

Comparison of Short-term Results of Laparoscopic (Transabdominal Preperitoneal) Versus Kugel Mesh Repair of Inguinal Hernia

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Abstract

Introduction: There has been an evolution in the treatment of inguinal hernia. While the transabdominal preperitoneal (TAPP) laparoscopic hernia repair is associated with reduced post-operative pain and faster recovery, the Kugel mesh repair offers the advantages of preperitoneal inguinal hernia repair without the need of general anesthesia, combining the advantages of the open technique and the laparoscopic repair of inguinal hernia.

Materials and Methods: The study was carried out in the Department of General Surgery of The Calcutta Medical Research Institute, Kolkata. A total of 50 patients for each procedure were recruited for the study. This study included patients above the age of 18 years requiring surgery for unilateral inguinal hernia who attended the outpatient department of Dr. Sanjay De Bakshi and Dr. Ajay Mandal in The Calcutta Medical Research Institute, Kolkata.

Results: Post-operative pain at 24 h and at 48 h of the patients who had undergone Kugel mesh repair was significantly higher than those of the patients with laparoscopic (TAPP) repair (post-operative pain – at 24 h: $P < 0.0001$ and at 48 h: $P < 0.001$). However, there was no significant difference in the post-operative pain at 7 days for the patients of the two groups ($P = 0.38$).

Conclusion: Short-term results of laparoscopic (TAPP) repair of inguinal hernia were better when compared to the Kugel mesh repair of inguinal hernia. Studies with longer follow-up are recommended so that the recurrences can be analyzed correctly. We recommend randomized and controlled trials with a larger sample size and compared over a longer period of time to draw any strong conclusions.

Key words: Hernia, Laparoscopy, Tissue

INTRODUCTION

Hernia is defined as an abnormal protrusion of an organ or tissue through a defect in the surrounding walls. Inguinal hernias constitute 75% of all hernias.^[1]

The first true anatomical repair of inguinal hernia was described by Bassini (1844–1924).^[2] There has been an evolution in the treatment of inguinal hernia since then due to the technological advances made in this field. One of the advancement includes the use of mesh. Open tension

free hernia repair is superior to conventional pure tissue repair due to less pain, lesser recurrence, and rapid return to normal activities.

Laparoscopic hernia repair was first introduced by Ger^[3] in 1981. Corbit^[4] and Arregui *et al.*^[5] introduced transabdominal preperitoneal (TAPP) laparoscopic hernia repair. A further development of the TAPP hernia repair was the establishment of the total extraperitoneal (TEP) laparoscopic hernia repair by Dulucq in Europe in the early 1990s.^[6]

Laparoscopic hernia repair is associated with reduced post-operative pain and faster recovery when compared to conventional anterior repair but is costly, requires high technical skills and longer operative time.

In 1999, Dr. Kugel introduced Kugel repair of inguinal hernia. It was a non-laparoscopic preperitoneal technique.^[7]

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In the classic Kugel groin hernia repair, the placement of the mesh in the preperitoneal space was through posterior approach. Thus, it had a steeper learning curve than the traditional anterior approach since entering of the preperitoneal space was through an anatomy quite different from the conventional open hernia methods. To minimize this learning curve, Modified Kugel (Bard-Davol Inc., RI, USA) repair was developed in which the mesh was placed in the preperitoneal space through the anterior approach.

The Kugel mesh repair of inguinal hernia has been found to be as safe as the Lichtenstein hernia repair with similar complication rates.^[8-10] Further, it offers the advantages of preperitoneal inguinal hernia repair without the need for general anesthesia thus increasing patient comfort postoperatively. It also does not require specialized instruments thus decreasing the cost considerably. This open technique of Kugel mesh repair aims to combine the advantages of the open technique and the laparoscopic repair of inguinal hernia.

However, recent studies differ in their reporting of superiority among these two procedures. While a prospective study^[11] favored Kugel repair over TEP laparoscopic repair, a retrospective study^[12] favored laparoscopic (TAPP/TEP) repair over modified Kugel repair.

Till date, there have been inadequate studies comparing the TAPP laparoscopic repair with the Kugel mesh repair of inguinal hernia. This study focuses on the short-term results of TAPP laparoscopic repair and the Kugel mesh repair of inguinal hernia thus further helping in the better understanding of these two procedures.

Aims and Objectives

Aim

The aim of the study was comparison of short-term results of laparoscopic (TAPP) versus Kugel mesh repair of inguinal hernia.

Objectives

To study and compare laparoscopic (TAPP) and Kugel mesh repair of inguinal hernia with respect to the following parameters:

1. Post-operative pain at 24 h, 48 h and at 7 days by numeric pain rating scale.
2. Resumption of routine activities at 24 h and at 48 h postoperatively by:
 - i. Mobilization out of bed:
 - With assistance
 - Without assistance.
 - ii. Ability to reach toilet
 - With assistance
 - Without assistance.

3. Length of post-operative stay in hospital in days
4. Failure rates as measured by recurrences at 6 months

MATERIALS AND METHODS

Study Site

The study was carried out in the Department of General Surgery of The Calcutta Medical Research Institute, Kolkata.

Study Population

This study included patients above the age of 18 years requiring surgery for unilateral inguinal hernia who attended the outpatient department of Dr. Sanjay De Bakshi and Dr. Ajay Mandal in The Calcutta Medical Research Institute, Kolkata.

Study Design

This was a prospective, observational, and comparative study.

Sample Size

Formula for computing sample size to compare two groups:

Mean of group 1 = M1

Mean of group 2 = M2

Common standard deviation (SD) = σ

Effect Size = Difference per SD (DSD) = $(M1-M2)/\sigma$

(Absolute difference of M1 and M2 is used for calculation).

As per the study by Li *et al.*,^[13] the mean duration of post-operative stay in hospital of the patients of modified Kugel group and laparoscopic (TEP/TAPP) group was 4.03 ± 2.49 days and 1.83 ± 1.59 days, respectively, (n1 = 530 and n2 = 1230).

Here, M1 = 4.03, M2 = 1.83, and Common SD = 2.05. Thus, the effect size = 1.07. From the Cohen Power Tables for effect size, it had been found that there was a need of 50 patients per group with 99% power at 2% level of significance. The number of patients in each group was in the ratio 1:1. Thus, the required sample size for the study was 100.

Study Duration

This study was conducted over a period of 1 ½ years from July 2016 to December 2017 in the Department of General Surgery of The Calcutta Medical Research Institute, Kolkata.

Inclusion Criteria

The following criteria were included in the study:

1. Consecutive patients of Dr. Sanjay De Bakshi for Kugel mesh repair and of Dr. Ajay Mandal for TAPP laparoscopic repair of inguinal hernia
2. Patients above the age of 18 years.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients who underwent another concomitant procedure
2. Patients with bilateral inguinal hernia
3. Patients with recurrent inguinal hernias
4. Patients with irreducible inguinal hernia
5. Patients with obstructed inguinal hernia
6. Patients with strangulated inguinal hernias
7. Patients with cardiac disease
8. Patients with respiratory distress
9. Patients with bladder outlet obstruction
10. Patients who had any orthopedic deformity that precluded ambulation
11. Patients who had any psychiatric illness.

Data Collection Technique and Tools

A detailed history of the patient, clinical examination, and post-operative pain at 24 h, 48 h, and at 7 days by numeric rating scale (which was enquired over the phone) was collected. Resumption of routine activities as measured by mobilization out of bed and the ability to reach the toilet with or without assistance at 24 h and at 48 h postoperatively was collected. Post-operative stay in hospital in days and failure rate as measured by recurrences at 6 months was collected. All data were noted in the study proforma (given in the appendix) and tabulated in Microsoft Excel.

Statistical Methods

Statistical analysis was performed with help of Epi Info (TM) 7.2.2.2. EPI INFO is a trademark of the Centers for Disease Control and Prevention.

Using this software, basic cross-tabulation, inferences, and associations were performed. Chi-square test was used to test the association between different variables under study. Fisher exact test was used in case of Chi-square test being not applicable. Z-test (Standard Normal Deviate) was used to test the significant difference between two proportions. *t*-test was used to compare the means. Odds ratio was calculated with 95% confidence interval to find different risk factors. One-way analysis of variance followed by Tukeys test with critical difference was used to compare the means of more than two groups.

$P < 0.05$ was considered statistically significant.

Ethical Issue

The study obtained the necessary clearance from the Scientific and Ethical Committee of the institute before data collection (attached in appendix).

RESULTS

The aim of this study was to compare the post-operative pain, resumption of routine activities, length of post-operative stay and recurrence for laparoscopic (TAPP), and Kugel mesh repair of inguinal hernia.

We observed that the post-operative pain at 24 h and at 48 h of the patients who had undergone Kugel mesh repair was significantly higher than those of the patients with laparoscopic (TAPP) repair (post-operative pain – at 24 h: $P < 0.0001$ and at 48 h: $P < 0.001$). However, there was no significant difference in the post-operative pain at 7 days for the patients of the two groups ($P = 0.38$).

Resumption of routine activities at 24 h and at 48 h postoperatively was noted. The need for assistance for mobilization out of bed at 24 h among the patients with Kugel mesh repair was 4.17 times more as compared to the patients with laparoscopic (TAPP) hernia repair ($P < 0.0001$). The need for assistance to reach toilet at 24 h among the patients with Kugel mesh repair was also 4.17 times more as compared to the patients with laparoscopic (TAPP) hernia repair ($P < 0.0001$). However, all the patients of the two groups were able to mobilize out of bed and were able to reach toilet at 48 h without any assistance.

It was observed that the post-operative hospital stay of the patients with Kugel mesh repair was significantly higher than that of the patients with laparoscopic (TAPP) repair ($P < 0.0001$).

There was no failure at 6 months for all the patients of the two groups.

There was no significant difference noted among the two groups when compared in terms of distribution of mean age ($P > 0.05$) and sex or diagnosis ($P > 0.05$) of the patients of the two groups [Table 1].

DISCUSSION

Inguinal hernias include direct, indirect, and femoral hernias. All these account for approximately 75% of abdominal wall hernias.^[14] The lifetime risk of inguinal hernia is 27% in men and 3% in females.^[15]

Inguinal hernia repair underwent transformation with the advent of minimally invasive surgery. Laparoscopic inguinal hernia repair (TAPP/TEP) minimizes post-operative pain and improves recovery.

Table 1: Distribution of diagnosis of the patients, post-operative pain at 24 h of the patients, post-operative pain at 48 h of the patients, post-operative pain at 7 day of the patients, mobilization out of bed at 24 h of the patients, ability to reach toilet at 24 h of the patients, and duration of hospital stay of the patients with two groups

	Kugel mesh repair (n=50)	Laparoscopic (TAPP) (n=50)	Total
Diagnosis			
Left direct	7	14	21
Row %	33.3	66.7	100.0
Col %	14.0	28.0	21.0
Left Indirect	16	11	27
Row %	59.3	40.7	100.0
Col %	32.0	22.0	27.0
Right Direct	14	9	23
Row %	60.9	39.1	100.0
Col %	28.0	18.0	23.0
Right Indirect	13	16	29
Row %	44.8	55.2	100.0
Col %	26.0	32.0	29.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Post-operative pain at 24 h			
1 – 4	17	41	58
Row %	29.3	70.7	100.0
Col %	34.0	82.0	58.0
5–8	33	9	42
Row %	78.6	21.4	100.0
Col %	66.0	18.0	42.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±s.d.	5.30±1.58	3.16±1.30	$t_{98}=7.39$
Median	5.00	3.00	$P<0.0001$
Range	3–8	1–6	
Post-operative pain at 48 h			
0–4	41	50	91
Row %	45.1	54.9	100.0
Col %	82.0	100.0	91.0
5–8	9	0	9
Row %	100.0	0.0	100.0
Col %	18.0	0.0	9.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±s.d.	3.00±1.56	1.74±1.19	$t_{98}=4.52$
Median	3.00	1.50	$P<0.001$
Range	1–8	0–4	
Post-operative pain at 7 day			
0–2	48	50	98
Row %	49.0	51.0	100.0
Col %	96.0	100.0	98.0
3–5	2	0	2
Row %	100.0	0.0	100.0
Col %	4.0	0.0	2.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±s.d.	0.98±0.94	0.22±0.42	$t_{98}=1.23$
Median	1.00	0.00	$P=0.38$
Range	0–5	0–1	

(Contd...)

Table 1: (Continued)

	Kugel mesh repair (n=50)	Laparoscopic (TAPP) (n=50)	Total
Mobilization out of bed at 24 h			
With assistance	23	1	24
Row %	95.8	4.2	100.0
Col %	46.0	2.0	24.0
Without assistance	27	49	76
Row %	35.5	64.5	100.0
Col %	54.0	98.0	76.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Ability to reach toilet at 24 h			
With assistance	23	1	24
Row %	95.8	4.2	100.0
Col %	46.0	2.0	24.0
Without assistance	27	49	76
Row %	35.5	64.5	100.0
Col %	54.0	98.0	76.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Duration of hospital stay (in days)			
1	0	40	40
Row %	0.0	100.0	100.0
Col %	0.0	80.0	40.0
2	38	10	48
Row %	79.2	20.8	100.0
Col %	76.0	20.0	48.0
3	12	0	12
Row %	100.0	0.0	100.0
Col %	24.0	0.0	12.0
Total	50	50	100
Row %	50.0	50.0	100.0
Col %	100.0	100.0	100.0
Mean±s.d.	2.24±0.43	1.20±0.40	$t_{98}=12.44$
Median	2.00	1.00	$P<0.0001$
Range	2–3	1–2	

The Kugel mesh repair of inguinal hernia is known to strengthen all three defect areas of the myopectineal orifice simultaneously. Besides, the Kugel patch is fixed by intra-abdominal pressure making the procedure sutureless, thus avoiding injuries to nerves and vessels. Even the preperitoneal space that the Kugel patch is inserted into, is a deep space that is devoid of nerves or vessels which results in the post-operative pain and the foreign body sensation to be less.

A number of studies have been conducted with the modified Kugel technique of inguinal hernia repair.

In the study conducted by Reddy *et al.*^[16] wherein 107 inguinal hernia repairs were analyzed, the visual analog pain scores ranged from 0 in 19 patients to a score of 10 in one patient reported on the first post-operative day. However, in similar studies, mild pain was reported which disappeared within 2–3 days of surgery.

Twelve of the 66 patients in the study conducted by Reddy *et al.*^[16] who previously had unrestricted walking ability

noted restriction on post-operative day 7. However, Li *et al.*^[17] in his study noted ambulation only 6 h after surgery.

The previous studies noted the mean post-operative hospital stay to be 4 days while recurrences were noted to be ranging from 0 to 4 over a period of 2 years.

The only study wherein comparative assessment was done between the laparoscopic (TAPP/TEP) ($n = 1230$: TAPP-451, TEP-779) repair and the modified Kugel repair ($n = 530$) was reported by Li *et al.*^[12] The visual analog score expressed as mean \pm SD was found to be 2.37 ± 1.1 for the modified Kugel repair group and 2.21 ± 0.98 for the laparoscopic (TAPP/TEP) repair group at 24 h after operation ($P < 0.01$). The duration of post-operative hospital stay expressed as mean \pm SD was found to be 4.03 ± 2.49 for the modified Kugel repair group and 1.83 ± 1.59 for the laparoscopic (TAPP/TEP) repair group ($P < 0.001$). In addition, more patients in the laparoscopic group (TAPP/TEP) returned to unrestricted movement at two post-operative weeks than the modified Kugel group ($P < 0.01$). The recurrence rate was found to be 1.19% ($n = 6$) in the open group and 0.51% ($n = 6$) in the laparoscopic (TAPP/TEP) group. All the recurrences were noted to occur within 3–35 months after surgery except for two recurrences in the open group which occurred later than 2 years after surgery.

Thus, the laparoscopic (TAPP/TEP) group had lower VAS scores with shorter duration of post-operative stay. Moreover, more patients in the laparoscopic (TAPP/TEP) group returned to unrestricted movements earlier. The recurrence was also noted to be lower in the laparoscopic (TAPP/TEP) group.

In the present study, we found that laparoscopic (TAPP) repair of inguinal hernia is better than Kugel mesh repair of inguinal hernia in terms of post-operative pain, resumption of routine activities, and length of post-operative stay in hospital.

In the present study, the post-operative pain at 24 h and at 48 h for the patients who underwent laparoscopic (TAPP) repair of inguinal hernia was significantly low as compared to the patients who underwent Kugel mesh repair of inguinal hernia (at 24 h: $P < 0.0001$ and at 48 h: $P < 0.001$) which was in concordance with the study conducted by Li *et al.*^[12] (at 24 h: $P = 0.006$).

We found that the necessity of assistance for mobilization out of bed and of the ability to reach toilet at 24 h among the patients with Kugel mesh repair was 4.17 times more as compared to the patients of laparoscopic (TAPP) inguinal hernia repair ($P < 0.0001$). In the study of Li *et al.*^[12] return

to unrestricted movements at second post-operative week was observed to be better ($P < 0.01$) in the patients who underwent laparoscopic repair of inguinal hernia.

In the present study, the mean post-operative hospital stay of the patients with Kugel mesh repair was significantly higher than that of the patients with laparoscopic (TAPP) repair of inguinal hernia ($P < 0.0001$) which is also in concordance with the study conducted by Li *et al.*^[12] wherein the same was observed ($P < 0.01$).

We did not find any recurrence when patients were followed up for a period of 6 months. In the study conducted by Li *et al.*^[12] the recurrence rate was found to be 1.19% for the Kugel mesh repair of inguinal hernia while it was found to be 0.51% in the laparoscopic repair of inguinal hernia.

This difference in recurrence might be due to the shorter time period of follow-up of the present study. However, in the study of Li *et al.*^[12] all groin hernia patients older than the age of 18 years who underwent Kugel mesh repair or laparoscopic inguinal hernia repair between January 2008 and December 2010 were recruited and thus the ratio of patients who underwent laparoscopic repair was not 1:1, whereas in the present study, the distribution of patients in each group was in the ratio of 1:1, thus resulting in the analysis being comparable. In the present study, single surgeon performed each procedure resulting in the analysis being more accurate.

The present study has certain shortcomings, such as small sample size, small period of follow-up, consideration of intra-operative and post-operative complications, and cost of treatment which we have not compared. Randomized and controlled trials (RCTs) on larger sample size and consideration of all the aspects mentioned above need to be done to establish the superiority of laparoscopic (TAPP) hernia repairs with Kugel mesh repair of inguinal hernia.

CONCLUSION

From the present study, we observed that the short-term results of laparoscopic (TAPP) repair of inguinal hernia were better when compared to the Kugel mesh repair of inguinal hernia in terms of post-operative pain, resumption of routine activities, and duration of post-operative stay in hospital. We, thus, recommend the use of laparoscopic (TAPP) repair for unilateral inguinal hernia in healthy adults.

However, the present study was a prospective study with a small sample size. Studies with a larger sample size are recommended to come to strong conclusions.

We recommend the use of one standardized anesthesia in further studies to allow the analysis to be made more accurately.

Studies with longer follow-up are recommended so that the recurrences can be analyzed correctly.

We recommend RCTs with a larger sample size and compared over a longer period of time to draw any strong conclusions.

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