Swing mesh *versus* Modified Kugel mesh for primary inguinal hernia repair. A prospective randomized clinical trial[1]

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ABSTRACT

PURPOSE: To evaluate the safety and efficacy of a new mesh in the pre-peritoneal repair of inguinal hernia.

METHODS: We randomly divided 120 patients undergoing pre-peritoneal repair into 2 groups between March 2012 and December 2013. The patients were randomized to receive the Swing mesh (n=60; study group) or the Modified Kugel mesh (n=60; control group). The primary end point of this study was to compare postoperative groin pain of the two groups. Complications, recurrence and analgesic use were also recorded.

RESULTS: There were no recurrent cases in either group throughout the study period. There was no significant difference between the groups with respect to postoperative complications. The VAS of early postoperative pain was 1.32±1.69 in study group and 1.52±1.93 in control group, with the difference being not statistically significant (p = 0.547). Concerning chronic pain, no remarkable statistically significant difference was observed between the two groups at 3-month, 6-month, 12- and 18-month follow-up period.

CONCLUSION: Swing mesh can be safely and effectively used in inguinal hernia repair with the same advantage compared to the Modified Kugel mesh.

Key words: Hernia, Inguinal. Surgical Mesh.

Introduction

Adult inguinal hernia is a commonly encountered disease in general surgery. Nowadays, the main treatment of inguinal hernia is tension-free repair surgery using a mesh[1,2]. Pre-peritoneal repair surgery has played a large role in the management of inguinal hernia with few complications and less postoperative chronic pain in recent years[3]. In this procedure, a mesh is placed in a deep position located between the peritoneum and the abdominal wall and secured over the musculoaponeurotic[4].

Disappointingly, although there are many types of patches for hernia repair, the decision regarding the choice of patches for hernia repair remains controversial. The main points of most disputes focus on postoperative chronic pain, recurrence, and foreign body feeling[5-7]. Currently, the Modified Kugel hernia repair through the pre-peritoneal space for inguinal hernias has become widespread. Additionally, there are a number of studies that have confirmed the therapeutic effects of Modified Kugel hernia repair, especially with the reduction of complications and chronic pain[8-10].

The aim of the present double-center study was to evaluate the effects of the open transinguinal pre-peritoneal repair technique using a new type of mesh in patients with inguinal hernia with respect to operative time, incidence of complications, groin pain, and post-operative hernia recurrence.

Methods

This study was approved by the Hospital Clinical Research Ethics Committee. All patients provided written consent and underwent standardized repairs performed by consultant surgeons experienced in pre-peritoneal repair. We recruited 120 patients with unilateral inguinal hernia undergoing pre-peritoneal repair in a prospective clinical randomized controlled study which designed and conducted at the surgical department of the Huadong Hospital affiliated with Fudan University and Shanghai Ninth People's Hospital from March 2012 to December 2013. Patients were excluded from the study if they were aged below 18 years, irreducible, strangulated, suffered from recurrent hernia, immune deficiencies, malignancy, were unable to understand the questionnaire, or did not consent to the study.

All patients were randomly allocated to either the study group (n=60) or control group (n=60) using the sealed envelope method. The envelopes were opened by the surgeon in the operation room. The investigator who conducted the follow-up examinations was blinded to the type of mesh that was used. Patients received the Swing mesh in the study group while the Modified Kugel mesh (BARD-Davol Inc., Cranston, RI, USA) was used in the control group. The Swing mesh consisted of two parts with an adjustable underlay mesh (maximum diameter of 9.5 cm) and a flat overlay mesh (5.5 cm × 9.5 cm), and was mainly composed of polypropylene monofilaments (THT Bio-science Inc., Labastide-Rouairoux, France) (Figure 1), while the oval Modified Kugel mesh was composed of polypropylene and was 8 cm × 12 cm in size.

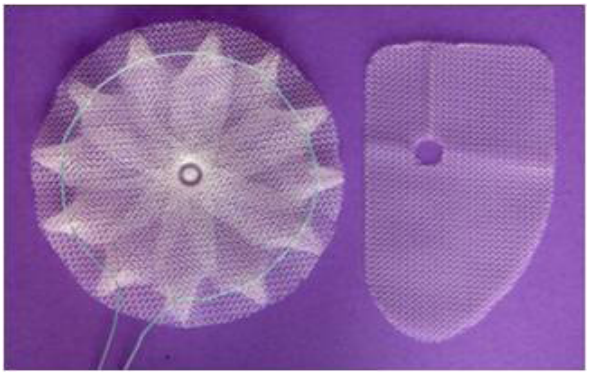

FIGURE 1 - The Swing mesh (No: SMP95958X, 80g/m2, Φ 9.5cm—5.5×9.5cm; THT Bio-science Inc., Labastide-Rouairoux, France) used in our study.

The surgeons participating in the study were trained adequately and performed surgery under spinal or general anesthesia. All inguinal hernia patients were operated by open transinguinal pre-peritoneal repair with the Swing mesh or the Modified Kugel mesh. The Modified Kugel mesh was placed according to established techniques in published studies[8]. In case of the Swing mesh, the surgical procedure was performed as follows. In the operation, an inguinal incision of approximately 5 cm in length was made, the external oblique aponeurosis was divided, and the dissected scope was placed on the superior border conjoining the tendon and reached the inguinal ligament.

The ilioinguinal, genitofemoral, and iliohypogastric nerves were identified, if possible, and carefully preserved, and the spermatic cord was freed. After exposure of the inner ring, surgical management depending on the type of hernia should be dealt with separately. In indirect hernias, the cremaster close to the internal ring was cut lengthwise, and the high site of the sac was freed. Then, the transversalis fascia was incised to enter the pre-peritoneal space. In direct hernias, after the sac was freed, the transversalis fascia was cut circlewise around the neck of the sac to enter the pre-peritoneal space. Subsequently, the pre-peritoneal space was developed so that the Swing mesh was placed by the blunt dissection after the hernia sac was

returned (Figure 2A). The underlay mesh was placed and flatted in the pre-peritoneal space (when a relatively large peritoneal adhesion exists, the size of the underlay mesh could be adjusted to adapt to the hernial orifice) (Figure 2B), and then the dissected transversalis fascia was intermittently sutured with a partial mesh for fixation (Figure 2C). The spermatic cord was passed through a slit made in the overlay mesh. The bottom of the overlay mesh was trimmed to an appropriate size and placed approximately 1.5 cm above the pubic tubercle. A running suture was used to close the external oblique (Figure 2D). Absorbable sutures were applied throughout the surgery.

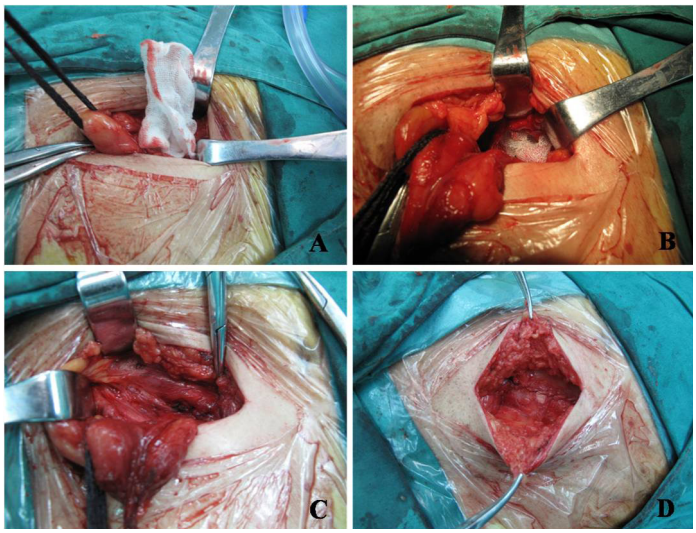

FIGURE 2 - A: Blunt dissection of the preperitoneal space using gauze swabs; **B**: The placement of mesh; **C**: The transversalis fascia was intermittently sutured with parial mesh; **D**: The external oblique was closed by the running sutured.

Follow-up examinations were performed 2 days, 3 months, 6 months, 12 months, and 18 months after the operation to review postoperative pain, complications and hernia recurrence. The visual analog scale (VAS) was used to measure the severity of each patient's postoperative pain[11]. The VAS of pain is usually shown on a 10-cm horizontal line on which zero represents the absence of pain and 10 cm represents the most intense pain. The patient expressed their perception of the amount of pain that was felt by marking a horizontal line between two points. The VAS score was measured in millimeters from the left end of the line to the point indicated by the patient. Various pre- and post-operative data details were recorded, including demographic data, body mass index, method of anesthesia, type of hernia (direct or indirect), site of hernia, duration of operation, and the experience of the surgeon. Postoperative analgesic consumption was also recorded.

The primary endpoints were the presence of postoperative groin pain 2 days, 3 months, 6 months, 12 months, and 18 months after the operation. The visual analog scale (VAS) was used to measure the severity of postoperative pain. The secondary endpoints were operation time, complications (e.g. infection, margin fat liquefaction, and scrotal effusion), and recurrence. The hypothesis was that clinical efficacy and safety of two kinds of meshes had no difference.

Statistical analysis

Statistical analysis was performed using SPSS (Statistical Package for Social Sciences, vol. 16.0, Chicago, IL, USA). Continuous variables were expressed with their mean ± standard deviation (SD) and compared using the t-test, while categorical variables were compared with Pearson's $\chi 2$ or Fisher's exact test, as appropriate. $P < 0.05$ was considered statistically significant.

Results

Between March 2012 and December 2013, a total of 120 patients (78 males and 42 females) with a mean age of 61.19 ± 12.33 years, suffering from primary inguinal hernia, fulfilled the criteria and were included in the study. In the end, 120 patients were evaluated, of whom 60 received treatment with Swing mesh. Figure 3 shows the flow diagram for the patients recruited into this study. There were no significant differences in the demographic variables between the allocated groups. Additionally, the mean duration of the operation and the hernia characteristics were found to be similar in both groups (Table 1).

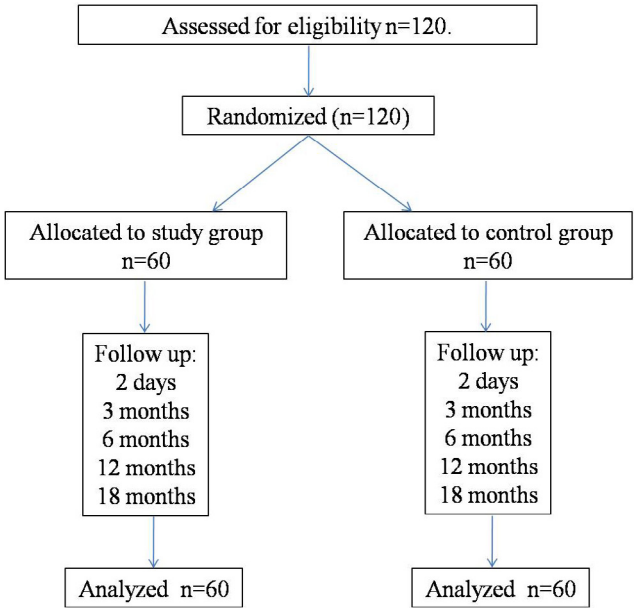

FIGURE 3 - Consort flow chart for the study.

TABLE 1 - Patient's characteristics and operative data described as means±SD or raw numbers.

	Control group (n=60)	Study group (n=60)	*P*-value
Age (years), mean ± SD	60.93±12.75	61.46±11.74	0.881
BMI (kg/m2), mean ± SD	22.61±2.37	23.22±1.42	0.529
Operation time (min) , mean ± SD	33.21±6.81	32.13±7.23	0.937
Gender			
male	59(98.3)	58(96.7)	0.559
female	1(1.7)	2(3.3)	
Surgical history			
yes	11(18.3)	12(20)	0.817
no	49(81.7)	48(80)	
Site of hernia			
left	31(51.6)	22(36.6)	
right	27(45.1)	36(60.1)	0.245
Combined	2(3.3)	2(3.3)	
Type of hernia			
direct	17(28.3)	20(33.3)	0.553
indirect	43(71.7)	40(66.7)	
Recurrent			
yes	0(0.0)	2(3.3)	0.154
no	60(100.0)	58(96.7)	
Type of anesthesia			
general	1(1.7)	2(3.3)	0.559
local	59(98.3)	58(96.7)	

The majority of patients had surgery under epidural anesthesia and all patients did not experience intra-operative complications. Postoperative complications occurred in one patient in the study group (foreign body sensation) and in three patients in the control group (infection) at three months. However, the number of patients who had postoperative complications did not increase in the subsequent follow-up times, with parallel changes observed in both groups (Table 2).

TABLE 2 - Postoperative following-up.

	Control group (n=60)	Study group (n=60)	*P*-value
2-day visit			
complications			
yes	1(1.7)	1(1.7)	1.000
no	59(98.3)	59(98.3)	
Recurrences			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Analgesic use			
yes	34(56.7)	29(48.3)	0.361
no	26(43.3)	31(51.7)	
Pain feeling (VAS)	1.52±1.93	1.32±1.69	0.547
3-month visit			
complications			
yes	3(5)	1(1.7)	0.309
no	57(95)	59(98.3)	
Recurrences			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Analgesic use			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Pain feeling (VAS)	0.73±1.31	0.68±1.32	0.836
6-month visit			
complications			
yes	3(5)	1(1.7)	0.309
no	57(95)	59(98.3)	
Recurrences			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Analgesic use			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Pain feeling (VAS)	0.45±0.98	0.36±0.88	0.626
12-month visit			
complications			
yes	3(5)	1(1.7)	0.309
no	57(95)	59(98.3)	
Recurrences			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	

Analgesic use			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Pain feeling (VAS)	0.27±0.84	0.25±0.67	0.895
18-month visit			
complications			
yes	3(5)	1(1.7)	0.309
no	57(95)	59(98.3)	
Recurrences			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Analgesic use			
yes	0(0.0)	0(0.0)	1.000
no	60(100.0)	60(100.0)	
Pain feeling (VAS)	0.05±0.29	0.03±0.18	0.704

The early and late post-operative pain scores were similar between the allocated groups. The mean VAS for early postoperative pain was 1.52 ± 1.93 in the control group and 1.32 ± 1.69 in the study group (p = 0.547). No significant differences were found in the mean VAS scores between the two groups throughout the study period. None of the patients used any analgesic in the follow-up period. In terms of hernia recurrence, no case of recurrence was recorded in either of the groups during the 18-month follow-up.

Discussion

The present randomized clinical trial study indicated that there were no significant differences in the pain score, recurrence, and complications between the two meshes when the same surgeon operated on the patients with the same surgical technique and anesthesia method. However, it is worth noting that patients in the study group felt less foreign body sensation and underwent shorter operative time than did those in the control group.

The Lichtenstein tension-free repair method was first introduced in 1989[12]. Rutkow then reported the satisfactory effect of tension-free repair of hernia ring fillings with polypropylene in 1993[13]. However, postoperative chronic pain and foreign body sensation had become challenging issues. To solve this problem, the Kugel posterior herniorrhaphy method, which was based on the Stopper operation, was introduced in 1999[13]. Unfortunately, the complicated posterior approach required additional time to master[14-17]. Alternatively, an anterior approach using the Modified Kugel patch has shown prominent clinical outcome with recognized conclusions. In our study, the pre-peritoneal repairs with the Swing mesh resulted in equally beneficial clinical results during the 18-month follow-up.

Additionally, it is of particular interest to note that the Swing mesh can be used as a plug in the tension-free repair of hernia ring fillings or as a mesh in pre-peritoneal repair. Detailed outcomes are as follows: in patients with a clear anatomic structure of the groin, whereby the pre-peritoneal space could be extensively dissected, the Swing meshes were placed and flatted by pre-peritoneal repair. On the contrary, patients with previous surgical history and who possessed severely adhesive pre-peritoneal space received the Swing mesh with a tightened underlay patch, which could fit well into the hernia ring by tension-free repair of the hernia ring filling.

In conclusion, the present study indicated that the Swing mesh used in the treatment of inguinal hernias displayed good effect and reliability as well as security 18 months after pre-peritoneal repair. In additional, the adjustable mesh provided surgeons with two choices according to the actual situation of the patients. Unfortunately, there were some potential limitations in our trial. Since the pre-peritoneal space was extensively dissected in all patients in the study group, the feature of the Swing mesh, which could be used in tension-free repair of the hernia ring filling, has not been manifested. A multi-center study with a larger cohort of patients is needed to further confirm the conclusion. Moreover, follow-ups of longer than one year would be needed to evaluate safety in terms of the rate of hernia recurrence and chronic pain.

Conclusion

Swing mesh used in the treatment of inguinal hernias displayed good effect and reliability.

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