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Fascial closure in giant ventral hernias after preoperative botulinum toxin a and progressive pneumoperitoneum: A systematic review and meta-analysis

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ABSTRACT

Background: The primary objective was to assess the perioperative efficacy of the preoperative use of progressive pneumoperitoneum or Botulinum Toxin A injections in ventral hernia repair.

Methods: Embase, Medline Ovid, Web of Science, Cochrane Central, and Google Scholar were systematically searched. Studies in English reporting on fascial closure, indications, complications or post-operative outcomes in adult patients that had undergone progressive pneumoperitoneum, Botulinum Toxin A injections, or both before ventral hernia repair were included. Study quality was assessed with the Oxford Levels of Evidence guidelines and the Methodological Index for Non-Randomized Studies criteria. A pooled fascial closure rate and recurrence rate were calculated with random effects models.

Results: Twenty studies were included from the 905 identified, comprising the use progressive pneumoperitoneum ($n = 11$), Botulinum Toxin A ($n = 6$), and both techniques ($n = 3$). The overall fascial closure rate was 0.94 (95% confidence interval 0.89–0.98). Indications for the use of progressive pneumoperitoneum or Botulinum Toxin A were based on objective (eg, computed tomography measurements) or subjective measures (eg, foreseen surgical problems). In contrast to the use of Botulinum Toxin A, reported complications with the use of progressive pneumoperitoneum were ample and sometimes severe. The cumulative reported recurrence rate was 0.03 (95% confidence interval 0.01–0.06).

Conclusion: Preoperative progressive pneumoperitoneum and Botulinum Toxin A can facilitate fascial closure without causing significant numbers of adverse events. Botulinum Toxin A qualifies for low-threshold use, yet progressive pneumoperitoneum should be used cautiously owing to a larger number of complications. Definitive recommendations cannot be made as the quality of included studies is low, bias is present, and comparative information is scarce.

Registration number Information about the design and conduct of this systematic review has been registered on PROSPERO, registration number CRD42020181679.

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Introduction

Large abdominal hernias with fascial defect diameters over 10 centimeters pose a problem in surgery, especially in the presence of loss of domain, where the hernia content cannot be fully reduced into the abdominal cavity.¹ For the patient, this loss of domain can influence quality of life through back pain, respiratory problems, and cosmetic complaints.¹ For the surgeon, these hernias with loss of domain complicate fascial closure and increase the risk of high

postoperative abdominal pressure, which may lead to loss of pulmonary capacity² and abdominal compartment syndrome.³

Fascial closure is desirable in hernia surgery, as it reduces the hernia recurrence rate.^{4–6} To achieve repair of giant hernias, Goni Moreño described in 1947 the preoperative progressive pneumoperitoneum (PP) for the stretching of the abdominal wall musculature.⁷ However, this technique did not come without complications^{8–10}, and—when performed on an inpatient basis—additional costs of care.

More recently, the use of preoperative Botulinum Toxin A (BT) infiltrations in the abdominal wall has been described.^{11,12} BT infiltrations result in lowered tension and elongation of the abdominal muscles, therefore facilitating hernia repair.^{13,14} However, the use of BT also has a looming price tag, as insurance companies do not always cover for the costs of BT when used for the preoperative preparation of giant hernia repair.

Despite the increasing number of reports on PP, BT, or a combination of both, it remains unclear how much can be gained preoperatively with these techniques, and whether this preoperative gain outweighs the complications that can occur by using these techniques. Therefore, no consensus on standardized indications exists for the use of PP and BT, and surgeons often use these preoperative aides based on their own clinical experience.

Therefore, the objective of this study was to give a comprehensive overview of the published articles on the use of PP and/or BT (excluding case reports or case series), aiming at assessing the efficacy of these aides intraoperatively through the fascial closure rate. Additionally, the described indications for PP and BT, the complications that occurred owing to their use, and postoperative complications and recurrences that arose in the patient groups that have been prepared with these techniques were reviewed.

Methods

In this study, information on fascial closure during ventral hernia repair, after preoperative preparation with PP, BT, or a combination of both, was collected. The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO, registration number CRD42020181679). For the reporting of the study, the Preferred Items for Reporting of Systematic Reviews and Meta-Analyses (PRISMA) guidelines¹⁵ and Meta-Analysis of Observational Studies in Epidemiology (MOOSE) guidelines¹⁶ were followed.

Search

A systematic computerized literature search was performed on the July 28, 2020, in the online databases Embase, Medline Ovid, Web of Science, Cochrane Central, and Google Scholar. A medical librarian specialized in conducting systematic reviews prepared the search strategy and database search. The syntax with the search strategy per database can be found in [Appendix 1](#).

Outcomes

The primary outcome was the fascial closure rate. Secondary outcomes included the indications for PP, BT, or their combination; the complications after the use of these preoperative aides; and postoperative complications in the form of SSO—including SSI—and recurrences.

Study selection and data extraction

Studies reporting on the use of PP or BT (or their combination) in preparation of ventral hernia repair were included. There was no

limit on publication date. Two reviewers (M.M.J.vR and Y.Y.) independently screened all records by title and abstract for eligibility using a standardized method.¹⁷ Subsequently, the full texts of the eligible articles were independently assessed. Discrepancies in article selection were discussed between both reviewers and included or excluded after reaching consensus.

Randomized controlled trials (RCTs), prospective or retrospective cohort studies, and case-control studies in English were included. Case reports, case series reporting on less than 10 patients, letters, reviews, and comments, were excluded. The following criteria were applied for inclusion: (1) patients aged 18 years or older; (2) patients had undergone PP or BT before abdominal ventral hernia repair; (3) reported outcomes included either fascial closure, complications with the use of PP or BT, postoperative surgical site occurrences (SSO), or hernia recurrences. All types of surgical techniques were allowed. Studies reporting on inguinal, scrotal, hiatal, or port-site hernias were excluded, along with studies not reporting outcomes split up for the (sub)group that received PP or BT.

Data extraction was performed using a standard form covering study characteristics (study type, year, evidence, number of patients), patient characteristics (age, body mass index, smoking, chronic obstructive pulmonary disease, hypertension, diabetes, cardiorespiratory disease, malignant disease, hernia type), type and protocol of preoperative treatment (indications for PP and/or BT; for PP: type of insufflation gas, catheter location, number of days, insufflated volume; for BT: units, infiltration location), complications of preoperative treatment, surgical characteristics (hernia width, hernia length, loss of domain, type of repair, mesh use, component separation technique [CST] use, operation time, fascial closure), postoperative outcomes (SSO, SSI, recurrence, mortality, reoperation, length of hospital stay), and follow-up.

In case of uncertainty around duplicate data, the authors of these studies were contacted and asked for confirmation or further elaboration. Upon confirmation of the contacted author, the article with the most patients treated was selected, and the remaining articles were excluded. Additionally, authors reporting the use of both techniques (PP and BT) in separate patients, without presenting data per subgroup, were contacted for information on the outcomes of the separate subgroups.

Quality assessment

Each article was assessed by 2 independent reviewers (M.M.J.vR and M.A.) for its level of evidence according to the Oxford Centre for Evidence-Based Medicine levels of evidence.¹⁸ Methodological quality of included nonrandomized studies was assessed using the Newcastle-Ottawa Scale criteria¹⁹ and the Methodological Index for Non-Randomized Studies (MINORS) criteria.²⁰

Data synthesis

An inverse variance random-effects model was used to calculate a pooled proportion for fascial closure and recurrence, using the Freeman-Tukey double arcsine transformation. Between-study variance was calculated through tau-squared with the DerSimonian-Laird estimator. All analyses were performed with R Statistical software version 3.3.3 (R Foundation for Statistical Computing, Vienna, Austria). Indications and complications described with the use of PP or BT are presented descriptively.

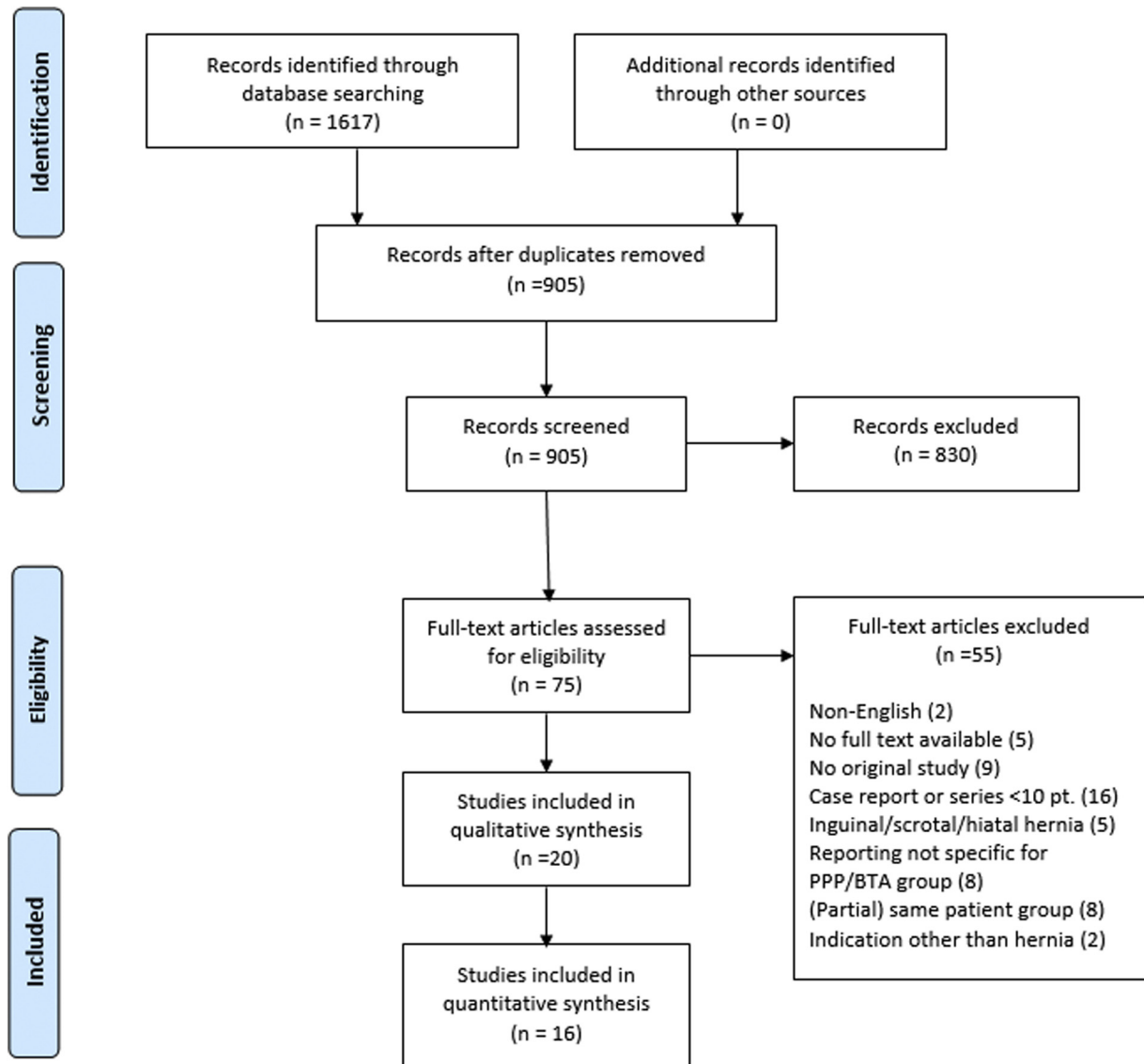


Fig 1. PRISMA flow diagram of article selection. PRISMA, Preferred Items for Reporting of Systematic Reviews and Meta-Analyses.

Results

Search and study characteristics

The selection of articles is depicted in a PRISMA flow diagram in Figure 1. Of the 905 articles identified (after removing duplicates), 75 remained for full-text assessment after title and abstract screening. Of these 75 articles, 20 were selected for inclusion.^{10–12,14,21–36} One article was a case-control study,¹¹ 2 articles were non-randomized trials,^{34,36} 1 was a case series with selected controls,²⁹ and all other articles were single-arm prospective or retrospective studies.^{10,12,14,21–28,30–33,35} Owing to the large number of single-arm studies, a minor deviation from the originally registered protocol³⁷ took place in the form of the additional use of the MINORS checklist for quality assessment, as this checklist is both applicable for comparative and non-comparative studies.²⁰ All articles scored between 25% and 75% of the maximum MINORS score, yet, nonetheless, all were included for analysis. None of the studies had a blind evaluation of the endpoint or a prospective calculation of the study size.

Eleven studies reported on the sole use of PP in 466 patients, 6 studies reported on preoperative BT infiltrations only in 164 patients, and 3 studies reported on the use of both techniques in 179 patients. These techniques were reported to have been used for incisional, midline, lateral, transverse, or parastomal hernias. Complete study details, including the Level of Evidence and MINORS score, are shown in Table 1.

Fascial closure

The primary outcome of interest was the fascial closure rate. Sixteen studies reported the fascial closure rate after the use of PP or BT. A 94% cumulative fascial closure rate was found under a random effects model (95% CI 0.89–0.98). In addition to this overall fascial closure rate, the cumulative rate per intervention is plotted in Figure 2.

Indications for PP and BT

All articles were assessed for the described indication for PP and BT use. The authors identified 6 main themes for the use of PP, and 3

Table 1
Article characteristics from included articles

Name	Study type	Loe	Minors	N	Age	BMI	Interven-Tion	Hernia width	Open/Lap (N)	Mesh Use	CST	Follow-up	FU range	Outcomes
Hamer 1972 ²⁹	Case series with selected controls	4	4/24	10	53.3	NR	PP	10.8	Open	20.0%	NR	NR	12–72	I C PC R
Astudillo 1986 ³⁶	Prospective non-randomized trial	3	9/24	12	NR	NR	PP	NR	Open	0%	0%	24	NR	I PC R
Caldironi 1990 ³³	Retrospective	3	4/16	41	58.5	NR	PP	5–15	NR	39.0%	0%	25.3	6–108	I C PC R
Coelho 1993 ³¹	Retrospective	3	4/16	36	52	NR	PP	NR	Open	16.7%	NR	10	1–48	F I C PC R
Tonatio 2002 ²³	Retrospective	3	7/16	77	56.6	NR	PP	15.8	Open	100%	0%	38.8	24–60	F I C PC R
Dumont 2009 ³⁰	Prospective	3	10/16	21	NR	38	PP	10.1	NR	61.9%	14.3%	NR	NR	F I C
Ibarra-Hurtado 2009 ¹²	Prospective	4	7/16	12	36.3	NR	BT	13.9	Open	0%	50.0%	9	4–18	F I PC R
Tanaka 2010 ²⁵	Prospective	3	4/16	23	55.6	38.5	PP	NR	Open	100%	4.3%	NR	0–24	F I PC R
Zendejas 2013 ¹¹	Case-control	4	15/24	22	61.8	30.9	BT	NR	Open 10 Lap. 12	100%	18.2%	15.6	NR	F I C PC R
Ibarra-Hurtado 2014 ²⁸	Prospective	3	12/16	17	34.9	NR	BT	14.7	Open	23.5%	52.9%	49	37–61	F I C PC R
Renard 2016 ³⁶	Prospective	3	9/16	45	60.5	NR	PP	14.7	Open	82.2%	0%	18.6	3–68	F I C PC R
Rodriguez-Aceveco 2018 ¹⁴	Prospective	3	6/16	56	59.7	30.9	PP + BT	11.6	Lap. 41 LOL 15	100%	14.3%	NR	NR	F I C PC R
Valezi 2018 ²²	Prospective	3	8/16	16	44	33	PP	NR	Open	100%	0%	2 days	NR	I C
Bueno-Lledo 2020 (Front Surg) ³⁵	Retrospective	3	9/16	100	59.4	NR	PP + BT	16.1	Open	100%	89.0%	34.5	11–62	F I C PC R
Mancini 2020 ¹⁰	Retrospective	3	6/16	162	57.8	33.2	PP	16.2	Open	87.3%	NR	NR	NR	F I C PC
Nielsen 2020 ²⁷	Retrospective	3	7/16	37	59.5	31.1	BT	12.1	Open	100%	40.5%	1	NR	F I C PC
Tang 2020 ²⁴	Retrospective	3	7/16	23	63.4	NR	PP	NR	Lap. 20 LOL 3	100%	NR	24	13–40	F I C PC R
Bueno-Lledo 2020 (Surg) ³⁴	Prospective non-randomized trial	3	13/24	40	51.5	NR	BT	15.5	Open	100%	0%	19.6*	11–35	F I C PC R
Catalan-Garza 2020 ²²	Retrospective	4	7/16	36	60.9	20.7	BT	13.9	Open	NR	58.3%	NR	Up to 24	F I C PC R
Yurtkap 2020 ²¹	Retrospective	3	12/16	23	61.9	32.6	PP + BT	20.2	Open	100%	95.5%	25.1	10–60	F I C PC R

Mean values reported (age in years, BMI in kg/m², hernia width in centimeters, follow-up in months).
 BMI, Body Mass Index; BT, botulinum toxin A; C, complications; CST, Component separation technique; FU, follow-up; F, Fascial closure; I, indications; Lap., laparoscopic; LoE, Level of Evidence¹⁸; LOL, laparoscopic-open-laparoscopic; NR, not reported; PP, progressive pneumoperitoneum; PC, postoperative complications including surgical site occurrences and/or surgical site infections; R, recurrences.
 * Median instead of mean.

main criteria for the use of BT infiltrations; both can be viewed in [Table II](#).

Complications during PP and BT

Along with the indications, the reported complications with the use of both techniques were reviewed. A total of 124 complications were mentioned in the 14 articles reporting on (combined) PP use. Complications reported more than once can be viewed in [Figure 3](#). Death has been reported 3 times: once in a patient with a history of severe respiratory failure, and 1 time PP caused acute respiratory failure owing to abdominal compartment syndrome, which subsequently led to multi-organ failure and death. The third patient died owing to a hemorrhage after catheter insertion for insufflation, which caused multi-organ failure. The one-off reported complications included, among others, the need for emergency surgery, respiratory distress, pneumocardium, metabolic acidosis, enterocutaneous fistula, and cardiac arrest. However, many more complications might have occurred, as reporting bias most certainly has taken place. The complications mentioned with the use of BT were a sense of bloating, a weak cough, back pain or pain in general, and superficial bruising at the site of the injections.^{14,27}

Postoperative complications

Secondary outcomes of interest were SSOs, SSIs, and recurrences. Eighteen articles reported on postoperative complications, of which 2 on SSOs only, 5 on SSIs only, and 11 on both SSOs and SSIs. In the 13 articles that mentioned SSO rates, 582 patients experienced 178 SSOs (30.6%), of which some patients experienced multiple SSOs. With regard to infections, a cumulative SSI rate of 10% (95% CI 0.04–0.18) was found after the use of PP, 7% after the use of BT (95% CI 0.01–0.18) and 19% after the use of PP and BT combined (95% CI 0.0–0.52).

With regard to recurrences, 16 authors reported a recurrence rate after the use of PP or BT. A random effects model renders a pooled proportion of 0.03 (95% CI 0.01–0.06). The recurrence rate per study, along with the mean follow-up is depicted in [Figure 4](#). Three studies have not been included in this figure as they did not report a mean follow-up time. Diagnosis of recurrence was solely clinical in 2 studies (12.5%), clinically detected and confirmed by CT in 3 studies (18.8%), and the method of detection was not reported in 11 studies (68.8%). Discussion

The primary goal of this study was to assess the efficacy of PP and BT intraoperatively through the fascial closure rate. From the synthesis of 16 articles, a fascial closure rate of 94% was observed after the use of PP, BT, or a combination of these preoperative aides. This is an acceptable rate, suggesting that the use of PP or BT is of additional value in preparation for complex hernia repair, as fascial closure probably will reduce hernia recurrence rates when compared with bridged repair.^{4,5} This decent fascial closure rate might be explained by the gain in muscle length in the axial plane after the use of BT.^{28,38} PP has been

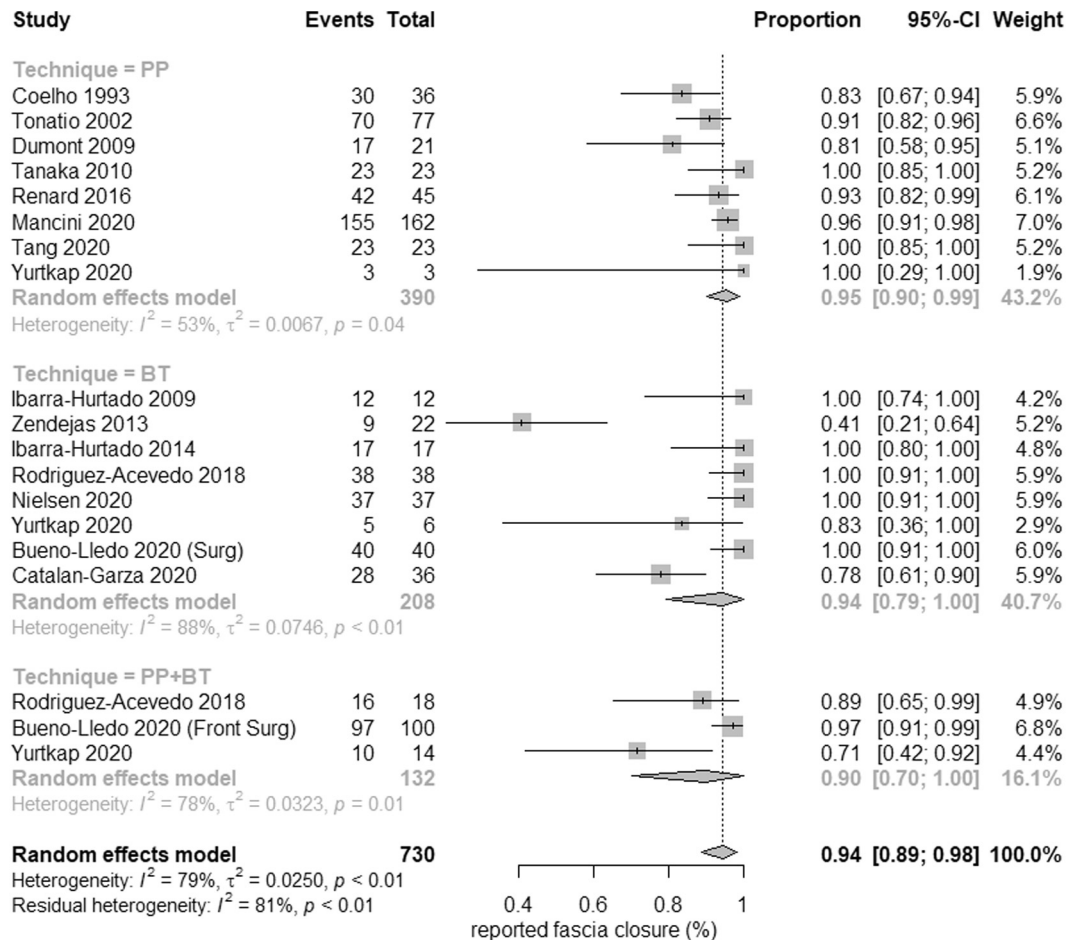


Fig 2. Forest plot for fascial closure rate.

Table II

Identified indications for the use of preoperative PP and BT

PP indications	BT indications
Loss of domain ratio >20% or >25% ^{22,24,25,35}	Measurements (hernia width or loss of domain ratio) ^{14,21,32,34,35}
Hernia width >10 cm ^{23,30}	
Hernia width cut-off + loss of domain ratio >20% ^{14,21}	Surgeon preference or expected difficulty closing midline ^{11,27}
Hernia contents cannot be reduced back to abdominal cavity ²⁶	
Foreseen problems during surgery ²⁹	Open abdomen ^{12,28}
Undefined/surgeon's decision ^{10,31,33,36}	

BT, Botulinum Toxin A; cm, centimeter; PP, progressive pneumoperitoneum.

reported to decrease the hernia-to-abdominal-cavity volume ratio,^{8,22,26} and to lead to lysis of adhesions in the hernia sac,³⁹ also facilitating hernia repair.

The recurrences and postoperative complications when PP or BT is used preoperatively are low compared with “regular” open hernia surgery without the use of these preoperative techniques, with 3% recurrences and 31% SSO. The number of recurrences may be distorted as many studies had no standardized follow-up protocol, lacked imaging, and had varying follow-up times. The number of postoperative SSI is rather high, especially in the group that was prepared with both PP and BT. However, this might not directly be related to the preoperative technique used, but to the “difficulty” of the patient population and specifically their hernia characteristics (ie, the combination of PP and BT is likely to have been used in more extensive, complex hernias that also resulted in more postoperative complications [confounding by indication]). Nonetheless, the

decision to use PP or BT preoperatively does not seem to significantly influence the postoperative course.

However, when these preoperative techniques should be deployed remains a matter of debate. Indications for the use of PP and BT varied from CT measurements with strict cut-off values to surgeon preference or even remained undefined. We suggest that BT can be used when fibrosed or thickened muscles are observed and without clear loss of domain. For defects with more pronounced loss of domain, PP could be used, and the possible additional effect of BT is thought to be small.

Not only did the included studies describe different indications, also different application methods of both techniques are presented. PP can be performed on an inpatient or outpatient basis, created with the use of air, nitrous oxide, or carbon dioxide, with varying lengths before surgery, and with volumes varying from less than 5 to over 25 liters. With regard to BT injections, the use of 200

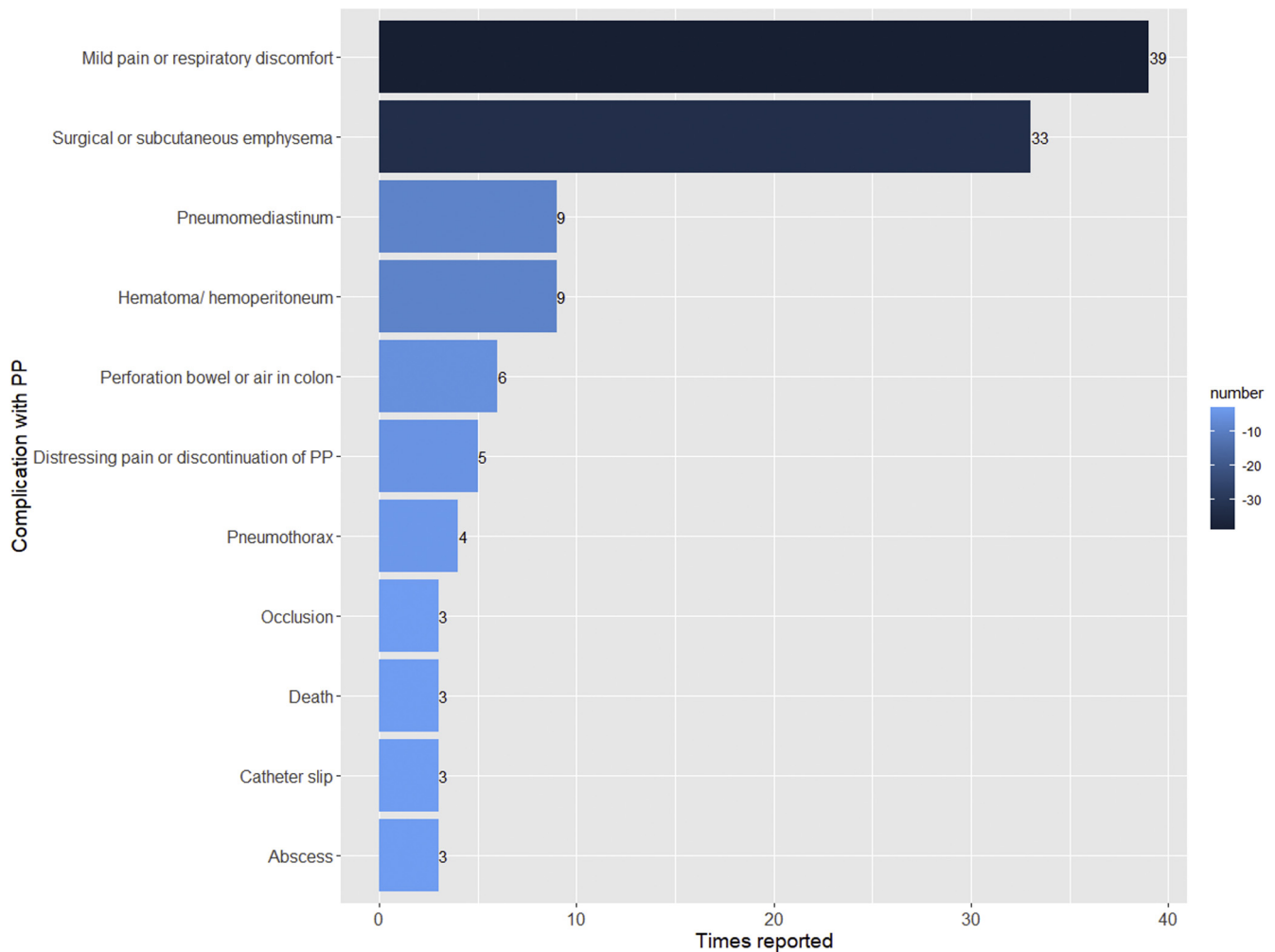


Fig 3. Complications after the use of PP, reported more than once. PP, progressive pneumoperitoneum.

to 500 units has been described, divided over 6 to 10 injection sites, in 2 or all 3 lateral abdominal muscle layers, and timeframes ranging from 45 to 6 days before surgery.^{11,12,14,21,27,28,35} One study even described the use of BT injections on the day of surgery itself, barely allowing the BT to enter into force, and, therefore, the observed effects could be obelized as the result of a placebo effect.¹¹

The reported complications after the use of BT seemed minor; complications during or after the use of PP, however, were frequent and sometimes severe. In addition, both techniques are costly. The costs of BT vary per country and depend on the amount of units used.⁴⁰ Costs are rarely reported, but are estimated to be between 400 and 600 euros when BT is injected into the abdominal wall musculature.^{21,34} These numbers seem considerable but become less so when reoperations owing to recurrences and severe post-operative complications—consequences of invasive techniques to obtain fascial closure—can be prevented. PP is a costly procedure, in particular when performed on an inpatient basis. Therefore, the use of these techniques should be in agreement with the patient and after careful consideration.

Limitations

Unfortunately, this study cannot provide comparative results, as nearly all articles lacked a comparison group. Only 4 studies reported outcomes for a comparison group. Additionally, the quality of included studies is very low; the maximum reached MINORS

score was 75% of the maximum score. Most studies are exploratory in nature, aiming to present the limited experience with the use of PP or BT. Small numbers of patients are included, and often no prospective protocol for data collection is described. This results, however, in non-comparative studies with selective reporting. Due to this reporting bias, the presented summary values for fascial closure rate and recurrences probably do not reflect the true general values of these outcomes and have wider confidence intervals.

In addition to reporting bias, selection bias might have taken place in the studies included in the analysis. The indications for the use of the preoperative aides were not always clearly reported, therefore it is possible that PP and BT were only applied in a selected group of patients (sampling bias), and that the combination of both techniques was only used in patients with very complex hernias. In addition, the inclusion of consecutive patients has not been described in all studies, which might indicate that some form of confirmation bias—“good results from a new and promising technique”—could have taken place. Further, the data used in this review might have been affected by unmeasured confounders, such as surgeon effort or differences in ethnicity, therefore possibly biasing the found summary measures. Not only unmeasured confounders, but also different types of hernias (incisional, primary ventral, or parastomal) and repairs (open, laparoscopic, use of CST) contribute to the found heterogeneity and prevent comparison.

A further limitation is that many included studies in this review had no standardized follow-up protocol for the assessment of

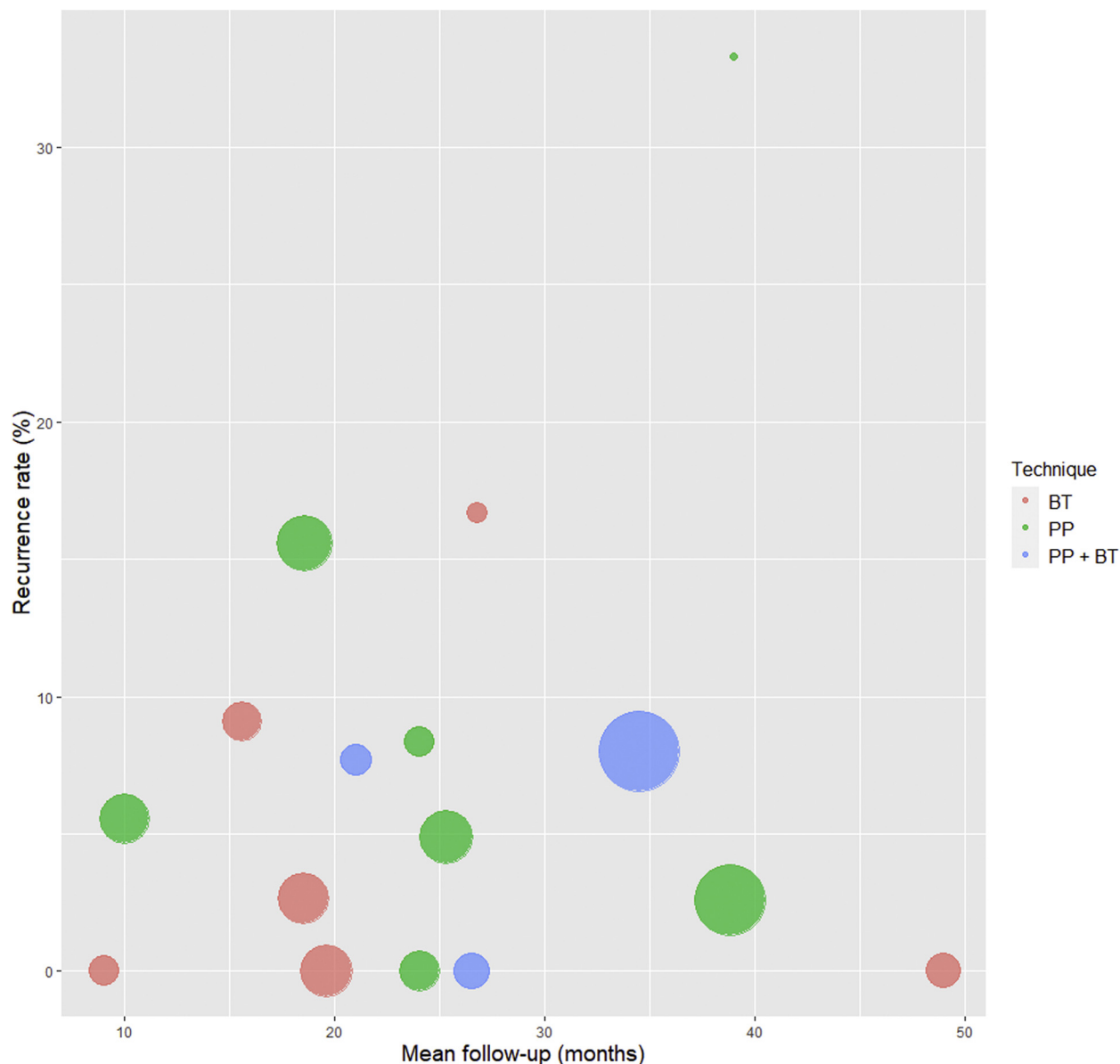


Fig 4. Bubble plot depicting the recurrence rate and mean follow-up per study. Bubble size represents the number of patients included per study; bubble color represents the used preoperative technique.

hernia recurrence, which might cause the pooled recurrence rate to be unreliably low. Another factor that might have led to under-detection of hernia recurrences is that the method for detection is often not described, implicating that recurrence assessment was performed by physical examination only. Small hernia recurrences can be easily missed without the use of radiological imaging.⁴¹

Implications

Owing to the possible presence of above forms of bias and the lack of comparative data, it remains hard to say how preoperative PP and BT compare to other surgical tools and techniques. The relative effect size of these preoperative aides, compared with tissue expanders, different component separation techniques, or other surgical ingenuities, remains unexplored. The lack of randomized clinical trials can be explained by the rarity of indications and the heterogeneity of groups. Nonetheless, the use of both preoperative techniques should be more widely explored, as lack of

comparison hinders the possibility to judge the utility of both aides. Ideally, an RCT would be performed to compare BT to CST, first in smaller hernias (for example with 10–15% loss of domain), to confirm the hypothesized non-inferior intraoperative effect, and to observe whether similar or less postoperative complications occur. Subsequently, the use of BT in larger hernias can be researched. Comparative research ideally takes place in a multicenter design, as CST can be subject to considerable inter-surgeon variability. The use of mesh should be standardized in these studies. Additionally, a meeting between specialized abdominal wall surgeons should take place to discuss the development of guidelines, including a proposal for standardized guidelines concerning the use of PP and BT. If such guidelines were to be created, intra- and postoperative results would be more comparable, and the true value of these aides in fascial closure could be better evaluated. In conclusion, the results from this review suggest that PP and BT can facilitate fascial closure and do not seem to have radical adverse effects on postoperative outcomes. Therefore, BT seems to qualify for low-threshold use.

However, surgeons should have some reservations on the use of PP, as complications are frequent and sometimes severe. Since no standardized indications for the use of both techniques exist, guidelines should be composed to make future effect assessment easier and to stimulate comparative research with other surgical techniques.

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Conflicts of interest/Disclosures

Authors have no related conflicts of interest to declare.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.surg.2021.03.027>.

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