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RESEARCH

Interim analysis of single – centre randomised controlled trial on incisional hernia repair with vs without synthetic mesh fixation

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Abstract

Introduction In a prospective randomised trial, we aimed to compare incisional hernia repair with mesh fixation versus incisional hernia repair without mesh fixation.

Methods The study was performed from June 2018 to August 2024 at a single centre in Vilnius, Lithuania. Fifty-seven patients with incisional abdominal wall hernia were randomly included into two groups: group one—"sublay" hernia repair with mesh fixation and the second – without mesh fixation. The duration of surgery, hospital stay, pain levels, quality of life and rate of complications were compared.

Results Of the 38 women and 19 men who were included in the study, 30 were with mesh fixation and 27 without mesh fixation. The median patient's body mass index was 31.57 ± 5.96 (19.5–49.6). The most common hernia width was W2 according to the European Hernia Society (EHS) classification. A significant difference between the groups was found in duration of surgery – 108.00 ± 47.35 (40–235) minutes in the mesh fixation group vs. 75.74 ± 30.25 (35–150)—without the mesh fixation group ($p < 0.05$). A higher pain level was observed on the 10th postoperative day—3.03 ± 2.54 in the mesh fixation group versus 1.67 ± 2.22 in the group without the mesh fixation group ($p < 0.05$). A statistically significant difference was also observed in seroma rate after 6 months (16.6% versus 0%, $p < 0.05$). There have been no hernia recurrences in either group so far.

Conclusions No mesh fixation on "sublay" hernia repair does not worsen the patient's postoperative condition. It does not increase postoperative pain, worsen the quality of life, or increase the risk of postoperative complications. On the 10th postoperative day, the non-fixed mesh group had less postoperative pain, however, later the pain was equal. A lower number of seromas was also observed in this group after 6 months. However, the operative time in the group without mesh fixation was significantly shorter.

Keywords Incisional hernia · Sublay · Sutureless · Mesh hernia repair

Introduction

Incisional hernias are one of the most common complications that occur after laparoscopic or open operations. According to various authors, the frequency ranges are from 2 to 20% [1–3]. Incisional hernia treatment is surgical and multiple types of operations are performed. Despite the increased prevalence of laparoscopic operations, open hernia repair using synthetic mesh still plays an important role in the treatment of incisional hernias [1–7]. According to the literature,"sublay"hernia repair is one of the most effective surgical techniques with the least complications and recurrences [1–7]. Mesh implantation preperitoneally or retromuscularly, is recommended.

Many authors recommend mesh fixation with sutures to the aponeurosis or muscles as a treatment of choice [1–5]. On the contrary, some authors recommend hernia repair without mesh fixation [6–14]. Not fixing the mesh would save operative time and operating costs. Some authors used simple meshes [6, 7], and others – self-gripping meshes [9–14] or fibrin glue for fixation [8]. However, there is only

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one randomised controlled trial comparing two techniques—sutureless "sublay" versus "onlay" with fixation [7], and two prospective studies without randomisation [6, 9]. In a study by Gondal [7], the follow-up period was only 6 months, and two different methods were compared – "sublay" and "onlay", and only in "sublay" hernia repair mesh was not fixed. A study performed by Witkowski [6] was non-randomized and had no comparator group. Meanwhile, Bueno-Lledó [9] included a comparator group (self-gripping mesh or simple mesh with fixation), but it was a non-randomised study with a small sample size. So far there is no randomised controlled trial comparing two different techniques.

In our randomised controlled trial, we aimed to compare mesh fixation to the abdominal wall versus hernia repair without mesh fixation. Here we present the interim analysis of our study on the safety aspects.

Methods

The study was performed at the Republican Vilnius University Hospital after Vilnius regional bioethics committee approval (number 158200–17–923–429). Envelops were used to randomise the surgery (with or without mesh fixation); patients were assigned and compared in two independent groups. The patients, data collectors, and analytics were blinded to the inclusion group. The primary endpoint was postoperative pain. The secondary endpoints were seroma formation and recurrence. Pain was assessed using a visual analogue scale, VAS- 10.

Study design and surgical technique

Patient's inclusion criteria:

a) the patient presented with an incisional hernia of the abdominal wall;
b) undergoing open hernia surgery using a synthetic mesh;
c) at least 18 and younger than 70 years old at the time of the surgery;
d) sign the consent form to participate in the study.

Exclusion criteria:

a) patients younger than 18 and older than 70;
b) patients with a mental illness not possible for signed consent;
c) surgical treatment contraindicated;
d) pregnancy;
e) the patient did not sign the informed consent form.

The patient underwent incisional hernia repair with a synthetic mesh, fixing it to the aponeurosis, or without fixing it depending on which group he was assigned (envelope was opened before the surgery in the operating room). Past medical history (previous surgery, duration of hernia symptoms, diabetes mellitus, oncological disease, chronic respiratory disease, use of hormonal medications) was assessed and abdominal wall ultrasound was performed to assess the hernia size.

All operations were performed under general anesthesia after antibiotic administration of 2 g Cefazolin ("IBE Pharma", Kaunas, Lithuania). After opening the hernia sac, the contents of the sac were evaluated, the length and width of the hernia size at the largest points were measured with a sterile ruler, and the hernia was graded according to the European Hernia Society (EHS) classification [15]. The space between the subcutaneous layer and the aponeurosis was separated. *M. rectus abdominis* sheath was divided, and the space between the muscle and the posterior leaf of the aponeurosis was distributed. The excess of the hernia sac was removed. The peritoneum and posterior leaf of the m. rectus abdominis aponeurosis with the resorbable Polyglycolide-co-Lactide 2–0 filament ("Wego", Hong Kong) was sutured. Polypropylene medium-weight macroporous mesh Polymesh ("Betatech Medikal", Turkey) was used for surgery. The same meshes with rounded edges were used for both groups of patients, they were placed in such a way that they fill the separated cavity, at least 5 cm in all directions from the edges of the aponeurosis defect. For patients in the "mesh fixation" group, the mesh was fixed to the posterior leaf of the *m. the rectus abdominis* aponeurosis in the four corners and at the upper and lower points of the midline, and the edges near the aponeurosis, the mesh was fixed every 5 cm. Non-resorbable Polypropylene 2–0 filament ("Wego", Hong Kong) was used for fixation (Fig. 1). For patients in the "without mesh fixation" group, the mesh was not fixed; it was only placed in a separate layer under the abdominal wall muscles (Fig. 2). In both groups the anterior sheath of the rectus abdominis aponeurosis was sutured with

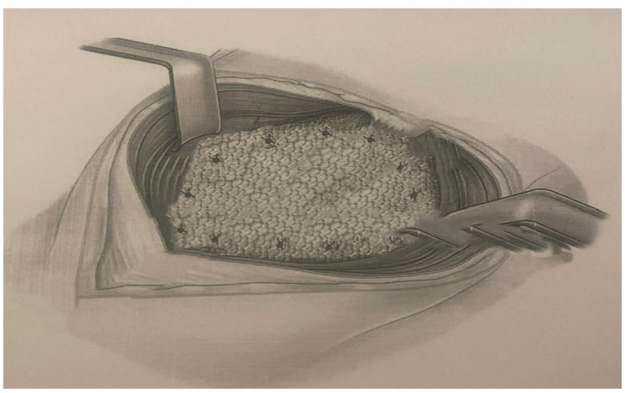

Fig. 1 Hernia repair with mesh fixation

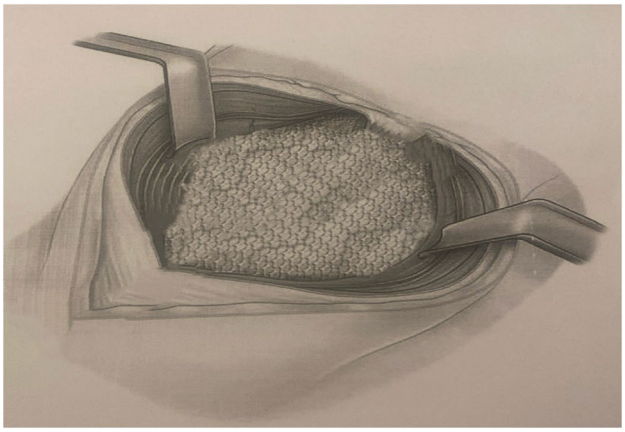

Fig. 2 Hernia repair without mesh fixation

Polydioxanone 2–0 looped suture ("Wego", Hong Kong). The wound was not drained during surgery.

All operations were performed by or with the participation of three leading surgeons. All three surgeons have extensive surgical experience—over 25 and 35 years of operating experience, respectively. All operations were performed according to the strict methodology outlined in the study description. Operations were monitored to avoid methodological inconsistencies.

After the surgery, the pain was relieved with analgesic injections. Non-narcotic Ketorolac 30 mg/ml was used as standard analgesia. At the request of the patient, in case of severe pain, narcotic analgesics Pethidinum 50 mg/ml were allowed. Postoperative pain was assessed using the visual analogue scale (VAS10) [16], and the use of narcotic analgesics from the patient's treatment sheet was counted. The pain intensity assessment is performed by the attending physician, the values are recorded in the medical history, and the data are later included in the Excel table.

On the third postoperative day or earlier, if the patient was discharged on the 1st or 2nd postoperative day, an abdominal ultrasound was performed, and the mesh in the abdominal wall was localized, and possible fluid collection was assessed. On the 10 th day, when the stitches were removed, an abdominal ultrasound was repeated, and the localization of the mesh in the abdominal wall and possible fluid collections were assessed. The patient was invited for a first follow-up (one month), then six months, one, three, and five years after the surgery. During the visit, the patient's condition is assessed, and an abdominal wall ultrasound is performed, during which the localization of the mesh in the abdominal wall and possible fluid concentration are assessed. Seroma of more than 150 ml or causing pain should be aspirated.

The patients filled the quality-of-life assessment Short Form 36 Medical Outcomes Study questionnaire (SF- 36) [17–19]. The results of the questionnaire were processed by the calculation program Orthotoolkit (https://orthotoolkit.com/sf-36/).

After the surgery, the patients were evaluated for possible complications. These consisted of:

a) seroma—is considered a fluid accumulation 1 month or later after surgery (on ultrasound);
b) surgical site infection—is considered an inflammatory process that can be treated with antibiotics or by opening the wound;
c) hematoma—accumulation of blood clots in the wound (on ultrasound);
d) dehiscence—the protrusion of contents of the abdomen through a defect or weakness in the abdominal wall;
e) hernia recurrence—the appearance of a hernia defect at the site of a previous hernioplasty (on ultrasound or CT if it needs).

Statistical analysis and tools

According to previous studies [20], VAS data for postoperative pain (5.88 ± 2.06 vs 3.88 ± 1.78, $p < 0.01$) was used to calculate the power of our study. G*Power 3.1.9.7 program was used for sample size calculation. The data suggest that a sample of 52 patients is sufficient for reliable study results. The planned study sample is 100 cases, and the follow-up is 1, 3 and 5 years. Our article reviewed the interim results of the first 57 patients in the first year of follow-up to ensure that both surgical methods are safe.

All data are summarized in an Excel table, which is stored on the researcher's laptop in a special research file, as well as paper copies in a secure cabinet. All data is blinded using encrypted codes. All three investigator surgeons were responsible for data collection, processing, and evaluation.

Statistical analysis was performed using the SPSS statistical software package (IBM SPSS Statistics for PC, Version 26.0). A descriptive analysis of the data was performed, the means of parametric data were compared using the Student t-test, and non-parametric data between two independent groups were compared using the Mann–Whitney U test. A p-value < 0.05 was considered to denote statistical significance.

Results

During the study from June 2018 to August 2024, 57 patients (30 with and 27 without mesh fixation) were operated on and subsequently examined. Study participants were included based on the CONSORT statement. The CONSORT flow chart can be seen in Fig. 3.

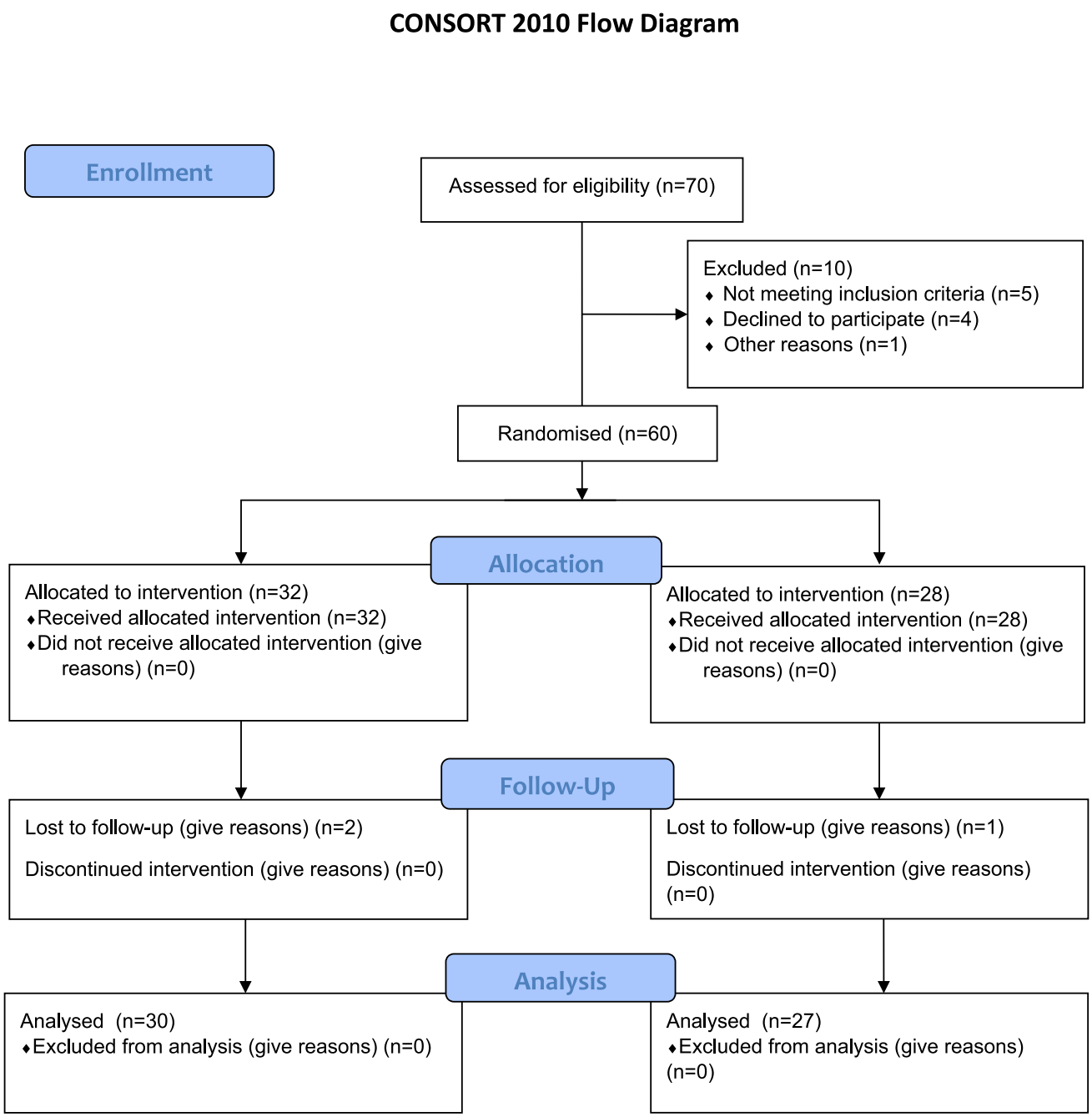

Fig. 3 CONSORT flow chart

Demographic data and characteristics of patients are presented in Table 1.

We have evaluated the primary surgeries that developed a postoperative abdominal wall hernia (Fig. 4). The distribution between the groups was similar, patients who developed incisional hernias after laparoscopic cholecystectomies (29.82%) or gynaecological operations (19.30%) prevailed.

Intraoperative data can be seen in Table 2 – midline, W2-sized hernias predominated.

We found that the operative and mesh implantation times were significantly shorter in a group without mesh fixation ($p < 0.05$). Moreover, less pain was observed in this group on the 10 th postoperative day assessed by the visual analogue scale VAS 10 ($p < 0.05$). Other variables did not show an advantage or disadvantage for either group in the first year after the surgery. A statistically significant difference was observed in seroma rate after 6 months (16.6% versus 0%, $p < 0.05$). We did not have cases for

Table 1 Demographic data and characteristics of the patients

	With fixation (N = 30)	Without fixation (N = 27)	*p*-value	Total (N = 57)
Age, year, SD*, (min–max)	57.20 ± 9.60 (34–70)	55.70 ± 7.22 (33–66)	0.513	56.49 ± 8.52 (33–70)
Gender: male vs. female	10 (33.3%) vs. 20 (66.7%)	9 (33.3%) vs. 18 (66.7%)	1.000	19 (33.3%) vs. 38 (66.7%)
Body mass index, kg/m^2, SD*, (min–max)	32.41 ± 6.73 (22.2–49.6)	30.65 ± 4.94 (19.5–42.2)	0.270	31.57 ± 5.96 (19.5–49.6)
Oncology	6 (20%)	7 (25.9%)	0.602	13 (22.8%)
Diabetes mellitus	5 (16.7%)	2 (7.4%)	0.531	7 (12.3%)
Use of hormonal medications	1 (3.3%)	1 (3.7%)	0.941	2 (3.5%)
Chronic respiratory diseases	3 (10%)	2 (7.4%)	0.735	5 (8.8%)
Duration of symptoms, months, SD*, (min–max)	16.67 ± 20.05 (2–90)	27.48 ± 30.42 (1–120)	0.115	21.79 ± 25.84 (1–120)

**SD* – standard deviation

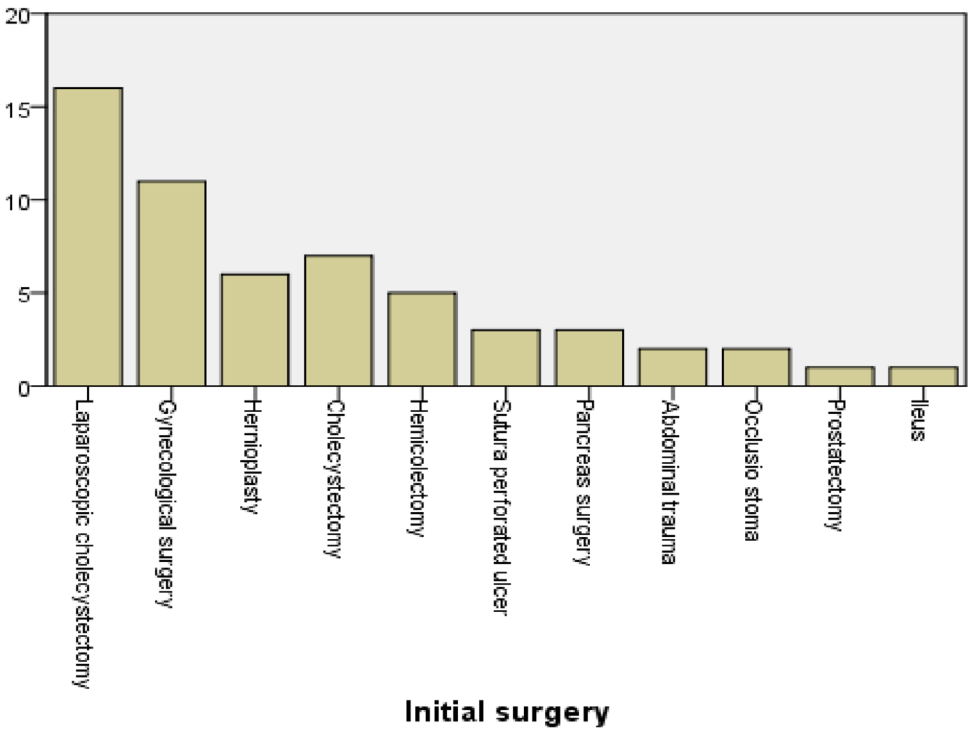

Fig. 4 Procedures performed as an initial surgery

seroma aspiration during our study. There were no hernia recurrences in both groups (Table 3).

Quality of life was also assessed one month, six months, and one year after surgery using the SF36 rating scale (Table 4). After comparing the data of both groups, no statistically significant difference was observed.

Discussion

Our study compared the intraoperative and postoperative data of incisional abdominal wall hernia repair with and without synthetic mesh fixation. We observed that the"without mesh fixation"group had significantly shorter operative and mesh implantation times. Similar observations were noted in the publications by Bueno Lledo [9] – (101 ± 29.5 min in the self-gripping mesh group vs. 121 ± 39.8 min in a group with fixation), and the Suciu [13] study (180 min vs. 120 min) better in the non-fixing group.

Bueno Lledo [9] and Khansa [11] showed less postoperative pain, when applying a mesh without fixation, which our data can partially confirm, the VAS 10 score on the 10 th postoperative day was significantly lower in the"without mesh fixation"group. Bueno Lledo [9] showed pain after 48 h using VAS was 3.1 ± 2.3 in self-gripping mesh group vs. 4.3 ± 3.5 in group with fixation (p-no data). Khansa

Table 2 Intraoperative data of patients included in the study

		With fixation (N = 30)	Without fixation (N = 27)	p-value	Total (N = 57)
Hernia size, cm^2, (min–max)		53.86 ± 66.65 (3.1–235.6)	36.92 ± 33.61 (3.1–125.7)	0.719	45.83 ± 53.83 (3.1–235.6)
Hernia width according to EHS*	W1	9 (30%)	9 (33.3%)	0.791	18 (31.6%)
	W2	16 (53.3%)	16 (59.3%)	0.659	32 (56.1%)
	W3	5 (16.7%)	2 (7.4%)	0.296	7 (12.3%)
Hernia length M size	1	12 (40%)	9 (33.3%)	0.610	21 (36.8%)
	2	11 (36.7%)	11 (40.7%)	0.758	22 (38.6%)
	3	5 (16.7%)	6 (22.2%)	0.603	11 (19.3%)
	4	2 (6.7%)	1 (3.7%)	0.624	3 (5.3%)
	5	0	0		0
Operative time, minutes, SD**, (min–max)		108.00 ± 47.35 (40–235)	75.74 ± 30.25 (35–150)	0.006	92.70 ± 43.01 (35–235)
Mesh implantation time, seconds, SD**, (min–max)		891.80 ± 336.61 (400–1800)	118.37 ± 122.82 (30–495)	0.000	525.40 ± 466.34 (20–1800)

**EHS* – European Hernia Society

***SD* – Standard deviation

Table 3 Postoperative data of patients included in the study

		With fixation (N = 30)	Without fixation (N = 27)	*p*-value	Total (N = 57)
Length of hospital stay, days, SD*		2.77 ± 2.65	2.89 ± 1.99	0.846	2.82 ± 2.34
The need for narcotic analgetics on the 1 st day, quantity		0.80 ± 0.76	0.59 ± 0.63	0.272	0.70 ± 0.71
Pain according to VAS10** on the 1 st day		7.10 ± 1.00	7.11 ± 1.58	0.974	7.11 ± 1.29
Pain according to VAS10** on the 10 th day		3.03 ± 2.54	1.67 ± 2.22	0.036	2.39 ± 2.47
Pain according to VAS10** in 1 month		0.31 ± 1.00	0.65 ± 1.33	0.280	0.47 ± 1.17
Pain according to VAS10** in 6 months		0	0.08 ± 0.39	0.295	0.04 ± 0.27
Pain according to VAS10** in 1 year		0	0	-	0
Seroma	After 1 month	13 (43.3%)	10 (37%)	0.730	23 (40.4%)
	After 6 months	5 (16.6%)	0	0.037	5 (8.8%)
	After 1 year	2 (6.7%)	0	0.179	2 (3.5%)
Complications during hospital stay		0	1 (4.2%)	0.296	1 (2.2%)
Complications after 10 days		1 (4.8%)	2 (8.4%)	0.603	3 (6.6%)
Complications after 1 month		0	1 (4.2%)	0.295	1 (2.2%)
Recurrence of hernia		0	0	1.000	0

**D* – Standard deviation

***VAS10* – Visual Analogue Scale 10

[11] found that postoperative pain was 66.5 using VAS 100 in the self-gripping mesh group vs. 133.1 in a group with fixation (p = 0.04).

In most studies, hernia recurrence was the primary endpoint [9–11]. Harpain [10], showed a hernia recurrence of 2.4% in the self-gripping mesh group vs. 2.6% in a group with fixation, other authors showed no recurrences [9, 11], similarly as in our study. However, two of our operated patients had wound dehiscence on the first postoperative day (4.4%). We have separately examined patients having this complication. Both patients – one with hernia repair with mesh fixation, and the second without mesh fixation had a high body mass index (BMI) of 42.24 and 45.36, which may have also played a role in the formation of dehiscence. Because complications occurred in patients with a BMI above 40, we think that a BMI above 40 should be considered an exclusion criterion in the continuation of the study.

Bueno Lledo [9] observed that the non-fixed mesh shortens the hospital time (5.8 ± 2.2 in self-gripping meh

Table 4 Assessment of quality-of-life using SF- 36 one, six months and one year following the surgery

	After 1 month			After 6 months			After 1 year		
	With fixation (N = 30)	Without fixation (N = 27)	p-value	With fixation (N = 30)	Without fixation (N = 27)	p-value	With fixation (N = 30)	Without fixation (N = 27)	*p*-value
Physical functioning	64.13 ± 25.14	65.58 ± 17.63	0.946	78.10 ± 19.88	80.96 ± 19.60	0.535	82.93 ± 20.81	83.46 ± 16.84	0.632
Role limitations due to physical health	28.45 ± 40.49	23.08 ± 36.00	0.806	68.97 ± 37.59	69.23 ± 38.28	0.971	73.28 ± 40.60	74.04 ± 37.74	0.779
Role limitations due to emotional problems	36.79 ± 42.11	55.13 ± 43.15	0.134	78.17 ± 38.08	78.21 ± 33.92	0.711	72.41 ± 41.85	84.62 ± 28.65	0.358
Energy/fatigue	61.21 ± 17.71	63.27 ± 16.55	0.748	68.62 ± 17.42	69.29 ± 15.41	0.832	68.79 ± 13.54	66.92 ± 16.38	0.665
Emotional well-being	69.24 ± 19.39	70.15 ± 16.05	0.780	70.21 ± 17.02	75.96 ± 17.66	0.171	68.28 ± 13.60	71.54 ± 17.97	0.666
Social functioning	68.97 ± 20.76	68.27 ± 26.04	0.898	80.60 ± 16.22	81.25 ± 18.11	0.713	81.47 ± 15.53	84.14 ± 19.22	0.231
Pain	61.21 ± 21.74	56.25 ± 26.01	0.352	80.26 ± 21.84	78.75 ± 23.12	0.848	87.93 ± 19.13	86.39 ± 17.07	0.518
General Health	63.10 ± 17.75	63.46 ± 16.84	0.760	66.90 ± 19.48	70.00 ± 21.73	0.629	65.52 ± 20.63	68.46 ± 15.61	0.416
Health change	81.03 ± 18.49	79.04 ± 19.94	0.724	81.90 ± 21.02	78.81 ± 22.11	0.586	76.55 ± 26.19	77.86 ± 22.72	0.993

group vs. 6.6 ± 2.9 in group with fixation). The advantage of the mesh without fixation in hospital stay was also noticed by Suciu [13] – 8.07 vs. 10.59 ($p < 0.05$). In our study, we did not observe a difference between the groups regarding hospital stay (2.77 vs. 2.89, p = 0.846). Witkowski [6] in a single-arm study of 111 included patients, showed that no fixation of the mesh was a safe method for a small and medium-sized hernia, the number of complications of these operations was low, and the recurrence rate of hernias reached 3%. It was a non-randomised study, without a comparison group. Gondal [7] in their randomised study of 64 patients compared "sublay" hernia repair without mesh fixation with "onlay" hernia repair with mesh fixation. The authors found no hernia recurrences in both groups, and the number of other complications (hematoma, wound infection, or seroma) was lower in the "sublay" without mesh fixation group. However, this was a small single-centre study, assessing two different methods (sublay—onlay), and non-fixation of the mesh was only in the "sublay" group, with a follow-up of only 6 months. J. Bueno Lledo [9] in their prospective non-randomised 50 patients' analysis showed no hernia recurrences and shorter operative time in the no-fixation group (12–20 months follow-up).

Ellis et al. [21] examined the issue of non-mesh fixation. They compared hernias with and without mesh fixation in their prospective randomised study. They also selected hernia recurrence and postoperative pain as outcomes. In the study authors observed that postoperative pain and recurrence rates were the same in both groups. Although they identified only a 1-year follow-up as their limitation, due to the large sample size (325 subjects), they concluded that non-mesh fixation did not worsen the results compared to mesh fixation. These findings allow us to believe that our chosen study, comparing mesh fixation with no fixation, has clinical significance.

Our study has some limitations too. First – this is a relatively small single-centre study. The second limitation is the long inclusion time (due to the COVID pandemic). A follow-up of only 1 year is another limitation of our study. However, this is only the interim safety analysis, with planned follow-ups at 1, 3 and 5 years. Moreover, we did not take into account smoking, which could affect the final results. We also noted the need for differentiation by BMI, which is limited to a maximum of 40.

Conclusions

No mesh fixation on "sublay" hernia repair does not worsen the patient's postoperative condition. It does not increase the postoperative pain, nor worsen the quality of life, nor increase the risk of postoperative complications. On the 10 th postoperative day, the non-fixed mesh group had less postoperative pain, however, later the pain was equal. A lower number of seromas was also observed in this group after 6 months. However, the operative time in the group without mesh fixation was significantly shorter.

Author contributions All authors wrote and reviewed the manuscript text, figures and tables.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethics approval This study was approved by the Vilnius Regional Biomedical Research Ethics Committee.

Human and animal rights No rights were violated.

Informed consent All patients read and signed the consent for the study.

Competing interests The authors declare no competing interests.

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