ORIGINAL ARTICLE

Prospective Randomized Study for Pain outcome after Modified Kugel Mesh Repair versus Lichtenstein Repair

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ABSTRACT

Background: Modified Kugel hernia repair is minimal access surgery with open preperitoneal approach for inguinal hernia is better and without the disadvantages of Laparoscopic procedure

Methods A total of 86 patients with primary inguinal hernia were randomized to undergo the open preperitoneal modified Kugel or the open anterior Lichtenstein procedure in Mayo Hospital. The outcome measures were operating time, Pain on visual analog scale (VAS) and consumed analgesics during the first fifteen days postoperatively and at 04 months time.

Results In Modified Kugel repair group the operation took less (42 minutes versus 55 minutes; p< .001) There were no difference in pain score or usage of analgesia in either group in first 15 days postoperatively. In Lictinstein repair the mean pain score at 4 months was about 0.9 versus 0.3 of Modified Kugel group with p= .002. The patients reporting for pain postoperatively were 4.34% versus 40% for modified Kugel repair and Lictinstein repair respectively p=.004.As more chances of damage to nerve in Lictinstein repair, so more cases reported with numbness and paresthesia in area of nerve distribution in this group.

Conclusions: Modified Kugel procedure is better alternative to Lichtenstein repair of inguinal hernia as it is less associated with chronic pain at 120 days. Neurological pain and paresthesia or numbness in Lichtinstein repair is due to risk of nerve damage during anterior approach.

Keywords: Kugel mesh repair, inguinal hernia, lichtinstein

INTRODUCTION

In inguinal hernia repair, TEPP or TAPP approaches is associated with less postoperative pain. Five years follow-up in two trials of laparoscopic preperitoneal repair, showed superior outcome in regard of chronic pain versus an open techniques[1,2]. However, the open methods are frequently used due to easy access and technical repair in compare with minimal access approach endoscopically. Further, Laparoscopic approach need general anesthesia, experience and costs. This endoscopic technique is reserved by many consultants surgeon for specific indications and in certain centre with expertise available. So modified Kugel repair is an open preperitoneal approach with open intent with minimal access without drawback of Laparscopy.

The major complication of inguinal hernia repair with anterior approach is chronic pain about 30% to 36% and not the recurrence[3]. Chronic pain is an enigma in regard of its origin and treatment. The hypothesis about this pain is that it may be due to position of mesh in anterior approach which causes pressure over nerve pathway. Further, the anterior approach required dissection of inguinal canal which contain iliohypogatric and ilioinguinal nerves. This manipulation of nerve might causes chronic pain in anterior approach. However, preperitoneal modified Kugel repair is with the benefit of open approach with minimal access to the preperitoneal space without disadvantage of endoscopic procedure and of open technique like lichtinstein repair[4].

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MATERIAL AND METHODS

The study was conducted between December 2010 and May 2012 in Mayo Hospital at Surgical Department of King Edward Medical University Lahore . The patients with inguinal hernia who have been referred for operation were randomized into modified Kugel group and lechtinstein group. Patients with type IV hernia or recurrent hernia were excluded from the study. The patients were given pro-forma for information about the study and its purpose and University ethical committee approved the protocols..

In this study 86 patients with unilateral hernia were included and randomization by using lottery draw pattern and patients were given one of the two repair according to group distribution either modified Kugel or Lichtinstein group depending upon their Draw outcome number. . However, patients do not know the operation used. Demographic aspect of the patients as shown in Table-1 were recorded.

Technique: Apart from half of the Lichtenstein repair and all Modified Kugel repair done by one senior surgeon and rest of operation by junior consultant. All patient were given 5mg medazolam and 75mg diclofenace sodium about half an hour before sending to Operation Room, as a protocol of study. All patients were given 750mg 2nd generation of cephalosporine at time of induction of anesthesia. The anterior mesh repair was performed as described somewhere[5]. We use 6-11 polypropylene mesh for anterior repair and tacked with iliopubic tract and above to conjoined tendon and laterally around the deep ring with non absorbable suture.

For the modified Kugel , preperitoneal approach was used as described by Kugel[4]. However, instead of Kugel Mesh Patch, 8- 11 cm polypropylene mesh was tacked with two point fixation as done in TEPP procedure, by using tacker through Kugel open approach. Nerves and vessels were spared whenever possible. In both techniques, the skin was closed with a subcuticular absorbable suture. Two patients out of 32 need general anesthesia due to incomplete block of spinal anesthesia, and about eight patients preferred to have general anesthesia

In the modified Kugel group about 35 patients had spinal anesthesia and 06 patients preferred GA from very beginning however, 03 patients in spinal anesthesia group need supplementary GA due to failure of block. At the completion of procedure patient's operative wound were infiltrated with 10 ml of 0.25% of bupiviacain. Postoperatively patients were given Tab. Paracetamol or Inj Dicloran or both depending upon the severity of pain nerves and vessels in the operative field were recorded. The Pro-forma in the study contain three sections: **first** section is about the demographic aspects of patients and informed consent.

In **second** section we recorded BMI, employment and time of hernia repair.

The **third** part of pro-forma contain variable about pain score on visual analog scale (VAS) and a questionnaire regarding use of pain killer and its reasons; (pain due to operation, headach, joint pain or others).The pain score scale from zero- no pain to 10 mean worse or unbearable pain. For purpose of calculation, the scores were rounded to the closest centimeter. Second part of pro-forma completed in ward by registrar preoperatively. Pro-forma was carried to home by patient and recorded daily pain scores on VAS as well as number and type of analgesics taken for pain in the first 15 days postoperatively. After 3 months of operation, the patient visited the surgeon but not the same who operated the patient for physical and neurological examination. The complications were noted. Any paresthesia, bulge or abnormal feeling of sensation at operative site were also noted. Bulge on standing or on raised intra-abdominal pressure by bearing down or detected on Ultrasound to confirm any recurrence were noted. For the sensory changes, a patient could choose from several sensory (neuropathic and nociceptive) and affective descriptors.

Statistical analysis: According to the power calculations, 38 subjects per treatment group were needed for the study to achieve a statistical power of 90% with an alpha of 5%. The calculations were made with a two-sided test for the VAS pain score at 4 months, considering a difference in VAS score of 1.0 as clinically significant. Based on a previous study, the standard deviation was set at 1.9[7].

Statistical comparison was made with the Wilcoxon test for continuous variables. For ordinal data, the Pearson v^2 test was used; $p < .05$ was considered statistically significant. Data were analyzed on the basis of intention to treat.

AIMS & OBJECTIVES

The study aims were to know that modified Kugel repair has less postoperative pain than the Lichtenstein repair, and the feasibility is comparable. For the first hypothesis, the endpoint was to note pain score at four months. If score is more than zero at this time, the patient was labeled as having chronic pain as defined by International Association for pain control as Study of Pain[5]. The second outcome measure of study was to measure the pain score and usage of analgesics in first 15 days postoperatively.

RESULTS

Table 1: Patient characteristic

	Lichenstein repair	**Modified Kugel**	**P value**
No. of patients	42	44	
Mean (SD) age (years)	54.4 (13.6)	55.6(15.8)	**.384**
Sex ratio (M:F)	85:1	85:1	1.00
Mean (SD) BMI (kg/m^2)	25.4 (2.7)	25.1 (2.9)	.447
ASA group			
I	29	27	
II	12	15	
III	1	2	.657
Employment			
Light	18	14	
Heavy	12	13	
None or retired	10	12	.315
Missing	02	05	
Presence of hernia			
Weeks	12	10	
Months	21	22	.843
BMI body mass index; ASA			
Years	07	07	
American Society of Anaesthesiologists SD standard deviation			
Missing	02	05	

A total of 86 patients were randomly allocated to receive one of the two repairs. Two patients did not turn for follow up and excluded from study. Ultimately, 84 of 86 patients (97.6%) were analyzed for the primary end-point (Fig.1). Baseline characteristics and pre-existent pain complaints were comparable between the groups (Table 1,2, Fig.3).

The mean VAS pain score was lower in the Kugel group than in the Lichtenstein group for every day of the first 2 postoperative weeks (Fig.3). During the same period there were no significant differences in the total number of consumed paracetamol tablets (19.9 versus 18.5; p=.400) or in the number of consumed diclofenace Sodium tablets (8.6 versus 7.0; p = .295). On the days that the patients did not consume any analgesics, the mean VAS pain score was 1.4. At 4 months, patients who underwent the open pre-peritoneal mesh repair reported significantly less pain (mean VAS score 0.3 versus 0.9, p = .002). The number of patients included in study after (n=86)

Fig. 1 Trial flow chart

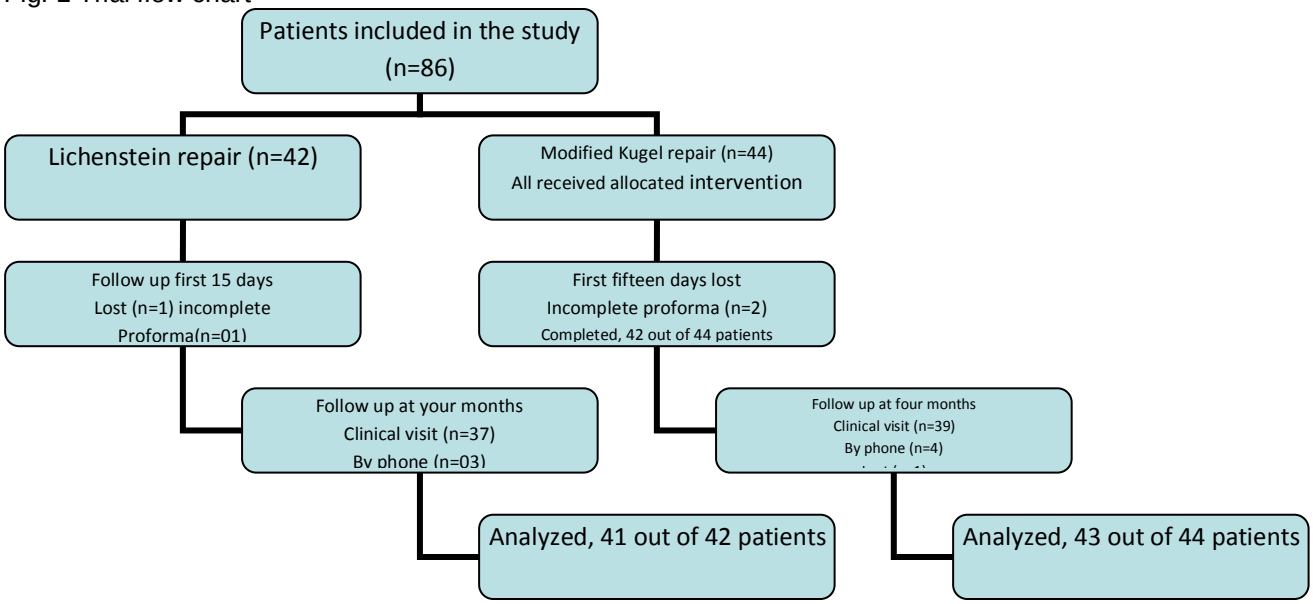


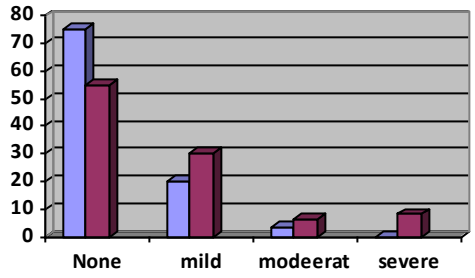
Table 2 Preoperative pain complaints

	Lichtenstein (n=41)	Modified Kugel (n=43)	P value
Mean Pain Score (voa)			
	1.3 (1.03)	1.8 (1.08)	.926
Use analgesics (N)			
Sometimes	03	09	
Regular	02	06	.952
Use analgesics (n)			
Back pain	04	02	
Arthritis	01	1	
Headache	13	10	
Hernia	11	14	.505

VAS visual analog scale

Pre- and postoperative day: Fig. 2 Mean visual analog scale (VAS) pain score per day. Patients reporting chronic pain was 02 of 43(4.47%) in the modified Kugel group and 17 of 41(42.5%) of the Lichtenstein group (p =.005).All modified Kugel repair and about 50% of Lichtenstein group were repaired by senior surgeon and rest of the cases done by other consultant. The postoperative pain was not significant in both surgeons group. The pain intensity distribution is detailed in Fig. 3. Six patients who reported pain at 04 months used analgesics; paracetamol (n=2), Diclofenace Sodium or ibuprofen (n=3), and combinations (n=3). Twenty four patients used nine different descriptors to describe their pain, mostly neuropathic (Table 3).

Fig 3: Chronic pain distribution



Blue depict : modified Kugel repair, and blue showed Lichtinstein repair.

In the Lichtenstein group the operation took significantly longer (54 min versus 41 min; p < .001). We come across with nerves during dissection in anterior approach frequently mostly iliohypogastirc and ilioinguinal nerve, and the inferior epigastric vessels were encountered almost in 99% percent of cases with the pre-peritoneal approach as this is the hallmark of this procedure to identify oneself about the anatomy of the preperitoneal space (Table 4). Complications included hematoma, which was treated conservatively (n=14); infection (n=5); and urinary retention were noted may be due to pressure of the mesh against the bladder in one the cases. Recurrence noted in two cases of Lichtenstein and none in modified Kugel repair. Diagnosed by either physical examination (n=02) and confirmed on ultrasound (n=2), Two patients with recurrences underwent reoperation within 3 months. Another 06 Lichtenstein and 01 modified Kugel patients complained about a swelling/bulging recorded by physical examination or in the patient questionnaire. However, on clinical evaluation by surgeon and confirmed on ultrasonography there was no recurrence as stated by patients.

Numbness was reported significantly more in the Lich-tenstein group (12 versus 01, p <.001). For patients with reported numbness, nerve damage was reported by the surgeon as the cause in 3 cases, and hypoesthesia was found on neurological examination in 15 cases. Sensory changes were found in 02 modified Kugel patients and 14 Lichtenstein patients. The nerves were the iliohypogastric (n=09), genital branch of genitofemoral (femoral branch n = 03 and genital branch n= 01), and ilioinguinal (n=02). The sensory changes were related to the number of nerves encountered (R=.152, p = .050). The Pearson v^2 test for patients with a cutaneous sensory change of reported numbness was 37.4 (p < .001); that of reported chronic pain, 18.3 (p<.001). Patients without any sensory changes scored their pain as significantly less (.41 versus 1.53, p < .001) at 4 months.

Table 3: Patients with pain

	Lichtenstein (n=17)	Modified Kugel (n=07)
Neuropathic aches	1	1
Ac. burning abdominal sensation	10	2
Sensation of pricking	12	03
Severe pain	2	04
Gnawing	0	1
Abdominal feeling	1	1
Acute Tender	7	2
Effective tiredness	2	0
Boring	2	2

Table 4 Procedure with morbidity and encounters

	Lichtenstein (n=42)	Modified Kugel (n=44)	P value
Ilioinguinal nerve	15	02	.000
Damaged	02	00	.025
Iliohypo-gastric nerve	31	02	.000
Damaged	01	00	.325
Genitofemoral nerve	10	00	.002
Damaged	02	00	.323
Inferior epigastric vessels	21	43	.000
Vas deferens	42	41	.413

For the entire group, the preoperative VAS pain score correlated with the scores in the first 2 weeks after the repair (R = .445, p < .001), the number of paracetamol taken (R= .260, p=.001), and the number of diclofence Sodium taken (R= .205, p = .010). No significant correlation with the pain score was found at 3 months. The preoperative consumption of analgesics had no influence.

DISCUSSION

The study of this randomized trial comparing the standard open anterior Lichtenstein approach to hernia repair with an open preperitoneal modified Kugel approach, some significant advantages were found for the open preperitoneal repair technique. The procedure was performed in less time; at a 4 months follow-up, a lower mean VAS pain score and a smaller proportion of patients with chronic pain were reported than in the Lichtenstein group. The chronic pain was mostly described as neuro-pathic, because nerves were encountered more frequently with the anterior approach. In the open preperitoneal repair group less numbness was reported and fewer cutaneous sensory changes were found at neurological examination.

The authors feel that chronic pain is incapacitating and worse than recurrence problem of the patient. Therefore the primary outcome measure of this study was the mean pain scores at 4 months. In spite of limitation of pain scoring scale as it measure only uni-directional outcome without regard of frequency, this method is by far the most useful for comparison as we made in the present study. The VAS pain score differed significantly between the groups, although the absolute difference was only 0.6. As stated in the Methods section, this might not be regarded as clinically relevant. Only four patients in each group used analgesics at this point. Seventeen Lichtenstein patients (42.3%), however, reported a VAS pain score higher than zero. This figure is relatively high

compared to some other published data[8,9,10] although similar results have been reported from studies with comparable designs[7,11,12]. In the present study, the chronic pain of 42.3% in the Lichtenstein group is almost ten time the rate found in the modified Kugel group (03 of 43, or 4.34%). The pain was described as neurological origin and arises from nerve dissection with some kind of damage which is more common with open method of anterior repair rather than preperitoneal approach. That is the reason for more hypoesthesia, paresthesia and cutaneous sensory changes with anterior approach.

A few parameter in both groups had similar outcome. In first 15 days postoperatively there was no significant difference in both group in regard of pain score and use of analgesic drug. Furthermore no difference in the type of complication and incidence noted in both groups. One specific complication to the preperitoneal approach was seen in this study was urinary frequency (1 patient). When CT scan was performed, there was compression of mesh noted on bladder and patient improved after removing the mesh. No recurrence in Modified Kugel repair while two recurrence were noted due to technical failure in Lichtinstein repair. However, Schroder et al[13] reported a recurrence rate of 7.7 in Kugel repair which is not seen in present study. As seen most failure occur in Kugel repair in first 36 cases, may be due to learning curve. They summarize other studies wherein preperitoneal repairs are noted for steep learning curves. In contrast, acceptable recurrence rates have been reported in numerous studies with long-term follow-up, with the recurrence rate varying from 0% to 0.8%[4,14,15,16,17]. As preperitoneal is more unknown space and approach to this area without previous knowledge definitely causes poor outcome in regard of any surgical intervention. We therefore established learning workshops before this study was begun. In addition, patients with recurrent her-nias and large direct hernias were excluded. One surgeon who performed the procedures does not have specified experience in this study and it is therefore possible that a procedure carried out under less experienced supervision might have failed, thereby contributing to the recurrence rate of 3.48% (3 of 86).

The Kugel Patch is not used in present study due to non availability and cost of mesh patch. So in modified Kugel repair authors used only ordinary polypropylen mesh. instead of kugel mesh patch which is heavier than a monofilament Prolene mesh. Thus it might be assumed that this modified Kugel repair has less impression on bladder, resulting in less frequency of urine[11]. At the 4-month follow-up, however, significantly less pain and less swelling/bulging was found in the modified Kugel group than in the Lichtenstein group.

Only one previous study known to the authors has compared the two hernia repair techniques, that by Dofru et al[16], who found similar results with regard to operating time and complications. However, no chronic pain-related outcomes were included. The present study has its own limitations: (1) The modified Kugel procedure is not previously done by any study, so comparing this procedure with other standard procedure definitely carry a lot of discussion in regard of validity of this procedure. However, Outcome of modified Kugel repair[21] showed its benefits over standard anterior procedure in regard of its outcome particularly the recurrence. (2) A few patients did not turn for follow up and to trace them through telephone was even problematic. So pain outcome cannot be overestimated due to prevailing circumstances. (3) As mentioned already that VAS have its limitation due to one-dimensional score and additional parameters of pain had to be employed to estimate the true incidence of pain. Nevertheless, it is difficult to express the significance of every VAS pain score higher than zero. In half of the immediate postoperative period, patients reported a pain score without taking any pain medication, as did 17 of 41 patients reporting pain at 4 months. This occurred even though the surgeons had advised patients concerning the standard pain protocol and explained the use of analgesics to the patients.

SUMMARY

If one master in modified Kugel repair, this preperitoneal approach has comparable outcome versus standard Lichtinstein repair with less recurrence and chronic pain.

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