The Tension-free Hernioplasty in a Randomized Trial

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BACKGROUND: The tension-free hernioplasty as introduced by Lichtenstein has gained increasing acceptance during the last decade although the technique has not been evaluated in a randomized trial.

METHODS: This randomized study compares the 2-year follow-up results after 102 tension-free hernioplasties with implantation of a prolene mesh in all groin hernias to 53 Cooper ligament repairs in direct hernias and 53 abdominal ring repairs in indirect hernias.

RESULTS: After tension-free repairs five hernias recurred (5%), and after either Cooper ligament or abdominal ring repair, 16 recurrences were found (15%) ($P = 0.025$). No indirect hernias recurred after a tension-free repair; 2 recurred after abdominal ring repair (4%; NS). The recurrence rate after tension-free repairs for primary direct inguinal hernias was 7% as compared with 30% after Cooper ligament repair ($P = 0.0081$). No difference in complicition rate between the tested methods was found.

CONCLUSION: Recurrence rate is reduced to one-third after tension-free herniotomies as compared with the conventionel herniotomies without increase in complication rate. *Am J Surg.* 1996;172:315–319.

Ever since Bassini in 1889 published his paper[1] on the treatment of groin hernia many modifications and alternatives to the Bassini operation have been suggested. A common problem in all these operations has been the creation of a solid, lasting obliteration of the defect in the abdominal wall without tension on the surrounding tissues and without uniting tissues of different origin, ie, suturing muscular tissue to tendinous or fascial tissue.

In 1989 Lichtenstein et al[2] published a study of 1,000 consecutive herniotomies operated with implantation of a prosthetic mesh to perform a tension-free hernioplasty. The method was reported to produce no recurrences, no infections, 2 hematomaes per 1,000 operations, and to be performed under local analgesia (LA), allowing the patient almost immediate return to full activity. Furthermore, the operation was the same one in the direct and indirect hernia, excepting the high ligation of the indirect hernial sac.

The aim of this study has been to evaluate the tension-free herniotomy applied to all groin hernias, primary and secondary, direct and indirect, in a controlled design with the daily routine, ie, Cooper ligament repair (McVay repair)[3] in the direct, femoral, and combined hernias, and abdominal ring repair (annulorrhaphi)[4] in the indirect hernias as the control group.

PATIENTS AND METHODS

During the study period (December 1, 1990 through February 28, 1993) all patients referred to the department for repair of a groin hernia were evaluated for inclusion in the study. Patients younger than 18 years of age or expectation of life less than 2 years, patients with large inguino-scrotal or small supposed uncomplicated hernias, non–Danish-speaking patients, patients operated after acute admission, and patients not consenting to participate in the study were excluded. Patients were randomized at the last visit to the clinic prior to operation, and withdrawal from the study was allowed at the operating surgeons' discretion in patients with indirect hernias randomized to a tension-free repair, if a sufficient abdominal ring repair could be performed with a maximum of two sutures in the transversalis fascia.

The tension-free hernioplasty was performed as described by Lichtenstein et al,[2] using a 6 × 11-cm polypropylene mesh (prolene; Ethicon, Norderstedt, Germany) and a continuous 0-0 prolene suture to retain the mesh in the desired position. The Cooper ligament repair and abdominal ring repair were both performed as described by McVay[3,4] using 0 polyglycolic acid absorbable suture (Vicryl; Ethicon) to reconstruct the posterior inguinal wall, a relaxing incision being omitted only exceptionally in the direct hernias.

As we wanted the operation tested as a routine procedure in the department, no particular surgeon or group of surgeons were assigned to perform randomized operations. All members of the staff (2 consultants, 9 senior registrars with 10 years surgical experience or more, and trainees) operated on the randomized patients. Being a university department we hold 6 positions for surgical trainees, each with 3–6 years surgical experience, who are assigned to the department for periods of 9 months as part of their surgical education, a fact resulting in a very large number of surgeons operating in the study. All surgeons were familiar with the Cooper ligament repair and annulorrhaphia, and all were taught the mesh-implantation technique and supervised until they felt confident with the method. Supervised operations were credited to the supervisor.

Primary operations were performed as same-day operations, with the patients leaving the hospital 2–8 hours after operation unless complication was suspected or concomi-

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TABLE I

All Hernias: Recurrence Rate

Type of Hernia	Operation	n	Recurrences (%)	Chi-Square
Indirect	Tension-free	44	0 (0)	$P = 0.317$
	Annulorrhaphia	53	2 (3, 8)	
Direct, femoral and combined	Tension-free	58	5 (8, 6)	$P = 0.014$
	McVay repair	53	14 (26, 4)	
Total		208	21 (10, 1)	

Two hernias were femoral and 8 hernias were combined. One combined hernia operated with a Cooper ligament repair had recurred at the 2-year follow-up. Four combined hernias were treated with a tension-free repair and none recurred. None of 2 femoral hernias, both operated with a Cooper ligament repair, had recurred at the 2-year follow-up. The two indirect recurrences were not true recurrences, both recurred as direct hernias within 1 year and probably represent direct hernias missed at the primary operation; both primary operations were performed by trainees.

TABLE II

Primary Hernias: Recurrence Rate

Type of Hernia	Operation	n	Recurrences (%)	Chi-Square
Indirect	Tension-free	38	0 (0)	$P = 1.0$
	Annulorrhaphia	46	1 (2.2)	
Direct, femoral and combined	Tension-free	44	3 (6.8)	$P = 0.0081$
	McVay repair	43	13 (30.2)	
Total		171	17 (9.9)	

tant disease indicated admission postoperatively. Primary operations were performed under LA if the patient accepted; all other operations were performed under spinal or general anaesthesia (GA). Antibiotics were not routinely used peroperatively. No hernia was included in the study more than once. Patients were given no restrictions in postoperative mobility and were recommended to return to work after 1–2 weeks (heavy workers after 4 weeks).

The aim of the study was a comparison between the two randomized groups regarding recurrence rate; a recurrence being defined as a bulge or weakness in the operation area exacerbated by a valsalva maneuver necessitating further operation or provision of a truss,[5] rate of postoperative infection and hematoma/seroma formation, frequency of long-term symptoms from the operation area, postoperative time off work, and the influence of the experience of the surgeon on recurrence rate in both randomized groups.

The patients were seen in the outpatient clinic 10 days postoperatively, to detect possible wound complications, and 3 months and 2 years postoperatively.

Statistical evaluation of the differences between study groups was performed using the chi-square test for binominal data and Mann Whitney U-test for continuous data. Level of significance was set at 5%. The study was approved by the Copenhagen Ethics Committee.

RESULTS

Five hundred and fifty-nine hernias were operated on in 538 patients during the study period of 27 months. Three hundred and fourteen hernias were excluded according to exclusion criterias and the remaining 245 hernias in 234 patients were randomized. In 28 patients the operation was not performed according to randomization: in 16 patients with a small indirect hernia randomized to tension-free repair an annulorrhaphy was done according to the exclusion criteria, in 5 patients a lipoma was found without a true hernia, 2 patients withdrew their consent to participate after randomization but before operation, 1 patient developed severe cardiac instability during induction to GA and the operation was cancelled, and 4 patients were not operated on as randomized due to clerical error. Of the remaining 217 patients operated on 8 patients had died at 2 years follow-up and 1 was lost to follow-up, leaving 208 herniotomies to be evaluated (99.5% of living patients, 95.8% of all patients).

In 102 hernias a tension-free hernioplasty was performed; in 106 hernias either a Cooper ligament repair or an annulorrhaphia was done. There was no difference between the two groups regarding age (median, 60 years; range, 23–85 years), sex (female, 11.5%) social status (details not shown), and types of hernias.

Recurrence Rate

In this study the recurrence rate was 10%. Five percent of hernias operated on with a tension-free hernioplasty recurred, and 15.1% of hernias operated on with either Cooper ligament repair or annulorrhaphia recurred (**Table I**). The difference significantly favors the tension-free repair ($P = 0.025$).

One hundred and seventy-one hernias (82% of total) were primary with an overall recurrence rate of 10%. Three primary hernias recurred after a tension-free hernia repair (3.6%), and 14 hernias recurred after either Cooper ligament repair or annulorrhaphia (16%) (**Table II**). The difference significantly favors the tension-free repair ($P = 0.014$).

In 37 secondary hernias (18% of total) the recurrence rate was 11%. Secondary operations were predominantly performed by specialized surgeons. Twenty had a tension-free repair performed with a recurrence rate of 10%, and 17 patients had either a Cooper ligament repair or annulorrhaphia resulting in a recurrence rate of 12% (NS).

TABLE III

Complication Rate in 208 Herniotomies

Complication	Tension-free		Cooper lig/annul	
	n	%	n	%
Infection	0	0	1	0.9
Hematoma/seroma	4	3.9	5	4.7
Prolonged pain	1	1.0	0	0
Total	5	4.9	6	5.3

One patient developed orchitis 14 days after a tension-free hernia repair, but had no wound complications.

Complications

The complication rate summarized in **Table III.** In 1 patient operated on for an indirect hernia with an annulorrhaphia and reoperated on for postoperative hematoma, an infection developed 4 weeks postoperatively and the wound was opened. Of the 9 patients with hematoma/seroma, 6 were reoperated on a few hours after the herniotomy due to rebleeding, and 3 were treated with aspiration in the outpatient clinic. The 1 patient with prolonged pain in the operation-area after a tension-free repair was reoperated on 3 months after the herniotomy on suspicion of reherniation. No cause for the pain was found, the ileoinguinal nerve was intact, the prolene mesh was left in situ, and the symptoms subsided postoperatively. No other complication was found.

Anesthesia

One hundred twenty-seven primary hernias (61% of all hernias in the study and 74% of all primary hernias), were operated on under LA, 44 were operated on under GA. Seventeen hernias (10%) recurred after primary herniotomy: 11 recurrences (9%) had been operated on under LA, and 6 (14%) had been operated on under GA (**Table IV**). The difference is not significant.

Same Day Surgery

One hundred fifty-seven (76%) of the 208 herniotomies were performed on a same day basis. Of the 171 patients with a primary hernia, 141 (83%) left the hospital on the day of operation, as did 16 (43%) of patients with secondary hernias. Seventy-eight percent of patients operated on with a tension-free repair and 74% operated on with Cooper ligament or abdominal ring repair left the hospital on the day of operation. The difference is not significant.

Days off Work

One hundred thirty-seven patients were able to specify a specific day after the operation for resuming full activity. Median time off work was 21.5 days (range, 1–64); 23.6 days (range, 1–64) after tension-free repair and 18.6 days (range, 1–56) after McVay repair or abdominal ring repair. The difference is not significant.

Surgeon's Experience

This did influence the recurrence rate in both randomized groups. Herniotomies performed by specialized surgeons recurred in 6% of cases, and for those performed by trainees the recurrence rate was 13% ($P = 0.157$) (**Table V**).

DISCUSSION

Comparisons of results of the many types of herniotomies have until recently mainly been based on large consecutive studies of individual herniotomy techniques performed in highly specialized hernia centers. The results of the consecutive study design in these studies characterize the operation studied no more than the ability of the operating surgeon, and the inspiring results achieved by these clinics have not been reproduced in recent randomized studies from less specialized surgical departments using the same techniques.[6–9]

One constant problem in herniotomy discussions during the last century has been how to avoid the tension created when tissue from the surroundings is used to cover the abdominal wall defect, which is the cause of the herniation. This problem seemed to be eliminated with the introduction of the tension-free hernioplasty. The method was introduced in a consecutive study of 1,000 operations from a specialized hernia clinic, the Lichtenstein Hernia Institute, however, the promising results in this study might again have been caused by the routine of the surgeons rather than the tension-free repair.

In the present study the tension-free hernioplasty is tested against the McVay repair in the direct hernia and the abdominal ring repair in the indirect hernia, methods that have been widely used for 50 years. This randomized study demonstrates that the tension-free hernioplasty equals the McVay repair/Annulorraphia regarding postoperative infection and hematoma formation, it can be performed under LA on a same-day basis as well as the well-known methods, and the patients return to work after an equal postoperative period off work in the two groups.

Recurrence rate is reduced to one-third after the tension-free hernia repair compared with McVay/abdominal ring repair, and in the primary direct hernia even to less than one-fourth. Recurrences after indirect hernias are rare in either group; only 2 were found in this study, both after abdominal ring repairs and both direct recurrences probably missed at the first operation. As no true recurrences were found after abdominal ring repair it is debatable whether it is justified to implant a foreign body in patients with small and medium sized indirect hernias although it seems as if the tension-free repair prevents the consequences of missing a direct hernia when operating on an indirect hernia.[10]

The large inguinoscrotal hernias were excluded from the study, and a possible beneficial effect of a tension-free repair in the large indirect hernia with destruction of the medial portion of the posterior inguinal wall (Nyhus type III hernia[11]) remains to be examined, but the assumption of a beneficial effect is likely as the recurrence rate in the direct hernia, which always represents a degree of destruction of the posterior wall, is reduced to less than one-fourth after tension-free repair compared with the McVay repair.

The number of recurrences after secondary herniotomy is small in the present study and allows no conclusion to be deduced. Any possible difference between the tested techniques requires larger series of secondary herniotomies to be detected.

TABLE IV

Anesthesiological Method: Influence on Recurrence Rate in Primary Herniotomies

Operation	Anaesthesia	n	Recurrences (%)	Chi-Square
Tension-free	LA	62	3 (4.8)	$P = 0.317$
	GA	20	0 (0)	
Cooper ligament/annulorrhaphia	LA	65	8 (12.3)	$P = 0.157$
	GA	24	6 (25.5)	
Total		171	17	

TABLE V

Influence of Doctor's Education

Education	Operation	n	Recurrences (%)
Specialized surgeon	+ mesh	47	1 (2.1)
	− mesh	38	4 (10.5)
Trainee	+ mesh	55	4 (7.3)
	− mesh	68	12 (17.6)
Total		208	21 (10.1)

The five recurrencies after tension-free repairs were all situated close to the pubic tubercle and confirm the importance of overlapping the mesh at the pubic tubercle.[12] We found it important to retain the mesh in the desired position and used a continous prolene suture. The question of absorbable or nonabsorbable sutures in herniotomy has been discussed for years. Prior to the initiation of the present study only three randomized studies on this particular subject had been published,[13–15] none of them demonstrating significant differences in recurrence rate depending on suture material. Accordingly, we decided to conduct the conventional herniotomies in this study using absorbable sutures, as had been routine in our department for years, and to perform the tension-free herniotomies as described by Lichtenstein et al[2] using prolene to retain the mesh in the desired position. One further study published later[16] confirms the lack of statistically significant differences in recurrence rate depending on suture material.

The 16 patients with small indirect hernias were excluded after randomization to a tension-free repair, resulting in a bias in the recurrence rate disfavoring the tension-free repair. All 16 had an abdominal ring repair performed and none had recurred at the 2-year follow-up. Had they been treated as randomized the recurrence rate after a tension-free repair would most likely have been further reduced.

A large number of small supposed uncomplicated hernias were excluded form the study according to the exclusion criterias, but in spite of this fact the recurrence rates after McVay repair for primary direct hernias are unacceptably high in the study. Possible explanations may partly be the very high follow-up rate (99%), which excludes the possibility of recurrences among drop outs, and partly the relatively low frequency of herniotomies in our department compared with the highly specialised clinics. We perform about 250 herniotomies per year and as in other studies[9,10] we find that the surgeon's experience influences the recurrence rate (Table V). A third possible explanation is the fact that no particular group of surgeons was selected and trained to perform randomized operations; we wanted the tension-free repair tested as a routine procedure in a general surgical department, and all members of the staff participated in the study. Furthermore we have a rapid turnover of relatively inexperienced trainees on short educational courses in the department (28 different surgeons operated on randomized patients), and a high incidence of recurrences after herniotomy performed under LA has been demonstrated with surgeons inexperienced with the LA technique.[17]

Although the recurrence rate after tension-free operations is reduced to 40% of the rate found after McVay/abdominal ring repair when performed by trainees (Table V), the difference in recurrence rate depending on experience emphasizes the nessecity of intense supervision in the early phase of hernia education, and that demand is not reduced when the method to be learned is the tension-free hernioplasty.

The tension-free hernioplasty is rapidly gaining acceptance and the high expectations of a reduction in recurrence rate are confirmed in the present study, but the study is small and follow-up is short. The tension-free hernioplasty should be tested against other well-established types of herniotomy in larger series with longer follow-up. Only randomized comparative studies can fully characterize the properties of the operations tested, and recurrence rates for direct and indirect herniotomies must be specified separately.

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