateral abdominal muscles, leading to their elongation and thinning. Simultaneously, the abdominal shape becomes more ovoid [10]. On the other hand, PPP increases the volume of the abdominal cavity by stretching the abdominal wall muscles and facilitates the reduction of herniated contents through the pneumatic dissection of adhesions [11–13]. The combined effects of both techniques can facilitate effective hernia downsizing. While BTA induces relaxation of the anterolateral abdominal muscles, PPP gradually expands the abdominal cavity, creating a more conducive environment for tension-free closure of the abdominal wall. Additionally, the use of BTA reduces the duration required for PPP insufflation [14, 15]. However, certain patients with hernias with significant myofascial retraction may benefit more from the administration of BTA followed by IFT - a controlled and time-limited mechanism designed to stretch the anterior aponeurosis during surgery [9, 16].

Preoperative planning is the cornerstone to achieve successful surgical outcomes. Based on the preoperative computed tomography (CT) some criteria can predict if the closure of the fascia will require CST, such as defect width greater than 8 cm, a rectus/defect ratio (RDR) below 1.34 [17], or a component separation index (CSI) exceeding 0.146 [18]. Guidelines recommend that only surgeons skilled in advanced techniques should perform surgery on hernias that meet or surpass these criteria [19].

Although some studies have already addressed the effects of adjuvants on the abdominal wall [10, 20], it remains unclear whether their application, particularly when used simultaneously, impacts the surgical technique used for the repair of complex midline hernias.

Our aim is to evaluate the rate of CST in abdominal wall reconstruction for complex midline hernias following adjuvant therapies, either alone or in combination, and to propose a structured algorithm for their use.

METHODS

Design and Setting

This was an cross-sectional study of patients operated by the Complex Abdominal Wall Unit of our centre from June 2020 to

June 2024. Written informed consent was obtained from the individuals for the publication of any potentially identifiable images or data included in this article. Ethical approval was obtained from the local ethics committee (CES n° 31_2024). The data were extracted from the electronic medical records. The study was designed and reported following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement to ensure transparency and completeness in reporting.

Participants

Inclusion criteria were patients who underwent midline complex abdominal hernia repair for primary or incisional hernias that were assigned to adjuvant therapies such as BTA administration, PPP, or IFT. Exclusion criteria were non-midline hernias (lateral, parastomal, synchronous ventral and lateral or inguinal), non elective surgeries, surgeries performed outside our hospital or operated on by individuals not belonging to the complex abdominal wall surgery unit. Patients with less than 3 months of follow-up were also excluded.

Variables and Data Measurement

The primary outcome was the rate of CST surgeries with the use of adjuvants. The secondary outcome was the complication rate and recurrence. Complications were classified according to the Clavien-Dindo classification [21]. Recurrence was considered whenever confirmed by CT scan. The tertiary outcome was to find predictors for CST with the use of adjuvants. Hernia's location and size were reported according to the EHS classification [22]. Defect width was measured. Loss of domain was defined as hernia/abdominal volume ratio greater than 20% [23]. Imaging predictors of abdominal wall closure such as RDR [17] and CSI [18] were calculate based on preoperative CT scans.

Preoperative Planning

All patients followed a preoperative program that included respiratory physiotherapy, smoking cessation, glycemic control, and comorbidities optimization in a multidisciplinary collaboration with endocrinology, pulmonology, internal medicine, and other medical specialties.

Patients with obesity were also evaluated by a multidisciplinary obesity team, with access to all treatment options, including bariatric surgery when deemed appropriate. Whenever possible, a staged surgical approach was adopted, with bariatric surgery performed first to achieve a lower BMI before proceeding with abdominal wall reconstruction. A synchronous approach, involving simultaneous bariatric surgery and abdominal wall reconstruction, was reserved for cases where primary laparoscopic surgery was not feasible. If the patient was deemed ineligible for bariatric surgery, they were enrolled in a non-surgical weight-loss program.

Adjuvants Protocols

Selection of adjuvants was determined according to EHS hernia classification [22], CT scan volumetric analysis of the hernia and abdominal cavity, as well as the surgeon's clinical judgment. Adjuvants were used either preoperatively or intraoperatively.

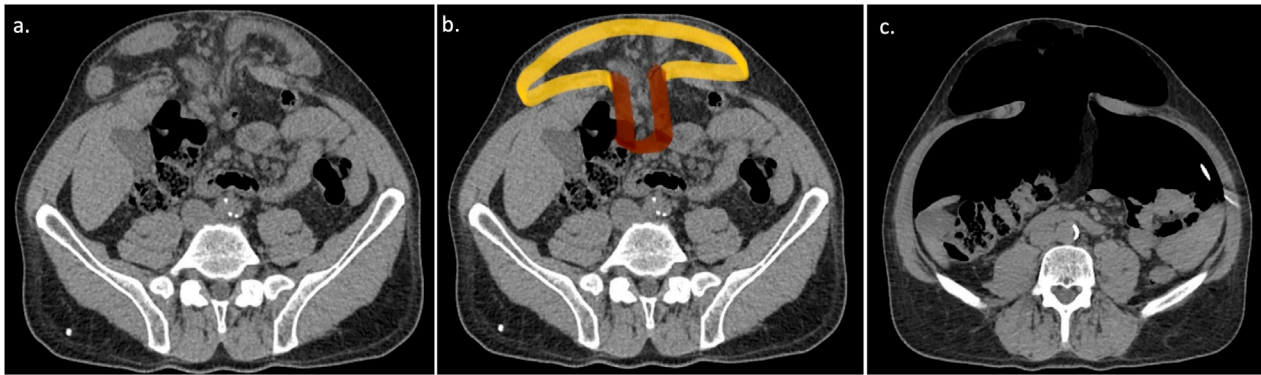


FIGURE 1 | “Mushroom” pattern is characterized by a relatively small hernia defect in hernias with large volume and loss of domain. A CT scan of a complex midline hernia with “mushroom” pattern is shown before **(A,B)** and after the PPP **(C)**.

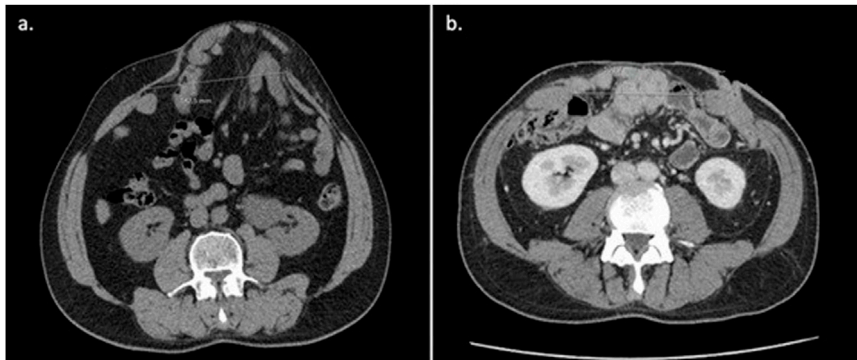


FIGURE 2 | Examples of lateral muscle retraction on CT patients submitted to BTA and IFT. Lateral muscle retraction is indirectly estimated by observing the relationship between an increase in muscle thickness and a corresponding decrease in muscle length. The decrease in muscle length is typically associated with increased hernia width.

Adjuvant therapy with BTA was performed in all hernias with width ≥ 8 cm or lateral muscles thickness ≥ 1 cm. Hernias with loss of domain were also assigned to BTA. The administration was ultrasound-guided, 4–6 weeks before surgery, by an abdominal wall surgeon. All patients received 500 U of Dysport in two or three points on both sides of the abdominal wall.

PPP was indicated for hernias with loss of domain and a simultaneously tight defect, characterized by what we termed the “mushroom” pattern (Figure 1). Patients were admitted 5–10 days before the surgery. A pigtail was inserted into the abdominal cavity. The insufflation was done daily with 500–1000 cc of air. The amount of air insufflated was calculated according to the herniary sac volume (HSV), employing the formula: $\text{Volume} = 3 \times \text{HSV} + 10\%$ [24]. Venous thromboembolism prophylaxis was performed using elastic compression stockings, administration of prophylactic enoxaparin (40 mg/day), and walking for a minimum of 1–2 h each day.

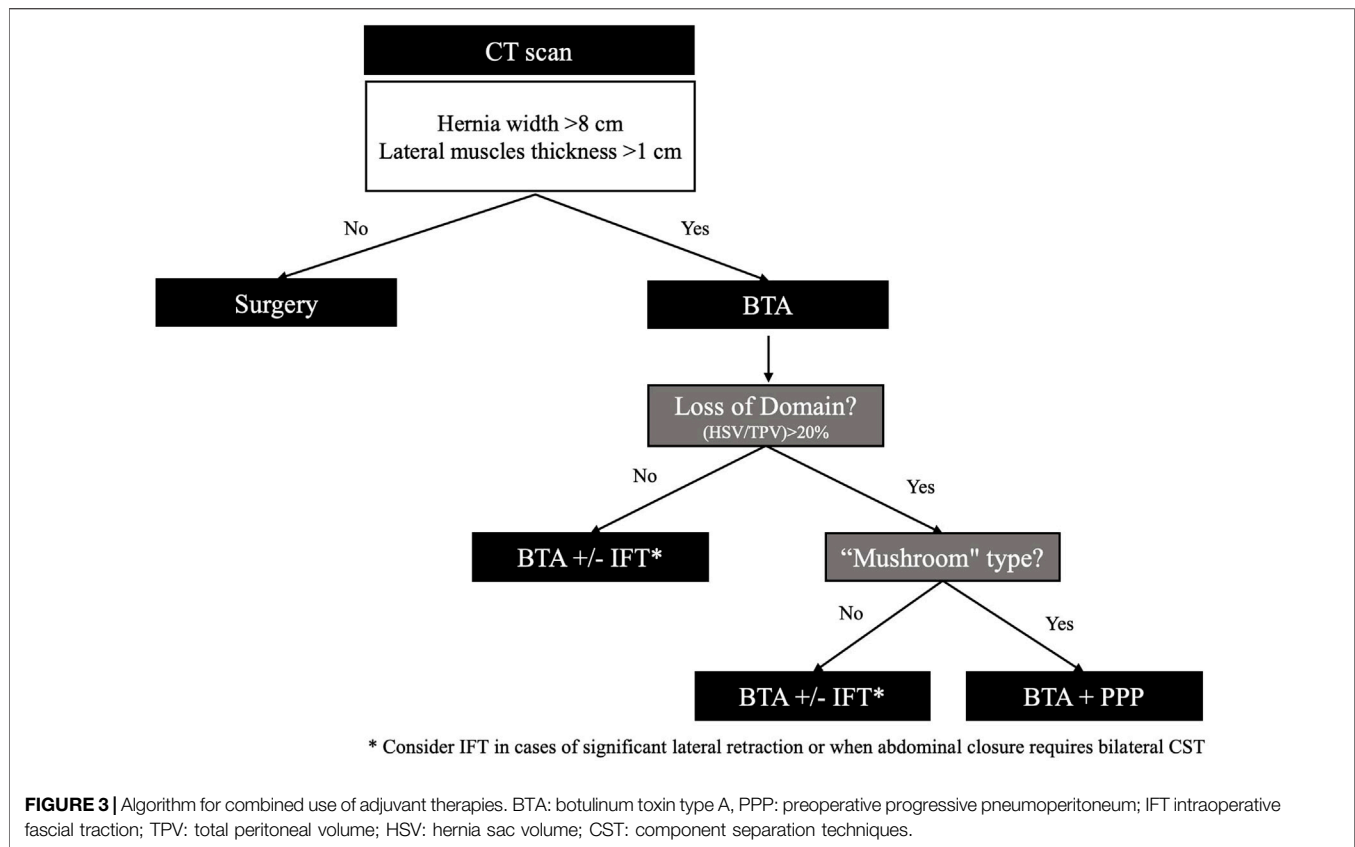
IFT was performed for W3 hernias with significant lateral muscle retraction, wherein closure of the abdominal wall was unachievable without a bilateral CST. The decision to use this

adjuvant could be made intraoperatively or predicted preoperatively (Figure 2).

The strategy for combining adjuvants was grounded in their potential to synergistically enhance each other’s effects: adjuvants with muscle relaxation and elongation properties (BTA) were paired with those capable of inducing muscle stretching according to hernia characteristics (PPP or IFT) (Figure 3).

Surgical Technique

We performed an open approach in all cases. The lateral dissection of the retrorectus space is carried out till the EIT Ambivium [25]. If the posterior rectus sheath could be closed without tension, we performed a Rives-Stoppa technique. Otherwise, the dissection progressed to a TAR. A macroporous, non-absorbable mesh was placed in the retromuscular plane covering the dissected area. Panniculectomy was performed if necessary, either through transverse or longitudinal incisions. In selected cases, anterior component separation was necessary when posterior component separation was not feasible due to prior violation of the



retromuscular plane from previous surgeries, including those for hernia repair. Hybrid techniques, staged approaches, or placement of mesh in more than one plane could be necessary according to the local conditions. All the surgical repairs were performed by surgeons of the Complex Abdominal Wall Unit, formed by three surgeons.

Postoperative Follow-Up

Patients were clinically reevaluated at 1 week, 6 months, and 2 years postoperatively. A CT scan was performed whenever there was suspicion of recurrence or complications.

Data Analysis

Categorical variables were quantified as the number of cases and percentage (%) and continuous variables were reported as mean \pm standard deviation, or median with interquartile range, as applicable. The statistical analysis was performed using the chi-squared test for categorical variables and the independent t-test or the Mann-Whitney U test for continuous variables, as applicable. Statistical significance was defined by $p < 0.05$. SPSS. Version 29.0.0.0 was used for statistical analysis.

RESULTS

A total of 58 patients underwent abdominal wall reconstruction after adjuvant therapy. Twelve (22.4%) were excluded due to hernia

location (lateral, parastomal, synchronous ventral and lateral, inguinal), and two (3.4%) due to less than 3 months of follow-up.

Preoperative patient demographic and hernia characterization are presented in **Table 1**. The mean hernia defect width was 9.97 ± 2.97 cm, with an equal proportion of W2 and W3 hernias. Twelve (27.3%) had loss of domain. The CSI was >0.146 in 52.3% of the hernias. The RDR was inferior to 1.34 in the same percentage of patients.

Eleven patients (25%) were enrolled in a surgical and/or non-surgical weight loss program before surgery. In this subgroup of patients, the mean initial and preoperative BMI were 39.8 ± 5.2 kg/m² and 30.0 ± 5.6 kg/m², respectively. Bariatric surgery was performed on eight patients, most of them before the abdominal wall reconstruction.

In 61.4% of the surgeries, the abdominal wall reconstruction was performed without CST. When it was needed, TAR was most frequently used (**Table 2**). The rate of posterior and anterior fascial closure was 100%. Ninety-six percent of the cases underwent adjuvant BTA. The median time from BTA to surgery was 38 days (31–55). PPP was performed in 25% of patients and IFT in 20.5%. There was no morbidity associated with BTA. However, two complications occurred during the PPP, one patient developed atrial fibrillation with rapid ventricular response and there was an inadvertent placement of catheter into subcutaneous tissue.

In the postoperative period, early complication rate was 20.5% (**Table 3**). Most of the complications were surgical site occurrences and classified with a Clavien Dindo I-IIIa [21]. The rate of superficial surgical site infection, seroma, and

TABLE 1 | Baseline and hernia characteristics.

Variable	N (%)
Age, years (mean)	63.3 ± 10.3
Sex	25 (56.8%) male; 19 (43.2%) female
BMI, kg/m ² (mean)	28.9 ± 4.3
Smoking/COPD	9 (20.5%)
Anticoagulation	7 (15.9%)
Diabetes	12 (27.3%)
ASA classification	
ASA II	30 (68.2%)
ASA III	13 (29.5%)
ASA IV	1 (2.3%)
Recurrent hernia	20 (46.5%) ^a
Previous mesh	14 (38.8%) ^b
Defect width, cm (mean)	9.97 ± 2.97
EHS classification (M)	
M1-3	4 (9.1%)
M1-4	3 (6.8%)
M1-5	1 (2.3%)
M2	1 (2.3%)
M2-3	8 (18.2%)
M2-4	12 (27.3%)
M2-5	1 (2.3%)
M3	8 (18.2%)
M3-4	3 (6.8%)
M3-5	2 (4.5%)
M5	1 (2.3%)
EHS classification (W)	
W2	22 (50%)
W3	22 (50%)
m-VHWGS	
Grade 1	9 (20.5%)
Grade 2	31 (70.5%)
Grade 3	4 (9.1%)
Loss of Domain	12 (27.3%)
Rectus/Defect ratio	
RDR <1.34	23 (52.3%)
Component Separation Index	
CSI >0.146	23 (52.3%)
Retro-rectus space, cm (mean)	12.95 ± 3.09

^a1 missing value.

^b8 missing values.

haemorrhagic complications was 6.8% for each complication among the patients. Additionally, 4.5% of patients experienced skin and subcutaneous dehiscence. One patient required surgical reintervention 20 months after the initial surgery due to an interparietal hernia, and a TAR was performed. Another case of hernia recurrence was reported 13 months after a Rives-Stoppa. These patients were submitted to BTA and BTA + IFT, respectively. During a median follow-up of 13 months (8–25), late complications occurred in four patients. Two patients with mesh infection underwent surgical removal of the infected mesh, 11 and 24 months after the initial surgery. Both patients had significant comorbidities, including obesity and diabetes, and underwent BTA plus PPP followed by TAR.

Comparing the abdominal wall reconstruction surgeries with and without CST, no significant statistical differences were observed in hernia characteristics, adjuvant treatments, or postoperative outcomes. However, a trend was observed towards a higher proportion of M1 hernias (23.5% vs. 14.8%) and hernias with

TABLE 2 | Operative data.

Variable	N (%)
Surgical technique	
Rives-Stoppa	27 (61.4%)
Unilateral TAR	6 (13.6%)
Bilateral TAR	9 (20.5%)
Bilateral ACS	1 (2.3%)
Unilateral TAR + Unilateral ACS	1 (2.3%)
Other procedures	
Panniculectomy	12 (27.3%)
Vertical Gastrectomy	1 (2.3%)
2nd stage Duodenal Switch	1 (2.3%)
Operative time, min (mean)	172.8 ± 43.7
Mesh dimensions	
Width, cm (median)	15 (12–19)
Length, cm (median)	30 (27–30)
ICU admission	21 (47.7%)

TABLE 3 | Postoperative complications and follow up.

Variable	N (%)
Intraoperative complications	5 (11.4%)
Intestinal perforation	5 (11.4%)
Diaphragm injury	1 (2.3%)
Early complications (<30 days)	9 (20.5%)
Seroma	3 (6.8%)
Wound dehiscence (skin and subcutaneous tissue)	2 (4.5%)
Superficial surgical site infection	3 (6.8%)
Hematoma	1 (2.3%)
Arterial active bleeding	2 (4.5%)
Respiratory infection	1 (2.3%)
Interparietal hernia	1 (2.3%)
Late complications (>30 days)	4 (9.1%)
Seroma	2 (4.5%)
Mesh infection	2 (4.5%)
Recurrence	2 (4.5%)
Duration of follow-up, months (median)	13 (8–25)

loss of domain (41.2% vs. 18.5%) in the CST group. The opposite was true for early complications rate (11.8% vs. 25.9%). Operative time and mesh width were higher in the CST group. The width of the hernia defect and the retrorectus space did not differ between the two groups. In patients with defects larger than 8 cm in width, 60% underwent repair without CST (**Table 4**).

A subset analysis was performed in hernias with CSI >0.146 and RDR <1.34. In patients with CSI >0.146, 65.2% underwent abdominal wall reconstruction without CST. Of those patients, 60% were W3 hernias and three patients had loss of domain. In the RDR <1.34 group, 60.9% did not require CST for abdominal wall closure. 58.8% were W3 hernias and two patients had loss of domain.

DISCUSSION

In our study, 61.4% of patients underwent surgery without CST after the use of adjuvant therapies, a percentage higher

TABLE 4 | Comparing group without CST versus group with CST.

Variable	Without CST	CST	p-value
Number	27	17	
Demographics			
Age, years (mean)	65.0 ± 10.7	60.71 ± 9.3	p = 0.180
BMI, kg/m ² (mean)	28.5 ± 4.6	29.4 ± 3.8	p = 0.504
Smoking/COPD	5 (18.5%)	4 (23.5%)	p = 0.716
Characteristics of hernia			
Defect, cm (mean)	9.74 ± 2.69	10.34 ± 3.43	p = 0.525
Defect >8 cm	20 (74.1%)	13 (76.5%)	p = 1.000
W3	13 (48.1%)	9 (52.9%)	p = 0.757
M1 region	4 (14.8%)	4 (23.5%)	p = 0.690
M5 region	3 (11.1%)	2 (11.8%)	p = 1.000
Retro-rectus space, cm (mean)	12.95 ± 3.34	12.60 ± 3.02	p = 0.729
Loss of Domain	5 (18.5%)	7 (41.2%)	p = 0.164
RDR <1.34	14 (51.9%)	9 (52.9%)	p = 0.944
CSI >0.146	15 (55.6%)	8 (47.1%)	p = 0.583
Adjuvants			
BTA	25 (92.6%)	17 (100%)	p = 0.515
PPP	6 (22.2%)	5 (29.4%)	p = 0.724
IFT	6 (23.1%)	3 (17.6%)	p = 1.000
Surgery			
Operative time, min (mean)	153.2 ± 28.4	221.8 ± 36.4	p = 0.002
Mesh width, cm (median)	14.5 (11.5–15)	18.5 (15–26.5)	p = 0.027
Mesh length, cm (median)	30 (24–30)	30 (29–33.5)	p = 0.121
Postoperative			
ICU admission	12 (44.4%)	9 (52.9%)	p = 0.583
Total length of stay, days (mean)	5.3 ± 3.3	5.8 ± 1.7	p = 0.572
Early complications	7 (25.9%)	2 (11.8%)	p = 0.445
Late complications	1 (4.3%)	3 (20%)	p = 0.282
Recurrence	1 (3.7%)	1 (5.9%)	p = 1.000

p < 0.05 values indicated in bold.

than previously reported by others [10, 20, 26]. The impact of adjuvant therapy on abdominal wall musculature before complex hernia surgery has been demonstrated in previous studies [10] however, information regarding their effect on final surgical technique remains limited. The available evidence primarily originates from systematic reviews and retrospective studies [8, 27–29].

The overall complication rate was 20.5% and 9.1% in the early and late postoperative period, respectively. These rates are lower than those reported in other studies [7, 26, 30]. Factors that may have contributed to these outcomes include a strong emphasis on the preoperative rehabilitation of patients, particularly concerning weight loss. The average BMI in our study was lower than that reported in other investigations [30, 31]. In contrast to previous studies, the complication rate in patients undergoing CST was not found to be higher than that in patients who did not undergo this procedure [24, 31].

Concerning the recurrence rate, two cases were observed during follow-up: one following a Rives-Stoppa repair, complicated by postoperative retrorectus bleeding, and another after a TAR, presenting with an intraparietal hernia. Nonetheless, our recurrence rate is lower than that reported in the existing literature [20, 28]. However, the median follow-up of 13 months may influence the findings, limiting the extrapolation of medium- and long-term conclusions.

There is established evidence of the reshaping of the abdominal cavity after adjuvant therapy with BTA. When applied at the lateral abdominal wall musculature, results in their elongation [32]. The increased length and reduced thickness of the lateral muscles, as well as the decrease in the width of the hernia defect, increase abdominal wall compliance [10, 29]. Due to the demonstrated benefits within our group, over recent years, the cutoff for utilization has progressively decreased and is now applied to hernias larger than 8 cm. Nonetheless, adjuvant therapies may prove beneficial in selected cases of smaller hernias. Careful, individualized assessment remains essential, as certain patients may require therapeutic strategies beyond those defined in the current algorithm. Tailoring treatment to specific patient or hernia-related factors may ultimately enhance clinical outcomes in appropriately selected cases.

Midline closure seems to be more related to compliance due to the elasticity of the muscle fibres elicited by the BTA blockade, rather than solely due to the value found for lateral fibre advancement [26]. Whether this effect is responsible for the downsizing of the hernia and prevention of the need for CST in some cases remains to be determined. Although the maximum effects of muscle paralysis is achieved after 3–4 weeks, its effect lasts for 6–9 months, allowing the abdominal wall to heal in a low-tension environment [33]. It is not yet known whether, regardless of the technique used, achieving midline closure with less tension is associated with a lower recurrence rate [29].

PPP induces a mechanical stretching of muscle fibres, that combined with the relaxation induced by BTA, increases the compliance of the abdominal wall and the volume that can be accommodated within the abdominal cavity. This combined approach of techniques was successfully used in a quarter of our patients. The gradual and steady increase in intra-abdominal pressure improves respiratory function adaptation and decreases the likelihood of developing a quaternary compartment syndrome in the postoperative period [13]. Because of that, in our group, those hernias presenting with a tight defect characterized by a “mushroom” pattern are assigned for adjuvant treatment with PPP, an indication never reported before to our knowledge.

In hernias with a greater separation between the rectus muscles and significant myofascial retraction of the lateral abdominal muscles, particularly in the middle and lower abdomen, better outcomes can be achieved with BTA muscle blockade combined with IFT. In these cases, PPP may result in insufflation of the hernia sac, causing stretching of the skin and subcutaneous tissue rather than increasing the abdominal cavity volume through lateral muscle elongation. This time-limited traction, applied during surgery, can facilitate a tension-free closure of the abdominal wall by stretching the temporarily paralyzed muscles [9].

In our study, 45.5% of patients received a combination of two adjuvant techniques due to their presumed synergy in hernia downsizing. Rather than applying all adjuvant methods simultaneously, we utilize a tailored approach based on specific clinical criteria. Our strategy does not prioritize one

adjuvant over another; instead, we acknowledge that each technique has distinct roles and is best suited for each clinical scenario. The comprehensive availability and expertise in utilizing these adjuvant methods contribute to enhanced patient care and allow for the individualized tailoring of treatment strategies.

The benefits of using adjuvants do not come without limitations. Although economic costs were not addressed in this study, the expenses associated with BTA and IFT are considerable, and PPP entails prolonged hospital stays with inherent costs. Outpatient protocols are already being described [34]. Regarding morbidity, we observed two cases of complications during the PPP, while other studies stated that complications can be as high as 25% [8].

The width of the hernia defect is considered a criterion that can define the need for CST. Traditionally, the Rives-Stoppa technique is an option for hernias up to 10 cm and thus possibly not applicable to W3 hernias [35]. In our study, 59.1% of patients with W3 hernias achieved abdominal wall closure without CST. Additionally, the width of the hernia defect did not differ between the two groups, showing the importance of factors other than diameter in determining hernia complexity.

Regarding hernia location, despite a higher proportion of patients with M1 hernias in the CST group, our study found no significant differences in the rate of component separation based on the hernia site, in contrast to the findings of some other authors [31]. There is still no evidence whether CST after adjuvant therapy can be reduced in certain hernia groups.

Another point of discussion is the size of the mesh used and its impact on the recurrence rate. The width, and consequently the overlap of the mesh, was smaller in the group of patients where CST was avoided. Whether downstaging the hernia with reduced mesh overlap will adversely affect long-term outcomes remains to be determined, and we aim to address this question through prospective follow-up of these patients.

No factors related to the patient or hernia characteristics were identified as predictors of the surgical technique used. Even in the subgroup of patients for whom CSI and RDR predicted the need for CST, it was avoided in 65.2% and 60.9% of the cases, respectively. This demonstrates the limitation of applying these tools to patients undergoing adjuvant treatments for hernia downstage.

Our study has several limitations that must be acknowledged. First, its retrospective design inherently restricts the depth of data that could be collected. Additionally, the absence of a control group, as we did not include all other hernia cases that were not treated with adjuvants, precludes the comparative analysis. Furthermore, we did not perform follow-up CT scans after adjuvant therapy, leaving unanswered whether certain subgroups of patients may experience a more pronounced benefit from these therapies. It did not alter our surgical approach, given that we initiated with a Rives-Stoppa technique and performed TAR on demand. It is also important to consider that, assessment of tension during

closure is subjective, and some variability between surgeons may have occurred. The strict application of our inclusion criteria to the patient cohort may have resulted in the exclusion of certain patients with smaller hernias who were not included in our study but who may nonetheless require component separation. We included two cases in which bariatric surgery was performed simultaneously with abdominal wall reconstruction, as preoperative bariatric surgery was not feasible. We acknowledge that this may introduce bias.

However, several strengths can be mentioned. To the best of our knowledge, this study is the first to demonstrate the simultaneous effects of different adjuvant therapies employed both before and during surgery, an effect that we believe is amplified by their combined application. Despite the small number of patients in our cohort, we are not aware of any previous studies reporting a comparable sample size. Furthermore, our focus on preoperative rehabilitation—particularly in managing patients with obesity—and the establishment of criteria for the use of BTA, PPP, and IFT contribute to reducing treatment heterogeneity.

Despite the encouraging results, individual responses to adjuvant therapies may vary among patients. The selection of patients or hernias that would benefit the most from each approach is still unknown, and further research is needed. Maintaining a holistic and individualized approach for each patient is critical in hernia repair.

CONCLUSION

The use of adjuvant therapies in patients with complex ventral hernias is safe and may influence the surgical strategy for abdominal wall reconstruction, potentially influencing the use of a less disruptive surgical technique. A structured approach to their application, guided by specific clinical criteria, may enhance their effectiveness and provide additional benefits.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

The studies involving humans were approved by Ethical approval CES no 31_2024 from Unidade Local de Saúde Entre o Douro e Vouga, Santa Maria da Feira, Portugal. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individuals for the

publication of any potentially identifiable images or data included in this article.

AUTHOR CONTRIBUTIONS

JM was involved in the investigation, methodology, data collection and drafting the manuscript; ER was involved in the investigation, methodology, data collection, formal analysis, reviewing and editing the manuscript; MG was involved in the investigation, and reviewing and editing the manuscript; AP was involved in the conceptualization, investigation, project administration and reviewing and editing the manuscript. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

GENERATIVE AI STATEMENT

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Establishing a Chemical Component Relaxation Service Using Botulinum Toxin For Abdominal Wall Reconstruction: Single-Centre Experience From a UK Tertiary Hernia Referral Unit

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Background: Botulinum toxin type A (BTA) is a valuable adjunct in abdominal wall reconstruction (AWR). Chemical component relaxation (CCR) involves injecting BTA into the lateral abdominal wall, leading to muscle paralysis and elongation which facilitates primary fascial closure during surgery without the need for extensive dissection. There are currently no standardised protocols for BTA administration in the perioperative period for AWR. We present a standardised protocol for CCR from our tertiary hernia unit and report our outcomes following surgery.

Methods: A retrospective analysis of a prospective dataset of all patients undergoing standardised pre-operative CCR between 1st May 2021 and 30th April 2024 for AWR were included in this study. Analysis of pre-operative multi-disciplinary team (MDT) planning, BTA administration, surgical procedure and outcomes were performed.

Results: During the 3-year-period, 35 patients underwent CCR with subsequent AWR. The median age was 58 and median BMI was 32. Median hernia defect width was 8 cm. Anterior and posterior sheath closure was achieved in 91% of cases. In total, 39% with defect size >8 cm did not require component separation and were considered “downstaged”. There were no complications following CCR, and the surgical site occurrence rate following AWR was 26%. Hernia recurrence occurred in 1 patient.

Conclusion: The presented protocol of pre-operative BTA appears to be a safe method of CCR. We demonstrate that its use may reduce the need for component separation and is associated with good post-operative outcomes.

Keywords: downstaging, abdominal wall reconstruction, component separation, complex hernia, botulinum toxin A

INTRODUCTION

Incisional hernias are increasingly common with occurrence rates of 9%–20% after primary laparotomy [1]. Within the surgeon's armamentarium for repair of large incisional hernias are the anterior and posterior component separation techniques described by Ramirez [2] and Novitsky [3]. These procedures, particularly transversus abdominis release (TAR), are challenging to perform, have steep learning curves, and carry elevated risk of complications. Moreover, muscle-releasing incisions interfere with abdominal wall integrity and core stability as the divided muscles atrophy over time.

Botulinum Toxin A (BTA) is now an established adjunct for abdominal wall reconstruction (AWR) as a chemical component relaxation (CCR) technique. It is a neurotoxin derived from *Clostridium Botulinum* that selectively blocks the release of acetylcholine from presynaptic cholinergic terminals to prevent nerve conduction. Its use was first presented in 2009 by the Mexican group Ibarra-Hurtado and colleagues [4]. Their group described 5 injections bilaterally in the lateral abdominal wall of 12 patients and demonstrated a reduction in mean hernia defect width of 5.25 cm after 4 weeks. Notably, half did not require intraoperative component separation.

Over the subsequent 15 years, the use of BTA has grown in popularity, with literature supporting its use in the pre-operative setting prior to AWR worldwide [5]. Administration of BTA can help achieve primary fascial closure (PFC) of both anterior and posterior rectus sheaths by flaccid paralysis and elongation of the lateral muscle complex, which facilitates medialisation during surgery. Some authors suggest that it can be used as the primary modality to assist with PFC [6, 7] rather than classic approaches of anterior or posterior component separation. It also confers an advantage of being non-invasive and can be performed in the outpatient setting. A systematic review of 995 patients demonstrated that BTA allowed an average elongation of lateral abdominal wall muscles by 3.2 cm bilaterally and was associated with a significant improvement in fascial closure rates [8].

However, the heterogeneity in techniques and regimens used for preoperative BTA is a notable concern. Uncertainty remains regarding its dosing, formulation, timing, number of injections, injection sites, and adjunctive techniques. Published data remains limited, with few protocols reported. Some studies fail to rigorously report on key technical steps such as number of injections, anatomical site, specific indication for the use of BTA and role of clinical governance to ensure patient safety. Despite rapidly evolving interest, there is no current standardised protocol for the administration of BTA. In this article, we therefore share our experience of establishing a BTA service in a UK tertiary hernia unit, with the aim of proposing a safe, reproducible, and standardised administration protocol.

MATERIALS AND METHODS

Type of Study and Participants

This was a retrospective single-centre case series. Consecutive adult patients aged 18 years or older who underwent (BTA)

administration for chemical component relaxation (CCR) were prospectively collected for inclusion in the database, which was retrospectively maintained and analysed for outcomes. The period of data collection was 1st May 2021 to 30th April 2024, which provided a 3-year overview of the development of a standardised service. Patients with known contraindications to BTA such as myasthenia gravis, multiple sclerosis, severe COPD, breastfeeding, and pregnancy were excluded from our study. For the analysis, patients undergoing parastomal hernia repair, flank hernia repair and those that were referred just for BTA injection (having subsequent AWR elsewhere) were excluded. Included patients therefore had ventral hernias and received both BTA and AWR at our centre.

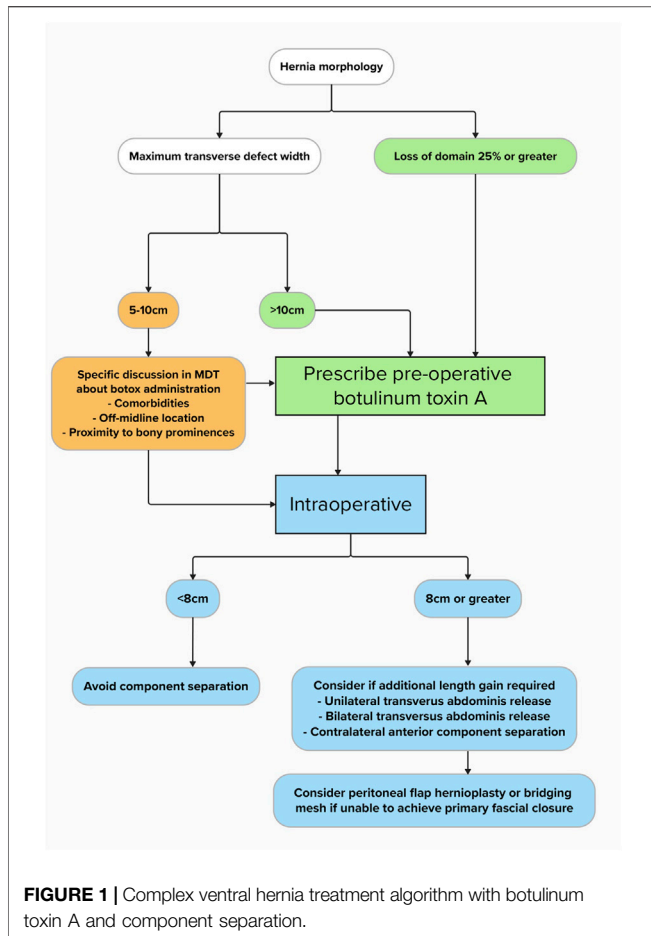
Establishing a Chemical Component Relaxation Service

The experience of establishing a protocol for BTA is described by authors SP and RT, as the senior authors and joint leads of our tertiary hernia centre. When building the CCR service, there were three main areas of focus: 1) hospital board approval; 2) maintaining a safe patient pathway; and 3) presenting all outcomes for review in clinical governance meetings.

Board Approval

In the UK, BTA is not licensed for CCR, therefore, approval from the local hospital board and medicines approval committee was necessary to allow regulated off-label dispensing and clinical use. Presentation of the literature supporting the use of BTA was presented to the committees, with approval from the hospital board, lead pharmacist and the elective surgery leads. In response to the committee's challenge to source an algorithm to determine cases where BTA is appropriate, the senior author (RT) discussed with consultants from 5 other AWR tertiary referral units in the UK. Anecdotally surgeons were unaware of such algorithms being in use, and it was down to the local multi-disciplinary team (MDT) to decide. However, there was consensus that hernia defect widths exceeding 10 cm and loss of domain more than 25% of the intraabdominal volume (Sabbagh method [9]) were indications for BTA. This was supported by a protocol published by Yurtkap et al. [10].

Initially, the first 9 patients in this series were selected if the transverse width of their hernia defect was 10 cm or greater. However, in 2022 when our service was still in its infancy, a team from Macquarie University (Australia) published their protocol showing BTA reduced the needed for component separation. Of note, they gave BTA to patients with hernia defects down to 5 cm [6]. Based on this, our protocol was adapted to include midline defects down to 5 cm where the risk of raised intraabdominal pressure and medical comorbidities may be ameliorated by BTA administration. BTA was therefore prescribed (Botox® due to local availability) more liberally according to our updated algorithm (shown in **Figure 1**) and was integrated into the patient pathway and local MDT. Our MDT service is already described elsewhere [11], and consists of abdominal wall surgeons, plastic surgeons, radiologists, anaesthetists, and other key service stakeholders. These members are responsible for



prescribing BTA based on the algorithm. The primary intention of BTA administration for all patients was to induce flaccid muscle paralysis in the elective setting to aid with PFC during surgery.

Patient Pathway and Technique for Administering BTA

To reduce strain on other services within the trust, it was important to create a pathway which facilitated patient flow using pre-existing structures, and without the requirement of additional training or staff. Patients selected for CCR were booked to attend elective theatres on a day the AWR team were operating. During a concurrent AWR case, the anaesthetic room was used as the BTA treatment room, with a dedicated anaesthetist (R) performing ultrasound-guided intramuscular injections according to a standardised protocol. A weight-based dose of 1% lidocaine local anaesthetic plus/minus Entonox was used for analgesia, followed by 300 IU of Botox® diluted across 150 mL of 0.9% normal saline (2 IU/mL of BTA).

BTA was divided into 3 injections per side into the external oblique, internal oblique, and the transversus abdominus muscles. Injections were placed in the anterior axillary line or at a safe point lateral to this if a giant ventral hernia encroached on it. An imaginary line was drawn between the lower border of

the costal margin and upper border of the iliac crest. The first injection was placed at a point halfway along this line, followed by 2 further injections: one halfway between the first point and edge of costal margin, and one halfway between the first point and iliac crest. After administration, patients were monitored for an hour in the recovery area for adverse effects, such as bleeding, urticaria or respiratory compromise. They were then discharged home same day when there were no concerns from medical or nursing staff.

Patients were called back for their elective AWR operation between 3-4 weeks after BTA infiltration unless there were clinical or logistical factors delaying the process. Micro-Delphi process [12] was performed routinely before knife-to-skin, ensuring the MDT operative plan was central to the dialogue and possible bail-out strategies had been discussed. Patients received an open approach and where possible, placement of mesh in the retrorectus or retromuscular plane. Our protocol states that component separation may be required if the maximal transverse defect width is 8 cm or greater, the choice of which (TAR or ACS) was discussed during MDT beforehand. If tension was apparent during PFC and the retromuscular plane not previously used, then unilateral TAR was the first line choice, followed by bilateral TAR or contralateral ACS. Anterior and posterior sheaths were closed with 2/0 PDS small bites technique [13]. In extreme cases where despite component separation PFC could not be achieved, a peritoneal flap hernioplasty or bridging mesh technique was performed.

Clinical Governance

Clinical governance is a central facet of our tertiary AWR service to ensure outcomes are scrutinised for efficacy and patient safety. As a newly established service with off-formulary use of BTA, it was mandatory for outcomes following BTA administration to be examined at least on a yearly basis. This was the rationale for establishing a database of patients undergoing BTA injection for an AWR indication and prompted this study to be conducted. The database was divided into the following sections: baseline demographics, hernia characteristics, operative characteristics, and patient outcomes.

Data Extraction and Outcomes

Approval from the Trust clinical governance department was granted for the retrospective collection and analysis of data for this study. Ethical approval was not required as this was conducted for service evaluation, with data captured as part of normal clinical care. Data were extracted from the Trust clinical documentation system, PowerChart, CernerWorks, and inputted onto a retrospectively maintained database stored on a secure Trust computer. All forms of documentation stored on the patient record were reviewed such as perioperative notes, clinic letters, operation notes, prescriptions, and multidisciplinary team (MDT) outcomes. Baseline demographics, preoperative MDT plan, BTA administration, surgical procedure and postoperative outcomes were of particular interest when the database was created. We defined “defect size” based on the maximum transverse width of a single defect documented radiologically or intraoperatively, or the

TABLE 1 | Summary of patient characteristics.

n = 45	Value (median with range or n with %)
Demographics	
Age (years)	58 (30–80)
BMI (kg/m ²)	32 (21–40)
Female sex (male)	22 (13)
Active smokers	7 (20%)
Diabetes	6 (17%)
ASA grade	
ASA 1	4 (11%)
ASA 2	26 (74%)
ASA 3	5 (14%)
Hernia characteristics	
Hernia defect width (cm)	8 (5–15.5)
Hernia type	
Off midline	5 (14%)
L1	2 (6%)
L3	3 (9%)
Midline	30 (86%)
M1	1 (3%)
M2	2 (6%)
M3	22 (63%)
M4	1 (3%)
M5	4 (11%)
Operative characteristics	
Component separation	
Anterior	18 (51%)
Posterior	5 (14%)
Unilateral TAR	13 (37%)
Bilateral TAR	9 (26%)
None (rives-stoppa only)	4 (11%)
None (rives-stoppa only)	17 (49%)
Operating time (mins)	237 (76–338)
Mesh type	
Synthetic	19 (54%)
Biologic	16 (46%)

BMI, body mass index; ASA, American Society of Anaesthesiologists; TAR, transversus abdominis release.

summed total of multiple Swiss cheese defects. “Downstaging” was defined as no TAR/ACS when the defect size was 8 cm or greater. We defined “upstaging” as the opposite situation, when TAR/ACS was required with a defect <8 cm. Recurrence was detected clinically during outpatient follow-up and/or radiologically if CT scan was performed for other reasons.

Statistical Analysis

Analysis was performed using preset summary functions on Microsoft excel (Microsoft Excel for Mac, Version 16.66.1, Microsoft Corporation, Washington, USA). Dichotomous variables were reported as number and percentage occurrence rate and continuous variables with skewed distributions were reported as median with range.

RESULTS

See **Table 1** for a summary of patient characteristics and **Table 2** for outcomes following BTA administration and AWR.

Baseline Demographics

During the 3-year period, a total of 45 out of the 200 patients discussed at the local MDT underwent BTA. Of these 45 patients, 35 were included in the analysis. The median age was 58 years (range 30–80), and median body mass index was 32 kg/m² (21–40). Sixty three percent of patients were female (n = 22). Within the cohort, 20% were active smokers and 17% were diabetic. The majority of patients were ASA grade 2 or 3 (89%).

Hernia Characteristics

Hernia defect widths ranged from 5cm to 15.5 cm with a median width of 8 cm. Midline hernias accounted for 86% and off-midline hernias 14%. According to the EHS classification for ventral hernia [14], the commonest location of the defect “centre-point” was M3 (n = 22), followed by M5 (n = 4) and L3 (n = 3). There were 2 hernias each for M2 and L1, and 1 hernia each for M1 and M4. Incisional or recurrent incisional hernias accounted for 91% (n = 32) of the cohort and primary hernias 9% (n = 3).

Operative Characteristics

Overall, component separation was performed in 51% (n = 18) of cases of which 72% (n = 13) were posterior component separation and 28% (n = 5) were anterior component separation. Of those patients who had posterior component separation, 69% (n = 9) were unilateral TAR and 31% (n = 4) were bilateral TAR. Successful PFC of both anterior and posterior rectus sheaths was achieved in 91% (n = 32). A synthetic mesh (Prolene, Ethicon) was placed in 54% (n = 19) and biologic mesh (Ovitex[®], TELA Bio) in 46% (n = 16). Median operating time was 237 min (range 76–338).

Outcomes

Median time from BTA administration to surgery was 29 days (range 12–78) and median length of follow-up after AWR was 335 days (range 15–1047). There were no reported complications following BTA administration, and all patients were managed as day cases. There were no re-admissions following BTA treatment.

At the point of surgery, 39% of cases (n = 9) were downstaged i.e. 39% of patients with hernia widths 8 cm or greater did not require component separation. A total of 49% (n = 17) did not require any component separation, and primary fascial closure of both anterior and posterior sheaths was achieved in 91% (n = 32) of cases. Upstaging occurred in 4 cases where the hernia width was <8 cm.

The rate of surgical site occurrence (SSO) was 31% (n = 11) and the rate of hernia recurrence was 3% (n = 1). The hernia recurrence occurred in an incisional hernia with defect width of 15 cm. Two patients required formal return to theatre—one for operative drainage of a large superficial seroma following reversal of transverse loop colostomy and bilateral TAR, and another for debridement of necrotic umbilicus after a combined AWR and abdominoplasty. The other re-interventions included bedside debridement of wound dehiscence and drainage of seroma by interventional radiology.

TABLE 2 | Summary of outcomes following botulinum toxin A (BTA) administration and abdominal wall reconstruction (AWR).

n = 45	Value (median with range or n with %)
General outcomes	
Length of follow up	335 (15–1047)
Time from BTA to surgery	29 (12–78)
BTA day case rate	35 (100%)
BTA complications	
Injection site complication	0 (0%)
Respiratory	0 (0%)
Cardiac	0 (0%)
Urticaria	0 (0%)
Anaphylaxis	0 (0%)
AWR complications	
SSO	11 (31%)
SSI	3 (9%)
Seroma	5 (14%)
Haematoma	1 (2%)
Superficial wound dehiscence	2 (6%)
Enterocutaneous fistula	0 (0%)
Other	
Hospital acquired pneumonia	3 (9%)
Urinary tract infection	1 (3%)
Ileus	1 (3%)
Venous thromboembolism	1 (3%)
Recurrence	1 (3%)
Re-intervention	6 (17%)
Bedside wound debridement	2 (6%)
Drainage of seroma	3 (9%) [2 by interventional radiology and 1 operative drainage]
Debridement of umbilicus	1 (2%)
Mortality	0 (0%)
Length of hospital stay	7 (5–48)

SSO, surgical site occurrence; SSI, surgical site infection.

DISCUSSION

A standardised BTA protocol is a valuable tool not only in tertiary AWR units, but also in lower-volume, lower-resource settings where downstaging of complex hernias can be pivotal for patient outcomes. Whilst we acknowledge that other UK centres are using preoperative BTA, we are not yet aware of any that have published their protocols or reported on their outcomes. We found no clinically important adverse events following BTA administration in our series which aligns with existing literature [8]. Publications citing serious complications following BTA seem to be infrequent [15] and this is comparable with our experience. We therefore believe this practice is unlikely to be detrimental in the short-term given that patients typically undergo surgery within 2–3 months of administration. Whilst we failed to measure any quality-of-life outcomes such as bloating, back pain and difficulty with defaecation, these could potentially be mitigated with careful preoperative counselling. As part of our protocol, we advocate the need for centres with existing or new BTA services to audit their

outcomes at least annually and review these outcomes in a local or regional clinical governance setting.

A key finding from our study is that BTA facilitated “downstaging” of the final operation in just over a third of cases which would have received component separation otherwise. This is important given that TAR is associated with increased operative time [16], higher complication rates [17], and prolonged recovery [18]. Furthermore, obviating the need for myofascial release maintains virgin planes in case of hernia recurrence and need for further surgery. While muscle elongation appears to be an objective, repeatable and quantifiable endpoint suitable for clinical trials, the concept of “downstaging” appears to be a pragmatic measure. It captures the essence of real-world intraoperative decision-making, where preoperative imaging may not fully represent the dynamic behaviour of tissues encountered during surgery. Complete PFC of both anterior and posterior sheaths together was successful in all cases except 3; two of these were midline hernias that despite component separation, required bridging of the posterior sheath with sac or omentum to restore the visceral protection layer, and one required bridging of the anterior sheath with mesh. Other studies describe a similar rate of PFC when utilising BTA protocols with or without preoperative progressive pneumoperitoneum (PPP) [6, 10, 19].

Jacombs et al. describe a protocol implemented over 7 years and routinely use BTA with hernia defects of 5 cm or greater. They found that BTA could facilitate PFC without the need for component separation when the defect was <12 cm. Our protocol was influenced by this and whilst initially using 10 cm as a cut-off point for which BTA is used, this was decreased to 5 cm if after discussion in the MDT was felt to provide benefit. These decisions were either to relieve the effects of comorbidities or pre-empt a technical challenge during surgery. Examples from our series included a patient with moderate COPD and several defects totalling 5 cm, and a patient with previous renal transplant secondary to diabetic nephropathy and a 6 cm defect. In such patients, mitigating the effect of raised intraabdominal pressure was important to prevent medical complications of respiratory failure or acute kidney injury. Operative challenges included a patient with a 6 cm M1 hernia and concurrent diaphragmatic hernia following colonic interposition repair of tracheo-oesophageal fistula and a patient with multiple previous caesarean sections with a 5 cm M5 Pfannenstiel hernia. In both cases we anticipated some difficulty with PFC due tight myofascial structures close to costal margin and pelvic brim.

Our group use the Rives-Stoppa repair as our standard approach assuming the retrorectus plane has not been violated. For hernia defects of 8 cm and above, this allows component separation to be applied for additional length gain. Our data suggests that BTA may reduce the likelihood of performing component separation, which is similar to results from other studies [7, 20]. However, it is worth noting that BTA may not entirely obviate the need for component separation since some cases with defect sizes <8 cm were unexpectedly “upstaged.” These cases were all off-midline hernias or close to bony prominences where myofascial tension is greatest. The choice for which method of component separation to use is decided

during the MDT but depends on multiple factors such as location of previous mesh, availability of mesh planes, rectus muscle bulk and lateral strap muscle retraction. Our preferred method of component separation is the transversus abdominis release. But this depends on good quality rectus muscle and an intact retrorectus plane. In this series, the majority of cases were incisional or recurrent incisional hernias, thus the choice of component separation could not always follow a strict algorithm but was tailored to individual circumstances.

An advantage of BTA administration is its simplicity and non-invasiveness, with ultrasound-guided injections relatively easy to learn and perform in the outpatient setting. In our unit, a dedicated anaesthetist performed BTA injections under ultrasound guidance, but this could be easily adopted by surgeons, radiologists or pain specialists depending on local expertise and resource availability. Electromyography (EMG) recording is reported in the literature [4, 7], but we believe this is impractical for routine clinical use. Ultrasonography skills are already well-established among anaesthetists who frequently perform transversus abdominis plane (TAP) blocks for other indications, whereas interpreting EMG signals is not a common skill for most medical professionals. Additionally, performing BTA injections in the anaesthetic room during an operative case presents logistical advantages. Since anaesthetists often have a trainee present who can oversee the patient undergoing surgery, BTA administration can be carried out simultaneously without disrupting workflow or need for extra procedure rooms.

In the absence of obvious contraindications such as allergy or severe neuromuscular compromise, we believe the risk benefit ratio appears to favour using BTA liberally. If an extensive dissection with increased risk of surgical site occurrences can be avoided, then it is probably worth doing. This is especially so as our team are moving towards complete extra-abdominal AWR with central zone skin excision which, anecdotally, is easier to perform due to increased soft tissue laxity. During the study period, other adjuncts to AWR such as PPP and Fasciotens® were not available and so are not described in our protocol. However, our PPP service has since developed and is used for patients with loss of domain >25% using the Sabbagh method [21]. In the future, we aim to integrate our BTA service into a perioperative care pathway which includes prehabilitation, supervised weight loss programme and progressive preoperative pneumoperitoneum (PPP) as required.

Limitations of the Study

This study has inherent limitations. As a retrospective case series from a single institution with a relatively small sample size, its findings may not be generalisable. Although patients were prospectively enrolled, there was no randomisation and there is potential for confounding by uncategorised variables. Furthermore, downstaging and PFC depends on multiple factors, not just abdominal wall compliance, which is the primary aim of BTA. For example, PFC is dramatically affected by defect size, loss of domain, and tissue quality which we were unable to control for.

A dual-centre cohort study by Zamkowski et al. [20] was able to report on clinically significant differences in PFC rates between

a BTA group and non-BTA control group of 50 patients each. In this study, patients undergoing preoperative BTA showed a significant reduction in component separation technique compared to the non-BTA group (46% and 84% respectively). Unfortunately, a notable weakness is that our study did not have a comparator arm. As the cohort grows, we plan to include a control group and perform propensity-matched scoring to allow more accurate comparison between BTA versus no BTA and reduce the influence of confounding variables. It would also be beneficial going forward to perform cost analysis in order to evaluate the economic impact of different BTA preparations and their feasibility in clinical practice.

In this cohort, we were not able to measure quality-of-life themes for patients after BTA including impact on psychology, social dynamics and daily life [22]. Several quality-of-life assessment tools have been shown to aid in a more holistic approach to patient outcomes [23] and we aim to incorporate these into future series. We are reassured however that there were no clinically important adverse events which may pose a future contraindication to BTA for eligible patients.

Conclusion

We have established a chemical component relaxation service where BTA is now used for AWR patients with hernia defects >5 cm. In summary, our protocol for BTA administration could be effective for downstaging hernias >8 cm where component separation would otherwise be required. High quality randomised controlled trials are needed to confirm the efficacy of BTA for CCR and would benefit from strict inclusion criteria to determine the situations where it is most valuable.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

Ethical approval was not required for the study involving humans in accordance with the local legislation and institutional requirements. Written informed consent has been obtained from patients where specific attributes are described which may potentially identify them.

AUTHOR CONTRIBUTIONS

RT contributed to conception of the study and study design. LN and OC performed data collection for the study. LN, OC and SZ made substantial contributions to data analysis, data interpretation and drafting the manuscript. Further significant contributions to interpreting the data and revisions to the manuscript were made by RJ, SH, AW, SP, and RT. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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A Preoperative Algorithm for Loss of Domain Hernia Repair: Stratified Management Using the Tanaka Index in 50 Cases

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Background: Loss of domain (LOD) in incisional hernias presents a significant challenge in abdominal wall reconstruction. Preoperative preparation of the abdominal wall is crucial to optimize surgical outcomes and prevent abdominal compartment syndrome (ACS). This study aims to develop an algorithm for selecting appropriate patients to undergo preoperative strategies based on the severity of LOD, measured by the Tanaka Index (TI).

Methods: We conducted a prospective study analyzing 50 cases of LOD hernias from a total of 558 incisional hernias treated over a 3-year period (2021–2024). Inclusion criteria were patients aged ≥ 18 years with a Tanaka Index (TI) > 0.25 who consented to surgery. For cases with TI between 0.25 and 0.30, we performed component separation using the Transversus Abdominis Release (TAR) technique, between 0.31 and 0.35 TAR with peritoneal flap reinforcement. In cases where TI exceeded 0.35, we implemented a structured preoperative preparation protocol involving botulinum toxin (BT) injections and progressive preoperative pneumoperitoneum (PPP) before proceeding with TAR and peritoneal flap reinforcement intraoperatively. In all groups, abdomen was reinforced with a 30 \times 30 polypropylene mesh.

Results: The efficacy of these techniques was assessed using both intraoperative and postoperative parameters. Intraoperatively, peak airway pressures (P_{peak} and P_{plateau}) were measured immediately after intubation and after abdominal wall closure. An increase in these pressures was used as an indicator of potential ACS risk. Postoperatively, intra-abdominal pressure was vigilantly monitored using a Foley catheter with serial readings recorded. Among the 50 cases following the algorithm, only two developed elevated intra-abdominal pressures (19 cm H₂O and 18 cm H₂O or 14 mmHg and 13.2 mmHg respectively) on postoperative day 0, which normalized by day 3. 6% cases experienced surgical site infections in the immediate postoperative period, and there were no recurrences during a standard 1-year follow-up.

Conclusion: This feasibility study establishes a structured algorithm for managing LOD hernias, tailoring preoperative preparation based on the severity of domain loss rather than standardizing it to all cases. By incorporating intraoperative airway pressure monitoring

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and postoperative intra-abdominal pressure surveillance, we successfully minimized ACS risk. The proposed approach optimizes fascial closure rates, reduces postoperative morbidity, and demonstrates favorable long-term outcomes.

Keywords: hernia repair, TAR, abdominal wall reconstruction, loss of domain, Tanaka Index, Botox, Peritoneal flap

INTRODUCTION

The number of ventral hernia repairs performed each year worldwide is increasing [1]. The primary reasons behind this are mainly attributed to the rising incidence of obesity [2], and the surge in intra-abdominal surgical procedures [3]. In patients with a history of abdominal sepsis and emergency laparostomies, the ventral defect is frequently left open and later closed using mainly fascial traction or skin grafts. This approach often results in fascial dehiscence or a weak anterior abdominal wall covered only by skin, ultimately leading to the development of large ventral hernias [4]. Complex Incisional Hernias present frequently with large sized defects, combined with a loss-of-domain-situation and in close proximity to bone. It may sometimes present with a full-thickness defect frequently associated with soft-tissue loss, scarring, or infection requiring debridement before reconstruction [5].

Loss of domain (LOD) hernias are large ventral hernias in which simple reduction of herniated contents and primary fascial closure is either not feasible without advanced reconstructive techniques or poses a high risk of complications due to elevated intra-abdominal pressure [4].

The repair of a loss of domain hernia is inherently complex. The abdominal cavity has adapted to the prolonged presence of a substantial portion of its contents outside its confines, within the protruded hernial sac. Reintegrating all the herniated contents into the abdominal cavity in a single surgical procedure can result in a sudden increase in intra-abdominal pressure, predisposing the patient to the potentially fatal complication of abdominal compartment syndrome (ACS). The incidence of ACS in abdominal wall reconstruction is 4.3% [6]. Its Surgical ICU admission and in-hospital mortality was significantly high (58.1%), with an Adjusted Odds Ratio of 3.84 [7, 8]. Hence, to prevent this, it is imperative to acclimatize the abdomen to the anticipated physiological changes through appropriate preoperative and intraoperative techniques.

Preoperative methods involve Intramuscular injection of Botulinum Toxin and Preoperative Progressive Pneumoperitoneum (PPP) [8] where the former induces paralysis of the lateral abdominal wall muscles, enhancing tissue elasticity and promoting the medial displacement of the rectus muscles and the latter subjects the abdomen to a gradual increase in the abdominal pressure with daily insufflation of atmospheric air which passively expands the abdominal cavity, allowing viscera to re-establish right of domain. At the same time, PPP helps to minimize the risks of postoperative abdominal compartment syndrome and the sequelae of fascial closure under tension [9–11].

This study aims to develop an algorithm for preoperative preparation and surgical management of LOD hernias, classifying patients based on the Tanaka Index (TI) [4]. The

study hypothesizes that, tailoring preoperative interventions according to the severity of LOD will improve fascial closure rates, reduce ACS risk and render it economically easier on the patient instead of standardising it to all LODs, making this study unique. Furthermore, the study explores how these interventions impact intraoperative abdominal conditions, patient recovery, and long-term outcomes, aiming to establish a standardized approach to complex hernia repair.

METHODS

This prospective study was conducted between 2021 and 2024. Of the 558 patients who underwent surgery for incisional hernias at our hospital, 50 cases of loss of domain (LOD) hernias were selected (**Figures 1A–G, 2**). Patients were classified primarily based on their Tanaka Index, which is defined as the ratio of hernial sac volume (HSV) to abdominal cavity volume (ACV). A ratio exceeding 0.25 indicates the presence of a loss of domain hernia [4].

Based on this ratio, and using the study by León-Beldarrain et al. (2020) [12], the study developed an algorithm that was approved by our Institutional Ethics Committee. The key distinction between our approach and that of León-Beldarrain et al. (2020) lies in both standardization and threshold selection: while we standardized the technique of posterior component separation (PCS) via transverse abdominis release (TAR) with retrorectus mesh repair for all LOD cases, our threshold for initiating preoperative augmentation ($TI > 0.35$) was based on institutional experience. At our center, patients with TI between 0.25 and 0.35 had been successfully managed without Botox or PPP, guiding our decision to reserve such interventions for higher-risk cases.

Algorithm for Incisional Hernias

For cases with a Tanaka Index of less than 0.25 (**Figure 3**), the choice of surgical procedure was determined by the location and size of the hernia. Depending on these factors, anterior component separation, retro-rectus repair, or onlay mesh repair was performed, with transverse abdominis release (TAR) being utilised only in select cases where the defect size exceeded 12 cm. These cases were not included in our study.

For patients with a Tanaka Index between 0.25 and 0.30, posterior component separation via TAR with retrorectus mesh was the preferred surgical approach. When the index ranged from 0.31 to 0.35, the former surgery was combined with an autologous peritoneal flap to facilitate fascial closure. In cases where the index exceeded 0.35, preoperative preparations with botulinum toxin (BT) and progressive preoperative pneumoperitoneum (PPP) were implemented based on



FIGURE 1 | (A–G) Clinical picture of LOD cases of varying sizes.



FIGURE 2 | Pre-operative picture of Loss of domain with tanaka index of 0.53.

reported outcomes and established indications for PPP from previous studies [9, 10, 13]. A pre-anesthetic evaluation was conducted for all patients, including an assessment of lung function. Patients were strictly advised to abstain from smoking and adhere to a weight loss regimen. Additionally, they were actively encouraged to perform incentive spirometry at 2-h intervals everyday. Informed consent was obtained from all patients undergoing the preoperative technique.

Botulinum toxin (BT) injection was administered as an outpatient procedure under ultrasound-guided infiltration 2 weeks prior to the PPP implementation, following the methodology described by Deerenberg EB et al [13]. The anatomical landmarks—costal margin and anterior superior iliac spine—were identified and marked. A line between these two landmarks, half-way between the anterior axillary line and the mid-clavicular line was drawn and divided into three equidistant segments.

A total of 300 units of botulinum toxin (BT) was reconstituted with 150 mL of normal saline, achieving a concentration of 2 units/mL. Under ultrasound guidance, the flat abdominal muscles were identified, and 25 mL of the solution was injected at each designated site, with approximately 8 mL

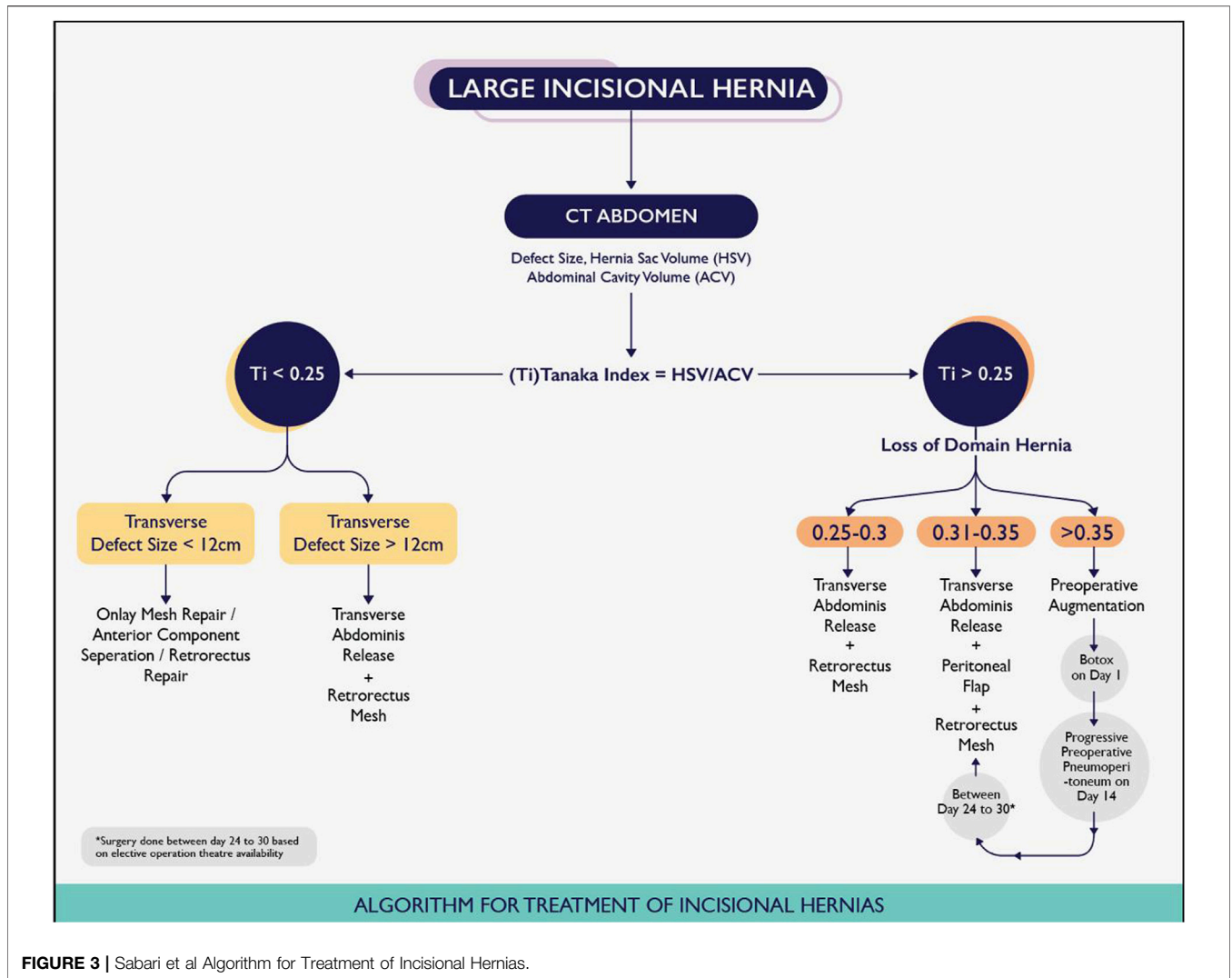


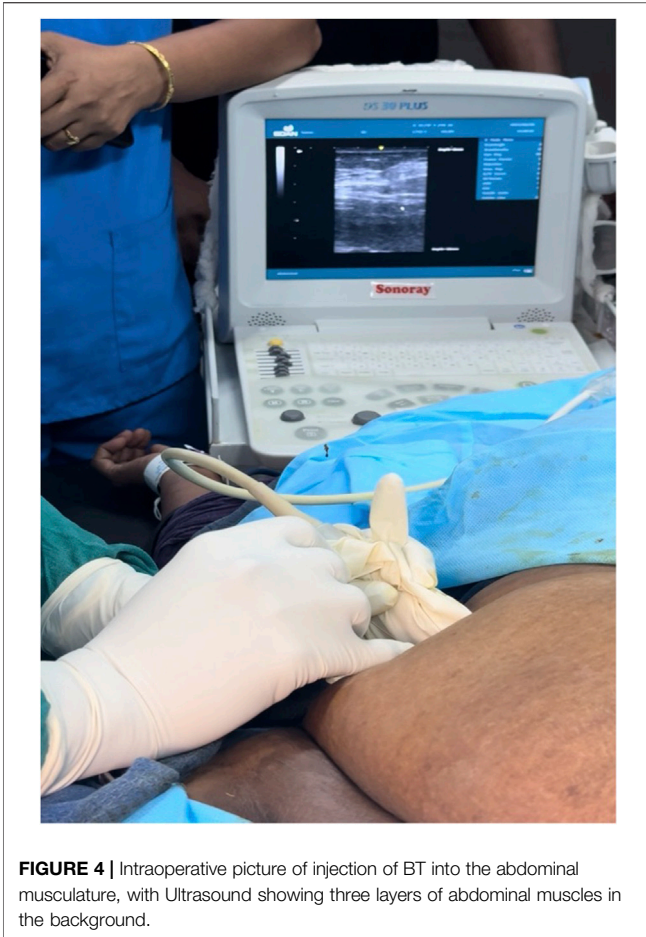
FIGURE 3 | Sabari et al Algorithm for Treatment of Incisional Hernias.

administered into each muscle group. A total of 150 units was injected on each side of the abdomen. (Figures 4, 5). Pre- and post-Botox CT scans were obtained to assess the increased laxity of the lateral abdominal wall muscles, evidenced by their elongation (Figures 6, 7).

For the implementation of progressive preoperative pneumoperitoneum (PPP), as previously described by [9, 14] an intraperitoneal double-lumen catheter was inserted, preferably in the upper left quadrant, under ultrasound. This procedure was done 14 days after the BT injection when paralyzing effect reaches a maximum [15]. The insertion was performed via an anterolateral approach in an area free from scarring or previous incisions. Initially, a 22G spinal needle was introduced into the peritoneal cavity, ensuring that the tip just crossed the peritoneal space (Figure 8A). A total of 300 mL of unfiltered ambient air was then administered via a syringe, followed by a confirmatory CT scan (Figure 8B). The largest pocket of intraperitoneal air was identified, and an 8Fr pigtail catheter was subsequently placed into that space.

The total insufflation volume was calculated as approximately three times the visceral-intraperitoneal hernia (VIH) volume determined by CT imaging [12]. Progressive insufflation was performed daily or every other day, either in an inpatient or outpatient setting, for a minimum of 7 days, continuing until the day of surgery using a three-way valve. The average volume of insufflation was 800–1,000 mL per day, adjusted according to patient tolerance. Monitoring included assessing abdominal wall distension, discomfort, and dyspnoea, which served as indicators for cessation of insufflation. Complications pertaining to BT injection, such as injection site reactions (pain, swelling, redness or bruising), allergic reactions (itching, dyspnea) or weakened cough, and those to PPP such as shoulder pain, metabolic acidosis, subcutaneous emphysema, pneumothorax, pneumomediastinum, bowel perforation were monitored. A multidisciplinary team including general surgeons, anesthesiologists, and physiotherapists was involved in patient assessment and perioperative care.

Patients underwent surgery under general anaesthesia with epidural cover, and initial peak airway pressures



(PAP) including P peak and P plateau were recorded, as a significant increase in PAP before the incision and following fascial closure could potentially lead to alveolar volutrauma [16].

All patients had abdominal wall reconstruction using the posterior component separation technique via transverse abdominis release (TAR), which was carried out unilaterally or bilaterally as per Reinhold et al [17], depending on intraoperative decisions made by the surgeon. Following midline incision, the sac is identified and dissected up to the fascial border of the hernial ring. The sac and peritoneum are then carefully mobilised from the fascial hernial ring, the posterior rectus sheath bilaterally, and the defect's cephalad and caudal aspects along the linea alba. A longitudinal incision, approximately 0.5 cm medial to the neurovascular bundle, is made along the posterior rectus sheath, ensuring its preservation while allowing for the complete separation of the rectus abdominis muscle from the posterior rectus sheath up to the lateral edge of the rectus compartment. The retromuscular plane is subsequently developed towards the junction of the posterior and anterior rectus sheaths, creating a suitable space for further surgical reconstruction. Released Transversus Abdominis Muscle is pushed away to enter the space between the Transversus Abdominis muscle and

Transversalis fascia. Inferiorly, the space of Retzius is entered and Cooper's ligament visualized. Superiorly, the retro muscular plane can be extended cephalad to the xiphoid and diaphragm if needed.

For patients with a Tanaka Index exceeding 0.3, the "Swinging Door" technique, a peritoneal flap method, was employed alongside transverse abdominis release (TAR) [18, 19] (Figure 9A). This technique utilises excess tissue from the hernial sac to close the fascial defect, effectively enlarging the abdominal domain at the herniation site without weakening the lateral abdominal wall [20].

A 30 × 30 cm polypropylene mesh was placed in the underlay space to cover the defect, extending laterally into the retroperitoneum and secured with 2-0 Prolene sutures (Figure 9B). A Romovac negative suction drain tube was positioned over the mesh within the retrorectus plane to facilitate drainage. Finally, the anterior rectus sheath was meticulously closed to restore the linea alba.

Redundant skin and subcutaneous tissue were excised, and a second subcutaneous drain tube (DT) was inserted. The skin was then sutured without tension, and a tight compressive dressing was applied. An increase in Peak Airway Pressures was noted. A rise of >10 cm H₂O suggested imminent abdominal compartment syndrome [21]. As described by Novitsky in his book *Hernia Surgery: Current Principles*, the study standardized an increase of >8 cm H₂O (>6 mm Hg) as significant and continued patients on elective ventilation [22]. We vigilantly monitored intra-abdominal pressure for Abdominal Compartment Syndrome (ACS) using a Foley catheter and a central venous pressure (CVP) manometer, following the previously described technique in Rao P et al and Hunter JD et al [23, 24]. Serial readings of IAP were noted to identify early signs of ACS. Post Extubation, patients were advised to perform incentive spirometry and early ambulation. Epidural top-ups were given with tramadol till day 3. The DTs were removed on Post operative day 3 or if output was <25 mL/day, whichever occurred later. Sutures were removed between Post operative days 10–14 in healthy wounds.

We considered various parameters, including age, sex, duration of hernia, past surgical history, smoking history, chronic medical conditions, and CT findings such as defect size and Tanaka Index. Additional factors assessed included intraoperative procedures, elevation in peak airway pressures, length of hospital stay, postoperative pain, postoperative complications (both local wound and systemic), date of discharge, postoperative follow-up, and recurrence rate.

STATISTICAL ANALYSIS

Data analysis was performed using IBM SPSS Statistics version 21.0. The Kolmogorov-Smirnov test was conducted to assess data normality, yielding a non-significant p-value, indicating that the data were normally distributed. Due to the small cohort size, non-parametric test was applied to check the difference between groups, descriptive statistics were reported as median

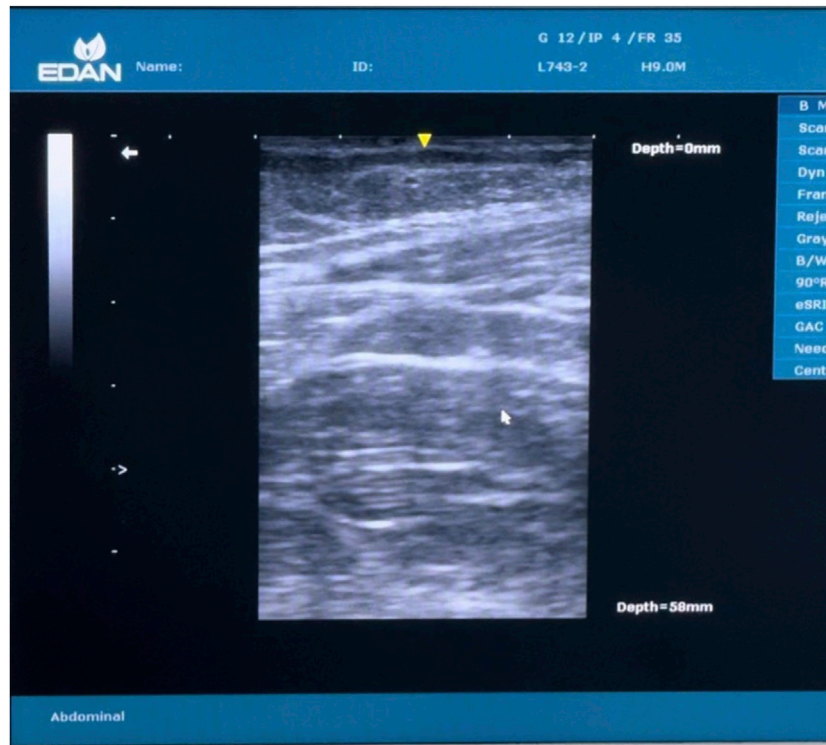


FIGURE 5 | Ultrasound image showing 3 layers.

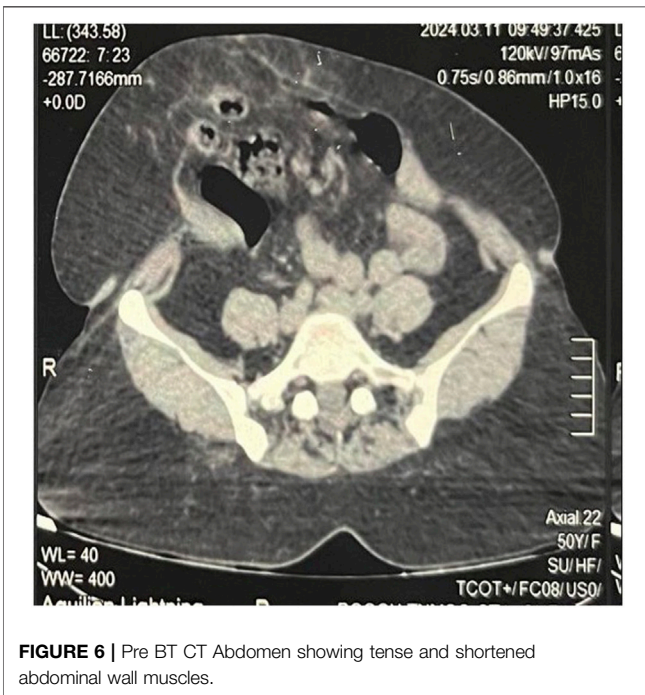


FIGURE 6 | Pre BT CT Abdomen showing tense and shortened abdominal wall muscles.

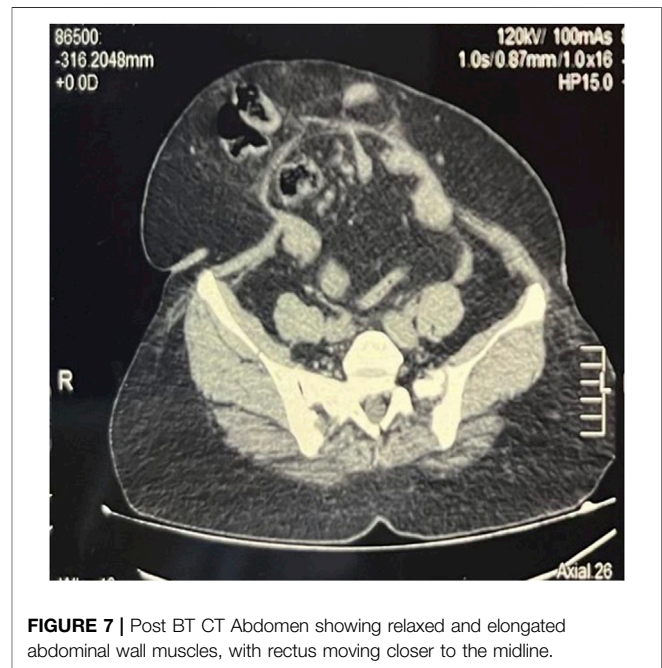


FIGURE 7 | Post BT CT Abdomen showing relaxed and elongated abdominal wall muscles, with rectus moving closer to the midline.

and interquartile range (IQR) for continuous variables, while categorical variables were presented as frequencies and percentages.

Comparisons between three independent groups were conducted using the Kruskal-Wallis test for continuous variables. The Chi-square test or Fisher’s exact test was applied to examine associations between categorical variables, as appropriate.

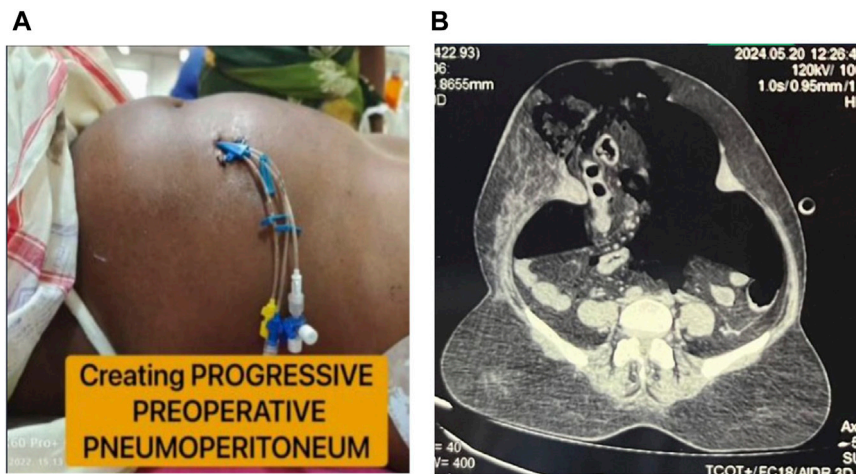


FIGURE 8 | Progressive preoperative pneumoperitoneum. **(A):** Clinical Picture of PPP with double lumen catheter *insitu*. **(B):** Post PPP CT showing pneumoperitoneum.

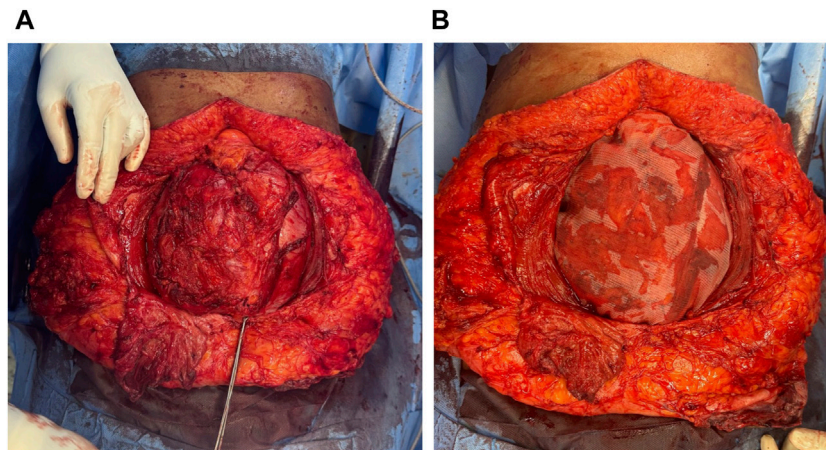


FIGURE 9 | Intraoperative pictures. **(A):** Transverse Abdominis Release with peritoneal flap. **(B):** 30 × 30 cm polypropylene mesh placed in Retro rectus plane.

A p-value <0.05 was considered statistically significant.

RESULTS

Normality of continuous variables was assessed using the Kolmogorov–Smirnov test. A p-value greater than 0.05 indicates that the variable follows a normal distribution. In this study, Age ($p = 0.06$), BMI ($p = 0.20$), Tanaka Index ($p = 0.05$), Defect Size ($p = 0.164$), and all intra-abdominal pressure values from post-operative days 0–3 (IAPONPOD0 to IAPONPOD3, all $p = 0.20$) showed no significant deviation from normality. However, Duration of Hernia had a p-value of 0.001, indicating a statistically significant deviation from normality (**Table 1**). Although most variables satisfy the assumptions for parametric testing, non-parametric methods

will be applied due to the small sample size of the cohort, to ensure more reliable and conservative results.

The Q-Q plots for the normally distributed variables (Age, BMI, Tanaka Index, Defect Size, and IAP ON POD0 to POD3) revealed points closely aligned with the diagonal reference line, supporting the normality suggested by statistical tests. The Q-Q plot for Duration of Hernia showed a clear deviation, confirming its non-normality. Despite overall normality in the visual and statistical tests, non-parametric tests will be used for analysis in light of the small cohort size, to minimize the risk of assumption violations and enhance the robustness of the findings.

Demographic Characteristics

A total of 50 patients with loss of domain (LOD) hernias were included in this study. Groups (I,II,III) were categorized based on Tanaka Index (**Table 2**). The median age of the cohort was 52 years

TABLE 1 | Normality test results for continuous variables (PAP normality).

Tests of normality	
Variables	Kolmogorov-smirnova Sig
Age	0.06
BMI	0.20
Tanaka index	0.05
Defect Size	0.164
Duration of Hernia	0.001
IAPONPOD0	0.20
IAPONPOD1	0.20
IAPONPOD2	0.09
IAPONPOD3	0.20

TABLE 2 | Categorisation of groups.

Management group	Tanaka index
Group 1	0.25–0.30
Group 2	0.31–0.35
Group 3	>0.35

(range: 36–66 years), with a male-to-female ratio of 1:1.78 (**Table 3**). The median BMI and the duration of hernia amongst the patients was at an increasing trend across the 3 groups and the association was found to be statistically significant (p value < 0.001). Age, sex distribution, ASA classification, and number of

prior surgeries did not differ significantly between groups. 28% ($n = 14$) were active smokers who were about 2.5 times less than nonsmokers ($n = 36$). Patients with hernia following just a single abdominal surgery was highest in Group I ($n = 16$), whilst Group III had the highest incidence of hernia following 3 surgeries ($n = 4$). Among the patients, all of whom have had a previous history of abdominal surgery, 44% ($n = 22$) had undergone an emergency laparotomy. 68% ($n = 22$) of females had history of Obstetric procedures. Preoperative comorbidities included hypertension (32%), diabetes mellitus (28%), and chronic obstructive pulmonary disease (12%). However, number of patients with preoperative comorbidities was more in Groups II and III.

Preoperative and Intraoperative Characteristics

As assessed on CT imaging, the median transverse defect size was increasing across the 3 groups. Among patients who received preoperative progressive pneumoperitoneum (PPP), the median air insufflation volume was 13 L.

All patients underwent posterior component separation with transverse abdominis release (TAR), with 26 patients (52%) requiring additional peritoneal flap augmentation. However only 12 of these 26 patients needed preoperative augmentation (**Table 4**). Intraoperative peak airway pressure (PAP) monitoring revealed significant difference (p value = 0.002), a median increase of 8.2 cm H₂O for Group II at the time of closure which was higher than other Groups (**Table 4**). The blood loss

TABLE 3 | Baseline characteristics of patients ($n = 50$) after separating by management groups.

Variables	Group I ($n = 24$) TAR	Group II ($n = 14$) TAR + peritoneal flap	Group III ($n = 12$) TAR + peritoneal flap + Botox	p value
	Med (IQR)	Med (IQR)	Med (IQR)	
Age (in years)	50 (48,54.5)	49 (48,52)	53 (48,56)	0.681
BMI (kg/m ²)	24.7 (23.85,26.45)	29.1 (28.3,29.8)	33.55 (32.6,36.6)	<0.001
Sex	n (%)	n (%)	n (%)	0.838
Male	10 (41.7)	4 (28.6)	4 (33.3)	
Female	14 (58.3)	10 (71.4)	8 (66.7)	
Duration of Hernia (in years)	1.5 (1,2.5)	4 (2,5)	7 (6,8)	<0.001
Median (IQR)				
ASA Classification	n (%)	n (%)	n (%)	0.235
1	10 (41.7)	2 (14.3)	2 (16.7)	
2	14 (58.3)	10 (71.4)	6 (50)	
3	0	2 (14.3)	4 (33.3)	
Risk Factors	n (%)	n (%)	n (%)	
Smoking	6 (25)	4 (28.6)	4 (33.3)	0.919
No. of abdominal surgeries				0.724
1	16 (66.7)	8 (57.14)	6 (50)	
2	6 (25)	4 (28.57)	2 (16.67)	
3	2 (8.3)	2 (14.28)	4 (33.33)	
Comorbidities	n (%)	n (%)	n (%)	
DM	8 (33.33)	4 (28.57)	2 (16.67)	0.655
HTN	10 (41.67)	4 (28.57)	2 (16.67)	0.358
COPD	0 (0)	4 (28.57)	2 (16.67)	-
Past Surgical History	n (%)	n (%)	n (%)	0.670
Emergency Laparotomy	10 (41.7)	6 (42.9)	6 (50)	
Puerperal Sterilisation	8 (33.3)	2 (14.3)	2 (16.7)	
Cesarean section	2 (8.3)	6 (42.9)	2 (16.7)	
Previous Hernia Surgery	2 (8.3)	-	2 (16.7)	
Colectomy	2 (8.3)	-	-	

TABLE 4 | Pre and intra-operative characteristics.

Variables	Group I (n = 24)	Group II (n = 14)	Group III (n = 12)	p value
	Med (IQR)	Med (IQR)	Med (IQR)	
Transverse defect size (in cm)	13.4 (12.5–14.3)	n.a	15.6 (15.0–16.5)	0.056
Total Volume of air insufflated in PPP (in litres) (n = 12)			13 (9.4,14)	
Increase in Peak Airway Pressure (cm H ₂ O)	6.8 (3.4,8.2)	8.2 (8.2,8.2)	4 (2.7,5.4)	0.002
Blood loss (in mL)	180 (155,205)	240 (220,250)	275 (270,300)	<0.001
Primary Surgeon	Surgeon (n)	Surgeon (n)	Surgeon (n)	
A/B/C	A (11) B (6) C (7)	A (14)	A (12)	
Assisting Surgeon	B (12)	B (8)	B (4)	
B/C	C (12)	C (6)	C (8)	

TABLE 5 | Post-operative characteristics.

Variables	Group I (n = 24)	Group II (n = 14)	Group III (n = 12)	p value	
	Med (IQR)	Med (IQR)	Med (IQR)		
Intra-abdominal pressure (cm H ₂ O)	POD-0	13.25 (12,14)	16 (13.5,17)	14.25 (11,16)	0.250
	POD-1	12.5 (11.5,13.75)	13 (11.5,15.5)	12.5 (10.5,14)	0.491
	POD-2	12 (11,12)	11.5 (11,13)	11.75 (10,13.5)	0.803
	POD-3	10.5 (10,11.25)	11 (10,12)	10.25 (9.50,11)	0.476
Length of Stay (in days)	11 (9, 12)	12 (10, 14)	9.5 (8, 12)	0.524	
	n (%)	n (%)	n (%)		
Patients under postop ventilator	12 (50)	12 (85.71)	2 (16.67)	0.002	
Day of Extubation (n = 26)	n (%)	n (%)	n (%)		
POD 1	8 (33.33)	8 (57.14)	-	0.008	
POD 2	4 (16.67)	4 (28.57)	2 (16.67)		
Postop Complications	n (%)	n (%)	n (%)		
SSI	-	2 (14.29)	2 (16.67)	0.131	
Seroma	-	2 (14.29)	4 (33.33)	0.014	
Systemic Complications	-	6 (42.86)	-	0.002	
		4 AKI/2ARDS			

increased over the 3 groups and was statistically significant ($p < 0.001$). A significant rise in PAP (>8 cm H₂O) was noted in 26 patients (52%), all of whom required elective postoperative ventilation.

Postoperative Outcomes

All patients were monitored from the postoperative day (POD) 0 for intra-abdominal pressure using a central venous pressure (CVP) manometer, which remained comparable across groups until POD 3 (all $p > 0.2$), with no values exceeding thresholds associated with abdominal compartment syndrome (ACS), suggesting the protocol was effective in mitigating this risk (Table 5). Patients who required elective postoperative ventilation ($n = 26$) were successfully weaned off within 48 h. However, the need for postoperative ventilator support was significantly higher in Group 2 (85.7%) compared to Group 1 (50%) and Group 3 (16.7%) ($p = 0.002$). With respect to complication, superficial surgical site infections (SSI) were seen only in groups 2 and 3 (14–17%) (Figure 10). Seromas were significantly more common in Group 3 (33.3%) versus Group 2 (14.3%) and absent in Group 1 ($p = 0.014$). Both these complications were managed conservatively. Systemic complications included acute respiratory distress syndrome, defined by acute onset, bilateral

lung infiltrates on chest radiography or CT scan of a non-cardiac origin, and a PaO₂/FiO₂ ratio of less than 300 mm Hg with the requirement of positive end-expiratory pressure (PEEP) or continuous positive airway pressure (CPAP) of greater than or equal to 5 cm H₂O, which occurred in 8% of cases [25]. The other complication was transient acute kidney injury, defined as temporary decline in kidney function with a return to baseline values in 48 h, was noted in 4% of cases [26]. Both the complications occurred in Group II. The median length of hospital stay for group II was 12 days which was the highest among the groups. Overall, while defect size and disease severity increased with the Tanaka Index, the structured intraoperative and postoperative protocols effectively prevented ACS, although systemic complications and ventilator dependence were more frequent in intermediate-risk patients.

Follow-Up and Recurrence

At a median follow-up of 12 months, 100% of patients achieved successful fascial closure without recurrence. One patient experienced recurrence during his 2-year follow-up who had a Tanaka Index of 0.34 at baseline. None of the patients required reoperation within the follow-up period. This study demonstrates



FIGURE 10 | Postoperative picture with wound dehiscence.

that posterior component separation with TAR, with or without peritoneal flap augmentation, is an effective technique for LOD hernias. While preoperative interventions remain valuable, our algorithm for surgical planning based on defect size and intraoperative PAP monitoring proved to be a safe and effective alternative in resource-limited settings.

DISCUSSION

A critical concern when forgoing preoperative preparation in LOD patients is the potential risk of abdominal compartment syndrome (ACS) due to a tense fascial closure during surgery. To prevent this preoperative augmentation was implemented in LOD hernias. However, this proved to be costly for patients and also required prolonged duration of preoperative stay.

When compared with previous studies, our findings align with those of León-Beldarrain et al. (2020), who advocated for the routine use of PPP and BT in all cases of LOD hernias. That said, our study sought to explore whether TAR along with a retrorectus mesh could be a viable alternative for cases with a Tanaka Index between 0.25 and 0.30, particularly in resource-limited settings. Our results indicate that TAR, with or without a peritoneal flap, facilitated fascial closure without excessive lateral wall tension, offering a practical solution for situations where preoperative techniques are unavailable. But this could also create tense closure leading to Intra abdominal Hypertension. To prevent this, monitoring of Abdominal Compartment Syndrome was

performed. Intraoperative peak airway pressure (PAP) as a surrogate marker for intra-abdominal hypertension [27] was monitored. A significant rise in PAP at the time of closure suggests the development of varying degrees of intra-abdominal hypertension, which can have severe postoperative respiratory consequences. This is primarily due to increased chest wall elasticity, elevated intrathoracic pressure, and subsequent reductions in lung volume, resulting in atelectasis [28]. However, increasing the natural compliance of the abdominal wall through positive ventilatory support allows for adaptation to elevated intra-abdominal pressure [29]. For this reason, in our study, patients demonstrating a marked intraoperative rise in PAP were electively ventilated postoperatively, to ensure a gradual adaptation to the rising abdominal pressure. Their Intra-Abdominal Pressures (IAP) were vigilantly monitored by Foley's catheter once every 4 h during the first post-operative day.

This study evaluates the effectiveness of the posterior component separation technique such as Transverse Abdominis Release (TAR) with retrorectus mesh placement in conjunction with a peritoneal flap for loss of domain (LOD) hernias, particularly in cases with a Tanaka Index greater than 0.3. Preoperative techniques such as progressive preoperative pneumoperitoneum (PPP) and botulinum toxin (BT) injections remain highly successful for managing LOD hernias even in cases with a Tanaka Index exceeding 0.25 [12]. But, their widespread application in government hospitals in India presents significant challenges. BT is difficult to procure in such settings, and PPP necessitates prolonged inpatient admission (often up to 10 days preoperatively), increasing hospitalization costs, which is particularly burdensome for patients of low socioeconomic status who seek treatment in these centers. Given these limitations, the study aimed to develop an alternative algorithm tailored to such constraints, employing TAR for smaller-grade LOD hernias while reserving preoperative augmentation for more extensive defects.

Nonetheless, this does not suggest that TAR is superior to surgeries done with preoperative augmentation. Rather, it underscores the need for adaptable surgical strategies in hospitals where access to BT and prolonged preoperative admissions for PPP is constrained.

Despite the promising findings, our study has certain limitations. The use of elective postoperative ventilation delays early recovery, can cause Ventilator Associated Pneumonia (VAP), Ventilator Induced Lung Injury (VILI) and may subject patients to additional physiological stress [30, 31]. Furthermore, vigilant monitoring for abdominal compartment syndrome in the early postoperative period remains challenging due to limited medical personnel and infrastructure constraints in resource-limited settings.

Further studies should also be conducted to examine whether alternative preoperative techniques such as tailored PPP protocols with shorter hospital stays could be developed to accommodate financial and logistical constraints in government hospitals. Future efforts should be applied to increase the threshold of elective post operative ventilation and hence subject lesser patients to VAP, VILI and stress.

Conclusion

The value of a systematic strategy to the management of loss of domain (LOD) hernias has been demonstrated by this study. Customised preoperative and intraoperative techniques after classifying patients according to the Tanaka Index, greatly increased fascial closure rates and has shown no complications of abdominal compartment syndrome. Botulinum toxin injections and progressive preoperative pneumoperitoneum (PPP) enhanced abdominal compliance for very large hernias, enabling safer hernia repair.

For intra-abdominal hypertension, intraoperative airway pressure monitoring has been shown to be a trustworthy surrogate marker, enabling early intervention such as elective postoperative intubation, to avoid problems after surgery. Additionally, postoperative intra-abdominal pressure surveillance through Foley catheter measurements was critical in reducing morbidity.

Our findings show that a targeted, patient-specific strategy is both economical and successful. The long-term success of this approach is further supported by the lack of recurrence during a 1-year follow-up period. Future research should focus on validating these findings through larger multi-center studies and exploring additional cost-effective alternatives for preoperative preparation.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving humans were approved by Institutional Ethics Committee Madras Medical College, Chennai 600 003. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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AUTHOR CONTRIBUTIONS

The conception and design of the study were carried out by MG. All authors (MG, AL, and MF) contributed to patient recruitment, clinical coordination, and the preoperative and postoperative management of all patients. MG developed the surgical algorithm, served as the primary operating surgeon for all cases, and supervised the overall project ensuring methodological integrity. AL handled data collection, performed the analysis, and prepared the manuscript draft. MF supported clinical coordination and assisted in overall study execution. All authors contributed to the article and approved the submitted version.

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Case Report: Combined Preperitoneal Enhanced-View Totally Extraperitoneal (PeTEP) Repair with Intraoperative Fascial Traction after Prehabilitation with Botulinum Toxin A in a Large Congenital Umbilical Hernia

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Introduction: Congenital umbilical hernia affects 10% of infants. While 80% of cases resolve spontaneously in early childhood, surgical treatment in adults poses challenges due to progressive growth presented over time. Minimally invasive approaches have gained prominence over the past two decades in abdominal wall surgery, with PeTEP (Preperitoneal Enhanced-View Totally Extraperitoneal) being the latest surgical technique introduced. However, its effectiveness in repairing large hernias remains unverified. In this regard, intraoperative fascial traction (IFT) could facilitate fascial closure and potentially expand the indications of this novel surgical technique.

Material and Methods: A 29-year-old male with arterial hypertension, a BMI of 29 and no prior surgical history was referred for surgical management of a congenital umbilical hernia. He presented with discomfort at the site of the umbilical hernia, exacerbated by movement. Preoperative CT scan revealed an 8.5 cm × 6 cm hernia defect (large-sized according to EHS guidelines) associated with a 10,1 cm rectus diastasis. Prehabilitation with botulinum toxin (BTA) injection followed by PeTEP surgical repair was performed. IFT was successfully used to assist in the closure of the hernia defect.

Results: Early postoperative recovery was favorable, with the patient experiencing low pain levels and being discharged within a day. A 6 cm asymptomatic seroma was observed 1 month postoperatively and was effectively resolved through conservative management. By the 3-month follow-up, the patient reported full functional recovery with no signs of recurrence and satisfactory cosmetic results.

Conclusion: This case report demonstrates that the PeTEP approach, complemented by BTA prehabilitation and intraoperative fascial traction, is viable for the repair of larger midline hernias. This combined method may enhance functional outcomes and recovery speed. However, additional research is needed to evaluate its long-term effectiveness.

Keywords: minimally invasive surgery, abdominal wall surgery, umbilical hernia, botulinum toxin A, prehabilitation, intraoperative fascial traction, PeTEP approach

INTRODUCTION

Umbilical hernia appears in 10% of infants, and it is more prevalent in preterm neonates, those with low birth weight, or in case of congenital hypothyroidism or Down syndrome. As it corrects spontaneously during the first years of life in up to 80% of the cases, its treatment is usually reported in the pediatric surgery field [1].

Surgical techniques in abdominal wall field are numerous and live in constant evolution. In this regard, minimally invasive approach has experienced an exponential growth over the past 10 years [2]. In this period we have witnessed a change from the initial intraperitoneal techniques, like the IPOM, IPOM+ and LIRA [3, 4]; to an endoscopic and more anatomical approach with the eTEP and the eTEP-TAR [5]. The benefits of endoscopic surgery seem to be evident when compared to laparoscopic ones, as lower postoperative pain is reported in certain studies, with no significant difference in the rate of other complications [6, 7]. Along these lines, Preperitoneal Enhanced-View Totally Extraperitoneal (PeTEP) is the most recent technique, for its first description was made by Valenzuela et al. in 2024 [8, 9]. The combination of an endoscopic extraperitoneal access with a preperitoneal hernia repair allows for a complete preservation of the musculoaponeurotic complex, with all the advantages this entails. However, its utility in medium-to-large abdominal wall hernias remain to be proven, as well as its long-term outcomes, as no evidence of late recurrence, pain and bulging rate is available at this point.

Parallel to this progress, methods to avoid component separation have been developed. Abdominal wall prehabilitation with botulinum toxin A (BTA) injection, as well as progressive pneumoperitoneum (PPP) have proved to facilitate primary fascial closure without adding significant morbidity [10]. Recently, intraoperative fascial traction has arisen as a surgical option to manage large hernia defects with or without loss of domain. Promising results have been obtained both in experimental and clinical settings, even though long-term outcome evidence is still scarce [11, 12].

The performance of PeTEP hernia repair combined with IFT in a patient prehabilitated through BTA injection has not been described in the literature up to now. This case report, in accordance to CARE guidelines [13], describes the initial experience of this mixed surgical approach in a patient with a large congenital umbilical hernia.

MATERIALS AND METHODS

Case Description

A 29-year-old male, natural from Mali, with no previous abdominal surgeries, hypertension as unique morbidity and no

known toxic habits was referred to our clinic. He presented with a congenital umbilical hernia that had progressively enlarged over the years, causing significant discomfort and interference with daily work activities. On physical examination, he had a large, reducible umbilical hernia without significant excess skin, and a BMI of 29. Neither excess panniculus tissue nor stretch marks were present.

As part of the preoperative preparation, an abdominopelvic CT scan with Valsalva maneuver was performed, revealing, as shown in **Figures 1A, B**, a large-sized defect (according to the EHS umbilical and epigastric classification), measuring 8.5 cm width × 6 cm length, with an area defect of 40.07 cm² associated with a severe supraumbilical rectus diastasis (according to EHS rectus diastasis classification) [14] of 10.1 cm.

Given the patient's young age and physically demanding occupation in the construction industry, a minimally invasive approach was selected. A preperitoneal extended-view totally extraperitoneal (eTEP) hernia repair via a superior access was therefore indicated. This technique offers key advantages, including preservation of the musculoaponeurotic wall and placement of the mesh in the preperitoneal (pretransversalis) space. The patient agreed with the proposed management.

The administration of 300 IU of botulinum toxin (Botox[®], Allergan Inc., United States) was performed following the Deerenberg technique [15], 6 weeks before the surgical intervention.

Surgical Technique

The procedure was performed under general anesthesia. A preoperative transversus abdominis plane (TAP) block was completed to minimize postoperative pain. The patient was placed in the supine position with legs and arms adducted. The surgeons were positioned at the head of the patient, while the laparoscopic equipment tower was placed at the foot of the operating table. A slight lumbar extension was applied to enhance the working space and improve ergonomic conditions (**Figure 1C**).

A video vignette is provided to illustrate the principal steps of the procedure (see https://www.youtube.com/watch?v=rPVN_svN_sc).

Preperitoneal Access and Trocar Placement

A 1.5 cm subxiphoid midline incision was made to achieve preperitoneal access. A Hasson trocar was inserted, allowing blunt dissection of the preperitoneal fatty rhomboid, facilitating the placement of two additional 5 mm trocars in both hypochondria (**Figure 1D**).

Pretransversalis Dissection

The pretransversalis space was accessed at the hypochondrium by incising the transversalis fascia, exposing the transversus

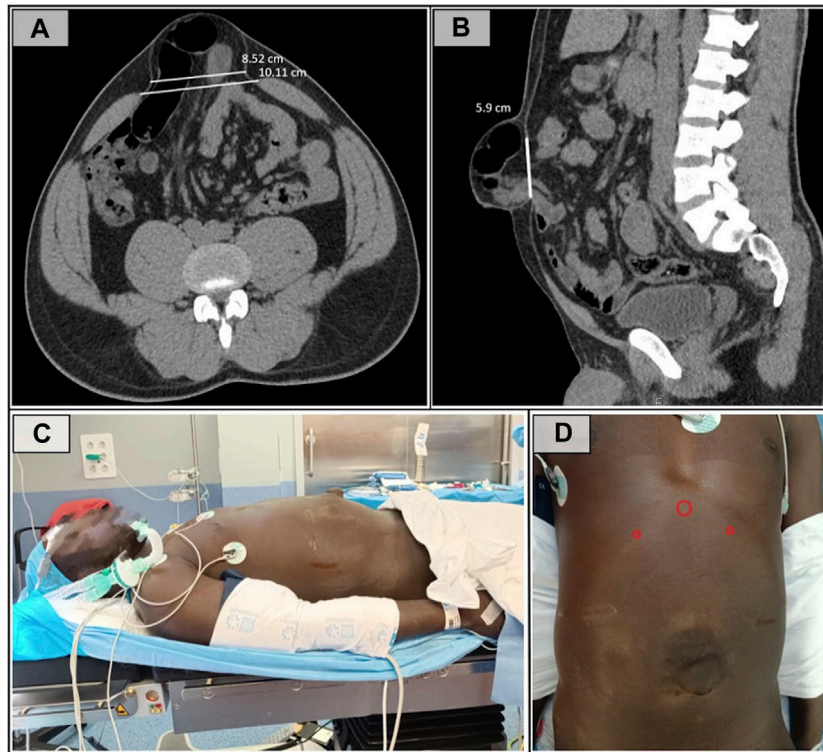


FIGURE 1 | (A) Preoperative CT cross-sectional image showing a defect with a transverse diameter of 8.5 cm. (B) Saggital CT section demonstrating the 6 cm length of the defect. (C) Patient in the supine position with arms adducted. (D) Trocar placement showing a 12 mm subxiphoid port and 5 mm trocars in both hypocondria.

abdominis muscle bilaterally (**Figure 2A**). Dissection was performed in a laterocaudal direction along the anatomical plane, following the natural insertion of the transversus abdominis into the posterior rectus sheath.

Central Preperitoneal Dissection and Hernia Sac Reduction

Only after accessing the pre-transversalis space on both sides, the preperitoneal midline dissection was performed. The hernia sac was only partially reduced, as a significant portion of it was strongly adherent to the skin. Thus, part of the sac was excised and left within the subcutaneous tissue.

After this maneuver, dissection was extended to the retropubic and retroinguinal spaces until the pubic symphysis was visualized (**Figure 2B**).

Midline Reconstruction

Hernia defect closure was performed using a fascial traction system (Ansabere[®], Assut[®]) due to the significant tension encountered during primary closure, which led to rupture of the suture lines. Six transfascial sutures (Assufile[®], Assut Europe[®]) were placed on each side along the medial border of the rectus muscles, exteriorized through the skin, and anchored to the traction system. This novel device consists of a fixed structure that is securely attached to the operating table, onto which two adjustable mechanisms are

mounted. These allow repositioning to modify the direction of traction according to the patient's needs. It also enables the application of progressive traction through the anchored sutures exteriorized through the patient's skin. The first phase of vertical traction was initiated (**Figure 3A**), adjusted to the defect size, aiming to elongate the aponeurotic tissue helped by the synergistic effect of botulinum toxin. During the 15 min of vertical traction, peritoneal gaps caused during the dissection were closed.

Subsequently, a second phase of horizontal traction (**Figure 3B**) was applied immediately prior to the midline reconstruction (hernia defect closure and diastasis plication), and stopped after its completion. This horizontal traction was not sustained for a defined period, but rather employed exclusively as an intraoperative adjunct to facilitate midline closure. Midline reconstruction was performed using a slowly absorbable sized 1 barbed suture with a 37 mm needle (Filbloc[®], Assut Europe[®]), as it allowed both midline closure and plication of the hernia sac, thereby reducing the risk of postoperative seroma (**Figure 3C**).

Prosthetic Repair

Finally, a 30 cm × 15 cm (area of 353,43 cm²) medium-density polypropylene mesh (Assumesh[®], Assut Europe[®]) was placed in the preperitoneal/pretransversalis space, without fixation (**Figure 3D**).

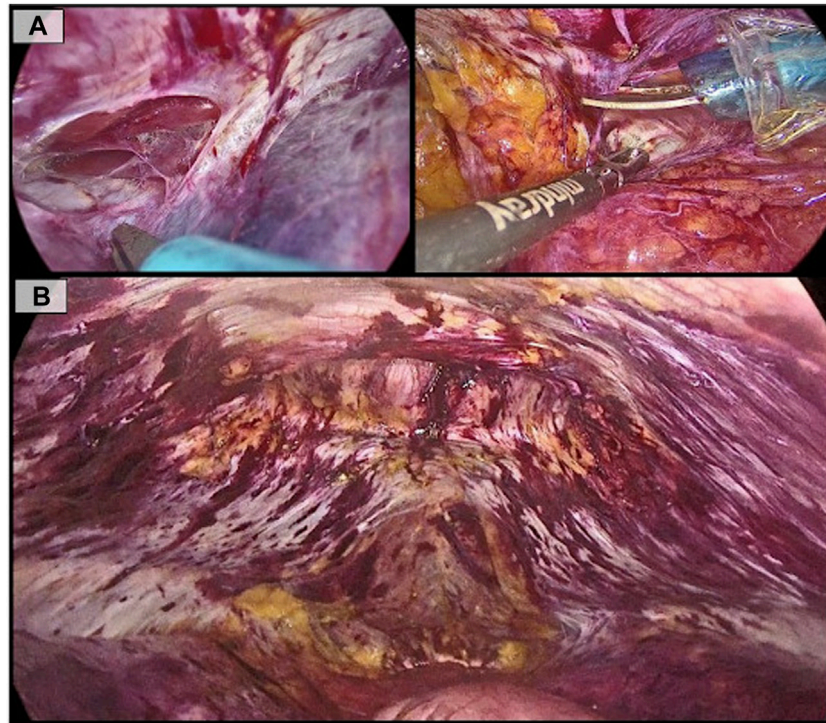


FIGURE 2 | (A): Pre-transversalis access in the left hypochondrium, showing the transversus muscle body. On the contralateral side, division of the transversalis fascia in the right hypochondrium; **(B):** Final view of the dissected space, showing the hernia defect at the top and both posterior rectus sheaths preserved.

RESULTS

Early postoperative course was favorable, as the patient exhibited proper oral tolerance, low levels of pain and early mobilization. The patient was discharged the first day after surgery without complications.

At 1 month postoperatively, the patient developed a 6 cm seroma without other signs of complications (**Figure 4A**). It was managed conservatively and no other incidents were recorded.

After 3 months of follow-up, the patient achieved full functional recovery, with no objective recurrence, no pain during physical activity and a highly satisfactory cosmetic outcome (**Figures 4B, C**).

DISCUSSION

Congenital umbilical hernias appeared due to the lack of obliteration of the umbilical duct, which lead to an incomplete closure of the abdominal wall. They are usually detected and subsequently corrected in the first years of life, but in the absence of proper treatment they can grow over time and reach large sizes, like in the present case [16]. Therefore, its management in adulthood can be challenging, even though general surgical principles of abdominal wall repair can be applied.

The main point to increase the effectiveness of any hernia repair is the primary fascial closure combined with a prosthetic

reinforcement in a posterior plane [17]. The first can be difficult or even impossible to achieve in case of large defects without performing an anterior or posterior component separation, an effective procedure that, nevertheless, adds significant morbidity [18]. On the other hand, the preperitoneal space has always been the best theoretical plane to place the mesh but the less used through history in midline medium-to-large hernias, being the Rives-Stoppa +/- TAR the gold standard in these cases [17, 19]. Thus, the reach of a complete fascial closure with a posterior mesh reinforcement seems to be the goal to reach.

The search for this ideal technique amidst the ongoing development of minimally invasive surgery has led to the development of the PeTEP. The sole section of the transversalis fascia allows for a complete functional and structural preservation, overcoming the disadvantages of the eTEP [20]. Moreover, the mesh placement in the preperitoneal/pretransversalis plane makes profitable use of the intraperitoneal pressure. Also, the prosthesis can be of great size, as the only dissection limit is the lumbar spine. We chose this technique due to the patient's youth, its physically demanding profession and the size of the defect. We use a cranial approach, as described by Munoz-Rodriguez et al. for the hernia location and the easier entry to the dissection plane it enables, especially when compared to the suprapubic access [21].

Nonetheless, the dissection of the pre-transversalis space does not allow for a greater approximation of the midline, which

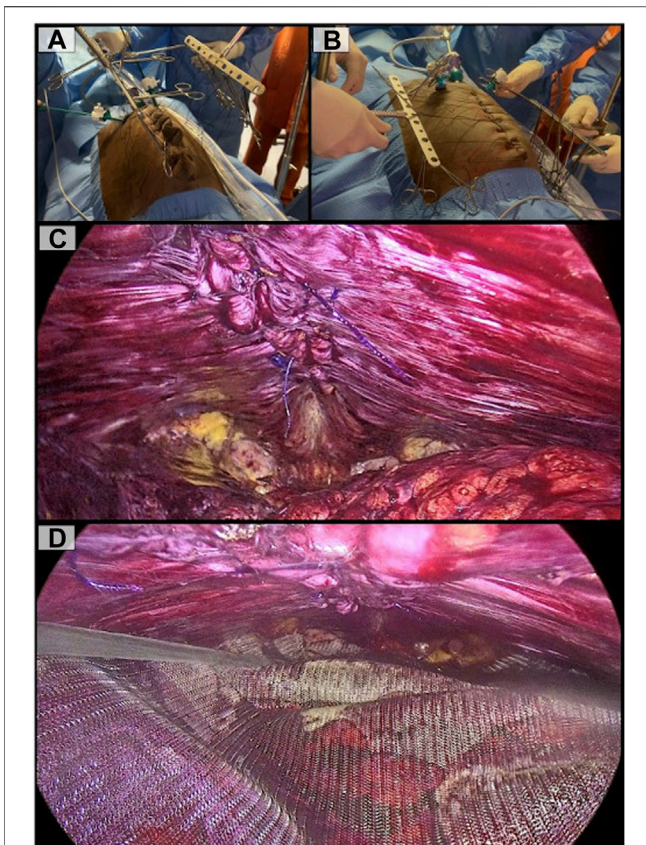


FIGURE 3 | (A): Vertical traction phase aimed at reducing closure tension; **(B):** Horizontal traction to assess midline reconstruction; **(C):** Complete plication of the linea alba is performed, closing the defect and restoring normal anatomy; **(D):** Reinforcement polypropylene mesh is placed in the preperitoneal space.

constitutes the main limitation of this technique and explains why only small-defect PeTEP series have been reported to date [8, 9, 21, 22]. In our specific case, we decided to use a combination of BTA injection and IFT to solve this issue.

BTA prehabilitation could be considered nearly a standard for EHS W3 hernias up to now [23]. However, its great utility in avoiding component separation is expanding its use to smaller defects. BTA injection causes a relaxation and consequent elongation of the three muscle layers of the abdominal wall, thus reducing the horizontal hernia diameter in approximately 4.2 cm, as shown previously by Elstner et al. [24]. This procedure significantly aids in achieving primary fascial closure in large defects, thereby simplifying their treatment.

Even though BTA prehabilitation could have been enough in this case, we decide to combine it with IFT. The hernia size defect, our intention to avoid any component separation and the lack of evidence about the use of botulinum toxin prehabilitation alone in a PeTEP repair leads us to this decision. Also, the excellent clinical results presented by Köckerling with the combination of these two methods provided us the necessary evidence to apply it in this case [25].

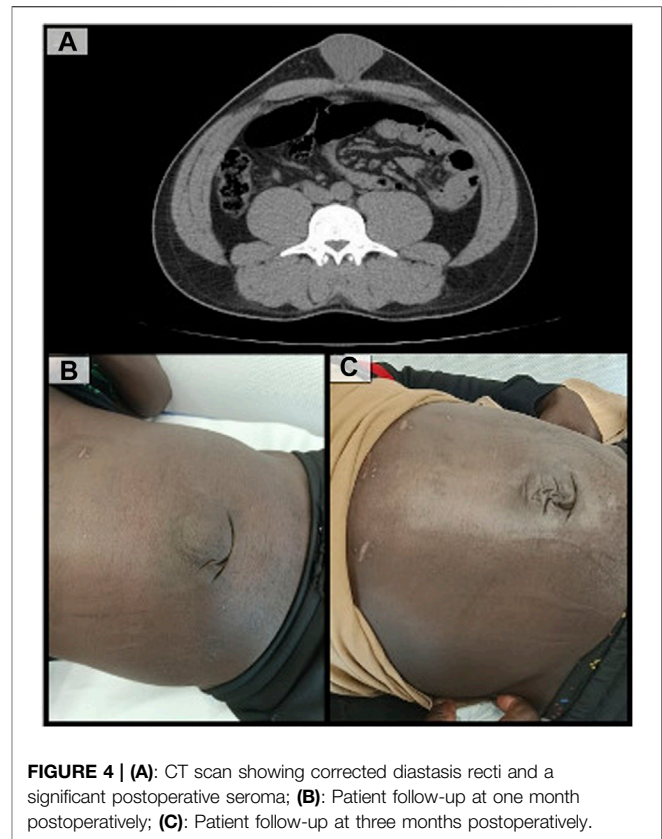


FIGURE 4 | (A): CT scan showing corrected diastasis recti and a significant postoperative seroma; **(B):** Patient follow-up at one month postoperatively; **(C):** Patient follow-up at three months postoperatively.

IFT is an easy-to-perform and effective technique. No significant complications specific to the technique or device have been reported to date [11, 25]. It can be combined with BTA, CST, and PPP techniques. It is essential to recognize that no single technique can be universally applied to all hernias. Tailoring is key. Each case must be evaluated individually to determine the most suitable approach, utilizing one or a combination of the aforementioned techniques to optimize patient outcomes.

In this specific patient, we put the scope in avoiding any disruption of the musculoaponeurotic complex, which constitutes the main strength of PeTEP. Nevertheless, the use of BTA plus IFT was necessary to achieve the closure, as the application of this technique in ≥ 8 cm defects is challenging and not proven yet, and is its main limitation at the present moment. ETEP + TAR and PeTEP with endoscopic anterior component separation (eACS) were also considered but both were dismissed to avoid the risk of postoperative bulging and a possible decrease in the functionality of the abdominal wall [20, 26].

A 6 cm seroma, defined as type II according to the Morales-Conde classification, was the only complication recorded [27]. Given the size of the hernia sac and its incomplete reduction, this outcome was anticipated by the team. Nevertheless, just a medium, not limiting discomfort during the usual physical activity was referred by the patient during the first month, and spontaneous resolution was achieved shortly after the first clinical review.

The main limitation of this case report, aside from the inherent methodological ones, is the 3 month follow-up period. Thus, this single result cannot be generalized and further investigation is required to establish the long-term outcome and clearly define the indications of this novel surgical method. Also, it is essential to understand that each case has specific characteristics, and no single technique is applicable to all hernias. The scope of abdominal wall surgery, encompassing the preoperative, intraoperative, and postoperative stages, offers surgeons a vast array of options. Consequently, tailoring approaches constitutes the cornerstone of both the present and future of hernia treatment.

CONCLUSION

As shown in this report, the preperitoneal approach can be used not only to repair W1-2 hernias, but also in case of larger defects. Moreover, therapeutic tools as BTA prehabilitation and intraoperative fascial traction can be associated in order to optimize postoperative results. The use of this combined approach in selected cases could enable the treatment of large defects while preserving the myofascial complex of the abdominal wall, leading to improved functional outcomes and faster recovery.

Nevertheless, further investigation is essential to determine the long-term effectiveness and benefits of both PeTEP repair as well as intraoperative fascial traction.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/Supplementary Material, further inquiries can be directed to the corresponding author.

ETHICS STATEMENT

Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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AUTHOR CONTRIBUTIONS

CB-R coordinated the overall process. JG-Q edited the video file and images, while JG-Q, AE-A, RS-O, and CB-R collaborated in writing the manuscript. All authors contributed to the review of the manuscript. All authors contributed to the article and approved the submitted version.

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Preoperative Botulinum Toxin for Complex Diaphragmatic Paralysis: A Case Series

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Introduction: The management of giant diaphragmatic paralysis remains a significant surgical challenge, frequently associated with high rates of recurrence and the risk of developing abdominal compartment syndrome. While the use of Botulinum Toxin Type A (BTX- A) as an adjuvant therapy has been established in complex ventral hernia repair, its application in diaphragmatic paralysis is novel and sparsely documented. This study aims to present our institutional experience with BTX-A as a prehabilitation strategy in patients with complex diaphragmatic paralysis and to evaluate short- and long-term outcomes.

Materials and Methods: Three patients with complex diaphragmatic paralysis underwent preoperative administration as part of a prehabilitation protocol prior to surgical repair. Loss of domain (LD) was calculated using the Sabbagh formula. According to Sabbagh, LD is defined as the ratio of herniated volume to total peritoneal volume ($LD = HV/TPV$), with a loss $>20\%$ being considered significant. All patients received a standardized BTX-A administration protocol consisting of ultrasound-guided injection of 500 units of botulinum toxin type A, administered at six sites following the technique described by Smoot, with three injection points on each side targeting the internal oblique muscle 4 weeks before surgery.

Results: Preoperative administration of Botulinum Toxin Type A (BTX-A) was safe in all three patients, with no postoperative complications or development of abdominal compartment syndrome, which was monitored through continuous intra-abdominal pressure measurements during the hospital stay (short-term outcomes). Six months postoperatively, all patients demonstrated significant improvement in respiratory function, assessed by standard pulmonary function tests, and reported improved quality of life, including relief from dyspnoea and enhanced daily functioning. At twelve months, two patients remained asymptomatic, with no clinical or radiological evidence of recurrence (long-term outcomes). Overall, preoperative BTX-A was associated with both short-term safety and sustained long-term functional benefits in this series.

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Conclusion: Preoperative BTX-A appears to be safe and well-tolerated in complex diaphragmatic paralysis. The results suggest that BTX-A may reduce complications, improve functional outcomes, enhance respiratory function, and increase quality of life, with effects maintained for at least 1 year in most patients.

Keywords: botulinum toxin type A, compartment syndrome, diaphragmatic paralysis, prehabilitation, surgical treatment

INTRODUCTION

Diaphragmatic eventration is a congenital or acquired condition characterized by abnormal elevation of the diaphragm due to muscular or phrenic nerve dysfunction while maintaining its continuity and attachment to the costal margins [1]. Phrenic paralysis, often secondary to nerve injury, thoracic or cervical surgery, trauma, or neurological disease, represents the most frequent functional disorder of the diaphragm [2, 3]. Symptomatic patients may present with dyspnoea, orthopnoea, hypoxemia, and nonspecific gastrointestinal complaints.

Surgical treatment, particularly diaphragmatic plication, remains the mainstay of therapy for symptomatic patients, aiming to improve respiratory function and relieve dyspnoea [1, 2]. However, giant or complex diaphragmatic paralysis poses significant challenges, with high recurrence rates and risk of abdominal compartment syndrome [4].

Botulinum Toxin Type A (BTX-A) has been increasingly used in complex ventral hernia repair. By inducing temporary flaccid paralysis of abdominal wall muscles, BTX-A facilitates fascial closure and reduces tension [5–12]. Its application in diaphragmatic paralysis remains scarcely documented. This study presents our experience using BTX-A as a prehabilitation strategy prior to diaphragmatic plication.

CASE REPORT

Case 1

A 44-year-old man (body mass index 39 kg/m²) was evaluated for chest pain and dyspnoea with a two-year history. After assessment by the pulmonology, cardiology, and neurology departments, a diagnosis of idiopathic left diaphragmatic relaxation was made, and the patient was referred for thoracic surgery. His medical history was notable for suspected obstructive sleep apnoea syndrome (OSAS), managed with non-invasive mechanical ventilation (NIV). Physical examination was unremarkable.

A neurophysiological study and thoracic computed tomography scan (**Figure 1**) revealed a serious elevation of the left hemidiaphragm and herniation of abdominal contents into the thorax, including stomach, spleen, and colon splenic flexure, occupying approximately 50% of the left hemithorax and causing right mediastinal shift, with 20% of abdominal viscera displaced into the thorax according to Sabag's formula [13]. Preoperative preparation focused on prehabilitation with respiratory physiotherapy.

Given the size of the defect, adjuvant therapy was performed with botulinum toxin injection following the Smoot technique [14], without complications.

Four weeks later, a left diaphragmatic plication was performed via posterolateral thoracotomy, using non-absorbable monofilament barbed sutures and reinforced with a Gore-Tex® mesh. Intraoperative findings confirmed significant diaphragmatic laxity, with the dome of the diaphragm reaching the level of the bronchial carina. A pleural drain and an epidural catheter were placed for postoperative management.

The patient was extubated in the operating room and transferred to the postoperative recovery unit, where he remained for 4 days, hemodynamically stable, eupnoeic, and without need for supplemental oxygen. Intra-abdominal pressure was monitored, with values of 10 mmHg preoperatively, 11 mmHg at the end of surgery, and less than 15 mmHg over the subsequent days. The epidural catheter was removed at 72 h, the pleural drain removed on postoperative day 5, and the patient was discharged on day 6.

At the six-month follow-up, the patient reported significant improvement in quality of life, including the ability to tolerate the supine position, which had previously been intolerable. He demonstrated good respiratory function, and a follow-up chest radiograph (**Figure 2**) showed no elevation of the left hemidiaphragm. At twelve months, the patient remained asymptomatic and recurrence-free.

Case 2

A 63-year-old woman (body mass index 35 kg/m²) was evaluated for dyspnoea and digestive symptoms of 2 years' duration. After being evaluated by the pulmonology department, idiopathic left diaphragmatic relaxation was diagnosed, and the patient was referred for thoracic surgery. Her medical history included being a former smoker for 20 years, and she was diagnosed with severe OSAHS (obstructive sleep apnoea-hypopnea syndrome). The physical examination was normal.

A chest CT (**Figure 3**) scan revealed a severe elevation of the left hemidiaphragm and herniation of abdominal contents into the thorax, including stomach, spleen, and colon splenic flexure, with a percentage of herniated viscera of 23% according to Sabag's formula [13], which occupied more than half of the left hemithorax. It is associated with compressive atelectasis and a moderate contralateral mediastinal shift. No image of a diaphragmatic defect was observed. Preoperative preparation focused on prehabilitation with chest physiotherapy. Given the size of the defect, adjuvant therapy was performed with botulinum toxin injection following the Smoot technique [14], without complications.

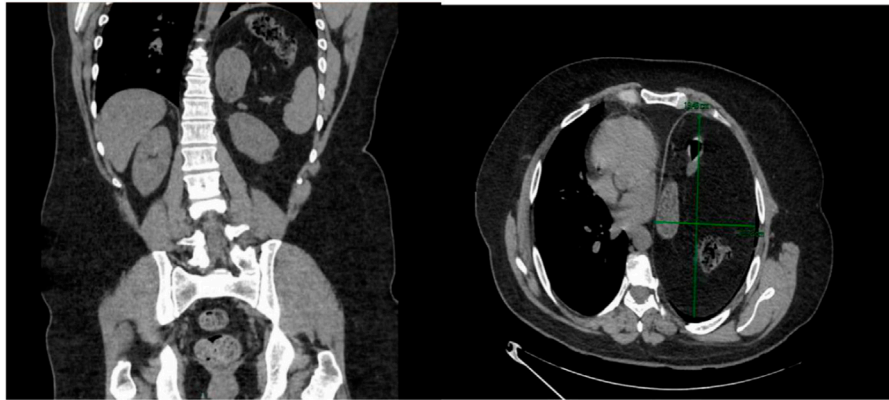


FIGURE 1 | Computed tomography scan (coronal and transverse section). Significant elevation of the left hemidiaphragm and infradiaphragmatic abdominal contents, including the stomach, spleen, and splenic flexure of the colon and deviation of the mediastinum to the right.

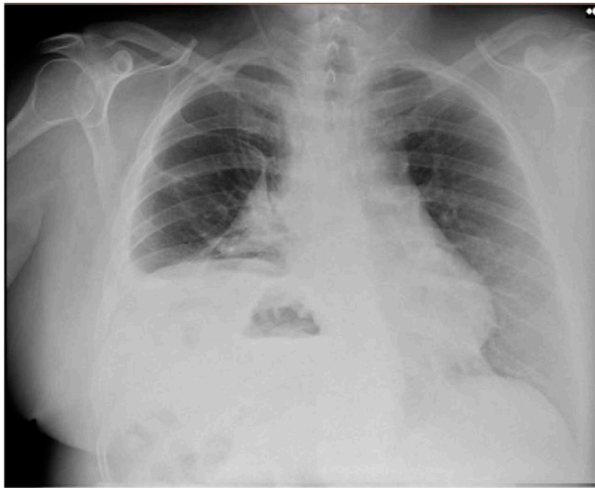


FIGURE 2 | Postoperative Chest X-ray showed no elevation of the left hemidiaphragm.

Four weeks later, a left diaphragmatic plication was performed via posterolateral thoracotomy, using nonabsorbable monofilament barbed sutures reinforced with Gore-Tex® mesh. Intraoperative findings confirmed significant diaphragmatic laxity, with the dome of the diaphragm reaching the main carina. A pleural drain and an epidural catheter were placed for postoperative management.

The patient was extubated in the operating room and transferred to the Postoperative Recovery Unit, where she remained hemodynamically stable, eupnoeic, and without the need for supplemental oxygen for 2 days. Intra-abdominal pressure was monitored, with values of 12 mmHg preoperatively, 12 mmHg at the end of surgery, and less than 15 mmHg in the following days. The epidural catheter was removed 72 h later, the pleural drain was removed on the fourth postoperative day, and the patient was discharged on the fifth day.

At a six-month follow-up, the patient reported a significant improvement in her quality of life, with improved respiratory function and digestive symptoms. At 12 months, the patient remained asymptomatic and without recurrence. The follow-up postoperative X-ray showing decreased—but not complete resolution of—left hemidiaphragm elevation compared to the preoperative state, which did not show an elevated diaphragm (Figure 4).

Case 3

A 45-year-old man (body mass index 30 kg/m²) was evaluated for mild haemoptysis, moderate exertional dyspnoea, episodes of central chest tightness, and exercise intolerance. After being evaluated by the pulmonology department, he was diagnosed with idiopathic left diaphragmatic relaxation and referred for thoracic surgery. His medical history included being a former smoker for 2 months, asthmatic bronchitis in childhood, and admission to the emergency department in November 2022 for extensive deep vein thrombosis in the right lower extremity and acute pulmonary thromboembolism in the inferior lobar pulmonary artery and left basal segmental pulmonary arteries. Physical examination was normal.

A chest CT scan showed left lung volume loss due to a large diaphragmatic elevation with intra-abdominal visceral contents in the chest and a right-sided mediastinal shift (Supplementary Figure 1). Preoperative preparation focused on prehabilitation with respiratory physiotherapy. Given the size of the defect, adjuvant therapy was performed with botulinum toxin injection following the Smoot technique [14], without complications.

Four weeks later, diaphragmatic plication was performed with a non-absorbable barbed suture without the need for reinforcing mesh using video-assisted thoracoscopy. A pleural drain and an epidural catheter were placed for pain control. The patient was extubated in the operating room and transferred to the postoperative recovery unit, where he remained for 24 h, hemodynamically stable, eupnoeic, and without the need for supplemental oxygen. Intra-abdominal pressure was monitored, with values of 13 mmHg at the end of surgery.

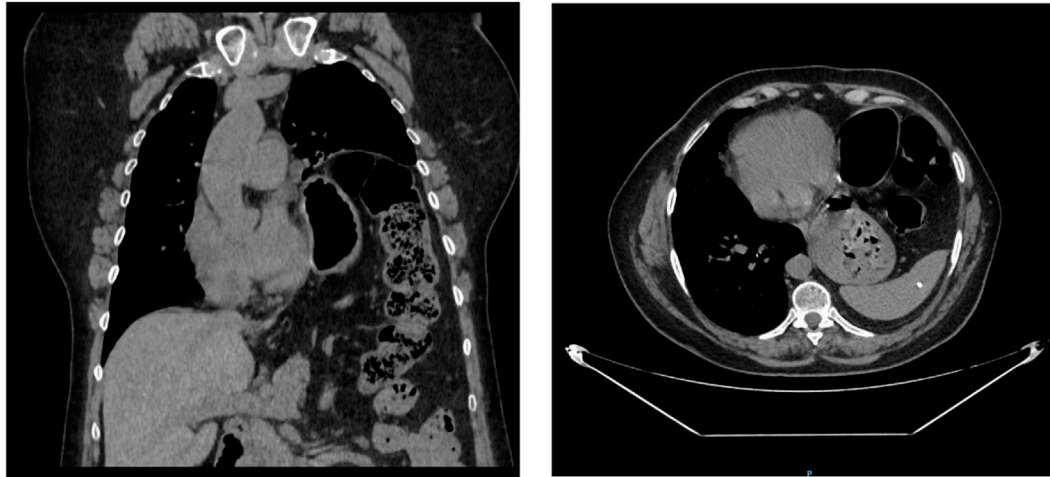


FIGURE 3 | Computed tomography (coronal and transverse section) marked elevation of the left hemidiaphragm and herniation of abdominal contents into the thoracic cavity, including the stomach, spleen, and splenic flexure of the colon with a moderate contralateral mediastinal shift.



FIGURE 4 | Postoperative image showing decreased—but not complete resolution of—left hemidiaphragm elevation compared to the preoperative state.

The epidural catheter and pleural drain were removed 48 h later, and the patient was discharged on the third day.

At a six-month follow-up, respiratory function improved without dyspnoea or recurrence (**Supplementary Figure 2**).

DISCUSSION

Diaphragmatic paralysis and eventration represent a complex surgical challenge, and several studies have evaluated diaphragmatic plication as a standard intervention.

Reviews and series in adults and children have consistently shown improvements in respiratory function, including increased forced vital capacity and reduced dyspnoea, as well as relief of

symptoms such as orthopnoea and exercise intolerance following plication [1–3], [15]. However, complications such as abdominal compartment syndrome, although rare, have been reported in cases of diaphragmatic paralysis or large diaphragmatic eventrations [4], highlighting the need for careful perioperative planning. In parallel, the use of botulinum toxin type A as a preoperative adjunct has been extensively studied in the context of large ventral hernias and abdominal wall reconstruction. Multiple studies and systematic reviews have demonstrated that preoperative botulinum toxin A increases abdominal wall compliance, reduces tension during closure, facilitates the reduction of herniated contents, and, in some series, decreases postoperative complications such as seroma, infection, or hernia recurrence [5–12]. Specifically, volumetric analyses and clinical

measurements have shown improved abdominal cavity accommodation and decreased intra-abdominal pressure after toxin administration [6, 9].

Evidence specifically addressing the use of botulinum toxin A prior to diaphragmatic plication is extremely limited. In isolated reports, such as the use in Morgagni hernias [16], botulinum toxin A facilitated abdominal wall relaxation, allowing for tension-free closure and reducing the risk of postoperative complications. Similarly, in giant hiatal hernias with loss of domain [17, 18], preoperative toxin injection improved diaphragmatic mobility and abdominal cavity accommodation, contributing to successful surgical reduction and repair without major adverse events. These findings suggest potential benefits, but the evidence is limited to case reports and small series, leaving a significant gap in systematic data for complex diaphragmatic eventrations.

To our knowledge, no previous study has systematically described the use of botulinum toxin type A as a prehabilitation strategy prior to diaphragmatic plication. Our series of three patients provides new evidence supporting the safety and feasibility of this approach in complex diaphragmatic paralysis with large eventrations. In all cases, preoperative botulinum toxin administration facilitated abdominal wall relaxation, allowed for tension-free plication, and was associated with favourable postoperative outcomes, including the absence of abdominal compartment syndrome and sustained clinical and radiological stability at 12 months in two patients. These findings suggest that the benefits previously observed in abdominal wall reconstruction may be extended to thoracic surgery, offering a novel strategy to optimize surgical conditions and patient outcomes in this underexplored field.

When comparing these findings with the present series, there is consistency in the effectiveness of botulinum toxin type A in improving preoperative abdominal and thoracic dynamics, reducing postoperative risks, and enhancing patient quality of life. However, it is important to note that most existing studies consist of case reports or small series, which limits the generalizability of their findings. Additionally, it would be of interest to assess the quantitative impact of botulinum toxin type A on intra-abdominal pressure, postoperative respiratory function, and objective markers of quality of life, which would enable the establishment of stronger and standardized recommendations for its use in thoracic surgery.

The present study has some limitations, such as its retrospective nature, the small number of patients included, short follow-up, and lack of a comparison group. However, this series contributes to the growth of evidence supporting the use of botulinum toxin type A as an adjunctive tool in prehabilitation before complex diaphragmatic eventrations repair.

In conclusion, although this is a novel and still underexplored indication, the preoperative administration of botulinum toxin type A as part of a prehabilitation protocol in patients with complex diaphragmatic paralysis appears to be a safe and effective strategy and may represent a significant advancement in the management of these conditions. Larger prospective studies are needed to establish standardized protocols and to validate these

findings in broader populations with long-term follow-up in order to draw definitive conclusions.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

For the purpose of this study and for the study design (case report) ethical approval was not required. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

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All authors participated in the design, interpretation of the studies and analysis of the data and review of the manuscript: ZV, JN, LS, and SM-C. All authors contributed to the article and approved the submitted version.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontierspartnerships.org/articles/10.3389/jaws.2025.14476/full#supplementary-material>

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Preoperative Botulinum Toxin A and Its Impact on Pulmonary Function in Giant Abdominal Wall Hernias: A Prospective Spirometry-Based Analysis

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Background: Botulinum toxin type A has become an increasingly used tool in the preoperative management of giant abdominal wall hernias. Its primary objective is to “downstage” the hernia by inducing temporary paralysis of the lateral abdominal wall muscles, thereby increasing their compliance and enabling safer fascial closure. While the muscular and anatomical benefits of this approach are well documented, the potential effects on pulmonary function remain poorly studied, despite the involvement of the targeted muscles in the process of breathing.

Objective: This study aimed to evaluate the impact of botulinum toxin type A on respiratory system function, using spirometry to assess whether any observed changes reflect true improvement, mechanical compensation, or potential impairment.

Methods: This prospective, observational study included 37 patients with large abdominal wall hernias and a Loss of Domain component. All patients received 300 units of botulinum toxin type A injected bilaterally into the external, internal oblique, and transversus abdominis muscles under ultrasound guidance. Spirometry was performed before the injection and again on the day of surgery. Evaluated parameters included forced vital capacity, forced expiratory volume in one second, the ratio of forced expiratory volume to forced vital capacity, peak expiratory flow, maximum mid-expiratory flow, maximal expiratory flow at 75, 50, and 25 percent of forced vital capacity, forced inspiratory vital capacity. Results were analyzed using paired statistical tests with a significance threshold of $p < 0.05$.

Results: No statistically significant changes were observed in forced vital capacity or forced expiratory volume in one second. However, statistically significant increases were recorded in maximum mid-expiratory flow and maximal expiratory flow at 50 percent of lung volume. Peak expiratory flow showed a trend toward improvement but did not reach statistical significance. These changes appear to reflect altered expiratory dynamics due to

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increased diaphragmatic excursion, rather than improved ventilation. Forced inspiratory vital capacity decreased slightly. Only two patients reported subjective changes in breathing.

Conclusion: Botulinum toxin type A does not impair core lung volumes but induces mechanical changes that may affect airflow velocity. Standard spirometry may not fully reflect these dynamics, and further investigation is warranted to better understand respiratory outcomes in this patient group.

Keywords: botulinum toxin A, abdominal wall hernias, pulmonary function, spirometry, abdominal wall repair

INTRODUCTION

The primary goal of optimal midline hernia repair is to achieve complete defect closure, restore the linea alba, and approximate the rectus muscles. While this represents the ideal outcome, it is not always feasible, especially in cases of giant hernias with a Loss of Domain component. In such situations, alternative techniques must be employed to bring us closer to the desired goal, often requiring certain compromises [1].

Avoiding the need for “bridging” mesh repair relies on both preoperative and intraoperative strategies. Intraoperative approaches primarily include “component separation” techniques, but newer tools, such as the Fasciotens® (GmbH®, Germany) device, are also gaining popularity [2, 3].

Preoperative preparation has increasingly incorporated botulinum toxin type A (BTA) injections into the lateral abdominal muscles. This method aims to induce temporary paralysis of these muscles, enhancing their compliance and facilitating the approximation of fascial edges for defect closure. [4–6]. One of the key advantages of BTA over component separation techniques is the temporary nature of its effects—once the BTA wears off, normal muscle function is expected to return. Unlike Anterior or Posterior Component Separation, BTA application does not require the permanent division of muscle attachments, thereby reducing intraoperative trauma and minimizing postoperative complications such as hematomas, seromas, and necrosis of skin flaps [7–9]. Additionally, compared to progressive preoperative pneumoperitoneum, BTA injections have fewer reported adverse effects in the literature [10–12].

However, this does not imply that BTA use is entirely risk-free. Rather, there is a lack of comprehensive scientific data on its potential negative effects, particularly on the pulmonary system. Although BTA injections are generally regarded as a safe and simple procedure, occasional reports of severe adverse effects have emerged [13, 14].

Most importantly, in the light of above cited paper [13], it remains uncertain whether BTA is equally beneficial for all patients or if there exists a subgroup in which negative outcomes outweigh the positive effects. This question is particularly relevant in the context of the respiratory system, as the lateral abdominal muscles play an active role in breathing.

To address this concern, we designed an observational, prospective, two-center clinical study, assessing respiratory function via spirometry in patients undergoing abdominal wall reconstruction. The aim of this study was to evaluate the impact

of botulinum toxin type A on respiratory system function using spirometry.

MATERIALS AND METHODS

The study was conducted in two centers: Swissmed Hospital in Gdańsk and the Surgical Clinic in Lviv. The enrolled patients had giant abdominal hernias with a Loss of Domain component (inclusion and exclusion criteria are provided in **Table 1**).

All patients underwent spirometry testing on the day of BTA administration and again on the day of surgery. Preoperative BTA injections were administered 4–6 weeks before surgery. The study included 8 patients from Lviv and 29 from Gdańsk. In addition to standard demographic data, detailed information regarding comorbidities and hernia characteristics was collected. Demographic data were gathered prospectively at the time of patient enrolment. The most common comorbidities among the 37 enrolled patients included hypertension ($n = 21$), type II diabetes mellitus ($n = 8$), hypothyroidism ($n = 4$), atrial fibrillation ($n = 2$), chronic venous insufficiency ($n = 2$), gastroesophageal reflux disease ($n = 2$), asthma ($n = 1$), chronic obstructive pulmonary disease ($n = 1$), chronic pancreatitis ($n = 1$), and systemic lupus erythematosus ($n = 1$). Hernias were classified according to the European Hernia Society (EHS) criteria, with the most frequent types being M2–M4W3 ($n = 10$), M1–M4W3 ($n = 9$), and M2–M5W3 ($n = 5$). Additionally, three patients presented with parastomal hernias (two type III, one type IV), and one patient had a giant scrotal hernia with loss of domain. The mean transverse diameter of the hernia defects was 14.6 cm ($SD \pm 3.19$), reflecting the complexity and magnitude of abdominal wall impairment in this cohort (**Table 2**). The procedure was performed in an outpatient setting under ultrasound guidance to ensure accurate needle placement. Each patient received 300 units of BTA (Dysport®, IPSEN, Boulogne-Billancourt, France), with 150 units injected per side. During preparation for BTA administration, the lower edge of the last rib and the upper border of the iliac crest were marked on the skin. A line was drawn along the anterior axillary line, connecting these two points, and three evenly spaced injection sites were identified. A total of 300 units of BTA were diluted in 150 mL of 0.9% saline. The solution was then divided into six portions of 25 mL each. Under ultrasound guidance, the needle was inserted into the transverse abdominal muscle, where 8 mL of solution was administered.

TABLE 1 | Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Large abdominal hernia (at least W3 in the EHS classification), requiring additional preoperative techniques to prevent abdominal compartment syndrome (ACS) in the postoperative period	Refusal to participate in the study
Age >18 years	
Written consent to participate in the study	
Health status allowing the safe conduct of surgery	

TABLE 2 | Demographic characteristics of the study Population general information.

Demographic Variable	Value
Age (years)	58.81 ± 12.82
BMI (kg/m ²)	30.59 ± 4.14
Comorbidities	Hypertension – 21 Gastroesophageal reflux – 2 Diabetes Mellitus type II – 8 Chronic Venous Insufficiency – 2 Hypothyroidism – 4 Systemic Lupus – 1 Asthma – 1 Chronic Pancreatitis – 1 Atrial Fibrillation – 2 COPD – 1
Hernia Types (EHS Midline Hernia Classification and EHS Parastomal Hernia Classification)	M1-M5W3 – 4 M1-M4W3 – 9 M1-M3W3 – 1 M2-M4W3 – 10 M2-M5W3 – 5 Parastomal Hernia type III – 2 Parastomal Hernia type IV – 1 L2-L3W3 (left side) – 2 L2W3 (right side) – 1 M2-M3W3 + L3W3 (left side) – 1 Giant scrotal hernia (type S3, LOD) right side – 1
Mean Defect Size (transverse diameter, SD)	14.6 (3.19)
Average interval between spirometry tests (weeks)	6.26 ± 2.38
Sex (female)	26
Gdansk Clinic	29/37

Abbreviations: COPD, Chronic obstructive pulmonary disease; LOD, loss of domain; EHS, European Hernia Society.

The needle was then partially withdrawn, and another 8 mL was injected into the internal oblique muscle. Finally, after further withdrawal, the remaining portion of the dose was delivered into the external oblique muscle. This procedure was repeated at each designated injection site. The described method has been previously documented in the scientific literature [9].

All patients underwent pulmonary function testing using spirometry on the day of botulinum toxin type A (BTA) injection and again on the day of planned hernia repair surgery. Spirometry was performed in accordance with American Thoracic Society (ATS) and European Respiratory Society (ERS) standards using a portable spirometer (BTL-08 Spiro Pro, BTL Industries Limited, Great Britain). Each test was performed in a seated position, with a nose clip, and

following standard instructions for maximal inspiration and expiration. At least three acceptable maneuvers were required for each test, with the best result used for further analysis.

The spirometry parameters evaluated included:

Forced Vital Capacity (FVC) – the total volume of air that can be forcibly exhaled after full inspiration;
 Forced Expiratory Volume in 1 Second (FEV1) – the volume of air expelled in the first second of the FVC maneuver;
 FEV1/FVC ratio—expressed as a percentage, assessing airflow limitation;
 Peak Expiratory Flow (PEF) – the maximum flow achieved during forced expiration;
 Maximum Mid-Expiratory Flow (MMEF) – the average flow rate during the middle half of the FVC maneuver;
 Maximal Expiratory Flow at 75%, 50%, and 25% of FVC (MEF75, MEF50, MEF25) – representing flow rates at different lung volumes;
 Forced Inspiratory Vital Capacity (FIVC) – the total inspiratory capacity following a maximal expiration;
 AEX (Area Under the Expiratory Flow–Volume Curve) – a spirometric parameter calculated as the total area beneath the expiratory flow–volume curve. It integrates both flow and volume to provide a composite measure of expiratory performance, reflecting the overall effort and efficiency of expiration.

Additionally, patients were asked a qualitative question regarding perceived changes in respiratory status after BTA injections: “Did you observe or feel any changes in your breathing function or physical exertion capacity?”

The data were subjected to statistical analysis using paired t-tests to compare pre- and post-injection values. Statistical significance was set at $p < 0.05$. For each parameter, the following were reported: mean values, standard deviation, and full range (minimum–maximum). When applicable, confidence intervals (CI) and odds ratios (OR) were calculated. Statistical analysis was performed using STATISTICA (data analysis software system, StatSoft. Inc. 2014. version 12.0).

The study was registered on ClinicalTrials.gov under the number NCT06485440, and received ethical approval from the Bioethics Committee by Regional Medical Chamber in Gdańsk (KB - 42/23).

Analysis of Spirometric Parameters in the Context of Respiratory Mechanics

In order to interpret the spirometric parameters described following the analysis of the recorded results, it is necessary to first explain the physiological mechanisms of inspiration and expiration [15].

The Mechanism of Inspiration Is Illustrated in Figure 1

Inspiration is an active process dependent on the simultaneous contraction of the diaphragm—which increases the thoracic volume by pulling the lungs downward—and the accessory muscles, namely the intercostal muscles and the sternocleidomastoid, which expand the thoracic cavity by lifting the ribs laterally and superiorly. The position of the diaphragm at the start of inspiration is high; during

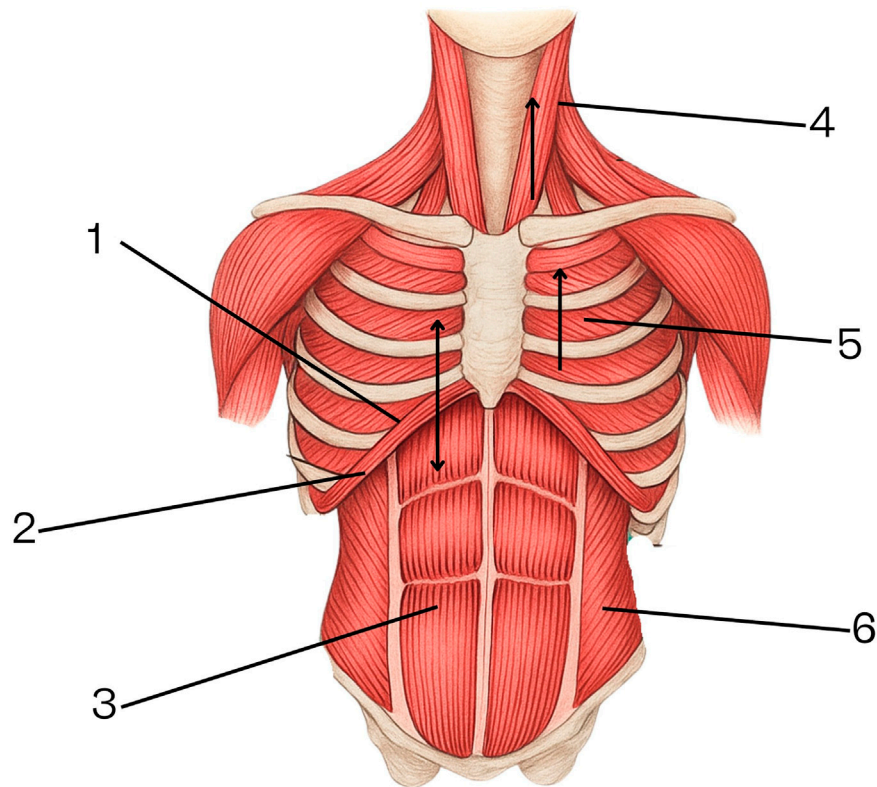


FIGURE 1 | Mechanism of inspiration. 1. Position of the diaphragm at the beginning of inspiration. 2. Position of the diaphragm at the end of inspiration. 3. Rectus abdominis muscles. 4. Sternocleidomastoid muscle. 5. Intercostal muscles (anterior and posterior). 6. Lateral abdominal wall muscles (transversus abdominis, internal oblique, external oblique).

contraction, it flattens its dome-shaped curve, shortens, and descends. The rectus abdominis and lateral abdominal wall muscles relax, allowing the abdominal contents to be displaced further into the abdominal cavity.

The Mechanism of Expiration Is Illustrated in Figure 2

Expiration is also an active process. It is important to note that the parameters assessed in spirometry do not reflect the mechanics of quiet breathing. During testing, the patient is asked to perform a maximal exhalation. The intercostal muscles and the sternocleidomastoid relax, allowing the thoracic cage to descend due to gravity, reversing the expansion that occurred during inspiration. The diaphragm also relaxes, becoming more compliant to external pressure—in this case, the increase in intra-abdominal pressure. This increase in intra-abdominal pressure is caused by the synchronous contraction of the rectus abdominis muscles (as the primary group) and the lateral abdominal muscles (as secondary contributors). This coordinated action pushes the diaphragm upward, reducing lung volume. The peak position of the diaphragm at the end of expiration is determined by the strength of this combined muscle contraction.

The potential impact of botulinum toxin administration—i.e., the temporary paralysis of the lateral abdominal muscle group—on the described mechanics of inspiration and expiration must be considered.

Based on the mechanisms outlined above, it can generally be stated that the administration of botulinum toxin does not affect the mechanics of inspiration. The key muscles responsible for this phase of breathing remain fully functional and are not subject to the effects of BTA.

In the expiratory phase, however, the following changes can be observed:

1. In the initial phase of expiration, the auxiliary activity of the lateral abdominal muscles is no longer present. Since these muscles serve only a supportive function, their inactivity does not significantly affect the FEV1 value. The observed increase of 1.95% was not statistically significant and may reflect natural variability or be caused by leak of lateral muscles activity as effect of BTA (rather than a physiologic effect of BTA).
2. The parameters PEF and MMEF show improvement (MMEF changes were statistically significant). This can be explained by the increased initial lung volume, which leads to a greater pressure gradient during the early and middle phases of expiration. This increased gradient originates from the greater expansion of the lungs at the beginning of inspiration (not expiration), which in turn results from passive stretching of the lateral abdominal muscles. This stretching enhances the downward pull on the diaphragm

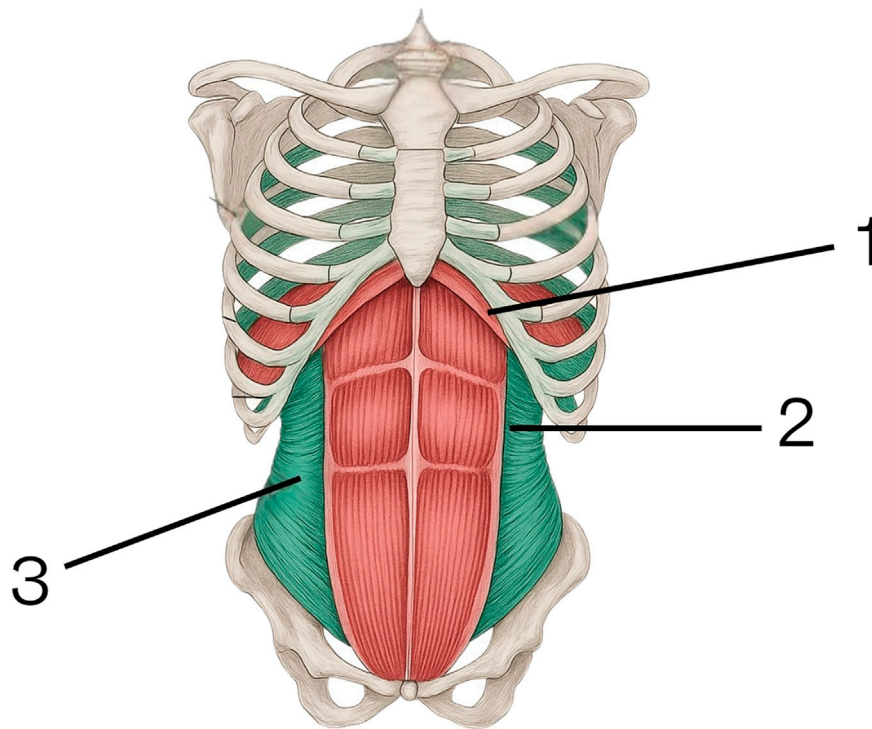


FIGURE 2 | Mechanism of expiration. 1. Diaphragm. 2. Rectus abdominis muscles. 3. Lateral abdominal muscle group.

during the initial phase of inspiration (see point 3 below). As a result, a larger volume of air can be expelled more easily in the early and middle phases of expiration using only the rectus abdominis muscles. In the described spirometry data, PEF and MMEF increased by approximately 10.5%. This moderate increase reflects changes in airflow velocity, not rather than a true improvement in overall respiratory efficiency (corelated with no changes in FEV).

3. The paralysis of the lateral muscle group eliminates the third phase of expiration. The abdominal viscera have considerable mass, and without active contraction of the lateral abdominal muscles, the compressive action of the rectus abdominis alone is insufficient to elevate the abdominal contents. As a result, the diaphragm settles in a lower position at the end of expiration. Although the residual lung volume increases, the amplitude of lung volume variation is reduced. The observed increase of 1.95% - which was not statistically significant and may reflect normal variability - suggests that the absence of lateral abdominal muscle activity has minimal impact on FEV1.

This process is illustrated in **Figure 3**.

RESULTS

The mean forced vital capacity (FVC) prior to injection was 5.51 L, with a range from 2.17 to 11.64 L. After BTA administration, the mean FVC was 5.54 L (range: 2.24–12.55),

with no statistically significant difference ($p = 0.7910$). Similarly, the forced expiratory volume in one second (FEV1) increased slightly from a mean of 4.61 L (range: 1.74–9.56) to 4.70 L (range: 2.14–10.90), which was also not statistically significant ($p = 0.2995$). The FEV1/FVC ratio improved modestly, increasing from 81.56% (range: 58.29–100.0) to 84.44% (range: 65.66–100.0), but this change did not reach statistical significance ($p = 0.0823$).

Peak expiratory flow (PEF), which represents the maximal speed of exhalation, increased from a mean value of 8.82 L per second (range: 4.25–15.49) before BTA injection to 9.75 L per second (range: 3.55–16.85) post-injection. This difference approached, but did not reach, statistical significance ($p = 0.0722$).

Statistically significant changes were observed in parameters associated with airflow in the smaller airways. The maximum mid-expiratory flow (MMEF) increased from a mean value of 5.02 L per second (range: 1.76–10.28) to 5.55 L per second (range: 1.98–13.38), with a p -value of 0.0168. A similar significant improvement was noted for MEF50, which rose from 5.29 L per second (range: 2.06–11.27) to 5.94 L per second (range: 2.27–15.61), with a p -value of 0.0234. For MEF75 and MEF25, the observed increases were not statistically significant.

The AEX parameter, measured in a subset of patients, increased from 30.75 (range: 4.86–92.96) to 35.31 (range: 7.02–132.77), with a statistically significant difference ($p = 0.0259$). All data are presented in **Table 3**. Subjective assessment was also collected. Patients were asked whether

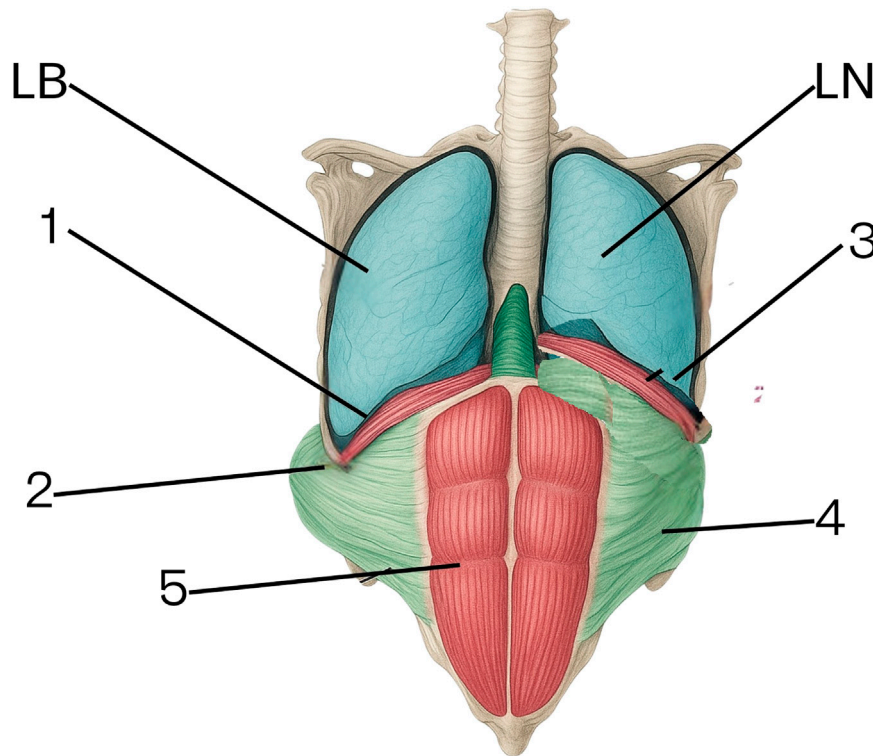


FIGURE 3 | Diagram of Diaphragm Positioning and Abdominal Mechanics Post-BTA Injection. 1. Diaphragm position at the end of expiration following botulinum toxin administration. 2. Passive stretching of the lateral abdominal wall creating more space for the abdominal viscera. 3. Diaphragm position at the end of inspiration under natural (non-BTA) conditions. 4. Lateral abdominal muscle position at the end of inspiration under natural (non-BTA) conditions. 5. Rectus abdominis muscles (function preserved in both conditions). 6. LB – representation of lung volume at the end of expiration post-BTA. 7. LN – representation of lung volume at the end of expiration without BTA.

they perceived any change in their breathing or physical exertion capacity between the two timepoints. The results of this self-assessment are presented as a supplementary in **Table 3** and were not subjected to statistical testing in this study phase. No adverse respiratory events were reported during the period between BTA administration and surgery. Spirometric testing was completed without complications in all participants.

In summary, BTA administration did not lead to a significant decline in primary lung function parameters such as FVC or FEV1. Improvements were observed in MEF50, MMEF, and AEX values, with statistically significant changes noted in some cases.

Conclusions From the Analysis

Physiological and Mechanical Interpretation of the Results

No significant changes were observed in FVC or FEV1 following the administration of botulinum toxin type A (BTA) to the lateral abdominal muscles. In fact, both parameters showed a slight, statistically non-significant increase. This suggests that the primary inspiratory muscles—such as the diaphragm, intercostals, and accessory muscles—remain unaffected by BTA, and that the rectus abdominis, the principal expiratory muscle, retains its functional integrity. As a result, the basic mechanics of respiration appear preserved and functionally compensated.

A marked increase was noted in PEF (+10.5%) and MMEF (+10.6%), which might be misinterpreted as improved airway function. However, the physiological explanation points elsewhere. BTA-induced relaxation of the lateral abdominal wall (external, internal oblique, and transversus abdominis) reduces intra-abdominal wall tension. This mechanical release allows for greater diaphragmatic descent during inspiration, thereby increasing the initial lung volume (preload) before expiration begins. Consequently, the pressure gradient at the onset of expiration is greater, enabling faster airflow—but not greater exhaled volume.

Thus, the observed increases in PEF and MMEF reflect elevated flow velocity, not improved gas exchange efficiency. They represent enhanced airflow dynamics, not ventilation capacity.

The MEF50 parameter—representing mid-volume expiratory flow—showed a statistically significant increase, supporting this model. It indicates improved flow at intermediate lung volumes, likely driven by the same preload-enhancing mechanism.

In contrast, MEF75 and MEF25 did not show significant changes. MEF75, representing early expiratory flow, remained stable, suggesting the initial phase of expiration is largely unaltered. MEF25, reflecting the terminal phase of expiration, also did not significantly increase—consistent with the hypothesis

TABLE 3 | Extended spirometry summary Table.

Parameter	Mean pre-botox (range)	Mean post-botox (range)	Mean difference	95% CI	p-value
FVC	5.51 (2.17–11.64)	5.54 (2.24–12.55)	0.03	–0.19 to 0.25	0.791
FEV1	4.61 (1.74–9.56)	4.70 (2.14–10.90)	0.09	–0.08 to 0.25	0.2995
FEV1/FVC	81.56 (58.29–100.0)	84.44 (65.66–100.0)	2.88	–0.39 to 6.16	0.0823
PEF	8.82 (4.25–15.49)	9.75 (3.55–16.85)	0.92	–0.09 to 1.94	0.0722
MMEF	5.02 (1.76–10.28)	5.55 (1.98–13.38)	0.53	0.10 to 0.96	0.0168
MEF75	5.97 (2.51–12.20)	6.13 (2.42–13.26)	0.16	–0.29 to 0.62	0.3535
MEF50	5.29 (2.06–11.27)	5.94 (2.27–15.61)	0.65	0.10 to 1.19	0.0234
MEF25	3.32 (1.23–8.92)	3.55 (0.87–10.05)	0.23	–0.20 to 0.66	0.2613
AEX	30.75 (4.86–92.96)	35.31 (7.02–132.77)	4.56	0.65 to 8.48	0.0259
FIVC	4.60 (1.77–8.59)	4.48 (0.65–8.39)	–0.12	–0.39 to 0.15	0.3677

Self-reported respiratory changes after botulinum toxin injection

Question

Answer: yes

Did you observe or feel any changes in your breathing function or physical exertion capacity?"

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that the third phase of expiration may be functionally diminished following paralysis of the lateral abdominal muscles. These muscles normally assist in compressing the abdominal contents and elevating the diaphragm in late expiration.

FIVC showed a slight, non-significant decrease (–0.12 L), possibly reflecting a compensatory reduction in inspiratory effort in some patients. However, this finding does not indicate impaired inspiratory function.

In summary, BTA administration does not negatively affect the inspiratory phase of breathing. However, it alters the mechanics of expiration—accelerating the second phase (MMEF) and potentially impairing the third phase (MEF25). As a result, expiratory flow velocity increases (PEF, MMEF, MEF50), but gas exchange efficiency may not improve—and may even decline—if the total exhaled volume is reduced.

Therefore, spirometric “improvements” may in fact mask mechanically driven limitations in breathing that are not detected through standard spirometry. This hypothesis should be the subject of further research, both in the early postoperative period (days 7–10) and in the long term, after the effects of botulinum toxin have fully subsided.

DISCUSSION

To date, most studies on the preoperative use of botulinum toxin type A (BTA) in patients undergoing complex abdominal wall reconstruction have focused on its effect on lateral muscle relaxation and its role in facilitating fascial closure. The primary endpoints in the literature are typically the extent of rectus muscle medialization and the reduced need for component separation techniques [5, 6, 9]. However, there is a clear gap in the analysis of BTA’s impact on respiratory physiology, particularly in the context of dynamic spirometric parameters.

Although rare reports have suggested possible respiratory compromise following BTA injections [13], no study to our knowledge has provided a systematic, spirometry-based assessment of how muscle paralysis might alter breathing mechanics in the perioperative period. The current study demonstrates that despite seemingly improved airflow metrics (PEF, MMEF), actual air exchange capacity - as reflected by FVC -

may decline due to loss of the third phase of expiration. These findings introduce a novel and clinically relevant perspective that has not been addressed in previous literature.

Given the lack of standardized spirometric protocols capable of detecting late expiratory phase deficits, our results highlight the need for refined diagnostic approaches when evaluating respiratory safety and functional outcomes following BTA use in abdominal wall reconstruction.

Two patients in the study had chronic respiratory conditions (one with asthma and one with COPD). Their spirometry results before and after BTA administration did not differ meaningfully from those of the broader cohort. No adverse respiratory outcomes were observed in these cases, but the small sample size precludes subgroup analysis.

SUMMARY AND GENERALISABILITY

The findings of this study suggest that the administration of botulinum toxin type A (BTA) is safe from a respiratory perspective, as it does not impair core spirometric parameters such as FVC or FEV1. In fact, both values showed slight, non-significant increases post-administration. Notable changes were observed in flow-related parameters including PEF, MMEF, and MEF50, some of which reached statistical significance. These alterations are best interpreted as mechanical effects—most likely stemming from greater diaphragmatic excursion during inspiration, enabled by reduced tension in the lateral abdominal wall. This mechanical shift likely results in increased lung preload and a steeper pressure gradient during the initial phase of expiration, thereby enhancing airflow velocity. However, these improvements in flow do not appear to correspond with improved gas exchange or total ventilatory output, as total exhaled volume remained unchanged. Moreover, the loss of active contraction in the lateral abdominal muscles may diminish the third phase of expiration, potentially affecting diaphragmatic positioning and long-term respiratory mechanics. These observations underscore the limitations of standard spirometry in capturing subtle or late-phase changes in respiratory dynamics. Future studies employing more advanced tools—such as body plethysmography or diaphragmatic imaging—are needed to better evaluate the true

physiological impact of BTA on respiratory function, particularly in the postoperative setting.

CONCLUSION

This study demonstrates that BTA, when used preoperatively in patients with large abdominal wall hernias, does not negatively impact core respiratory function as assessed by spirometry. While certain flow-related parameters showed statistically significant increases, these changes appear to reflect mechanical shifts rather than functional improvement or impairment. Spirometry alone may not be sufficient to capture the nuanced effects of BTA on breathing dynamics, particularly during the late expiratory phase. Further research using more advanced diagnostic tools is needed to fully understand the respiratory implications of BTA and to determine its role in guiding patient selection and perioperative care.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The studies involving humans were approved by Bioethics Committee by the Medical Chamber in Gdańsk, Poland. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

MS: Conceptualization of the study, supervision of clinical protocol, methodological guidance, manuscript drafting and critical revision. MZ: Data curation, formal analysis, statistical interpretation, manuscript writing, preparation of tables and

figures. IS and MP: Patient recruitment and follow-up, spirometry testing supervision, coordination of clinical data collection. OL: Patient enrollment and procedure execution in the Lviv cohort, clinical data acquisition. AP: Co-supervision of patient management, contribution to manuscript review and editing. ZU: Data collection in the Ukrainian center, assistance in BTA protocol execution and documentation. VK: Ethical oversight in the Lviv cohort, contribution to literature review and manuscript editing. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

GENERATIVE AI STATEMENT

The author(s) declare that no Generative AI was used in the creation of this manuscript.

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Patient Experience and Surgical Outcomes of Botulinum Toxin A Treatment in Complex Abdominal Wall Hernias: A Retrospective Analysis

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Background: Botulinum toxin A (BTA) is increasingly used for preoperative conditioning in patients with large or complex abdominal wall hernias. Injection into the lateral abdominal muscles 4–6 weeks before surgery induces temporary muscular relaxation and facilitates primary fascial closure, even in extensive defects (EHS W3), potentially reducing the need for component separation. While surgical outcomes are well documented, data on patient-reported experiences during the preoperative period remain limited. This retrospective study evaluated patient-reported symptoms between BTA injection and surgery and analyzed surgical results in this cohort.

Methods: Between 2018 and 2024, 50 patients with complex abdominal wall hernias received preoperative BTA treatment followed by surgical repair. Demographic and surgical data, as well as BTA-related complications, were analyzed descriptively. A retrospective questionnaire assessed subjective experiences from injection to surgery, focusing on pain, physical changes (e.g., abdominal contour, trunk stability), and functional impairments (e.g., breathing, urination, defecation).

Results: The study included 31 men and 19 women (mean age 63.5 years, BMI 28 kg/m²). The mean transverse defect width was 12.06 cm, with an average area of 170.24 cm². Thirty eight patients had W3 hernias according to EHS (≥ 10 cm), while BTA was also used in selected cases with smaller defects with complicating factors. No major BTA-related complications occurred; minor hematomas were observed. The mean interval between injection and surgery was 39 days. Primary fascial closure was achieved in all patients. Mesh reinforcement was used in all cases, most commonly in sublay position ($n = 47$). A transversus abdominis release was performed in 28 cases (52%), and anterior component separation in five. Twenty-two patients (44%) completed the questionnaire. Injection pain ranged from NRS 1–8, typically resolving within 1–3 days; three patients reported no pain. Eight noticed abdominal contour changes, and two reported altered trunk function. One patient experienced mild shortness of breath and another constipation; no urinary issues occurred.

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Conclusion: Preoperative BTA conditioning is a safe and effective adjunct for abdominal wall reconstruction in complex hernias. The treatment facilitates fascial closure, avoids major complications, and causes only minor, short-lived discomfort or functional limitations, maintaining overall quality of life in the preoperative phase.

Keywords: abdominal wall hernia, abdominal wall reconstruction, botulinum toxin A infiltration, patient reported outcome measures, preoperative conditioning

INTRODUCTION

Incisional hernias are common complications after abdominal surgery, with reported incidences of 10%–23% depending on follow-up duration [1–6]. Surgical repair of complex abdominal wall hernias (W3, ≥ 10 cm) remains challenging despite their recent definition by the European Hernia Society in 2024, as these procedures are technically demanding and associated with high morbidity and mortality, particularly when (anterior) component separation is required [6–9]. The primary aim of abdominal wall reconstruction is anatomical restoration with improvement of patients' quality of life. To facilitate tension-free closure in complex cases, preoperative strategies such as progressive pneumoperitoneum and chemical component separation using Botulinum toxin A (BTA) have gained increasing attention [10]. First described in 2009, BTA induces a temporary, reversible paralysis of the lateral abdominal wall muscles, allowing medial fascial advancement and potentially avoiding more invasive component separation techniques associated with higher complication rates [11–13].

The use of BTA for large incisional hernias is currently limited to individual therapeutic attempts (off-label use), as no standardized injection protocol has yet been established [14, 15]. Additionally, although no specific international protocol has been accepted, some consensus proposals have been reported [16].

Moreover, there are no systematic data on how patients experience BTA therapy or whether physical or functional impairments occur between injection and surgery.

With the increasing emphasis on patient-centered endpoints in abdominal wall reconstruction, patient-reported outcome data are particularly relevant in the context of preoperative BTA, as its effects persist throughout the interval between injection and surgery. Recently, the first international survey has provided initial data on treatment tolerance and symptom burden following BTA [17].

In this context, this study contributes to this growing field of research by not only evaluating the patient experience, including physical changes, but also examining the surgical outcomes in our patient cohort who underwent preoperative abdominal wall conditioning with BTA for large hernias.

MATERIALS AND METHODS

Between 2018 and 2024, a total of 50 patients with complex abdominal wall hernias underwent preoperative conditioning of the lateral abdominal muscles using BTA. Patients with

abdominal wall defects ≥ 8 cm in width were routinely treated with BTA as part of an individualized off-label treatment approach. Smaller defects complicated by additional risk factors according to the EHS-supported Delphi consensus were also treated [7]. The indication was based on the surgical expertise of the designated surgeons at the Hernia Surgery Reference Center and were carried out according to a standardized modified BTA protocol based on Zendejas et al. [18].

Injections were administered in an outpatient setting under sterile conditions approximately 4–6 weeks prior to the planned hernia repair, each patient received five ultrasound-guided injections per side into the lateral abdominal wall (500 IU Dysport[®], Ipsen, Boulogne-Billancourt, France, diluted in 80 mL NaCl plus 20 mL Ropivacaine 0.75%). Three injections were placed along the anterior axillary line and two along the mid-axillary line. Targeted muscle layers included the *obliquus externus*, *obliquus internus*, and *transversus abdominis*, each infiltrated with 3.3 mL of the solution per muscle per injection site.

Exclusion criteria included age under 18 years, pregnancy or breastfeeding, metastatic malignancies in a palliative setting, local or systemic infections, and known hypersensitivity to BTA. Neurological conditions such as myasthenia gravis, Lambert-Eaton syndrome, amyotrophic lateral sclerosis, or peripheral neuropathies were also considered contraindications for BTA therapy.

The data collection included the following parameters: demographic and biometric data, comorbidities, the size of the fascial defect, BTA-related complications, surgical procedures performed, and component separation techniques used.

Postoperatively, patients were retrospectively interviewed during the hospital stay using a clinically based questionnaire with ten items (see **Supplementary Appendix 1** “Patient Questionnaire–Botulinum Toxin A Injection” [17]). The questionnaire assessed patients' experiences during BTA infiltration and during the four to 6 weeks preceding surgery. The questionnaire has not been validated.

Data were analyzed descriptively. Nominal data were presented using absolute numbers with percentages, and metric data were recorded using the mean. All analyses were performed using SPSS (version 25, IBM, Armonk, United States).

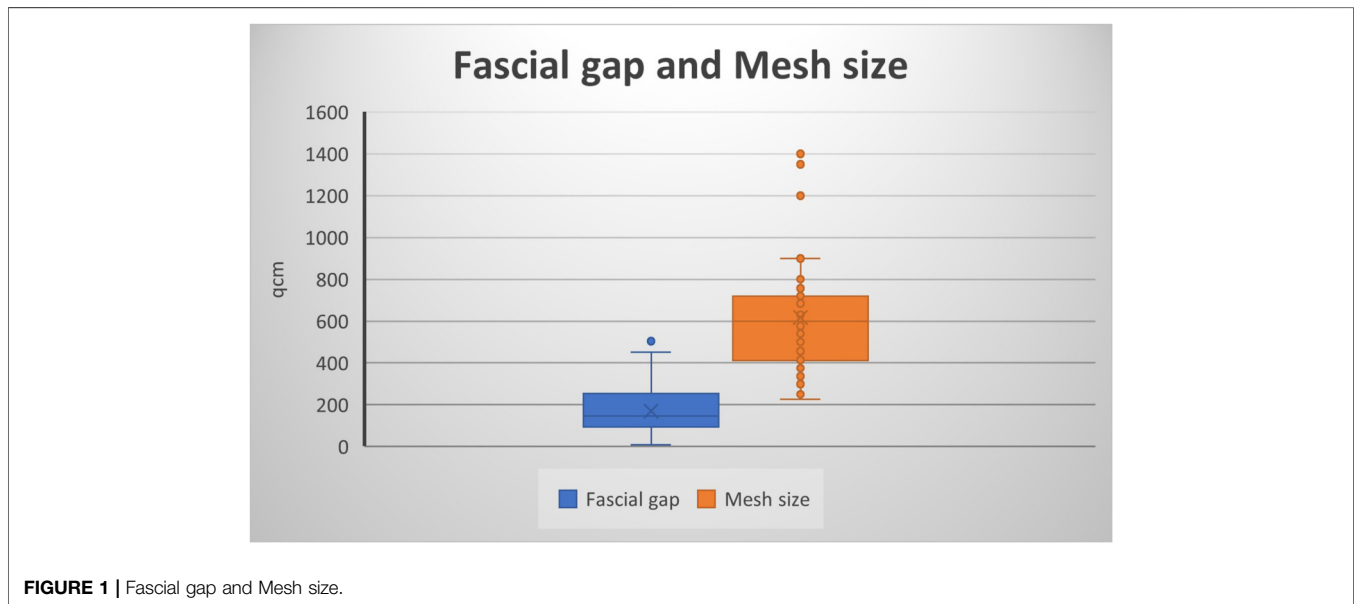
The Ethics Committee approved this retrospective study of the State of Rhineland-Palatinate (2021-16034). The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements. Written informed consent was obtained from the individual(s) for the

TABLE 1 | Patient characteristics and comorbidities.

Comorbidities	%	n
Cardio-vascular diseases	68%	36
Diabetes mellitus	26%	14
COPD/OSAS	28%	15
Chronic renal disease	16%	8
Smoking	43%	23
History of malignant disease	19%	10
Adipositas		
BMI ≤ 29	57%	31
BMI 30-34,9	34%	18
BMI ≥ 35	9%	5
ASA <3	39%	21
ASA >3	61%	33

TABLE 2 | Hernia characteristics according to EHS classification.

EHS-classification	n	% Of BTA-Patients	
Midline	M1	2	3%
	M2	14	26%
	M3	32	59%
	M4	13	24%
	M5	6	11%
Lateral	L1	1	2%
	L2	2	3%
	L3	1	2%
Combined (midline + lateral)	M + L	7	13%
Width	W1	1	2%
	W2	11	20%
	W3	38	70%

**FIGURE 1** | Fascial gap and Mesh size.

publication of any potentially identifiable images or data included in this article. Also, the study was registered in the German Clinic Trials Registry (DRKS00028557) according to the ICMJE standards.

RESULTS

Patient Cohort and Preoperative Conditioning

During the study period, a total of 50 patients with large incisional hernias were conditioned with botulinum toxin A (BTA); no patients met any contraindications or rather exclusion criteria, so all could be included in the analysis. The cohort included 31 male and 19 female patients with a mean age of 63.5 years (25–83 years). The average body mass index (BMI) was 28 kg/m² (18–38 kg/m²). All patients had undergone at least one and up to ten previous abdominal surgeries. The most common comorbidities included cardiovascular diseases such as arterial hypertension,

coronary artery disease, atrial fibrillation, obesity, nicotine abuse, and diabetes mellitus. **Table 1** show most common patients characteristics and comorbidities.

In 72% of the cases (n = 39), a midline hernia was present (including parts or the entire midline, e.g., M1-5, M2-4 etc.); four patients (7%) had lateral hernias, seven patients (13%) had midline and lateral hernia. The mean transverse hernia defect measured 12.06 cm (3–28 cm), the average vertical defect was 13.17 cm (3–28 cm), and the mean defect area was 170.24 cm² (9–504 cm², **Figure 1**). Five Patients had smaller defects <8 cm with complicating factors like a present stoma, off midline hernia, hernia recurrence with previous mesh implantation or parastomal plus midline hernia. In particular the patient with a 3 × 3cm defect (M5 W1) had a present urostomy (Mainz-Pouch) with umbilicus-stoma. A total of 38 patients had large transverse defects greater than or equal to 10 cm. Patients with W2 hernias (4–10 cm) routinely received BTA therapy when the defect measured approximately 8 cm or more. Hernia characteristics are shown in **Table 2**.

Operative Course and Surgery Associated Complications

The average interval between BTA injection and surgery was 39.24 days (28–65 days).

In the preoperative planning, an anatomical reconstruction with tension-free midline closure was planned in all cases. The surgical techniques employed included retromuscular sublay and open IPOM implantation, hybrid approaches such as video-assisted mini-open sublay (VAMOS), as well as anterior and posterior component separation. Primary fascial closure was achieved in 100% of cases. Overall, mesh implantation was performed in 50 patients. The mean mesh size was 617 cm² (range: 225–1,400 cm², **Figure 1**).

Intraoperative fascial traction was required in five patients. A transversus abdominis release (TAR) was performed in 28 cases (52%), while anterior component separation was used in five patients; in 17 cases, primary fascial closure was achieved without additional techniques. Mesh reinforcement was predominantly performed in a sublay position (*n* = 47), using polyvinylidene fluoride (PVDF) meshes. A long-term absorbable monofilament mesh was used as an additional onlay mesh (*n* = 1) and in one case of lateral hernia.

Early postoperative complications occurred in 28% of patients (*n* = 15), mainly hematomas and seromas (Clavien–Dindo I–II). Clinically relevant complications (Clavien–Dindo IIIb) were observed in three patients, including one wound healing disorder and two abdominal wall infections, all managed successfully with vacuum therapy and mesh preservation [19].

Botox-Associated Complications and Patient Feedback

No serious BTA-related complications (e.g., allergy, respiratory depression, bleeding, post-interventional bleeding, infection, sepsis) were observed. Only minor hematomas at the injection sites were reported. Twenty-two patients (44%) participated in the retrospective survey. The pain during the injection was rated between one and 8 Numerical rating scale (NRS) [20]. 86% (*n* = 19) reported pain lasting no more than 1–3 days, while three patients (*n* = 13%) experienced no pain at all. Eight patients (36%) noticed a change in abdominal shape, and two (9%) reported functional changes when sitting up or lying down. One patient each reported shortness of breath and difficulty with bowel movements. No issues with urination were reported. In response to the open-ended question regarding their experience with BTA injection, 13 patients (59%) reported positive memories and good tolerance of the treatment, 8 patients (36%) did not comment; one patient expressed surprise at the use of botulinum toxin in hernia surgery.

DISCUSSION

In our retrospective study, 50 patients with ventral incisional hernias who underwent preoperative treatment with botulinum toxin A (BTA) were analyzed over a seven-year period (2018–2024). Of these, 42% were obese with a body mass index (BMI)

greater than 30 kg/m². More than half of the patients had cardiovascular diseases and/or diabetes mellitus. All patients had at least one prior abdominal surgery; several had undergone multiple procedures.

These comorbidities resulted in morphologically complex or combined incisional hernias, often with large fascial defects, unstable abdominal wall structures, and altered anatomical conditions.

The size of our study population is comparable to other cohort studies [11, 18, 21–23].

According to the literature, obesity (BMI >30 kg/m²) is one of the most frequent comorbidities and risk factors in hernia surgery [24–26].

Surgical treatment of incisional hernias remains challenging. The primary goal is an anatomically correct and tension-free fascial closure, ideally supported by mesh reinforcement in the sublay position [27]. Transversus abdominis release (TAR) and/or anterior component separation (CS) is often required to achieve midline closure in large defects. Ibarra-Hurtado et al. reported performing anterior CS in 53% of their cases [22]. Bueno-Lledó et al. identified anterior CS and TAR as the most commonly used surgical approaches [25, 26, 28], while Nielsen et al. applied them in 40% of cases in 2020 [21]. Due to the morbidity associated with anterior CS—such as wound healing disorders, infections, or dehiscence [13]—and the technical limitations in achieving sufficient lateral mobilization, additional techniques may be necessary.

The use of BTA as a “chemical” or pharmacological component separation for large ventral hernias was first described by Ibarra-Hurtado et al. in 2009 and has since been widely adopted and modified [11]. The principle relies on temporary paralysis of the lateral abdominal muscles (external and internal obliques, and transversus abdominis) [12]. The ideal timing for administration remains undetermined; in the literature, BTA is usually applied 2–6 weeks before surgery [21, 23–26]. The maximum effect is believed to occur around 4 weeks after injection and gradually diminishes over the following months [13]. In our study, BTA was administered approximately 4–6 weeks prior to surgery.

Two pharmacological BTA preparations are commonly reported: Dysport® (Ipsen, France) and Botox® (Allergan, Ireland). A systematic review by Timmer et al. found Botox® to be used most frequently; five studies used Dysport®. Almost all authors describe ultrasound-guided injections into the external, internal oblique, and transversus abdominis muscles [13].

A high average fascial closure rate following preoperative BTA administration is documented in the literature [10, 29, 30]. Our findings support this, with a closure rate of 100%. Although this fascial closure rate cannot be attributed solely to the effect of BTA, it likely reflects the combined contribution of BTA and anterior and posterior component separation techniques. Importantly, BTA does result in fascial medialization, which may help reduce the need for anterior component separation, a procedure associated with increased morbidity [31]. This potential benefit may be explained, in part, by BTA-induced muscle relaxation and elongation of the lateral abdominal wall [22]. Based on four

studies, Timmer et al. demonstrated a significant lateral elongation of the abdominal wall of up to 3.2 cm per side [13].

Rodriguez-Acevedo et al. reported mild BTA-related side effects in a survey of 27 patients, including occasional coughing, injection-site pain, superficial hematomas, and back pain [24]. Nielsen et al. observed injection pain in 2.7% of cases [21]. Larger cohorts from Bueno-Lledó et al. and Ibarra-Hurtado et al. also reported no BTA-related complications [22, 25]. This finding is further supported by a recent systematic review [13]. In our cohort, no serious adverse events occurred. Pain during (NRS 1-8) or shortly after injection was reported by patients and resolved within 1–3 days. In this context, the current protocol of five injections per side seems debatable. Two studies compared different BTA injection protocols: three sites in two muscles versus three sites in three muscles, and three sites versus two injection sites [32, 33]. No significant differences were observed between the groups, suggesting that two injections may be sufficient [32, 33]. However, there is still no evidence to support this, and further studies are required in the future.

There were no reports of functional limitations when sitting up or lying down. Bowel function was only minimally affected, and urination was not impaired. These results align with current literature.

However, cardiopulmonary complications like respiratory insufficiency and pneumonia were described by Zwaans et al. in 2024: The authors hypothesized that injection into the transversus abdominis muscle, which functions as an accessory respiratory muscle, may have contributed to the issue and recommend cardiopulmonary function tests [34]. While the impact of BTA on respiratory function has been a subject of discussion, prospective data based on spirometric assessment are now available and warrant consideration when evaluating the safety profile of this intervention in patients with large abdominal wall defects [17]. In our study, one patient—without a history of a chronic obstructive pulmonary disease or asthma—experienced mild respiratory impairment. As such, careful consideration should be given when administering BTA in patients with relevant pulmonary conditions, and in select cases, the transversus abdominis should be excluded from injection.

This study has several limitations. It is a single-center study without a control group, which limits the strength of the conclusions and precludes causal inference. The descriptive study design without comparative or statistical analyses further restricts the interpretability of the results and their generalizability. The sample size was small, and only 44% of patients completed the postoperative questionnaire. The reasons for the non-participation of the remaining patients are unknown, or they did not submit the questionnaire. Furthermore, no preoperative symptom assessment was performed prior to the BTA injection, which somewhat limits the evaluation of the extent of symptoms attributable to BTA. The questionnaire was completed postoperatively during the hospital stay, which may have led to memory and perception biases, possibly influenced by postoperative outcomes or complications. Finally, the heterogeneity of surgical techniques, despite high fascial closure rates, can be considered a further limitation. Despite these limitations, the study provides initial evidence

that BTA can be safely used in this context. However, the results cannot be generalized, and further prospective, multicenter studies with larger samples and appropriate control groups are needed. Patient-reported outcomes in combination with surgical results should be further investigated.

Conclusion

The study demonstrates that preoperative administration of Botulinum toxin A (BTA) into the abdominal wall appears to be a safe and effective method to improve outcomes in complex abdominal wall hernias and has minimal impact on patient-reported symptoms. Therefore, it would be desirable to establish clear guidelines for the use of Botox therapy in large abdominal wall hernias and to obtain official approval for this treatment in the future.

DATA AVAILABILITY STATEMENT

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

ETHICS STATEMENT

The Ethics Committee approved this retrospective study of the State of Rhineland-Palatinate (2021-16034). The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article. Also, the study was registered in the German Clinic Trials Registry (DRKS00028557) according to the ICMJE standards.

AUTHOR CONTRIBUTIONS

RS, CG, AW and SS performed the surgical treatment; AK, AW and SS did the data analysis, AK wrote the manuscript. All authors contributed to the article and approved the submitted version.

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CONFLICT OF INTEREST

AW and SS declare medical consultancy with fasciotens® GmbH Essen.

The remaining author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

GENERATIVE AI STATEMENT

The author(s) declared that generative AI was not used in the creation of this manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: <https://www.frontierspartnerships.org/articles/10.3389/jaws.2026.15899/full#supplementary-material>

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