Short-term complications after onlay *versus* preperitoneal mesh repair of umbilical hernias: a prospective randomized double-blind trial

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Abstract

PURPOSE: To compare the incidence of surgical site occurrences (SSOs) following onlay versus preperitoneal mesh placement in elective open umbilical hernia repairs.

METHODS: This study presents a secondary analysis of a randomized double-blind trial conducted on female patients with primary umbilical hernias admitted to a general hospital, in a residency training program setting. Fifty-six subjects were randomly assigned to either onlay (n=30) or preperitoneal (n=26) mesh repair group. Data on baseline demographics, past medical history, perioperative details, postoperative pain (visual analogue scale, VAS), wound-related complications and recurrence were assessed using a standardized protocol.

RESULTS: No statistically significant differences were observed between groups regarding patients' demographics, comorbidities or defect size. Operative time averaged 67.5 (28 – 110) minutes for onlay and 50.5 (31 – 90) minutes for preperitoneal repairs, p=.03. The overall rate of SSOs was 21.4% (n=12), mainly in the onlay group (33% vs 7.7%; p=0.02, 95% CI 0.03 – 0.85) and mostly due to seromas. There were no between-group significant differences in postoperative VAS scores at all timepoints. After a maximum follow-up of 48 months, one recurrence was reported in the onlay group. By logistic regression, the onlay technique was the only independent risk factor for SSOs.

CONCLUSION: The presented data identified a decreased wound morbidity in preperitoneal umbilical hernia repairs, thus providing a good level of evidence for recommendations regarding mesh place selection in future guidelines. Further cases from this ongoing study and completion of follow-up are expected to also compare both techniques in terms of long-term outcomes.

Introduction

Current evidence supports mesh reinforcement to improve long-term results after surgical treatment of primary uncomplicated umbilical hernias [1, 2]. Recent meta-analysis and guidelines indicate a significant decrease in recurrence with similar wound-related complication rates for mesh repairs [1–3] compared to suture repairs, even for small defects (< 1cm) [4].

The anatomical plane for mesh insertion has been suggested to have several implications on the incidence of surgical site occurrences, postoperative pain, and risk of recurrence in ventral hernia repairs (VHR) [5]; however, its ideal location for umbilical defects is not yet established. Current trends lean toward matched sublay repairs (pooling retromuscular and preperitoneal) due to the lower risk of local wound and intra-abdominal complications, though evidence is limited to primary ventral and incisional hernias [3, 6]. Extrapolation of these findings for umbilical defects is questionable, given the anatomical intricacies of the umbilicus, e.g., the cutaneous folds, its thin merged fascial layers, and terminal circulation, which may have a direct bearing on surgical outcomes.

This report presents a secondary analysis from a randomized double-blind trial designed to determine the optimal mesh placement for umbilical hernias by assessing both short and long-term outcomes of open onlay *versus* preperitoneal mesh repair. We sought to test the hypothesis that preperitoneal umbilical hernia mesh repair is associated with lower rates of wound-related complications than the onlay technique. The authors herein compare the incidence of surgical site occurrences (SSOs) following mesh insertion into these different anatomical planes.

Materials And Methods

Study design and patient selection

This is a secondary analysis of data from an ongoing prospective randomized double-blind trial in which female patients undergoing umbilical hernia repair were randomly assigned to either onlay or preperitoneal mesh placement. The study was conducted at the Presidente Vargas Women's and Children's Hospital, in Porto Alegre, Brazil, and its protocol was approved by the institutional Ethics Comittee under the registration number 2.146.387. The trial is registered in the Brazilian Registry of Clinical Trials (ReBEC), UTN code: U1111-1205-0065.

All female subjects of at least 18 years of age referred for elective repair of primary umbilical hernias were eligible for recruitment. Informed written consent was obtained from all subjects. The diagnosis was mainly based on clinical examination, and abdominal wall ultrasound scan was performed in cases of diagnostic doubt. Umbilical hernia was defined according to the European Hernia Society (EHS) designation as a primary hernia in the midline located in the center of the umbilical ring [8]. Exclusion criteria were strangulated, recurrent or incisional umbilical hernia, concurrent abdominal wall hernias, body mass index (BMI) > 40 kg/m^2, current pregnancy, previous midline laparotomy, ascites or liver cirrhosis.

Data on baseline demographics, past medical history, perioperative details, postoperative pain scores, wound-related complications and recurrence were assessed. The primary outcome for the trial was hernia recurrence whilst for this analysis was the incidence of surgical site occurrences. Secondary endpoints included operative time, postoperative pain and short-term recurrence. We included all patients from the primary study who met inclusion criteria; a sample size estimation was not performed *a priori*.

Randomization and masking

Randomization was based on a computer-generated schedule concealed in sealed envelopes, in a 1:1 allocation ratio to either onlay or preperitoneal mesh repair. Assignments were made by consecutive opening of envelopes just prior to anesthesia induction. All data were collected prospectively, and postoperative details were assessed by research assistants blinded to the allocation during the study period and not participating in patient care.

Operative technique

All surgical procedures were performed by general surgery residents in training with the participation of either of two senior staff surgeons, according to a standardized protocol. General or spinal anesthesia was chosen based on the attending anesthesiologist's discretion. All patients were placed in the supine position and received a single dose of preoperative prophylactic antibiotic (cefazolin sodium 2g dose intravenous) prior to induction. Operative time was recorded as skin-to-skin interval.

Through a standard curvilinear supraumbilical skin incision, the umbilical stalk was detached from surrounding subcutaneous tissue and underlying fascia. The hernia sac and margins of the defect were dissected. The hernia diameter was measured with a sterile ruler and registered according to the EHS definition as the greatest transverse distance in cm between the lateral margins of the defect on both sides [8]. After reduction of the hernia sac contents, a flat monofilament polypropylene mesh (Prolene®; Ethicon, Summerville, NJ, USA) was inserted according to each technique, as detailed below. Following mesh insertion and closure of the defect, the undersurface of the umbilicus was secured to the previous attachment point to the fascia with a single absorbable suture (polyglactin 910, Ethicon, Inc), and the wound was then closed with a running subcuticular suture of 4 – 0 nylon (Ethicon, Inc). No drains were inserted after either onlay or preperitoneal repair, irrespective of the hernia size. Surgical dressing was standardized and performed with microporous adhesive bandages.

Onlay mesh repair: the fascial defect was closed using continuous monofilament non-absorbable sutures and the anterior layer of the rectus sheath was exposed through dissection of the skin and subcutaneous tissue, overlapping 3-cm from each side. The flat mesh was deployed and then fixed to the aponeurosis with multiple interrupted absorbable sutures.

Preperitoneal mesh repair: the preperitoneal space was created between the posterior rectus sheath and the peritoneum, with 3-cm overlap from each side. In case of narrow defects (< 1 cm), orifice widening was performed to adequately place the flat mesh into the space. Any eventual disruptions of peritoneal tissue exposing the abdominal contents were closed with continuous absorbable sutures to avoid direct contact with viscera. The mesh was then inserted in the created plane. The defect was closed with continuous non-absorbable sutures and the center of the mesh secured to the fascia to avoid displacement.

Post-operative care and follow-up

All operations were planned as day cases. Postoperative management included oral analgesic and nonsteroidal anti-inflammatory drugs for pain relief. Patients were followed-up in the outpatient clinic and assessed for wound-related complications and pain by an independent blinded surgeon at the 7th and 30th postoperative day. Extra outpatient appointments or emergency department visits within 30 days postoperatively were classified as a revisit. The intended follow-up duration for the trial to assess for long-term results was 60 months, with regular follow-up appointments every year.

Postoperative pain was recorded using a visual analogue scale (VAS, 0–10). SSOs were determined by a thorough examination of the wound during each follow-up and classified according to the VHWG

definitions [9] in superficial/deep incisional surgical site infection (SSI), wound dehiscence, seroma or enterocutaneous fistula; and also to the expanded list of SSO (e-SSO) [10] that further includes wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch abscess, hematoma, and infected or exposed mesh.

Statistical analysis

Data analyses were performed in accordance with the per-protocol principles. Parametric data were reported as means with standard deviation and nonparametric as median with interquartile range (p25 – p75). The Kolmogorov-Smirnov test was used to assess the normality of continuous variables. Univariate analysis was performed by using the Student t test to compare continuous variables with normal distribution, and the Mann-Whitney U test for quantitative variables with asymmetric distribution. Pearson's $\chi 2$ test or Fisher's exact test were applied to compare categorical values where appropriate.

A binary logistic regression model was used to identify independent risk factors for the development of wound-related complications, which were presented as odds ratios (ORs) with 95% confidence intervals (CI). Candidate predictor variables included those of clinical importance for hernia outcomes or with statistical significance in the univariate analysis. For categorical values, a cut-off was set based on pathophysiologic considerations. Model fit was assessed with the Hosmer-Lemeshow goodness-of-fit test. The significance threshold was set at a level of 5% ($p < 0.05$). All statistical analysis was carried out using IBM SPSS v24.

Results

In this analysis, 56 total subjects were allocated to study groups – 30 (53.6%) to onlay mesh repair and 26 (46.4%) to preperitoneal mesh repair (Fig. 1.). The median age at surgery was 42 (range 18–61, IQR 35–49), and the majority were multiparous women (66%; n = 37). The median BMI was 27.7 kg/m^2 (range 20.2–40, IQR 25.1–32) with 15 patients (26.7%) identified as having a BMI of 30 kg/m^2 or greater. No significant differences were observed between groups regarding patients' demographics, underlying medical conditions or defect size (Table 1).

Table 1
Baseline characteristics of study groups; *ns = statistically non-significant.

	Onlay (n = 30)	**Preperitoneal (n = 26)**	**Total (n = 56)**
Age *(years)*	39.5 (18–60)	44 (18–61)	42 (18–61)
Height *(m)*	1.59 (1.41–1.75)	1.57 (1.45–1.74)	1.58 (1.41–1.75)
Weight *(kg)*	65.5 (54–108)	71.5 (52–96.5)	68 (52–108)
BMI *(kg/m^2)*	26.7 (20.2–40)	28.3 (21.3–39)	27.7 (20.2–40)
Comorbidities			
CVD	3 (10%)	6 (23%)	9 (16%)
Diabetes	1 (3%)	4 (15%)	5 (9%)
COPD/Asthma	0	3 (11.5%)	3 (5.4%)
Smoking	4 (13%)	5 (19%)	9 (16%)
Other	2 (6%)	2 (7.7%)	4 (7%)
Parity	2 (0–8)	3 (0–5)	2 (0–8)
ASA PS			
I	20 (66%)	10 (38.5%)	30 (53.5%)
II	9 (30%)	15 (57.7%)	24 (43%)
III	1 (3%)	1 (3.8%)	2 (3.5%)
Hernia size *(mm)*	15 (5–65)	15 (6–50)	15 (5–65)

BMI = body-mass index; CVD = cardiovascular disease; ASA PS = American Society of Anesthesiologists Physical Status; COPD = chronic obstructive pulmonary disease.

Procedures in both groups were mainly conducted under spinal anesthesia (n = 50; 89.2%). Operative time averaged 67.5 minutes for onlay (range, 28–110) and 50.5 minutes for preperitoneal repairs (range, 31–90); p = .03 (Fig. 2). Crossover to onlay repair was required in 2 cases due to extensive peritoneal or sac tearing that prevented adequate coverage of the mesh. There were no intraoperative anesthetic or surgical complications. All patients were discharged within 24h after the procedure and none required readmission to hospital.

One patient did not complete any follow-up appointment within 4-weeks of surgery and was excluded from the analysis. The overall rate of SSO was 21.4% (n = 12), mainly in the onlay group (33%; n = 10 vs 7.7%; n = 2; p = 0.02, 95% CI 0.03–0.85). The incidence of e-SSO was also statistically significantly higher in the onlay group (43%; n = 13 vs 11.5%; n = 3; p = 0.01; IC 0.06–0.86), mostly due to seromas and

skin/soft tissue necrosis. No patient had evidence of deep incisional surgical site infection or required mesh removal. All wound complications resolved successfully requiring none or minor interventions such as antibiotics, dressings and/or drainage.

Intraoperative data and postoperative results are disclosed in Table 2. Cumulative median (range) VAS pain score was 3 in the onlay group and 2 in the preperitoneal group. There were no between-group significant differences in postoperative VAS scores at all timepoints (Fig. 3). After a maximum follow-up of 48 months, one clinical recurrence was recorded in the onlay group 2.5 years post-surgery, and reoperation was performed using the preperitoneal technique. By logistic regression analysis, the onlay technique was the only independent risk factor for wound-related complications (Table 3).

Table 2
Intraoperative findings and outcomes. *ns = statistically non-significant.

	Onlay (n = 30)	**Preperitoneal (n = 26)**	**Total (n = 56)**	**P value**
Operative time *(min)*	67.5 (28–110)	50.5 (31–90)	58 (28–110)	**.04**
SSO	10 (33%)	2 (7.7%)	12 (21.4%)	**.02**
Seroma	8 (27%)	1 (3.8%)	9 (16%)	**.02**
SSI	3 (10%)	1 (3.8%)	4 (7%)	ns*
Wound dehiscence	1 (3%)	0	1 (1.8%)	ns*
Enterocutaneous fistula	0	0	0	-
e-SSO	13 (43%)	3 (11.5%)	16 (28.5%)	**.01**
Seroma	8 (27%)	1 (3.8%)	9 (16%)	**.02**
SSI	3 (10%)	1 (3.8%)	4 (7%)	ns*
Wound dehiscence	1 (3%)	0	1 (1.8%)	ns*
Enterocutaneous fistula	0	0	0	-
Skin/soft tissue necrosis	3 (10%)	0	3 (5.3%)	ns*
Stitch abscess	1 (10%)	1 (3.8%)	2 (3.5%)	ns*
Hematoma	1 (10%)	0	1 (1.8%)	ns*
Other	0	0	0	ns*
Revisit	6 (20%)	3 (11.5%)	9 (16%)	ns*
Recurrence	1 (3.3%)	0	1 (1.8%)	ns*

SSO = surgical site occurrence; e-SSO = expanded list of SSO [9].

e-SSO	13 (23.2%)	4 (7.1%)	17 (30.4%)	.02
Skin/soft tissue necrosis	3 (5.4%)	0	3 (5.4%)	ns*
Stitch abscess	1 (1.8%)	1 (1.8%)	2 (3.5%)	ns*
Hematoma	1 (1.8%)	0	1 (1.8%)	ns*
Other	0	0	0	-

Table 3
Logistic regression analysis of risk factors for wound-related complications.

Variable		**OR**	**95% IC**		**P value**
			Lower	**Upper**	
Age		1.068	0.96	1.189	0.224
BMI	< 30 kg/m^2	1.00 (ref)	–	–	–
	> 30 kg/m^2	1.413	0.154	12.97	0.760
Smoking		1.198	0.023	63.25	0.929
ASA	I	1.00 (ref)	–	–	–
	II or III	6.524	0.073	585.6	0.414
Hernia size		1.048	0.942	1.166	0.390
Technique	Onlay	11.12	1.146	107.9	**0.038**
	Preperitoneal	0.09	0.009	0.873	
Operative time		0.992	0.942	1.045	0.768

OR = odds ratio; CI = confidence interval; ref = reference.

Discussion

Wound-related complications are amongst the leading causes of surgical morbidity in hernia repair. Although most events do not require reoperation, their management usually involves multiple revisits, medical treatments, outpatient procedures and hospital readmission, which increases the financial burden of the healthcare system and has a negative impact on patients' quality of life [10–13]. SSOs are also known independent risk factors for recurrence after VHR, particularly surgical site infections [14, 15].

The actual rate of postoperative wound events following umbilical hernia repair is unknown, as these short-term results are poorly documented in the literature [1, 11]. The overall incidence of SSOs after VHR (pooling umbilical and epigastric defects) ranges from 0.7 to 63.3% [10]. This high variability is likely due

to the heterogeneity of surgical techniques and the lack of standardized definitions for diagnosing and reporting postoperative wound events [10, 16]. Among previous studies that actually report wound-related complications using standardized definitions, SSOs after VHR occurs in up to 45-56.3% of patients [10], which is more consistent with the 21.4–30.4% rate observed in our study.

Such a high proportion of SSOs is not surprising, as the navel skin microbiome predisposes pathogenic bacterial growth adjacent to the surgical wound, and the limited vascular supply of the umbilicus may impair the wound healing process [17]. These unique features are of particular interest when determining the optimal technique for umbilical hernia repairs. Evidence from both experimental [18] and clinical studies [19] suggest surgical outcomes are directly affected by the anatomical layer for mesh position, as its dissection results in different degrees of surgical trauma, tissue vascularity, bacterial clearance, mesh integration and fascial tensile strength. Holihan *et al.* [5] thus advocate the ideal repair must avoid the development of devascularizing skin flaps; the selected anatomical plane should provide adequate mesh-tissue incorporation and tissue coverage to minimize exposure to both superficial SSIs and abdominal viscera; and the surgeon's preference may be influenced by the technical ease of the procedure.

This prospective, randomized, double-blind trial compared the short-term outcomes of two popular techniques for umbilical hernia open mesh repair. In the onlay technique, the *linea alba* is reapproximated and the flat mesh is placed over the anterior fascia, which requires more extensive detachments of skin and subcutaneous flaps to achieve adequate overlap. This may compromise an already frail periumbilical vascularity, leaving this anteriorly placed mesh potentially more amenable to superficial wound complications, such as seroma and infection [5]. As for the preperitoneal technique, peritoneal flaps are developed circumferentially, and the mesh is placed between the *transversalis fascia* anteriorly and the peritoneum posteriorly [20].

The rationale for the preperitoneal plane selection is the limited dissection of subcutaneous tissue with preservation of the peritoneum, which protects the mesh from both superficial wound complications and contact with the underlying bowel. Within this space there is also a varying amount of adipose and connective tissue, which enables tissue ingrowth and faster integration of the mesh into the abdominal wall [21]. Preperitoneal dissection also eliminates the risk of injury to the epigastric and perforating vessels and causes less surgical trauma compared to creating a retromuscular space [4, 22].

The placement of a flat mesh in the preperitoneal space can be otherwise challenging, if not impossible, in some cases. The preservation of a thin layer of peritoneum which is often pre-ruptured or adherent to overlying fascia and subcutaneous tissue can render this place limited in size or even nonexistent, particularly in narrow defects and obese patients [5, 23]. Indeed, two of our cases required crossover to onlay repair due to technical issues for the development of the preperitoneal space and we consider this a valid first approach to these difficult cases.

No compelling evidence from randomized clinical trials (RCT) has so far supported the superiority of any method of umbilical hernia mesh repair, and choice of mesh placement is mainly based on surgeon's preference rather than on clinical outcomes. Previous prospective studies have reported conflicting

results arising from several methodological issues, such as unclear definitions of umbilical hernia, heterogeneous surgical techniques, poor external validity and bias regarding patient selection, outcome definitions and measurements [24–25]. Despite the limited evidence available, the EHS guidelines [3] advise the open preperitoneal mesh repair with a 3-cm overlap as the technique of choice for the treatment of umbilical hernia. Data from the America Hernia Society Quality Collaborative already reveal a clear preference for sublay repairs in the United States, with more than 90% of meshes placed in retromuscular, preperitoneal or intraperitoneal spaces [26], though these anatomical planes within the sublay group were not specified.

The difference in operative times warrants discussion. The median operative time for preperitoneal repair was significantly lower than the onlay group (50 vs 67 minutes), contradicting previous evidence. Several retrospective studies have reported variable OR times, though sublay VHR repair, particularly retromuscular, tends to be longer in view of its technically more challenging dissection [27]. We do suppose the umbilical merged fascial layers facilitate a straightforward dissection of the preperitoneal plane from the hernia sac border, with minimal need for hemostasis, as this space is relatively avascular [22]. Also, eliminating the step of mesh fixation with transfacial sutures simplifies the procedure without compromising the quality of the repair [28], given that the mesh is secured by an equally distributed tension exerted by the intraabdominal pressure and the muscular tone of the abdominal wall [25]. On the other hand, onlay repairs require creation of larger skin flaps to sufficiently expose the aponeurosis, careful hemostasis of subcutaneous tissue following dissection, and wide affixation of the mesh to the fascia, which might take longer to perform.

In full transparency, we assume this difference could also be partly attributed to the relative inexperience of the residents in training enrolled, particularly in the mesh fixation step during onlay repairs – which might not be reproducible among all general surgeons and hernia specialists. This potential study limitation can instead represent more realistic data from several trainees with varying experience and be reasonably extrapolated to non-hernia specialists. We highlight the importance of resident training and reiterate the EHS guidelines on the impact of the learning curve on operative outcomes, which should be limited to possibly longer operative times [3]. Our average OR times were indeed lengthy compared to a former study that reported a mean of 36 and 47 min for onlay and preperitoneal repair, respectively [25].

The onlay technique has shown an unfavorable influence on the incidence of surgical site occurrences, though no definitive conclusion can be made regarding other risk factors due to the small number of observations for other variables in logistic regression. Nonetheless, those inherent risks of the onlay repair might be controlled with appropriate patient selection and management of well-known risk factors for postoperative complications in VHR, such as current smoking, higher BMI, defect size, ASA class III or greater and others [15, 29].

Our findings provide a good level of evidence for recommendations regarding mesh positioning in open umbilical hernia repairs. A major strength of this trial was the study design, as patient selection was strict to primary and uncomplicated umbilical hernias and the operative methods in both groups were clearly

defined. Because it was conducted at a women's hospital, only female patients were included, which may limit generalizability of our findings.

Although the preperitoneal technique was associated with a decreased wound morbidity rate, we believe the onlay repair remains an acceptable approach for patients with challenging defects in which the preperitoneal plane dissection is limited or unfeasible. Other possible mesh positioning planes, such as open intraperitoneal and retromuscular repair, as well as laparoscopic techniques, should also be compared in future trials, with a particular emphasis in alternative outcomes such as wound complications, postoperative pain, return to daily activities and quality of life.

Conclusion

The primary goal of VHR is performing a successful primary repair without postoperative complications and recurrence [3]. This study identified a decreased wound morbidity for preperitoneal umbilical hernia repairs, thus providing a good level of evidence for recommendations regarding mesh place selection in future clinical practice guidelines. Further cases from this ongoing study and completion of follow-up are also expected to compare both techniques in terms of long-term outcomes.

Declarations

Compliance with Ethical Requirements

The study protocol was approved by the institutional Ethics Comittee under the registration number 2.146.387. Informed consent was obtained from all individual participants included in the study.

Competing interests

Prof. Dr. Leandro Totti Cavazzola is a proctor for Intuitive INC. The other authors have no conflicts of interest to disclose.

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AUTHORS'CONTRIBUTIONS

Study conception and design: LC, LT

Acquisition of data: MK, LT, JG

Analysis and interpretation of data: MK, LC

Drafting of manuscript: MK, LT

Critical revision of manuscript: LC, JG

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Figures

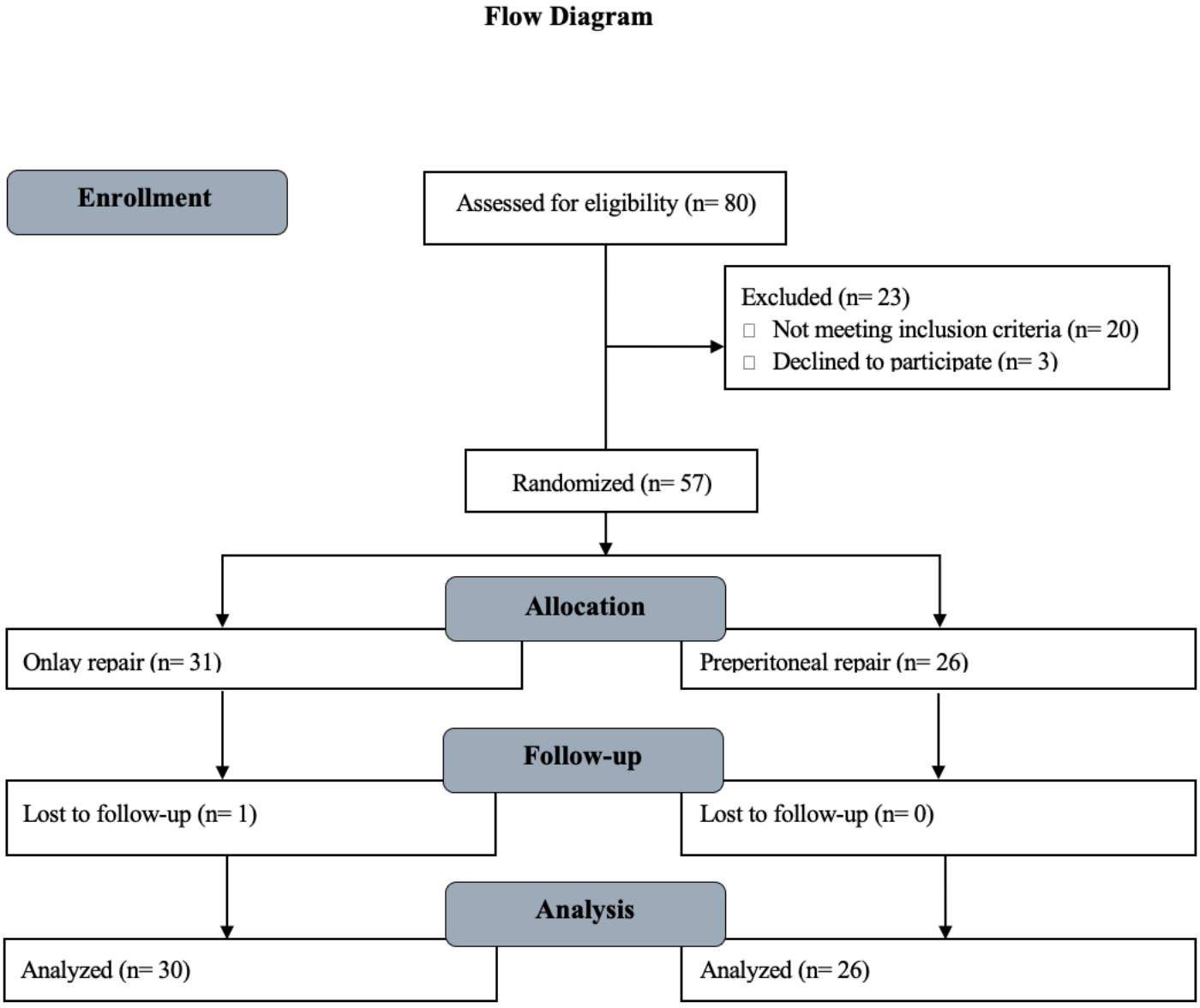

Figure 1

Study design and patient selection.

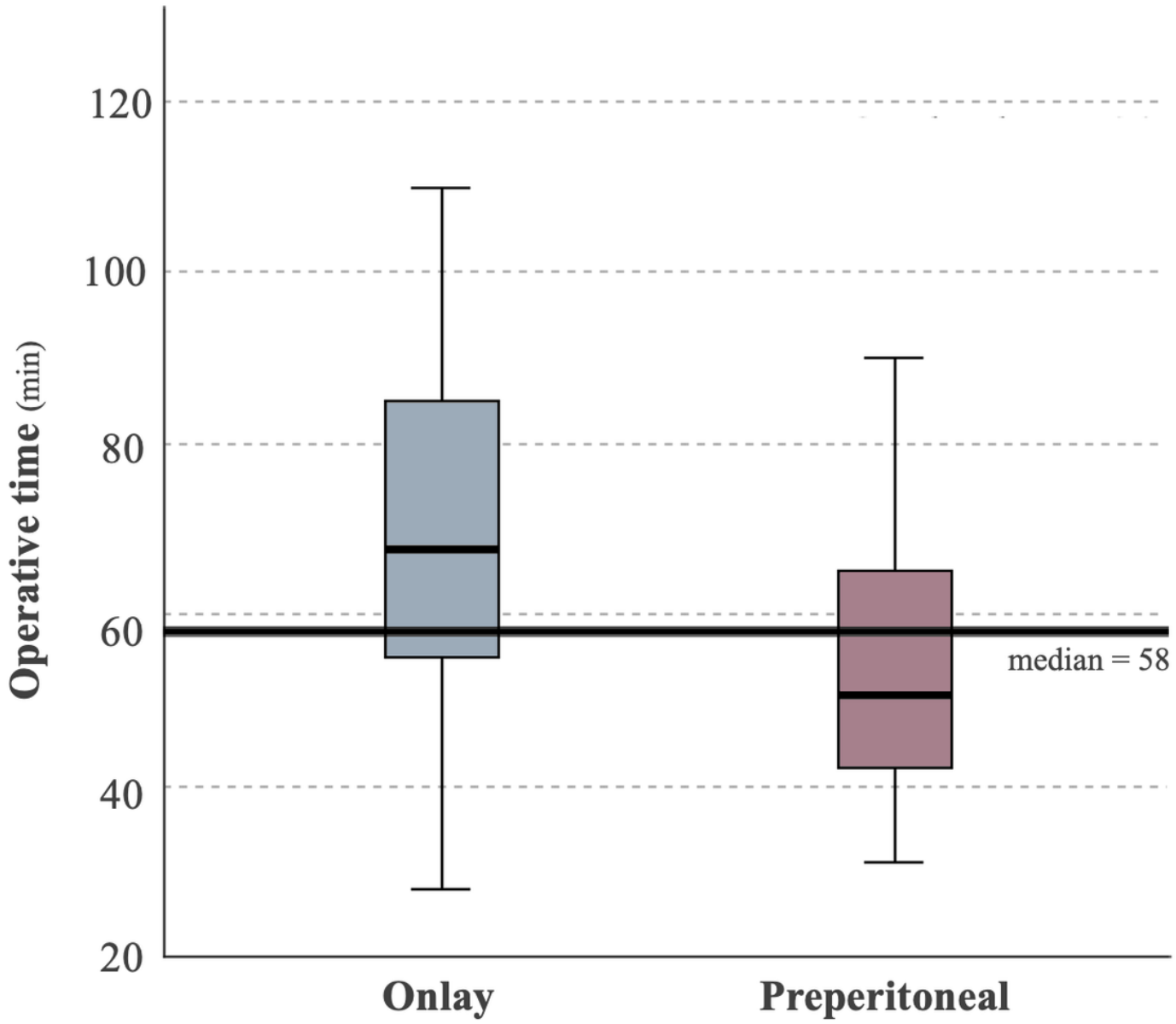

Figure 2

Boxplot of operative times in onlay versus preperitoneal groups.

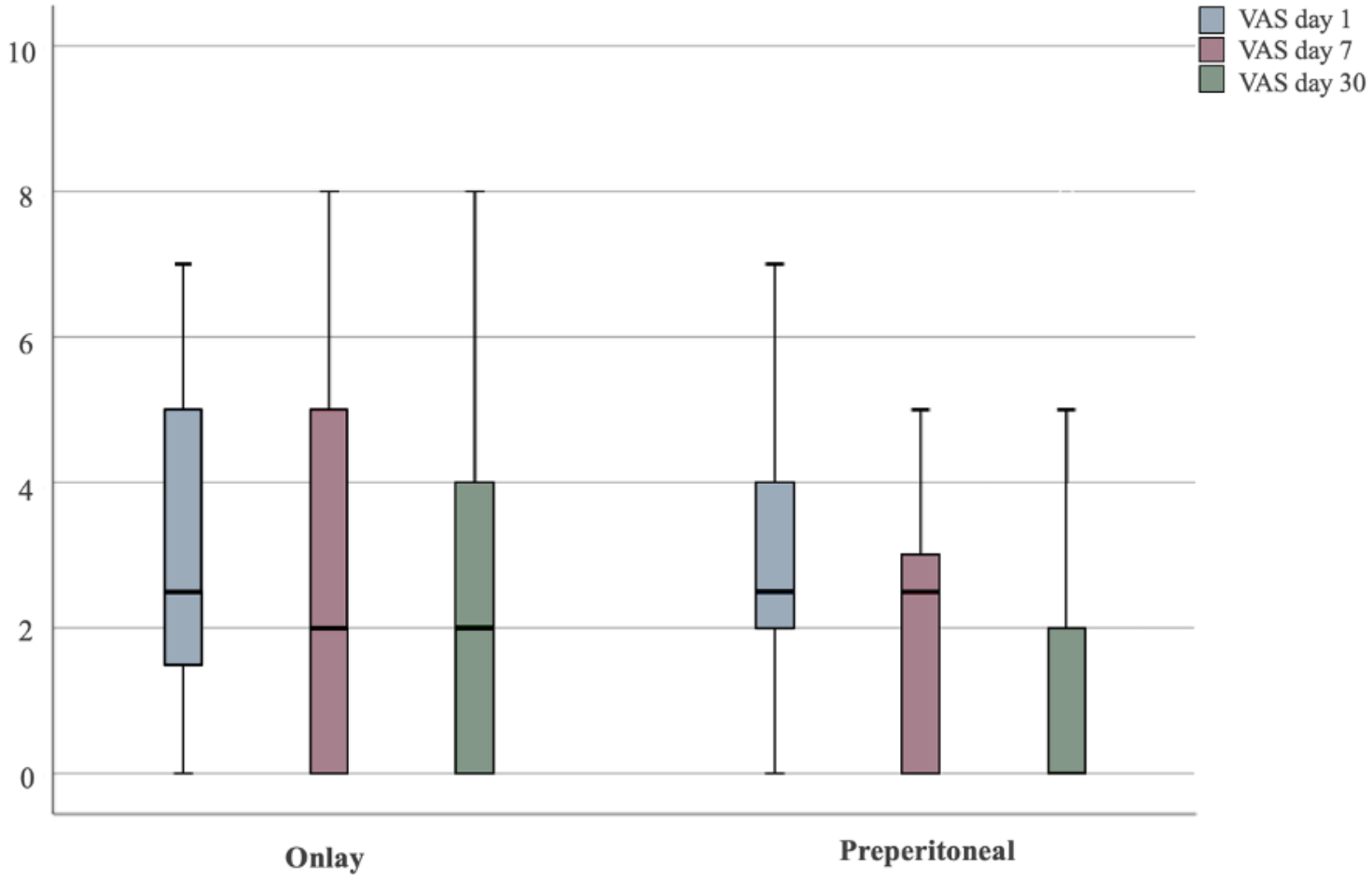

Figure 3

Boxplot of VAS pain scores (horizontal bar = median VAS score; box = interquartile range; upper and lower error bars = VAS scores greater or lower than the 75th or 25th percentile).