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Is Kugel Herniorraphy Really Minimally Invasive?: A Prospective, Randomized Study+

Cüneyt Kırkıl*, Erhan Aygen*, Nurullah Bülbüller*, Osman Doğru*, Ahmet Ödekmerdan**, Mustafa Girgin*, Mehmet Saraç*

* Fırat Üniversitesi Tıp Fakültesi, Genel Cerrahi AD. Elazığ
** Fırat Üniversitesi Tıp Fakültesi, İmmünoloji AD. Elazığ

Background: Kugel herniorraphy had been advocated as a minimally invasive technique. The purpose of this study was to compare inflammatory responses and clinical outcomes after Kugel and Lichtenstein procedures.
Patients and methods: Thirty patients with unilateral inguinal hernia were randomized into Kugel and Lichtenstein repair groups. Peripheral venous blood samples were collected, to measure the levels of interleukin-6 and C-reactive protein, just prior to surgery and then 12 and 48 hours postoperatively. Postoperative acute and chronic pains were evaluated. Time to return normal activities and work was recorded.
Results: Interleukin-6 levels significantly increased after Lichtenstein procedure. C-reactive protein levels were significantly increased in both groups. Patients had less postoperative pain and they recovered earlier after the Kugel procedure.
Conclusions:In conclusion our data show that Kugel herniorraphy causes less inflammatory response, less postoperative acute pain and rapid recovery compared with Lichtenstein technique.

Key Words: Kugel herniorraphy, Lichtenstein procedure, Inflammatory response, Minimally invasive

Kugel Fıtık Tamiri Gerçekten Minimal İnvaziv midir?: Prospektif Randomize Bir Çalışma

Amaç: Kugel fıtık tamirinin minimal invaziv bir teknik olduğu ileri sürülmektedir. Bu çalışmanın amacı Kugel ve Lichtenstein girişimlerinden sonra gelişen enflamatuvar yanıtları ve klinik sonuçları karşılaştırmaktı.
Hastalar ve Metotlar: Tek taraflı kasık fıtığı olan 30 hasta Kugel ve Lichtenstein tamir gruplarına rastgele ayrıldılar. Cerrahi girişimden hemen önce ve girişimden sonraki 12. ve 48. saatlerde, interlökin-6 ve C-reaktif protein seviyelerini ölçmek için periferik venöz kan örnekleri alındı. Cerrahi sonrası akut ve kronik ağrı değerlendirildi. Normal aktivitelere ve işe dönüş süreleri kaydedildi.
Bulgular: Lichtenstein girişiminden sonra interlökin-6 düzeyleri belirgin olarak artarken Kugel fıtık tamiri, interlökin-6 düzeylerinde anlamlı olmayan bir artışa neden oldu. C-reaktif protein düzeyleri her iki grupta da belirgin olarak arttı. Kugel girişiminden sonra hastaların ağrısı daha azdı ve daha erken iyileştiler.
Sonuç: Sonuçlarımız göstermektedir ki, Kugel fıtık tamiri Lichtenstein tekniği ile karşılaştırıldığında daha az enflamatuvar yanıta, daha az ameliyat sonrası ağrıya ve daha hızlı iyileşmeye neden olmaktadır.

Anahtar Kelimeler: Kugel fıtık tamiri, Lichtenstein ameliyatı, Enflamatuvar yanıt, Minimal invaziv

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The Lichtenstein procedure with various prosthetic materials is a popular method for the treatment of groin hernias. It has been preferred by surgeons because the technique is simple, rapid, effective, and safe, with less postoperative pain, discomfort, and low recurrence rate.[1-3] The Kugel herniorraphy is a recently developed tension-free procedure for the treatment of inguinal hernias. It had been advocated as a minimally invasive technique which had an acceptable recurrence rate when it was compared with the Lichtenstein technique.[4] The value of minor access may be quantified by different parameters such as influence upon the immunologic function, postoperative pain, time to return to work and duration of convalescence, as well as a comparison of the effects upon the quality of life index.

The measurements of serum levels of certain interleukins and acute phase proteins, especially interleukin-6 (IL-6) and C-reactive protein (CRP) allow to objective determination of tissue trauma after surgery.[5-7]

The aim of present study was to investigate the extent of tissue trauma with the inflammatory response and clinical outcomes after inguinal hernia repair with the Lichtenstein and the Kugel procedures.

PATIENTS AND METHODS

Local ethics committee of Firat University, School of Medicine has approved the study. Thirty patients with unilateral inguinal hernia without complications or recurrence were included into the study. Patients with metabolic, endocrine, hepatic, pulmonary or renal disease and receiving steroids or non-steroid anti-inflammatory drugs or any transfusions were excluded from the study. The procedures were explained in detail to all patients and written informed consent was obtained. Fifteen patients were randomized into two groups. Group I underwent Kugel herniorraphy using small-oval Kugel hernia patch (Bard® Kugel Hernia Patch, Davol Inc., Cranston, Rhode Island, USA) which is made by polypropylene. The patients in group II (n=15) underwent Lichtenstein hernioplasty using polypropylene mesh (PMII Prolene Mesh®, Ethicon Inc., Johnson&Johnson Co., Somerville, New Jersey, USA). The hernias were classified according to the modified Gilbert's classification by Rutkow and Robbins.[8,9] Indirect hernia sacs were resected in both groups. The meshes were secured in position by 00 polypropylene sutures in group II.

Postoperative pain was evaluated at 2nd and 12th hours following the operation by means of a visual analogue scale (VAS) which its score was 0 to 10 in all patients. In the case of pain which was tolerated or not expressed by the patient, analgesic medication was not given up to postoperative two hours. Otherwise, postoperative pain evaluated immediately and then Pethidine HCl 100 mg injected I.M. After VAS was obtained, Pethidine HCl 100 mg was administered to all patients within 8 hours intervals during postoperative first day. During the second and third days after the operation, paracetamol 500 mg was given per os routinely tid. In the following days, the patients were told to take parasetamol if they needed. No anti-inflammatory drug was given. Time to return to normal activities and working was recorded for each patient except for retired and unemployed patients. Time to return the normal daily activity described as walking, wearing, sitting onto the toilet without any assistance.

Five mL venous blood samples were obtained just prior to beginning the operation and postoperative 12th and 48th hours for detection of serum IL-6 and CRP levels. Samples were centrifuged at 3000 rpm for 5 minutes within 30 minutes of venipuncture. Then they were frozen at –80°C until assayed. Serum IL-6 level was studied by ELISA using human IL-6 kit (Biosource®, Camarillo, California, USA) with <2 pg/mL minimum detectable dose (range 0 to 500 pg/mL). Serum high sensitive CRP was measured by N High CRP sensitivity kits (Dade Behring GmbH, Marburg, Germany) and a Behring Nephelometer 100 Analyzer (Dade Behring GmbH), using the immunonephelometric method. The lowest limit of detection was 0.175 mg/dL.

Patients underwent clinical review and examination at 12 months. Chronic pain was asked with a questionnaire as described by Bay-Nielsen et al.[10]

Statistical Analysis

Contunies data were presented as mean ± standard deviation (SD) and were compared with independent samples t-test. Non-continues data were analyzed with chi-square test. The Wilcoxon Ranks test was used to evaluate paired continues data. A p value less than 0.05 was considered statistically significant.

RESULTS

Because hematoma was known to induce circulating levels of soluble cytokines as IL-6.[11,12] Three patients in Group I and one patient in Group II were excluded because of inconsistency with study protocol or complications as seroma and hematoma. Age, gender, working condition, types of hernia and anesthesia, and duration of operation were summarized in Table-1. There were no differences between groups, except the type and location of hernia. But numbers of the resected indirect sacs were similar.

Table-2 shows mean serum IL-6 and CRP levels. While mean serum IL-6 level at 12 hours was significantly increased in group II compared with its baseline level (107.7±84.9 vs. 63.5±69.5 respectively, $p<0.05$), there was no significant increasing in group I (71.8±49.9 vs. 58.2±49.6 respectively, $p>0.05$). Mean serum IL-6 levels in both groups were declined to their baseline levels at 48 hours following

operations. Mean CRP levels were significantly increased in both groups at 12 hours when they compared with their baseline values (21.8±28.5 vs 47.7±34.8 and 19.8±35.7 vs 46.6±32.8, for group I and group II, respectively). CRP levels were remained high in the both groups at 48 hours.

Mean VAS pain score on 2nd hour after operation was significantly high in group II compared with group I (4.2±1.3 vs 3.2±0.9, $p<0.05$, Table-3). But at 12 hours, mean VAS pain scores of groups were similar. Patients in group II returned to normal activities and to work later than patients in group I (3.1±0.8 days vs 1.2±0.4 days, $p=0.001$ and 20.8±7.3 days vs 10.0±2.3 days, respectively, $p<0.001$).

One year after operation, there was no recurrence in both groups. Two patients (16.7 %) in Group I suffered from chronic groin pain, whereas 3 patients (21.4 %) in Group II suffered from this kind of pain. These patients reported that they had pain without restriction during activity. Except one patient in-group II who had temporary pain sometimes, all of these patients described rare pain occurrence. The chronic pain ratios were not significantly different between the groups.

Table 1. Patient characteristics

	Group I(n=12)	Group II (n=14)
Age	47.8±14.5	50.6±7.7
Gender (Male/Female)	12/0	13/1
Working conditions		
Retired or Unemployed	4	2
Official or Student	7	10
Worker	1	2
Right/Left	4/8	10/4
Hernia (Type modified Gilbert)		
2	8	3
3	1	1
4	3	6
6	0	4
Anesthesia (General/Regional)	11/1	12/2
Duration of operation (min)	40.4±7.2	44.6±8.9

Data are expressed as mean ± standard deviation.

Table 2. Mean serum IL-6 and CRP levels.

Mean Serum Level (± S.D.)		Group I (n=12)	Group II (n=14)
IL-6	Preoperative	58.2±49.6	63.5±69.5
	At 12 hours	71.8±49.9	107.7±84.9*
	At 48 hours	59.2±59.1	74.9±76.4
CRP	Preoperative	21.8±28.5	19.8±35.7
	At 12 hours	47.7±34.8*	46.6±32.8*
	At 48 hours	38.9±25.4*	32.4±29.6*

* $p<0.05$ significance vs preoperative value.
There was no significant difference between groups at any moment.

Table 3. Mean VAS, time to return to normal activities and to work and chronic pain incidence

	Group I	Group II
VAS at 2 hours (mean±S.D.)	3.2±0.9	4.2±1.3*
VAS at 12 hours (mean±S.D.)	1.7±0.6	1.8±0.9
Time to return to normal activities (mean±S.D	1.2±0.4	3.1±0.8†
Time to return to work (mean±S.D.)	10.0±2.3	20.8±7.3‡
Chronic pain incidence (%)	16.7	21.4

* $p<0.05$ significance vs group I †$p=0.001$ significance vs group I
‡ $p<0.001$ significance vs group I

DISCUSSION

In this study, we determined that the increase of IL-6 did not reach significance after the Kugel herniorraphy whereas it was significant after the Lichtenstein herniorraphy. However, there was no significant difference between the groups. On the contrary, the variations of CRP levels were similar in both groups. Patients had less postoperative pain and they returned earlier to normal activities and to work after the Kugel procedure, although there was no statistically difference between chronic pain indices.

Although tension-free techniques are accepted worldwide for repairing inguinal hernia, ideal method can not be described yet. A new, minimally invasive and non-laparoscopic procedure for herniorraphy was described by Dr. Robert D. Kugel in 1999.[4] Senior author emphasized the technique as minimally invasive, because the small dissection area limited the amount of surgical trauma. But, there was no evidence supporting this argument except some clinical observations such as less postoperative pain, early recovery, and no activity restriction. The extent of tissue trauma after surgery can be evaluated on the basis of the severity of the inflammatory response. In general, intensity of inflammatory response is correlated to the severity of the surgical trauma.[5,7] IL-6 and CRP are commonly used parameters to assess the inflammatory response. Moreover, IL-6 is a pivotal cytokine of acute phase response.[13] In the present study, since pre- and postoperative serum IL-6 levels were taken into consideration it was shown that the Kugel herniorraphy caused an insignificant increase in circulating IL-6 levels while its levels significantly increased after Lichtenstein procedure. However, there was no difference between the groups. This observation has suggested that Kugel herniorraphy caused less immune response as well as surgical trauma. Significantly increased CRP levels after surgery might be attributed to using prosthetics materials constructed of polypropylene. Di Vita et al. evaluated the immune response after mesh repair for groin hernia and suggested this argument.[14]

The Kugel hernia repair does have many of the advantages of a laparoscopic approach, while eliminating many of the constraints. It is inexpensive and can be done under local anesthesia.[4,15] There is limited data about outcome after inguinal hernia repair with Kugel patch in the literature. In three series, it was concluded that Kugel repair had excellent or good results with respect to acceptable recurrence rate, less postoperative pain, early recovery, and without any activity restriction.[4,15,16] In these series, recurrence rates were reported as 0.47 per cent to 2.8 per cent. Additionally, Baroody et al. reported only 6% recurrence in high-risk patients with recurrent inguinal hernias.[17] In contrary to these good results, Schroder et al. reported an unacceptable recurrence rate after Kugel herniorraphy, as of 27 per cent.[18] However, they noted that recurrence rate reduced to 2.9 per cent after first 36 cases due to learning curve. This situation suggests that the experience of the surgeon performing the operation is an essential for factor determining recurrence rate. The present study was started after approximately 200 Kugel herniorraphies. Therefore, we strongly believe that learning curve effect was already ruled out, and there was no recurrence in both groups after a short follow-up as of 1-year.

Postoperative pain is an important factor which has a direct influence on the patients' quality of life. Especially, chronic pain after groin hernia repair is a serious problem and it occurs in 5 to 30 % of patients.[19,20] The few available studies on outcomes of the Kugel herniorraphy have reported less postoperative pain and early recovery . But, a comparison between Kugel and Lichtenstein technique on the basis of clinical results is not found in the English literature.[4,15-18] The present study is unique because outcomes after Kugel and Lichtenstein procedures were compared as well as inflammatory response. Our data show that Kugel herniorraphy is associated with less postoperative pain and rapid recovery compared with Lichtenstein procedure. But, there was no difference with regarding to chronic pain incidence following both procedures.

This study might be criticized because general anesthesia was preferred rather than local anesthesia. It has been reported that general anesthesia has a great effect on the inflammatory response which can mask the difference between two technical procedures.[21] On the other hand, in a recent study, Schwab et al. reported that immune activity in response to the Shouldice operation was slightly lower (but not significant) when the procedure was carried out under local anesthesia.[22]

CONCLUSION

As a result, our data show that Kugel herniorraphy causes less tissue trauma in according to the technique which is associated with a less inflammatory response compared to Lichtenstein procedure, as attested to by low IL-6 level. Furthermore, it causes less postoperative acute pain and rapid recovery compared with Lichtenstein technique.

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Yazışma Adresi
Yrd.Doç.Dr.Cüneyt KIRKIL
Fırat Üniversitesi Tıp Fakültesi,
Genel Cerrahi AD, 23200 Elazığ
E-posta : ckirkil@yahoo.com
Tel : 424 233 3555
Fax : 424 238 8096