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ORIGINAL ARTICLE

Surgical outcome of mesh and suture repair in primary umbilical hernia: postoperative complications and recurrence

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Abstract
Purpose To compare recurrence and surgical complications following two dominating techniques: the use of suture and mesh in umbilical hernia repair.
Methods 379 consecutive umbilical hernia repair procedures performed between 1 January 2005 and 14 March 2014 in a university setting were included. Gathering was made using International Classification of Diseases codes for both procedure and diagnosis. Each patient record was scrutinized with respect to 45 variables, and the results entered in a database.
Results Exclusion <18 years-of-age (32), non-primary umbilical hernia (25), wrong diagnosis (7), concomitant major abdominal surgery (5), double registration (3) and pregnancy (1) left 306 patients eligible for analysis. Gender distribution was 97 women and 209 men. There was no difference between mesh and suture with regard to the primary outcome variable, cumulative recurrence rate, 8.4 %. Recurrence was both self-reported and found on clinical revisit and defined as recurrence when verified by a clinician and/or radiologist. Results presented as odds ratio (OR) with 95 % confidence interval (CI) show a significantly higher risk for recurrence in patients with a coexisting hernia OR 2.84, 95 % CI 1.24–6.48. Secondary outcome, postoperative surgical complication ($n = 51$ occurrences), included an array of postoperative surgical events commencing within 30 days after surgery. Complication rate was significantly higher in patients receiving mesh repair OR 6.63, 95 % CI 2.29–20.38.
Conclusions Suture repair decreases the risk for surgical complications, especially infection without an increase in recurrence rate. The risk for recurrence is increased in patients with a history of another hernia.

Keywords Hernia · Umbilical · Recurrence · Surgical complication · Suture · Mesh

Introduction

Based on American incidence figures [1], umbilical hernia repair is the second most common surgical hernia procedure in the western world, second only to groin hernia repair [2]. Incidence rates are steadily increasing [3] but its etiology is multifaceted. According to Colavita et al. 90 % of umbilical hernias are acquired, and the major contributing risk factor is increased abdominal pressure caused, for example, by chronic obstructive pulmonary disease, constipation, ascites, morbid obesity, prostate hypertrophy and multiparity [4, 5]. Furthermore specific tissue degenerative drugs such as corticosteroids may lead to an increased risk for hernia [6], as may connective tissue disease, even though the literature on these is limited. Despite this, treatment of a symptomatic hernia is primarily surgical and publications on outcome from large cohorts are surprisingly scarce [7], and consensus on which surgical technique is gold standard has as yet to be decided [8–10]. The two dominating techniques are suture [11] and mesh repair [7, 12]; both having multiple subtechniques and a plentitude of suture/mesh material choices [7, 13]. This diversity per se constitutes evidence of disagreement in what is the ideal technique. In papers

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published during the past decade, the pendulum has been slightly in favor of mesh repair [8, 14], with a lower recurrence rates [7, 15, 16]. In a meta-analysis of a pooled series of umbilical and epigastric hernias the recurrence rate was 2.7 % [8]. Corresponding postoperative complication rates range between 3.5 [15] and 11.8 % [17]. The most recent randomized clinical trial dating back to 2001 came out in support of mesh repair [5], and is frequently cited despite the somewhat outdated material. Meanwhile, other authors challenge the pole position of mesh [15], and the most recent meta-analysis found no significant difference in complication rates [7]. In addition, with some mesh techniques up to 35 % of patients experience some discomfort 1 month after surgery [13]. In spite of this, Christoffersen et al. found no significant difference in long-term experience of pain when comparing suture with mesh repair [16].

Although surgical site infection rates may be low with mesh, all foreign bodies potentiate the inflammatory response to surgery, and once infection has occurred in the area it may cause devastating damage to the abdominal wall [13, 17], as well as increase postsurgical pain and the risk for recurrence [18]. Furthermore, infection may cause migration of the mesh as noted from the very beginning of mesh use [19] and still today [13].

There is also a monetary incentive for evaluating these techniques; an American estimate from 2012 states that for ventral hernia repair, every 1 % reduction in hernia recurrence would result in an annual saving of 32 million USD in procedural costs alone [3]. Although extrapolation should be made with caution since the cost of incisional hernia repair is higher than umbilical or epigastric hernia repair, these procedures have a higher incidence, and the 2012 estimate indicates that there is considerable potential to increase efficacy and thereby reduce costs. Information available on umbilical herniorrhaphy or hernioplasty alone, however, is scarce and often pooled with other types of ventral hernia repair, probably to gain power. However, umbilical hernias do not necessarily share the pathophysiology of other ventral hernia; hence the material in this study isolates umbilical hernia from other forms of ventral hernia. There is a clear benefit in investigating recurrence and complication rates of umbilical hernia repair alone, since this could lead to an improvement in treatment algorithms. To do so, a study on prospectively registered data was performed. The main objective was to compare mesh with suture, for primary umbilical hernia repair. The primary outcome was recurrence and the secondary outcome was surgical complication rate. Gender, age and hernia size were patient characteristics of specific interest, and were scrutinized to see if any of these are related to surgical outcome.

Materials and methods

Database validation

Patients were identified by the procedure codes (Swedish "Klassifikation av vårdåtgärder", KVÅ) and International Classification of Diseases codes (ICD). ICD codes included K42.0, K42.1 and K42.9, and procedure KVÅ codes JAF10–JAF84. A research nurse registered the codes prospectively at the time of surgery. Retrospect catchment and completion of surgical procedures were achieved in 2014. The use of a research nurse to record patient data was made to "blind" the surgeon, hence avoiding confounding as well as selection and confirmation bias. There were 379 consecutive cases undergoing umbilical hernia repair between 1 January 2005 and 14 March 2014 at University Hospital of Umeå, all cases being registered in the database. Database validation was performed on 40 patients, testing consistency between surgical notes and procedure codes, and between surgical procedure notes in the surgical records and discharge notes in the medical records.

Database compilation

Predefined research parameters and length of study was set prior to start, as to build a prospectively gathered database, with data compiled in January 2005 to March 2014 by a research nurse. In 2014 review of all 379 cases' medical-, surgical- and, if applicable, radiological records were made retrospectively. Study data were handled with Access® 2011 (Microsoft Corporation, Redmond, Washington, USA), and statistical calculations with Stata® software release 13.1 (StataCorp LP, College Station, Texas, USA). Data collected included 45 pre-, peri- and postoperative parameters. Variables were first analyzed with univariate logistic regression, and variables found to be significant were analyzed again in a multivariate regression model to investigate any confounding elements. Results are presented as odds ratio (OR) with 95 % confidence interval (CI), where CI above or beneath one is considered significant.

This study was approved by the Ethics Committee of Umeå University Hospital (d-nr 2012 1961 31/1 SLL).

Definitions

Umbilical hernia was defined, according to the European Hernia Society's classification [1], as a hernia in the region 3 cm above to 3 cm below the umbilicus, situated in the midline with rectus muscle forming the lateral margins. A post-operative follow-up visit at the surgical outpatient clinic was offered to all patients, and patients were also

asked to seek additional medical attention if abdominal symptoms appeared. Follow up of recurrences included regular follow-up at the outpatient clinic, such visits initiated by the patient and all relevant radiological examinations [computed tomography (CT) and ultrasound of the abdominal area] performed for any reason during the follow-up time. A patient was considered to have a recurrence if diagnosed clinically by a surgeon, stated in a radiology report, or being obvious on imaging. Patients without any record of recurrence were not further contacted for follow-up. Surgical complications were defined as those commencing within 30 days after surgery and included bleeding necessitating transfusion, reoperation, infection treated with antibiotics, seroma, abdominal pain either prolonged or leading to hospital admission, abscess, wound rupture, fistula/intestinal leakage, dermal necrosis, enterocutaneous fistula, fistula without intestinal communication and other complications. Complications were graded according to Clavien–Dindo [20]. Surgical parameters recorded included types of mesh-/suture repairs, mesh used and duration of surgery. Smoking was defined as any record of smoking within 3 months prior to surgery. Diabetic patients included all patients classed as diabetics in the medical records or radiological referrals, and patients with any diabetic intervention such as prescriptions of diabetic drugs or dietary treatment. For exploratory reasons patients with signs of a coexisting hernia or having a history of previous surgery on another hernia were recorded as possibly having some form of collagen dysfunction.

Results

Database validation resulted in 95 % conformity (38 patients out of 40). Of the total 379 cases reviewed, 306 patients remained suitable for analysis—patients excluded are listed in a flow diagram (Fig. 1) according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [21]. All patients under 18 years-of-age at the time of surgery were omitted. Concomitant major abdominal surgery was considered an exclusion criterion, since patient outcome was highly dependent on that procedure. "Other hernia" at patient presentation included other ventral hernia, groin hernia, prolapse, rectus diastasis and hiatus hernia. Emergency and urgent procedures were noted separately but these were not considered to be exclusion criteria. The most common reasons for exclusion were age under 18 years and diagnosis other than primary umbilical hernia (i.e. recurrent hernia and incisional hernia). By the time of analysis, 18 patients had died. None of these died during their stay in hospital for hernia repair, and hence none were excluded. Three patients received laparoscopic surgery and all others underwent open repair. There were no intraoperative complications. Mesh techniques were sub-lay (preperitoneal, under the rectus muscle), on-lay, intraperitoneal on-lay mesh (IPOM) and other (e.g. "plug"), with sub-lay being the most common (66 %) (Table 1). Both simple interrupted, i.e. Mayo, and the shoelace technique according to Abrahamson were used for suture repair. A wide range of meshes were used (Table 2) with the Prolene mesh most frequently used (57 %). Somewhat more suture repairs (53 %) were performed during the first half of the study period, whereas mesh repair (52 %) was the most frequent during the second part. The majority of patients (85 %) received general anesthesia, otherwise local anesthetics were used, particularly in the suture group. No

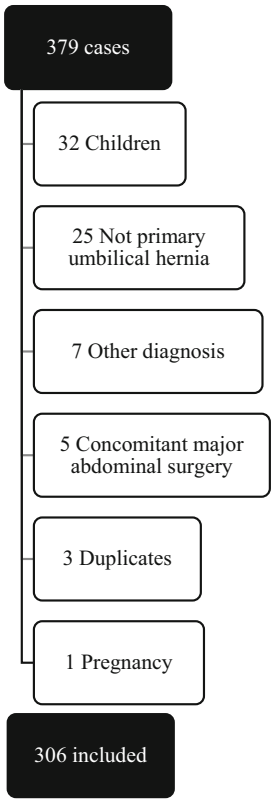

Fig. 1 Exclusion flow diagram. Flow diagram, according to STROBE, of excluded cases from the primary cohort of all umbilical hernia operations

Table 1 Type of repair

Type of repair	*n*
Suture	122
On-lay	23
Sub-lay	132
IPOM	2
Other	27

Other techniques included 24 "mesh plug" and three non-documented

IPOM intraperitoneal on-lay mesh

Table 2 Mesh type and placement

Mesh type	*n*	Placement
BARD softmesh	32	31 sub-lay, 1 on-lay
Prolene	104	64 sub-lay, 19 on-lay, 21 other
Ultrapro or vypro	16	14 sub-lay, 2 on-lay
Other (e.g. Atrium prolite)	32	23 sub-lay, 2 IPOM, 1 on-lay and 6 other

IPOM intraperitoneal on-lay mesh

drains were used. Prophylactic antibiotic treatment was not registered, but was unusual in the cohort since this is not standard practice.

As can be seen in baseline and clinical characteristics (Table 3), the mesh group had a larger median defect of 20 mm (95 % CI 7–40) compared to the suture repair group that had a median of 10 mm (95 % CI 4–20). Both groups had a similar female:male ratio (suture 34:66, and mesh 30:70). Median overall age at intervention was 48.2 years (range 18.4–88.0) and overall median time of follow-up was 6.8 years (range 0.9–9.7). Suture repairs were performed at a median age of 45.5 years (range 18.4–83.9) with a median time to follow-up of 8.6 years (0.9–9.7). Mesh group median age at intervention was 49.6 years (range 19.8–88.0) with a median time to follow-up of 5.5 years (1.4–9.7).

According to (Table 3) the groups did not differ with respect to burden of disease; the suture respectively mesh group had similar prevalence of smokers (15 and 9 %), diabetics (8 and 13 %), median body mass index (BMI) (26 and 29), share of American Society of Anesthesiologists score (ASA) class 1–2 (92 and 85 %), share of ASA class 3–4 (5 and 11 %) (ASA class was not recorded in four suture repairs and six mesh repairs), other recorded hernias (37 and 39 %).

Table 3 Number of patients with baseline data

Baseline data	Suture $n = 122$	Mesh $n = 184$
Age	48 (18–84)	50 (20–88)
ASA class		
1–2	112	157
3–4	6	21
BMI	26 (20–36)	29 (21–39)
Smoker	18	17
Diabetes	10	24
Male	80	129
Hernia size	10 (4–20)	20 (7–40)
Other hernia	45	72
Day surgery	89	130

Suture, combined group of patients operated with one of several commonly used suture techniques; Mesh, combined group of patients operated with one of several commonly used mesh techniques; Age, median years by the time of surgery, with minimum and maximum values; Hernia size in (mm) median and CI

ASA American Society of Anaesthesiologists classification ($n = 296$), *BMI* body mass index (kg/m^2) median and CI, *CI* 95 % confidence interval

The recurrence rate was 9 % in the suture group and 8 % in the mesh group, OR 0.90, 95 % CI 0.40–2.02. With respect to hernia recurrence, the only significant risk factor was other coexisting hernia OR 2.84, 95 % CI 1.24–6.48. Gender, age, hernia size, BMI, ASA-classification score, specific type of repair, smoking, and diabetes all proved insignificant in this material, see (Table 4). Subdivision of the mesh group according to mesh type or location of mesh provided insufficient power for further firm conclusions regarding complications or recurrence (data not shown).

A major and significant difference between the suture group and mesh group was the overall incidence of complications, with 4 % in the suture and 25 % in the mesh group (Table 5). The number of complications did not differ between the first and the second half of the study period. Recorded complications included infection, seroma, abdominal pain, abscess, wound rupture and other complications (nausea, adverse reaction to sutures, dissatisfied patient). The difference of complications remained significant when analyzed with logistic multivariate regression OR 6.63, 95 % CI 2.29–20.38, see (Table 6). Deep infection and abscess only occurred in the mesh group, and infections treated with antibiotics were more common in the mesh group OR 6.24, 95 % CI 1.84–21.14 (Table 5). Hernia size and BMI showed significance with respect to complications in binary logistic regression, but not in multivariate analysis (Table 6).

Discussion

Complication rate was significantly lower with suture repair compared to mesh repair, and intriguingly, abscesses only developed in the mesh repair group. Recurrence rate was not significantly higher in the suture repair group, failing to support previous reports showing a slightly higher risk for recurrence with suture repair [7]. In this material the differences in median hernia size was 10 mm, which aggravates a direct comparison between the groups but interestingly the median values in both groups were far

Table 4 Primary outcome results

	Elective and emergency repairs ($n = 306$)	
	Recurrences *n*/no at risk (%)	Univariate model OR (95 % CI)
Age		
<Median	14/153 (9.2)	1 (ref)
≥Median	12/153 (7.8)	0.84 (0.38–1.89)
Gender		
Female	11/97 (11.3)	1 (ref)
Male	15/209 (7.2)	0.6 (0.27–1.37)
ASA ($n = 296$)		
Class 1–2	22/269 (8.2)	1 (ref)
Class 3–4	3/27 (11.1)	1.40 (0.39–5.03)
BMI		
<Median	16/155 (10.3)	1 (ref)
≥Median	10/139 (7.2)	0.67 (0.29–1.54)
Smoking		
No	23/271 (8.5)	1 (ref)
Yes	3/35 (8.6)	1.01 (0.29–3.56)
Diabetes		
No	25/272 (9.2)	1 (ref)
Yes	1/34 (2.9)	0.30 (0.04–2.28)
Repair type		
Suture	11/122 (9.0)	1 (ref)
Mesh	15/184 (8.2)	0.90 (0.40–2.02)
Hernia size		
<Median	11/158 (7.0)	1 (ref)
≥Median	13/121 (10.7)	1.61 (0.69–3.73)
Other hernia		
No	10/189 (5,3)	1 (ref)
Yes	16/117 (13,7)	2.84 (1.24–6.48)*

Significant results marked with asterisk. Number of hernias subjected to analysis, unless stated otherwise ($n = 306$). Hernia size ($n = 279$). No multivariate analysis could be performed on "other hernias", this being the only eligible variable. Emergency repairs ($n = 29$). In groups divided by median, median values are grouped as to best balance the denominator size

ASA American Society of Anaesthesiologist classification ($n = 296$), *BMI* body mass index ($n = 294$)

below 30 mm, which is the current surgical cut-off praxis for the use of a mesh procedure. Yet, it is not surprising that this material demonstrates a deviation from that praxis, since mesh has been advocated for progressively smaller hernias during the past years, with the intended aim to decrease the rate of recurrences. As no significantly higher recurrence rate was seen in the present suture group, it may be that the equilibrium approaches between use of mesh and suture in terms of recurrences. It seems, however, that the price of using mesh repair is significantly higher risk for complications such as deep infection as shown in this present material, which is in line with the latest meta-analysis on ventral hernia surgery [8]. This highlights an important consideration that must be taken into account when deciding a suitable repair strategy, even for small hernias, as it challenges the current surgical praxis of 30 mm being the cut-off point for mesh, and also the trend of increased mesh use. Although due to this current surgical praxis, there is a risk of selection bias where large hernias are designated mesh repair to a slightly higher extent than small ones, there was no clear trend in our material with median hernia sizes of 10 and 20 mm respectively. Extrapolation of conclusions from this study to larger sized hernias should nevertheless be made with caution.

The only factor that significantly increased the risk for recurrence was if the patient had another known hernia. This agrees with recently published material showing a significantly higher risk for recurrence in patients with rectus diastasis [18], and a Swedish multigenerational

Table 5 Number of patients with primary and secondary outcome

Outcome	Suture	Mesh
Recurrence	11	15
Clinical	5	8
Radiological	6	7
Complications	5	46
Clavien grade 1–3a	4	43
Clavien grade 3b–4	1	3
Wound dehiscence	0	1
Infection	3	17
Abscess	0	8

Suture, combined group of patients operated with one of several commonly used suture techniques ($n = 122$); Mesh, combined group of patients operated with one of several commonly used mesh techniques ($n = 184$); Recurrence, method of earliest discovery

study on multiple hernias [22]. This interesting finding suggests that a collagen defect may be the most important factor for recurrence. The pathophysiology of hernia development is still not completely clear, but it has already been shown that individual collagen quality has a considerable impact on tissue regeneration [23]. Patients with multiple hernias might constitute a special group where treatment strategy is of extra importance. Köhler et al. [24] suggests that patients with concomitant rectus diastasis require mesh repair for midline hernia repair regardless of size. However, a randomized prospective trial on that subject could not find a difference in recurrence rate between suture (Quill plication) and retro muscular polypropylene mesh at one-year follow-up [25]. It may even be possible that patients with rectus diastasis constitute a treatment group where not only the umbilical hernia but also the whole diastasis should be repaired to prevent recurrence.

Smoking [16], gender and diabetes all proved not to be significant predictors for primary or secondary outcomes. The percentage of smokers in this material is somewhat lower than the 14 % in the Swedish population. Gender distribution at baseline in our material, with predominately males, differs radically from previous publications. In previous studies males have usually been in the minority, which may be why female sex has formerly been considered a risk factor. The second largest exclusion group (27 cases due to not being primary umbilical repair) actually included a majority of women. However, this group was far from large enough to explain the low female:male ratio in this study.

To date this study is one of the largest register studies on isolated umbilical hernia repair, with respect to both time and number of patients included. The results also represent an isolated patient group and not a cocktail of different ventral hernia procedures. The liberal inclusion criteria assure that the results represent as many patient types as possible among those undergoing umbilical hernia repairs. However, even results from this large material must be interpreted with caution since the use of liberal inclusion criteria increases the risk of confounding and selection bias. Indeed this may possibly explain the different outcomes in our uni- and multivariate analyses for the variables BMI and hernia size. One such confounder may be the effect of time since recurrence from mesh repair usually manifests later in relation to the index repair than after suture repair. Since it was not possible to determine the exact time of recurrence in this study, logistic regression analysis was used rather than the Cox proportional hazard model. However, such an effect should confound analyses in favor of mesh repair, which would thus further strengthen the conclusions we have drawn comparing mesh and suture repair. Furthermore, despite the large number of patients, no conclusions could be drawn from data concerning individual patient characteristics such as gender, age and hernia size.

This epidemiologic study comparing mesh with suture repair was based on prospective data recording with retrospective completion of data from medical records. Our aim was to investigate patient characteristics and current treatment methods, and their outcomes in common clinical practice. Strict blinding was not possible, but since the research nurse, not the surgeon, registered data the risk of confirmation bias exists but is considered very small. Weakness of this study includes selection bias, information loss through medical records, and no structured recording of information during hospital stay. Delay in patient presentation and delay on the part of the physician may influence selection and the subsequent time of surgery. Several recurrences were seen on CT where no patient complaint was registered. These were probably asymptomatic, but it clearly affects our analysis of recurrences—a fact that should be taken into account in future research. The long timespan of this study, 9 years, has its draw-backs with possible change in the characteristics of patients admitted and a shift in surgical traditions, leading to selection bias. Since 13 years have elapsed since the last randomized clinical trial, it is high time that one is performed where patients are asked specific questions about abdominal discomfort and other symptoms possibly related to a hernia recurrence, preferably using a validated tool such as the VHPQ [26] for structured follow-up.

Our data have shed light on several interesting aspects of primary umbilical hernia repair. The relative safety of suture repair with few complications and without an increase in recurrence rate, leads us to recommend this technique. Furthermore we highlight an important group at

Table 6 Secondary outcome results

	Elective and emergency repairs ($n = 306$)		
	Complications *n*/no at risk (%)	Univariate model OR (95 % CI)	Multivariate model OR (95 % CI)
Age			
<Median	27/153 (17.6)	1 (ref)	
≥Median	24/153 (15.7)	0.87 (0.48–1.59)	
Gender			
Female	19/97 (19.6)	1 (ref)	
Male	32/209 (15.3)	0.74 (0.40–1.39)	
ASA ($n = 296$)			
Class 1–2	40/269 (14.9)	1 (ref)	
Class 3–4	8/27 (29.6)	2.41 (0.99–5.88)	
BMI ($n = 294$)			
<Median	17/155 (11.0)	1 (ref)	
≥Median	30/139 (21.6)	2.23 (1.17–4.26)*	1.68 (0.82–3.48)
Smoking			
No	46/271 (17.0)	1 (ref)	
Yes	5/35 (14.3)	0.82 (0.30–2.21)	
Diabetes			
No	45/272 (16.5)	1 (ref)	
Yes	6/34 (17.6)	1.08 (0.42–2.76)	
Repair type			
Suture	5/122 (4.1)	1 (ref)	
Mesh	46/184 (25.0)	7.80 (3.00–20.27)*	6.63 (2.29–20.38)*
Hernia size			
<Median	17/158 (10.8)	1 (ref)	
≥Median	28/121 (23.1)	2.50 (1.29–4.82)*	1.21 (0.58–2.50)
Other hernia			
No	26/189 (13.8)	1 (ref)	
Yes	25/117 (21.4)	1.70 (0.93–3.12)	

Significant results marked with asterisk. Number of hernias subjected to analysis, unless stated otherwise ($n = 306$). Hernia size ($n = 279$); multivariate model ($n = 270$). Emergency repairs ($n = 29$). In groups divided by median, median values are grouped as to best balance the denominator size

ASA American Society of Anaesthesiologist classification ($n = 296$), *BMI* body mass index ($n = 294$)

risk for recurrence, i.e. patients with a coexisting hernia or previous history of hernia.

Compliance with ethical standards

Conflict of interest AW, MH, UG and KS declare no conflict of interest. The sponsors had no role in the study design, data collection, data analysis, data interpretation, or in the writing of this report.

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