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Laparoscopic bilateral groin hernia repair with one large self-fixating mesh: prospective observational study with patient-reported outcome of urological symptoms and EuraHS-QoL scores

Filip Muysoms[1] · Maxime Dewulf[1] · Iris Kyle-Leinhase[1] · Rita Baumgartner[1] · Filip Ameye[2] · Barbara Defoort[1] · Pieter Pletinckx[1]

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Abstract

Background Laparoscopic bilateral inguinal hernia repair may be completed with one large self-fixating mesh crossing the midline. No studies have investigated in detail whether preperitoneal mesh placement induces temporary or more lasting urinary symptoms.

Methods Urinary and hernia-related symptoms were evaluated preoperatively and postoperatively at 1, 3 and 12 months using the ICIQ-MLUTS questionnaire and EuraHS-QoL score in patients undergoing bilateral inguinal hernia repair.

Results One hundred patients were included. Voiding symptoms and bother scores were unchanged at 1 or 3 months, but there was significant improvement at 12 months compared with preoperative findings (symptoms $P<0.001$; bother score $P<0.01$). Incontinence symptoms improved at 1 month ($P<0.05$) but not at 3 or 12 months, with a bother score significantly improved at 1 month ($P<0.01$) and 12 months ($P<0.01$). Diurnal and nocturnal frequency did not change significantly postoperatively, but 12 months nocturnal bother score was decreased ($P<0.05$). EuraHS-QoL scores showed statistical significant improvement in all three domains for all measurements at the different follow-up moments compared to previous measurements. Postoperative symptoms were improved at 12 months, compared with preoperative pain scores (−6.1), restriction of activity (− 10.1) and cosmetic scores (−4.7) These findings were statistically significant ($P<0.001$). At 12 months, there were no patients with severe discomfort (score ≥5) for any of the three domains. No recurrences were diagnosed with 95% clinical follow-up at 12 months.

Conclusion Laparoscopic bilateral groin hernia repair with one large preperitoneal self-fixating mesh did not cause new urinary symptoms and demonstrated significant improvement in voiding symptoms at 12 months. Incontinence and nocturnal bother score were significantly improved.

Clinical trial registry identifier Clinical.Trials.gov: NCT02525666.

Keywords Inguinal hernia · Groin hernia · Laparoscopic surgery · Urinary symptoms · Quality of Life · Self-fixating mesh · ICIQ-MLUTS · EuraHS-QoL score

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✉ Filip Muysoms
filip.muysoms@azmmsj.be

[1] Department of Surgery, Maria Middelares, Buitenring Sint-Denijs 30, 9000 Ghent, Belgium

[2] Department of Urology, Maria Middelares, Ghent, Belgium

Introduction

Background and rationale

Laparoscopic surgery for the treatment of groin hernias has become standard of care for many surgeons. It has been one of the recommended treatment options when local expertise is available [1–3]. No advantage has been identified between the laparoscopic techniques, either transabdominal preperitoneal (TAPP) or totally extraperitoneal repair (TEP) [4, 5]. For bilateral groin hernia repair, the recent updated international groin hernias guidelines (Herniasurge)

strongly recommend laparoscopic repair, provided that surgical expertise and sufficient resources are available [3].

Fixation of the mesh in laparoscopic groin hernia repair was originally performed with penetrating fixation, using staples or tackers. Alternatives to penetrating fixation using glue or self-fixating meshes, or no fixation at all have been proposed to avoid postoperative pain [6, 7]. The Herniasurge guidelines suggest that penetrating fixation can be omitted in laparoscopic groin hernia repair, except for large medial (direct) hernias (EHS classification, type M3) where mesh fixation is recommended to avoid recurrences [3]. The EAES consensus conference on laparoscopic groin hernia repair stated that sufficient overlap of mesh is more important than fixation of the mesh and that tack and suture fixation of mesh should be avoided, with the exception of large medial inguinal hernias [8].

Rene Stoppa described a technique for treatment of bilateral or multi-recurrent groin hernias by placing a large mesh in the preperitoneal position through a midline incision in 1973 [9, 10]. In this technique, a large mesh without fixation is placed in the preperitoneal position. During a laparoscopic bilateral groin hernia repair, a similar preperitoneal mesh repair is performed via an endoscopic approach. For the laparoscopic approach, two separate unilateral meshes are most commonly used. The EAES consensus states that the mesh size for laparoscopic repair of a unilateral groin hernia should be at least 15 cm in width and 10 cm in length [8]. There is no data to guide us regarding whether one large mesh covering both groins might be beneficial over the use of two separate meshes.

The first report on the use of one large mesh in bilateral minimally invasive groin hernia repair was by Geis et al. [11]. Deans et al. introduced the term 'bikini mesh' to describe their large mesh covering the Fruchaud's Myo-Pectineal Orifice (MPO) on both sides [12]. Subsequently, Knook et al. reported on the use of one giant 'slipmesh' to cover both groins [13]. In the largest patient series to date comparing the use of two separate meshes with one large mesh in laparoscopic bilateral groin hernia repair, no difference in recurrence rates was seen [14]. Regarding urinary symptoms, one bladder perforation was reported in the single mesh group, and there was no significant difference in postoperative urinary retention. Recently, Kohler et al. reported on the early results of a mesh designed specifically for bilateral groin hernia repair in a small case series [15]. They found a high recurrence rate which they attributed to the design of the mesh with a central slit on the midline.

We have been using self-fixating mesh for laparoscopic groin hernia repair since 2009 and have published a favorable patient-reported outcome evaluated with the EuraHS-QoL score after unilateral repairs [16]. We initially used two separate meshes of 15×13 cm for bilateral laparoscopic groin hernia repairs. When the larger 30×15 cm mesh became available, we started using one large mesh for bilateral laparoscopic groin hernia repair as our standard approach. Laparoscopic bilateral groin hernia repair includes the placement of mesh in the retro-pubic plane in front of the bladder. Studies have not investigated whether a large mesh, in this position, causes temporary or more lasting urinary symptoms.

Objectives

To evaluate the presence of urinary symptoms preoperatively and until 12 months postoperatively using a validated urinary quality of life score in a prospective cohort study of 100 patients undergoing a bilateral laparoscopic groin hernia repair with one large self-fixating mesh.

Methods

Study design

The study is a prospective single-center observational cohort study of laparoscopic bilateral groin hernia repair using one large self-fixating mesh.

Setting

The study was performed at the Department of Surgery at the Maria Middelares Hospital in Ghent, Belgium. Operations were performed by three surgeons with extensive experience in laparoscopic groin hernia repair. The study was approved by the ethics committee at the University of Antwerp and by the local ethics committee at Maria Middelares Ghent hospital with the Belgian trial number B300201525248. The study protocol was submitted at ClinicalTrials.gov (NCT02525666) before the start of the study.

Inclusion criteria

Adult male patients scheduled for treatment of bilateral groin hernias with a laparoscopic technique were eligible.

Exclusion criteria

Excluded from participation in the study were: unilateral hernias, recurrent hernias, hernia repair combined with another surgical procedure, female gender, patients under 18 years or above 80 years of age, ASA score 4 or higher, emergency operations, patients unable to perform the QoL assessment because of language barriers or intellectual incapacity, and patients preferring not to participate in the study.

Follow-up

All patients were invited to a standard clinical outpatient follow-up visit with the surgeon at 4 weeks and at 12 months postoperatively. Preoperatively and during the control visits, patients were asked to complete the EuraHS-QoL questionnaire (European registry of abdominal wall hernias Quality of Life score) and the ICIQ-MLUTS (International Consultation on Incontinence modular Questionnaire—Male Lower Urinary Tract Symptoms). During the clinical outpatient follow-up visit at 1 month, patients were provided with additional questionnaires to be completed at 3 months postoperatively and returned by mail with envelopes provided with adequate postage.

Surgical technique

Patients were operated with a laparoscopic approach either by TAPP or TEP according to the surgeons' preference. Groin hernia repair was performed according to the standard surgical principles, with mesh placement after appropriate preperitoneal dissection and critical view of the myopectineal orifice, as described by Jorge Daes and Edward Felix.[17] One large self-fixating mesh (Parietex Progrip™ Self-Fixating Mesh, Medtronic, Minneapolis, MN, US) with a width of 28 cm and a length of 13 cm was tailored as shown in Fig. 1. The mesh is folded, introduced, unfolded and positioned in the dissected preperitoneal plane with no additional fixation. Care was taken to properly close the peritoneum after mesh placement in TAPP patients using a barbed suture (V-Loc™ 90, Medtronic, Minneapolis, MN, US).

A video of the technique is available at https://www.youtube.com/watch?v=ZpwYdzE5AY0.

We did not use a urinary catheter during surgery. The patients were asked to void prior to surgery. In patients who experienced postoperative urinary retention, in-and-out bladder catheterization was used.

Variables

Primary endpoints of the study were the level of urinary symptoms and bother scores according to the ICIQ-MLUTS at 12 months postoperative compared to the preoperative levels. Secondary endpoint were recurrence rate, assessment of urinary symptoms at 1 month and 3 months, assessment of the Quality of life with the EuraHS-QoL score at 1 month, 3 months and 12 months, intra-operative and postoperative complications, postoperative hospital stay, and skin to skin operating time. All patients and surgical variables were entered prospectively in the EuraHS online database (European Registry for Abdominal Wall Hernias) [18].

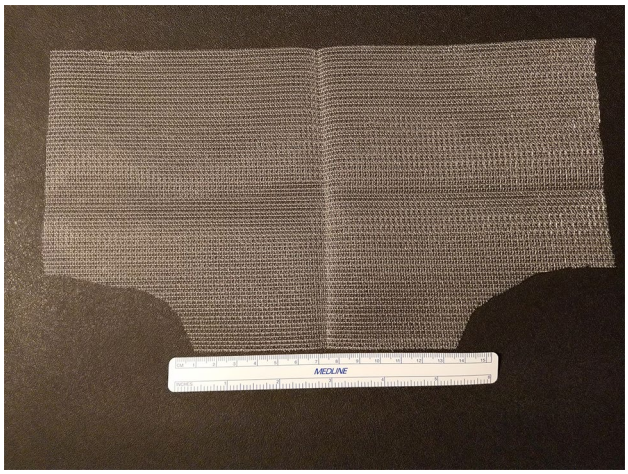

Fig. 1 Configuration of the mesh used in a prospective observational study on patient reported outcomes of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh. The mesh is tailored from a 30 × 15 cm out-of-the-box rectangular configuration (Parietex Progrip™ Self-Fixating Mesh, Medtronic, Minneapolis, MN, US) to a width of 28 cm and a length of 13 cm and the two lateral corners are cut to position the mesh over the iliac vessels and the cord structures

Data measurement

During the preoperative consultation, patients were instructed about the study and invited to participate. Informed consent forms together with the ICIQ-MLUTS questionnaire and the EuraHS-Qol score questionnaire were given to the patients. At the time of admission, patients were asked if they had any further questions and if they wanted to participate in the study. The questionnaires filled out prior to admission were collected. At the 1 month postoperative visit, patients completed the questionnaire independently, and were assessed clinically. A self addressed envelope was given to patients with questionnaires to complete at 3 months. At 12 months the same procedure with clinical examination followed by independent completion of the questionnaires was performed. All data, including the EuraHS-Qol scores, were entered into the prospective online EuraHS database we maintain in the department for all abdominal wall surgeries, and extracted at the end of the study in an excel file. The European Hernia Society classification for groin hernias was used [19]. The data of the ICIQ-MLUTS questionnaires were entered in a separate excel file from the patient case report forms. The database was closed July 30th 2018 after the last 12 months follow-up was scheduled. The database was completely double-checked by two co-authors who were not involved in the original data input.

The database was given to an independent statistician who chose the most appropriate statistical methods to analyze the results.

Quantitative variables

The ICIQ-MLUTS has been constructed and validated by the International Consultation on Incontinence [20–22]. In this study, a Dutch version for Belgium was used. An English version of the questionnaire is available in addendum I. The questionnaire has 13 questions and relates to the symptoms experienced in the last 30 days. Each question consists of two items, Xa and Xb in a specific format. An example of the questionnaire format is shown in Fig. 2 for Q4. The QXa answer to the question relates to the frequency or the intensity of the symptoms to be answered in a five-point scale from 0 to 4. For analysis, we grouped questions in a *voiding symptoms subscale* (Q2a + Q3a + Q4a + Q5a + Q6a) with a range from 0 to 20 and an *incontinence symptoms subscale* (Q7a + Q8a + Q9a + Q10a + Q11a + Q12a) with a range from 0 to 24. Questions 13 and 14 have a similar format, but relate to the number of times a patient has to urinate during daytime (*diurnal frequency*, Q13a) and during nighttime (*noctural frequency*, Q14a). The QXb answer is an eleven-point numeric rating scale from 0 to 10 where the patient is asked to answer how much the symptoms bother him (bother scale). When QXa was answered with "never" or "normal", the QXb often was not answered by the patients and those answers were considered as having a bother score of 0. For analysis we also grouped questions in a voiding bother score (Q2b + Q3b + Q4b + Q5b + Q6b) with a range from 0 to 50 and an incontinence bother score (Q7b + Q8b + Q9b + Q10b + Q11b + Q12b) with a range from 0 to 60. The *diurnal frequency bother score* (Q13b) and the *nocturnal frequency bother score* (Q14b) have a range from 0 to 10. (methodology of ICIQ-MLUTS analysis in addendum II).

The results of the EuraHS-QoL score were analyzed as described in our previous validation study for groin hernia repair [16]. Data were analyzed overall for all nine questions (range 0–90) and for the three domains: pain (range 0–30), restriction of activity (range 0–40), and cosmetic (range 0–20) (methodology of EuraHS-QoL score assessment in addendum III).

Bias

Care was taken to explain the questionnaires to the patients at time of obtaining the informed consent, but the actual filling out of the questionnaires was performed independently in absence of the surgeon. Often patients arrived at outpatient visits accompanied by a family member, who might have assisted the patients in completing the questionnaires. No interim analysis was performed and no completed ICIQ-MLUTS questionnaires were seen or handled by the participating surgeons. Until the completed result came back from the statistician, the participating surgeons were completely unaware of any result of the patient reported outcomes on urinary symptoms.

Study size

Because no published data on the frequency of urinary symptoms postoperatively after laparoscopic preperitoneal groin hernia repair were available at the start of the study, a

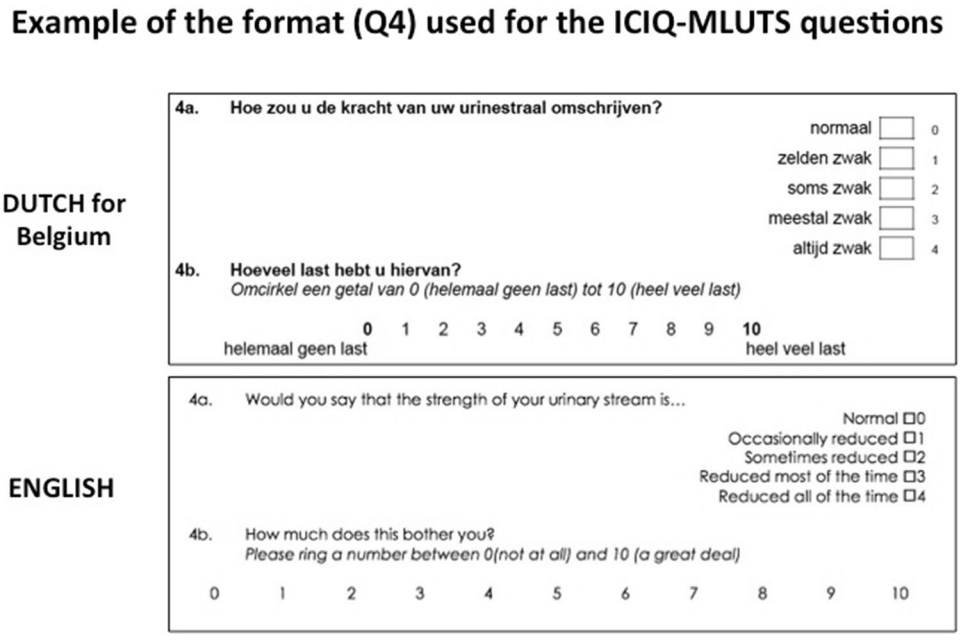

Fig. 2 Example of the format of question Q4a and Q4b of the ICIQ-MLUTS questionnaire. The questionnaire has 13 questions and each question consists of two items, Xa and Xb. In the study the Dutch version for Belgium was used

sample size of 100 patients was empirically chosen as being large enough to evaluate the effect of a preperitoneal mesh on urinary symptoms and small enough to be performed within a reasonable time frame.

Statistical methods

The statistical methodology was chosen and performed by an independent statistician. The distributions of patient characteristics, operative data and postoperative complications were summarized using proportions (%, n/N) or means with standard deviations (SD). The ICIQ-MLUTS scores were summarized using means, medians and interquartile ranges (IR P25–P75) for the symptoms scores and the bother scores separately. Changes over time during follow-up in comparison to preoperative baseline measurements were analyzed according to linear mixed models with unstructured covariance structure. Average scores were graphically displayed using bar charts and, specifically for the EuraHS-QoL domains scores, a spider web chart using average values normalized to 100. P values < 0.05 were considered as indicating statistical significance. The results were graphically depicted with a bar chart using the mean scores of the three domains. All analyses were performed using SAS software (release 9.4, Cary, NC, US).

Results

Participants

Between September 2015 and June 2017, 100 patients were prospectively enrolled in the study and operated by three surgeons. Distribution amongst surgeons was 61, 25 and 14 cases, with 75 patients undergoing TAPP and 25 patients TEP. Clinical outpatient follow-up at 1 month was 100%, questionnaires received at 3 months was 89% and clinical follow-up at 12 months was 95%. Two patients did not want to participate at 12 months and three patients only wanted to fill out the questionnaire. Overall follow-up with the questionnaire at 12 months was 98%.

Descriptive data

Patient characteristics at baseline, operative data, and postoperative complications are shown in Table 1. The operation was performed with less than 24 h admission in 98%: day clinic in 68% and one night stay in 30%. Postoperative complications were urinary retention in 3%, readmission in two patients and seroma at 1 month follow-up in 8% of patients. No long-term complications or recurrences were seen at 12 months clinical follow-up ($n = 95$).

Table 1 Patient data at baseline, operative data and postoperative complications of 100 patients included in a prospective observational study on patient reported outcome of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh

	% (n/N)[a] or Mean (SD)[b]	
Age at the time of surgery (years)	57 (13.4)	
Body mass index (kg/m^2)		
< 25	57%	
25–30	33%	
≥ 30	10%	
Mean (SD)	25 (3.5)	
Daily smoker	16%	
Anticoagulant therapy	15%	
Pulmonary disease (COPD, asthma)	6%	
Cardiac disease	15%	
Arterial hypertension	12%	
Hemodialysis	2%	
Preoperative symptoms		
Pain and discomfort	85%	
Esthetical discomfort	10%	
Asymptomatic	11%	
Operative technique		
TAPP	75%	
TEP	25%	
EHS Hernia classification[c]		
Right side		
Lateral	54/100	
Medial	51/100	
Femoral	3/100	
Obturator	1/100	
Left side		
Lateral	70/100	
Medial	35/100	
Femoral	2/100	
Obturator	0/100	
Duration of surgery (min)	76 (range 40–168)	
Intraoperative complications		
Bleeding from epigastric vessels	1	
Conversion to open surgery	0	
Intrahospital complications		
Urinary retention	3%	
Re-admissions	2%	
Hematoma: laparoscopic drainage	1	
Ileus needing naso-gastric tube	1	
Hospital stay		
Day clinic	68%	
One night stay	30%	
> 24 h	2%	
Postoperative complications	1 month	12 months
Seroma	8	0
Hematoma	2	0
Surgical site infection	0	0
Recurrence	0	0

[a]% (n/N): n number of patients/N total number of patients

[b]Mean (SD): mean value of variable (standard deviation)

Table 1 (continued)

[c]Classified according to the European Hernia Society [19]

Outcome data

The outcome data for our primary endpoint, urological symptoms, preoperatively and postoperatively, measured with the ICIQ-MLUTS are shown in Table 2. Time effect during follow-up are graphically depicted using the mean scores in Fig. 3 for the ICIQ-MLUTS symptom scores and in Fig. 4 for the ICIQ-MLUTS bother scores.

Main results

Table 3 shows the average change in ICIQ-MLUTS scores at follow-up compared to the preoperative scores, with the change at 12 months being our primary endpoint.

Table 2 Patient reported outcome data using the ICIQ-MLUTS score (International Consultation on Incontinence modular Questionnaire—Male Lower Urinary Tract Symptoms) at baseline, 1 month, 3 months and 12 months follow-up of 100 patients included in a prospective observational study on patient reported outcome of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh

		ICIQ-MLUTS scores[a]			
		Pre-operatively	1 month	3 months	12 months
	N patients	100	100	89	98
Voiding					
Maximum	/20				
Mean		4.88	4.71	4.83	4.09
Median (IR)		4.5 (2.0–7.0)	4.0 (2.0–7.0)	4.0 (2.0–8.0)	3.0 (2.0–7.0)
Voiding bother					
Maximum	/50				
Mean		5.74	4.52	4.67	3.82
Median (IR)		3.0 (0.0–7.0)	3.0 (0.0–7.0)	2.0 (0.0–6.0)	2.0 (0.0–6.0)
Incontinence					
Maximum	/24				
Mean		2.38	2.02	2.27	2.20
Median (IR)		2.0 (1.0–4.0)	1.0 (0.0–3.0)	2.0 (1.0–3.0)	2.0 (0.0–4.0)
Incontinence bother					
Maximum	/60				
Mean		4.10	2.69	3.22	2.99
Median (IR)		2.0 (0.0–5.0)	1.0 (0.0–4.0)	2.0 (0.0–4.0)	1.0 (0.0–5.0)
Diurnal frequency					
Maximum	/4				
Mean		0.55	0.56	0.51	0.54
Median (IR)		0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)	0.0 (0.0–1.0)
Diurnal frequency bother					
Maximum	/10				
Mean		0.66	0.48	0.39	0.45
Median (IR)		0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)
Nocturnal frequency					
Maximum	/4				
Mean		0.80	0.90	0.87	0.89
Median (IR)		1.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)	1.0 (0.0–1.0)
Nocturnal frequency bother					
Maximum	/10				
Mean		1.29	1.11	1.14	0.97
Median (IR)		1.0 (0.0–2.0)	0.0 (0.0–2.0)	1.0 (0.0–2.0)	0.0 (0.0–2.0)

Time effect (according to linear mixed modeling with unstructured covariance structure)

Voiding $P=0.0028$; Voiding bother $P=0.06$; incontinence $P=0.23$; Incontinence bother $P=0.019$; Diurnal frequency $P=0.52$; Diurnal frequency bother $P=0.13$; Nocturnal frequency $P=0.50$; Nocturnal frequency bother $P=0.17$

N numbers of patient at follow up

[a]Mean value and Median values (interquartile range P25–P75)

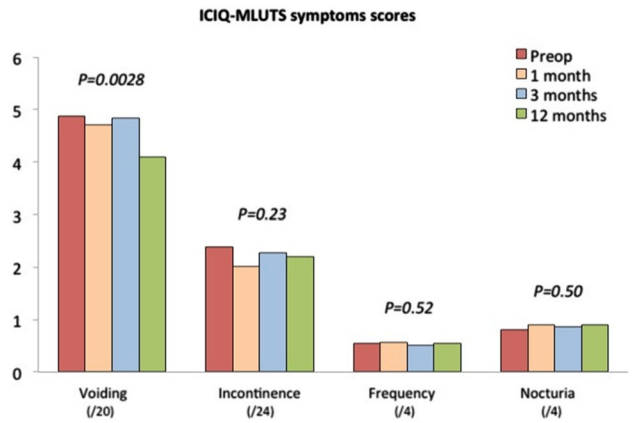

Fig. 3 Evolution of symptoms scores using the ICIQ-MLUTS score at baseline, 1 month, 3 months and 12 months follow-up of 100 patients included a prospective observational study on patient reported outcome of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh. *P*-values indicate the statistical significance of changes over time

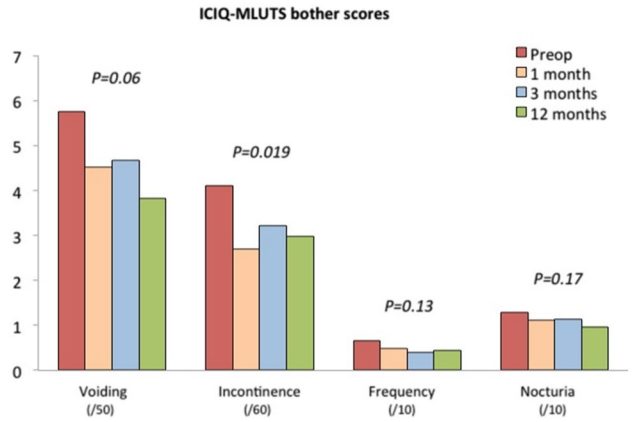

Fig. 4 Evolution of bother scores using the ICIQ-MLUTS score at baseline, 1 month, 3 months and 12 months follow-up of 100 patients included in a prospective observational study on patient reported outcome of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh. *P*-values indicate the statistical significance of changes over time

Significant lower scores were measured for voiding symptoms ($P < 0.001$), voiding bother ($P < 0.01$), incontinence bother ($P < 0.01$) and nocturnal frequency bother ($P < 0.05$). Importantly, no significant worsening of any of the scores was seen at any time point in follow-up.

Other analyses

Table 4 shows the result for the EuraHS-QoL evaluation preoperatively and postoperatively. Time effect during follow-up are graphically depicted using the mean scores of EuraHS-QoL for the three domains in Fig. 5. There was a significant decrease for the overall score and for the three domains individually (all $P < 0.0001$). When analyzing the EuraHS-QoL score, between 75% and 98% of patients noted a score = 0 (% no discomfort) for the 9 QoL questions at 12 months. Looking at the patients with a score ≥ 5 (% severe discomfort) this was 0% for all of the 9 QoL questions at 12 months.

Discussion

Key results

The placement of one large self-fixating mesh in the preperitoneal plane in front of the bladder during laparoscopic repair of bilateral hernias did not produce urinary symptoms, either in the short term, nor at 12 months follow-up. There was a significant improvement at 12 months in voiding symptoms, the voiding bother score, the incontinence bother score and the nocturia bother score.

Limitations

The ICIQ-MLUTS is designed to follow patients with urinary pathology and was not designed specifically for hernia patients. Nevertheless, we found it an interesting tool to investigate our concerns about the potential impact of a preperitoneal mesh on urinary symptoms. We did not find a good description or recommendation of how to analyze the results of the ICIQ-MLUTS data and thus we asked the independent statistician to suggest the methodology.

Interpretation

Placement of a mesh in the preperitoneal position during laparoscopic groin hernia repair might raise concerns about the development of urinary symptoms because of the position of the mesh in front of the bladder. Our study suggests that these concerns may be unwarranted, even when using one large self-fixating mesh for bilateral repairs.

Others have reported the use of one mesh to cover both groins during laparoscopic groin hernia repair [11–15]. It seems that the configuration of the mesh and the size of the mesh are important, since Köhler et al. have found recurrences in 5.6% (2/36) at 12 months, likely related to the mesh configuration with a slit in the middle on the cranial part of the mesh [15]. The configuration of the mesh used in this study, as shown in Fig. 1, is similar to the mesh configuration suggested as most effective by Knook et al., which they called the "slipmesh" [13]. They found a high recurrence rate in a rectangular mesh configuration with a width of 30 cm and a length of 10 cm in a first series of 17 patients (six recurrences; 35%), which was remediated by using a

Table 3 Change from the preoperative score of patient reported outcome data using the ICIQ-MLUTS score (International Consultation on Incontinence modular Questionnaire—Male Lower Urinary Tract Symptoms) at 1 month, 3 months and 12 months follow-up of 100 patients included in a prospective observational study on patient reported outcome of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh

	ICIQ-MLUTS: change from pre-operative score[d]		
	1 month versus preop	3 months versus preop	12 months versus preop
Voiding	−0.21 (0.27)	−0.07 (0.26)	−0.81 (0.23)[a]
Voiding bother	−1.28 (0.67)	−1.14 (0.65)	−1.93 (0.68)[b]
Incontinence	−0.36 (0.18)[c]	−0.08 (0.17)	−0.20 (0.18)
Incontinence bother	−1.40 (0.44)[b]	−0.83 (0.59)	−1.14 (0.42)[b]
Diurnal frequency	−0.00 (0.06)	−0.08 (0.07)	−0.03 (0.06)
Diurnal frequency bother	−0.18 (0.13)	−0.31 (0.13)[c]	−0.22 (0.13)
Nocturnal frequency	+0.09 (0.06)	+0.02 (0.06)	+0.06 (0.06)
Nocturnal frequency bother	−0.18 (0.15)	−0.21 (0.16)	−0.35 (0.16)[c]

Significances (according to linear mixed models)

[a]$P < 0.001$, [b]$P < 0.01$, [c]$P < 0.05$

[d]Mean value (standard deviation)

Table 4 Patient reported outcome data using the EuraHS-QoL score at baseline, 1 month, 3 months and 12 months follow-up of 100 patients included in a prospective observational study on patient reported outcome of urological symptoms after bilateral laparoscopic groin hernia repair with one large self-fixating mesh

		EuraHS-QoL scores[a]			
		Pre-operatively	1 month	3 months	12 months
	N patients	95	100	89	98
Total score	/90				
Mean		23.17	13.44	5.65	2.26
Median (IR)		20.2 (11.0–31.5)	10.7 (4.5–20.0)	3.0 (1.0–9.0)	1.0 (0.0–3.0)
Pain domain	/30				
Mean		7.01	4.49	2.21	0.76
Median (IR)		5.0 (2.0–11.0)	3.5 (1.5–6.0)	1.0 (0.0–4.0)	0.0 (0.0—0.0)
Restriction of activity	/40				
Mean		10.98	7.00	2.45	0.83
Median (IR)		8.0 (4.0–18.0)	4.7 (1.0–10.8)	1.0 (0.0–4.0)	0.0 (0.0–1.0)
Cosmetic	/20				
Mean		5.44	1.95	0.99	0.66
Median (IR)		4.0 (2.0–8.0)	1.0 (0.0–3.0)	0.0 (0.0–2.0)	0.0 (0.0–1.0)

Time effect (according to linear mixed models with unstructured covariance structure)

Total score $P < 0.0001$; Pain score $P < 0.0001$; Restrictions score $P < 0.0001$; Cosmetic score $P < 0.0001$

N numbers of patient at follow up

[a]Mean value and median values (interquartile range P25–P75)

"slipmesh" configuration with a width of 30 cm and a length of 15 cm in 81 patients (two recurrences; 2.5%). Thus, it does seem important to have a mesh overlapping the pubic bone caudally for several cm to allow enough overlap of medial hernias and avoid recurrences. Halm et al. described a mesh configuration of 30 × 30 cm in a similar configuration with a recurrence rate of 3.7% (1/27) [14]. They did not find a difference with a group of patients receiving two separate meshes, who had a recurrence rate of 3.5% (3/86). We did not detect any recurrence at 12 months by clinical examination. This suggests that the 1 year recurrence rate is low. We have sporadically observed recurrences after this technique of bilateral groin hernia repair with one large self-fixating mesh in patients outside of this study.

Urological symptoms after groin hernia repair have not often been investigated in detail. In a prospective cohort study of 101 patients undergoing elective groin hernia repair (67 open and 34 laparoscopic) the American Urological Association Symptom Score (AUASS) was used to document the impact of groin hernia repair on LUTS

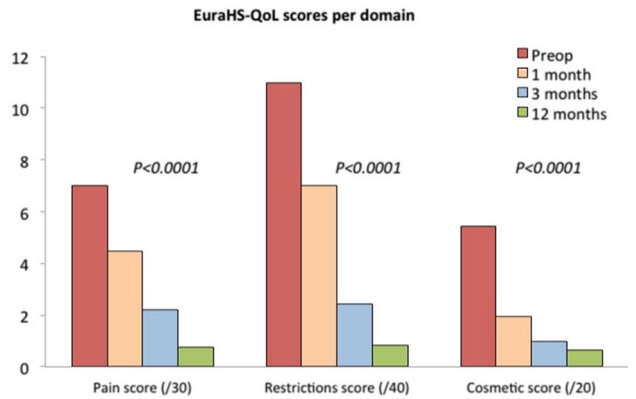

Fig. 5 Evolution of domain scores using the EuraHS-QoL instrument at baseline, 1 month, 3 months and 12 months follow-up of 100 patients included in a prospective observational study on patient reported outcome after bilateral laparoscopic groin hernia repair with one large self-fixating mesh. *P*-values indicate the statistical significance of changes over time

[23]. When compared to preoperative values, a reduction in urinary symptoms was seen 30 days postoperatively, provided no intra-operative catheter was used. Reis et al. compared the presence of LUTS in patients with a groin hernia ($n = 32$) to patients without a groin hernia ($n = 20$) using the International Prostate Symptom Score (IPSS) [24]. Higher scores were seen in patients with a groin hernia. Looking for a patient-reported outcome score to use in our prospective study, we chose the ICIQ-MLUTS score that has been extensively investigated and used in the urological literature [20–22]. We have found the questionnaire to be user friendly and believe that it addresses our concerns on the use of a large preperitoneal mesh in front of the bladder. We were pleased to note that there did not seem to be any negative impact of the bilateral groin hernia repair when evaluating urological symptoms with this questionnaire. Moreover, we did detect some improvement at 12 months compared with preoperative assessment. The presence of a groin hernia is known to impact LUTS [23]. Our data suggests that the treatment of the groin hernias might alleviate some of these LUTS. We were unable to identify any literature on the outcome of the ICIQ-MLUTS in a normal population without groin hernias or urological pathology, figures could have been used for baseline comparison before surgery.

Similar to our previously published study on unilateral groin hernia repair with a self-fixating mesh, this study demonstrated improvement of pain, restriction of activity and cosmetic concerns by treating the hernias [16]. At 12 months, there were no patients who reported a score higher than 5/10 for any of the nine questions of the EuraHS-QoL questionnaire. We believe that this study supports the value of the EuraHS-Qol questionnaire as a useful tool for patient-reported outcome measurement before and after groin hernia repair.

Generalizability

Our study suggests that urological symptoms are not produced by placing a mesh in the preperitoneal position during laparoscopic groin hernia repair with a self-fixating mesh. This finding is probably also valid with the use of other meshes where no penetrating fixation is used. This may not be valid when mesh is fixed to the pubic bone.

Conclusion

The laparoscopic treatment of bilateral groin hernias with the placement of one large self-fixating mesh in the preperitoneal plane did not produce temporary or more permanent urological symptoms. This technique has demonstrated favorable 12 months results with a low recurrence rate and without significant chronic pain.

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Compliance with ethical standards

Disclosure Dr. Muysoms reports having received research grants from Medtronic, Dynamesh and received speakers honorarium from Medtronic, Bard-Davol, Dynamesh, Intuitive Surgical and received consultancy fees from Medtronic, Intuitive Surgical, CMR Surgical. Drs. Dewulf, Kyle-Leinhase, Baumgartner, Ameye, Defoort and Pletinckx have no conflicts of interest or financial ties to disclose.

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