A randomised controlled trial of excision versus invagination in the management of indirect inguinal hernial sac

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ABSTRACT

INTRODUCTION Lichtenstein tension-free mesh hernioplasty of primary inguinal hernia is currently considered as the preferred method for the plastic reconstruction of inguinal hernia by the majority of surgeons. Several studies have examined the best way to manage the hernial sac in this surgery, but no consensus has been reached. This study was designed to compare the effects of excision of sac and invagination of sac on post-operative outcomes.

METHODS AND METHODS This prospective randomised study included a total of 70 patients with primary unilateral uncomplicated indirect inguinal hernia. Group A (35 patients) underwent high dissection and invagination of the hernial sac and group B (35 patients) underwent high ligation and excision of the hernial sac. The repair of the posterior wall of the inguinal canal was done according to Lichtenstein tension-free technique. The primary outcome of this study was postoperative pain and secondary outcomes were wound infection, chronic sepsis, sinus formation, persistent pain, testicular atrophy and recurrence during the one-year follow-up period.

RESULTS There was a significant difference ($P < 0.01$) in pain experienced by the patients in the immediate post-operative period between the two groups; group A experienced less postoperative pain than group B. There was no significant difference in incidence of infection between the groups.

CONCLUSIONS Invagination of the sac results in less postoperative pain compared with excision, with no significant difference in other postoperative outcomes.

KEYWORDS

Herniorrhaphy – Postoperative pain – Indirect inguinal hernia

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Introduction

Inguinal hernia repair is one of the most common operations performed by general surgeons around the world. Lichtenstein tension-free mesh hernioplasty of a primary inguinal hernia is currently considered as the preferred method for the plastic reconstruction of inguinal hernia by the majority of surgeons. This technique combines many advantages such as simplicity, effectiveness, safety, rapid return to unrestricted activities, impressively low recurrence rates and high patient satisfaction.

Persistent postoperative pain and recurrence are two major problems encountered with different inguinal hernia repairs. At the end of nineteenth century, Edoardo Bassini recommended high ligation and excision of indirect hernia sac.¹ One of the cardinal causes of recurrence was thought to be failure to perform a high ligation of the sac. Today,

the emphasis has shifted from the sac to the defect and the need to ligate the sac has been questioned. In modern operations for inguinal hernia, including laparoscopic repairs, the sac is not ligated but is simply inverted or excised without ligation.

Several studies have examined the best way to manage the hernial sac but no consensus has been reached.^{2–5} Nevertheless, these studies show that management of the indirect hernial sac may influence the rate of recurrence and the development of postoperative pain. This study was designed to compare the effect of two techniques of dealing with indirect inguinal hernia sac in tension-free mesh hernia repair (excision and invagination of the sac) on postoperative pain and early recurrence rates.

The study was performed after approval of the protocol by our institutional ethics committee and in accordance with 1964 Helsinki Declaration and its later amendments. Written

informed consent was obtained from all individual participants.

Materials and methods

A single blind randomised controlled trial was conducted in 70 patients diagnosed with primary unilateral uncomplicated indirect inguinal hernia scheduled for undergoing elective open Lichtenstein tension-free inguinal hernioplasty after written informed consent. Randomisation was done using random number table generated from computer software. Random treatment assignment was placed in serially numbered, opaque and sealed envelopes. These envelopes were opened in theatre just before the surgery and patients accordingly divided into two study groups: invagination and excision. Thirty-five patients underwent high dissection and invagination of hernial sac (group A) and thirty-five underwent high ligation and excision of hernial sac (group B). Patients with recurrent inguinal hernia, complicated inguinal hernia requiring emergency surgery, female patients, patients consenting only for laparoscopic repair and patients younger than 18 years of age were excluded from the study. After detailed history and physical examination, investigations (haemoglobin estimation, total leucocyte count, differential leucocyte count, random blood sugar, urea, creatinine, chest x-ray and electrocardiogram) were carried out pre-anaesthesia. Patients were admitted for open hernia repair using Lichtenstein technique with mesh placement under regional anaesthesia. Spinal anaesthesia was used for all the patients.

In group A, after high dissection, the entire sac was inverted with a finger into the peritoneal cavity. The repair of the posterior wall of the inguinal canal was carried out by Lichtenstein's mesh repair in the usual way. In group B, the sac was transfixated and ligated at the neck and the distal part excised in the traditional manner. At the time of induction, all patients were given combination of amoxicillin with clavulanic acid as antibiotic prophylaxis.

The primary outcome of this study was postoperative pain and secondary outcomes were wound infection, chronic sepsis, sinus formation, persistent pain, testicular atrophy and recurrence. Postoperative pain was assessed using a visual analogue scale (VAS) of 1–10 for first 24 hours. VAS was recorded after 6 hours, 12 hours and 24

hours after surgery. The patients were given the VAS chart and asked to score their pain at 6, 12 and 24 hours after surgery. The number of diclofenac (analgesic) injections used was similar in all patients in both the groups. At discharge, the patients were evaluated for local wound complications (bruising, haematoma and wound infection) and for systemic complications (chest infection and urinary retention). Following discharge from hospital, patients were reviewed after 7 days, 21 days and 1 year for complications (wound infection, recurrence of hernia, chronic sepsis, sinus formation, persistent pain and testicular atrophy).

Data were analysed using appropriate software. *P*-values were calculated by using Chi-square, Fisher's exact and Student's *t*-test as appropriate. A *P*-value of less than 0.05 was considered significant. Analysis was done by intention to treat.

Results

The mean, standard deviation (SD), standard error of mean and *P*-values of the two groups for the age, body mass index and operative time of study participants are shown in Table 1. The age of the patients in the study ranged from 18 years to 76 years. The majority of the patients (83%) were under 50 years of age. The minimum operative time was 40 minutes and maximum 110 minutes. From the *P*-values we obtained, we concluded that group A and B were matching and comparable in terms of all three variables; namely, age group of patients, body mass index and duration of surgery (Table 1).

Primary outcome

The primary outcome for the study was pain in the immediate postoperative period. There was significant difference in the VAS among group A and B at 6 hours, 12 hours and 24 hours (Table 2).

Mann–Whitney and Wilcoxon signed rank non-parametric tests were applied to test significance. *P*-value for difference in VAS between the groups at 6 hours, 12 hours and 24 hours was 0.018, 0.004 and 0.004, respectively. This indicates that there was a significant difference in the pain experienced by the patients in the immediate postoperative period between the two groups, with group A (invagination group) experiencing less postoperative pain compared with

Table 1 Demographic profile of patients in group A (invagination of hernial sac; *n* = 35) and group B (excision of hernial sac; *n* = 35) showing that the two groups are comparable.

Comparator	Mean		Standard deviation		Standard error of the mean		<i>P</i> -value
	A	B	A	B	A	B	
Age (years)	37.71	37.63	15.029	13.554	2.540	2.291	0.582
Body mass index	21.7420	22.0651	3.37482	2.91302	.57045	.49239	0.669
Operative time (days)	70.14	71.43	15.073	9.438	2.548	1.595	0.670

Table 2 Visual analogue score (VAS) score of the two groups at 6, 12 and 24 hours; group A invagination of hernial sac ($n = 35$); group B excision of hernial sac ($n = 35$).

Score	6 hours		12 hours		24 hours		Total	
	A	B	A	B	A	B	A	B
Minimum	0	1	0	0	0	1	2	2
Maximum	8	9	6	8	4	6	16	21
Range	8	8	6	8	4	5	14	19
Mean	3.37	4.40	2.66	3.77	1.97	3.00	8.00	11.17
Standard deviation	1.699	1.701	1.434	1.784	1.294	1.328	3.464	4.047
Median	4.00	4.00	2.00	4.00	2.00	3.00	8.00	12.00
Standard error of mean	.287	.288	.242	.301	.219	.225	.788	.788

group B (excision group). Analysis also revealed that the difference in the degree of pain experienced between the groups was more significant at 12 hours ($P = 0.004$) and 24 hours ($P = 0.004$) of surgery than at 6 hours ($P = 0.018$).

When VAS score at 6 hours, 12 hours and 24 hours were totalled and compared between the two groups, the total VAS score was significantly lower in group A compared with group B (Table 2). Mann-Whitney and Wilcoxon tests were used to evaluate these data. P -value was calculated as 0.001, which indicates that there was a significant difference in the total pain experienced between group A and B; group A experienced relatively less pain than group B.

Secondary outcomes

Following discharge from the hospital, patients were reviewed after 7 days, 21 days and 1 year for complications included under secondary outcomes which were wound infection, recurrence of hernia, chronic sepsis, sinus formation, persistent pain and testicular atrophy.

Wound infection was defined as purulent discharge from the wound site, erythematous rash around local wound site indicative of cellulitis and wound dehiscence. Superficial wound infection was seen in 2 of 35 (5.7%) patients in group A and 1 of 35 (2.9%) patients in group B in follow-up visits. When chi-square was applied to the result, there was no significant difference in incidence of infection in group A and B ($P = 0.555$). Thus, group A (invagination of sac) is equally prone to wound infection as group B (excision of sac).

There was no recurrence in either group during the follow-up period. There was also no incidence of chronic sepsis, sinus formation, persistent pain or testicular atrophy in any patient in either study or control group.

Discussion

High ligation of the sac and excision was previously considered as the method of choice for hernial sac management in indirect inguinal hernias. However, studies have shown that ligation and excision of the sac is a needless step and adds to postoperative pain by causing ischemic necrosis of

peritoneum.^{6,7} In our study, the pain experienced by patients in the immediate postoperative period was significantly less in the group with invagination of sac compared with the group with excision of the sac. This was first shown in a controlled study by Smedberg *et al* in 1984, which proved that postoperative pain is lower after invagination of sac when compared with excision of the sac.⁶ This has also been demonstrated by Delikoukos *et al* in a double-blind randomised controlled trial comparing high hernia sac ligation and excision.⁷

In our present study, there was no recurrence in either group during the follow-up period of one year. At autopsy, 20% of adult males have a patent peritoneal sac with no history of hernia.⁸ Therefore, a patent processus vaginalis cannot be the cause of hernia, nor can its elimination per se be the cure.

Several studies have experimentally demonstrated rapid healing of peritoneal defects.^{9–11} The whole surface regenerates simultaneously and healing is complete in about one week. Clinical experience also confirms the ability of the peritoneum to heal even large defects after colorectal surgery with only scant development of adhesions.^{12,15} Suturing of the peritoneum causes local ischaemia, affects healing and causes adhesions.¹⁴ Ellis and Heddle in 1977 presented a prospective randomised study showing no increase in wound rupture or incisional hernia if the peritoneum was not sutured at laparotomy.¹⁵ Thus, one might postulate that the high ligation of the hernia sac is not necessary to prevent recurrence, provided that the repair is correctly performed.

It was earlier believed that failure to undertake high ligation of the sac might be the cause of recurrence of hernia. Failure of high ligation of the sac was postulated as the cause of peritoneal cul de sac.¹⁶ More recent studies done have shown that ligation of sac does not affect the recurrence rate.^{6,17,18} Thus, invagination of sac is not considered to be associated with higher recurrence rates. In modern laparoscopic hernia surgeries, including transabdominal preperitoneal repair and totally extraperitoneal repair, the sac is simply invaginated and the recurrence rate in laparoscopic hernia repair has been found to be equal to the open repair.

Complications of Lichtenstein tension-free mesh hernioplasty include wound infection, persistent pain, testicular atrophy and sinus formation. The technique of dealing with hernial sac, invagination of sac or ligation and excision of sac, does not affect these outcomes. In our study, there were two patients in the group with invagination of the sac and one patient in the group with excision of the sac who had superficial wound infection. This difference was not found to be statistically significant. There was no reported incidence of recurrence, persistent pain, testicular atrophy or sinus formation in our study during the one-year follow up period.

Conclusions

The results of our study demonstrate that invagination of the sac results in less postoperative pain as compared with excision of the sac. There was no difference in either group in terms of recurrence, wound infection, persistent pain, testicular atrophy and sinus formation.

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