



## Laparoscopic Hernioplasty versus Conventional Hernioplasty (Shouldice): Results of a Prospective Randomized Trial

Dietmar Lorenz, M.D., Eberhard Stark, M.D., Kerstin Oestreich, M.D., Axel Richter, M.D.

Surgical University Clinic Mannheim, University of Heidelberg, Theodor-Kutzer-Ufer 1-3, 68167 Mannheim, Germany

**Abstract.** The results of our randomized trial of 176 patients comprising primary hernias [Shouldice versus transabdominal preperitoneal approach (TAPP)] showed only slight advantages for the laparoscopically operated group compared to the conventionally operated group: less subjective pain (significant only on fifth postoperative day,  $p < 0.05$ ), reduced analgesic requirement (significant only on third postoperative day,  $p < 0.05$ ), significantly shorter duration of hospitalization (4 days vs. 6 days,  $p < 0.05$ ) and faster return to work (27 days vs. 34 days, NS). Regarding the incidence of recurrences, there was no significant difference between the groups (two recurrences vs. one recurrence) within a follow-up period of 2 years. Postoperative morbidity was similar and the total cost was less for the TAPP group.

The benefits of laparoscopic hernioplasty are still controversial. Opponents claim comparable results mainly using the conventional Shouldice [1] or Lichtenstein [2] technique under local anesthesia.

Some randomized trials have been published so far, comparing laparoscopic and open herniotomy [3–13]. Most of the studies compared the transabdominal preperitoneal approach (TAPP) to open procedures. Only two publications [7, 11] compared the totally extraperitoneal laparoscopic repair (TEP), which so far is less commonly used, with an open hernia repair.

Supporters of the laparoscopic technique initially saw only the positive results without mentioning complications [14–19]. In the above listed randomized studies [3–13], the results did not always agree, due to the small numbers of patients: from 61 [9] to 200 [12] for TAPP and 182 [11] for TEP. In addition, the follow-up range of 3 months [7] to 16 months [4] was rather short.

The initial enthusiasm disappeared in view of major complications [3, 5, 9, 10]. Above all, in the long run the results were not as good as reported earlier [3, 5, 9, 10]. The postoperative morbidity of some randomized studies increased compared to that reported for open methods [3, 5, 9, 10].

To test the thesis that laparoscopic hernia repair is superior to the anterior operation we initiated a prospective randomized study with two groups of patients with primary hernias. The study compared open Shouldice hernioplasty to TAPP, each performed under general anesthesia. For bilateral hernias both sides were

treated equally. To gain a comparable and standardized evaluation we restricted the study to uncomplicated and primary hernias only.

### Patients and Methods

From October 1992 to April 1993 a pilot study was first initiated implanting 109 transabdominal preperitoneal meshes by laparoscopy (TAPP). From May 1993 to June 1995 a prospective randomized study followed. During this period 475 patients with 540 hernias underwent operation. Of those screened, 380 patients (80%) passed the exclusion criteria [age below 18 years, recurrent or scrotal hernia, previous lower abdominal surgery, high general anesthetic risk according to the American Society of Anesthesiologists (ASA > 2)] and were fully informed about the Shouldice and the laparoscopic procedures. Inclusion criteria were uncomplicated primary unilateral or bilateral hernias (Table 1).

Of the 380 patients meeting the inclusion criteria, 176 patients (46%) agreed to randomization and signed an informed consent. There were 161 male and 15 female patients participating. Fourteen patients in the laparoscopic group and ten patients in the Shouldice group had bilateral hernias.

The randomization was blinded by drawing sealed envelopes containing the “TAPP” participants and the “Shouldice” participants. The sample size was not estimated on the basis of an expected effect on predefined outcome parameters but, rather, on the number of patients predicted to present with primary inguinal hernias over a predefined recruitment period of 2 years. We assumed a number of 400 patients during a 2-year study period because in a 6-month pilot study phase 109 patients matched the inclusion criteria. During the study period all suitable patients were randomized as soon as they agreed to participate in the study. As a result, during the 2 years 475 patients presented with various hernias, among whom 380 fulfilled the inclusion criteria. From these 380 patients a group of 176 patients agreed to be randomized for the study. Hence in 2 years 37% of all patients with inguinal hernias ( $n = 475$ ) were included in the study. Comparative results for two independent samples were analyzed using the Mann-Whitney U-test with a two-tailed alpha level of 0.05.

The Shouldice operation was performed by opening the hernia

Correspondence to: D. Lorenz, M.D., e-mail: dietmar.lorenz@chir.ma.uni-heidelberg.de

**Table 1.** Study design.

Parameter	Description
Type of study	Prospective randomized clinical study
Study of period	May 1993 to June 1995
Type of hernia	Primary inguinal hernia
Type of operation	Shouldice or TAPP
Analgesics	Tramadol (oral or intravenous)
Follow-up	After 14 days and 6, 12, and 24 months
Endpoints	Time of operation
	Duration of hospital stay
	Subjective pain (visual analogue scale)
	Analgesics intake
	Complications (intra- and postoperative)
	Time off work
	Cost analysis
	< 18 Years of age
	Recurrent, incarcerated, and scrotal hernias
	High general anesthetic risk (ASA > 2)
Previous lower abdominal surgery	
Exclusion criteria	< 18 Years of age
	Recurrent, incarcerated, and scrotal hernias
	High general anesthetic risk (ASA > 2)
	Previous lower abdominal surgery

TAPP: transabdominal preperitoneal approach; ASA: American Society of Anesthesiologists.

sac (indirect hernia) and ligating, dividing, and excising the sac after having freed the adherent structures. The transversalis fascia was incised and doubled with a running 0 polypropylene (Prolene, Ethikon GmbH, Norderstedt, Germany) suture. A second continuous 0 polypropylene (Prolene) suture approximated the internal oblique muscle to the undersurface of the inguinal ligament. The cord structures were returned to their bed, and the external oblique fascia was closed over the cord again with a resorbable 2-0 suture (Maxon, B. Braun-Dexon GmbH, Spangenberg, Germany). The Shouldice repair was done by residents with the assistance of consultants.

The transabdominal preperitoneal hernioplasty was done by implanting a 8 × 13 cm polypropylene mesh using titan staples. A curved incision of the peritoneum was thus made, and the hernia sac was inverted and dissected from the cord structures. Having incised the mesh oblique at its bottom laterally and below, the mesh was positioned under the cord structures and fixed with four or five staples, carefully avoiding the so-called triangle of pain. Finally, the peritoneum was repositioned and stapled to the anterior abdominal wall. The laparoscopic operations were performed by five consultants only with experience in laparoscopic surgery.

In both groups the patients were operated on under general anesthesia. For postoperative analgesia all patients were exclusively given tramadol (intravenously or orally) on demand after the operation. Additional analgesics nonsteroidal antiinflammatory drugs [i.e., (NSAID)] or prophylactic antibiotic treatments were not given. For deep venous thrombosis (DVT) prophylaxis low-molecular-weight heparin was applied subcutaneously.

As "endpoints" of the investigation (Table 1), the following were considered: (1) postoperative subjective pain [assessed daily by a visual analog scale (VAS), ranging from 0 (no pain) to 10 (unbearable pain), preferably at the same time in the evenings]; (2) the incidence of intraoperative (i.e., bleeding, bowel injury) and postoperative (i.e., bleeding, adhesions, neuralgia) complications; and (3) the incidence of early and late recurrence of the hernia, duration of hospital stay, and time of return to work. The personnel (doctors, nursing staff) who treated the patients post-

**Table 2.** Characteristics of 176 randomized patients.

Characteristic	TAPP	Shouldice
Age (years)	49	50
Gender (M:F)	80:6	81:9
Unilateral hernia (no. of patients)	72	80
Bilateral hernias (no. of patients)	14	10
Follow-up (median)		
Percent	92	90
Months	17	15

**Table 3.** Distribution of occupations.

Occupation	Distribution (%)	
	TAPP	Shouldice
"Blue collar"	49	56
Self-employed	5	8
Retired	24	17
"White collar"/civil servant	22	19

operatively and prepared the study documentation was not double-blinded.

The follow-up rate was 92% ( $n = 79$ ) in the laparoscopic group and 90% ( $n = 83$ ) in the conventional group; the median follow-up was 17 months (14 days to 24 months, laparoscopic group) and 15 months (14 days to 24 months, conventional group). The postoperative follow-up was done on an outpatient basis after 14 days and 6, 12, and 24 months; it included the history, clinical examination, and ultrasonography.

As a basis for cost evaluation of the two operative treatments, the study of Lefering et al. [20] was applied, which by German standards compiled a rather detailed cost evaluation. The general costs evaluated in the Lefering et al. study were supplemented by the specific costs in our clinic.

## Results

No significant differences were found between the two groups concerning age, gender ratio, or type of hernia (Table 2). There was also no significant difference in operating time for the two groups with unilateral herniotomy (median 60 minutes for both groups). Considering physical requirements of patients at work, the two groups showed comparable distribution of occupations or employment status (Table 3). Table 3 distinguishes between "blue collars" (laborers, physically stressful professions), self-employed people, retired people, and "white collars"/civil servants (office staff, administration staff; no physically stressful occupation).

No intraoperative complication forced us to convert to an open procedure. Minor bleeding of the inferior epigastric vessel occurred twice and could be controlled by laparoscopy. We did not see any injury of the bladder or intestines. Postoperative complications are shown in Table 4, with no significant differences between groups.

In the TAPP group there were three nerve irritations of the lateral femoral cutaneous nerve, and in one patient the genitofemoral nerve was affected. In the conventional group three patients developed symptoms of neuralgia that were attributable to the genitofemoral nerve. The duration of pain was 20 weeks at the most.

**Table 4.** Postoperative complications (randomized study).

Complication	TAPP (%)	Shouldice (%)
Seroma/hematoma (inguinal or scrotal)	4	3
Neuralgia	4	3
Wound infection	1	2
Recurrence	2	1

**Table 5.** Postoperative complications (nonrandomized patients).

Complication	TAPP (n = 402 hernias)	Shouldice (n = 463 hernias)
Seroma/hematoma (inguinal or scrotal)	13 (3.2%)	14 (3%)
Neuralgia	15 (3.7%)	5 (1.1%)
Ileus (reoperation)	1 (0.2%)	0
Wound infection	3 (0.7)	8 (1.7)
Recurrence	16 (3.9%)	9 (2%)

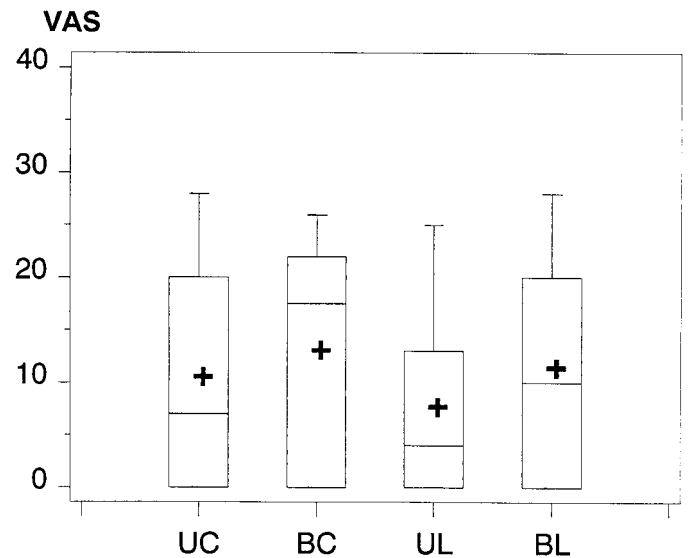
In the laparoscopic group two recurrences were seen 2 weeks and 15 months after operation. The Shouldice group showed only a single recurrence 9 months after operation. Table 5 lists the complications of the nonrandomized patients after the TAPP and Shouldice procedures from October 1992 to December 1996.

After unilateral laparoscopic hernioplasty the postoperative subjective pain score was significantly less only on the fifth postoperative day ( $p = 0.02$ ). Although subjective pain was obviously less after unilateral laparoscopic hernioplasty during the initial 4 postoperative days, the difference from that of the Shouldice group was not significant. After bilateral hernioplasty the TAPP group indicated less pain than the Shouldice group. The difference was not as distinct as for unilateral hernioplasty, either for each of the 5 postoperative days or for the sum of the first 5 postoperative days, but a significant difference was seen between the groups (Fig. 1).

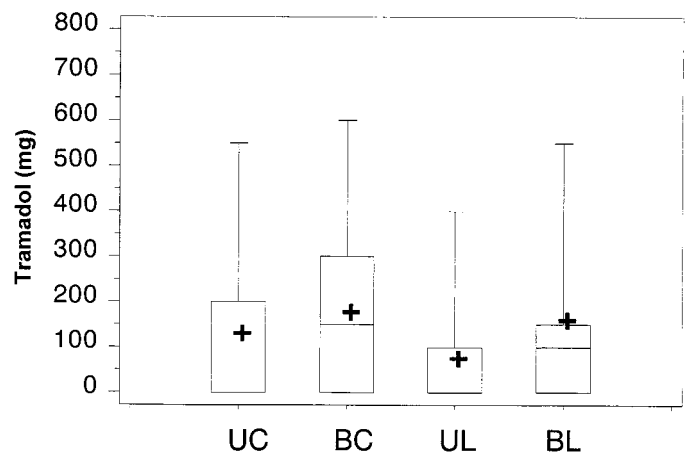
In addition to the subjective comparison of pain, an objective evaluation via analgesic intake was recorded (Fig. 2). The postoperative amount of tramadol demanded after unilateral herniotomy was less in the TAPP group during each of the first 5 postoperative days. Considering the total sum of analgesic intake (mean 100.56 mg vs. 51.17 mg;  $p = 0.17$ ), a significant difference was seen on the third postoperative day ( $p = 0.04$ ). After bilateral herniotomy, fewer analgesic doses were needed in the TAPP group on each day of investigation, except on the first postoperative day, where the proportion was turned around in favor of the Shouldice group (mean 72.22 mg vs. 103.85 mg;  $p = 0.94$ ). There were no significant differences after bilateral herniotomy at any time. From the fourth postoperative day onward after TAPP (uni- and bilateral), on average no analgesics were needed at all. On the fifth postoperative day after the Shouldice operation patients also did not take any analgesics.

An evident improvement was found in the unilaterally and bilaterally laparoscopic groups concerning hospital stay (median 4 days vs. 6 days;  $p = 0.00008$ ) but not in the return to work (unilateral: mean 34 vs. 27 days; bilateral: mean 42 vs. 38 days; NS) (Fig. 3).

A breakdown of the costs of laparoscopic hernioplasty compared to the conventional technique is given in Table 6. The mean



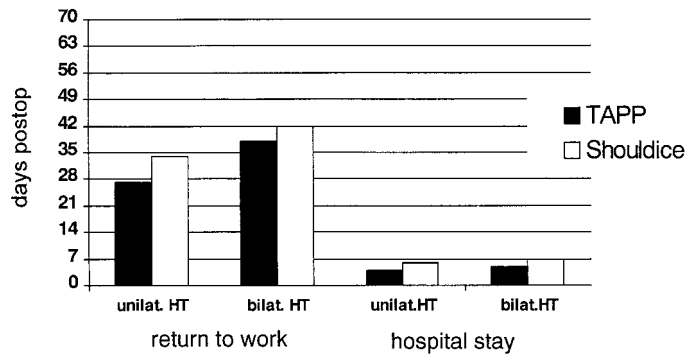
**Fig. 1.** Boxplot (visual analogue scale): mean, median, and percentiles of postoperative pain score after unilateral and bilateral transabdominal preperitoneal approach (TAPP) or Shouldice procedure. There was less pain after unilateral TAPP (NS). The difference between the TAPP and Shouldice procedures is less distinct after bilateral herniotomy (NS). UC: unilateral conventional herniotomy; BC: bilateral conventional herniotomy; UL: unilateral laparoscopic herniotomy; BL: bilateral laparoscopic herniotomy; VAS: total score of visual analogue scale; +: mean.



**Fig. 2.** Boxplot (tramadol intake): mean, median, and percentiles for postoperative analgesic intake after unilateral and bilateral TAPP or Shouldice procedure. The analgesic intake was decreased after unilateral TAPP, but due to the wide deviation it was not significant. There was little difference between the TAPP and Shouldice procedures in terms of total tramadol intake after bilateral herniotomy.

charge for laparoscopic hernia repair was DM 2146, which included preoperative diagnostics, the operation itself (including instruments and material), medical staff, and a 4-day hospital stay. The amount for the Shouldice operation was DM 1863, including a hospital stay of 6 days.

The non-hospital costs, comprised of a visit to the family doctor and time off work that concerned the national economy were even higher: DM 3052 in the laparoscopic group including 4 weeks off



**Fig. 3.** Duration until patients returned to work (days, mean) and time of hospital stay (days, median) after unilateral (unilat. HT) and bilateral (bilat. HT) TAPP and Shouldice procedures.

**Table 6.** Hospital and nonhospital costs (DM) in inguinal hernia repair, Surgical University Clinic Mannheim and [20].

Costs	TAPP	Shouldice
<b>Hospital costs</b>		
Preoperative investigations	225.00	225.00
Operation	948.60	171.00
Medical staff, nursing	480.00	711.00
Board and lodging	491.40	756.00
Total	2145.00	1863.00
<b>Nonhospital costs</b>		
Off work (DM 108/day)	2916.00	3672.00
Visit at home	54.00	54.00
Total	5198.00	5589.00

DM: German mark.

work and 4.008 DM in the conventional group including 5 weeks off work [20].

## Discussion

Perhaps the results of this randomized study are less powerful owing to the high rate of nonrandomized patients, the acceptance of only primary hernias, and the exclusion of scrotal hernias and patients in poor general health who could not undergo general anesthesia. Moreover, only patients with "simple" hernias were included. Finally, quite a few patients (228 of 380) did not agree to randomization. Therefore a strong positive selection took place in our study. On the other hand, it seems logic to test a new technique for one type of hernia only, considering the increased number of complications and recurrences for reoperations of recurrent hernias according to some authors. For instance, Schumpelick and Arlt [21] stated the percentage of complications to be five times higher after reoperations than after primary repairs.

There was no difference in our study between the two types of operation comparing the operating time for unilateral herniotomy. Stoker et al. [8] and Vogt et al. [9] noted a prolonged operating time of 30% and 20% in the conventional group. According to Barkun et al. [3], Leibl et al. [4], Payne et al. [6], and Wright et al. [22], the laparoscopic procedures took longer; Bessell et al. [23] reported some to be almost twice as long (69 vs. 37 minutes).

Fortunately, we had no serious complications among the randomized patients. Indeed there was one ileus in the nonrandomized group of 250 patients during the same interval caused by incarceration into a former trocar incision and one spermatic cord cut. Madden et al. [5] reported one ileus of the small bowel, and Payne et al. [6] recorded an incarceration of the omentum between the clips used to close the peritoneum.

Patients in the conventional group (unilateral herniotomy) reported more pain during the first 5 postoperative days, although a significant difference was observed only for the fifth postoperative day. Schrenk et al. [7], Stoker et al. [8], and Wright et al. [22] also applied a visual analog scale to evaluate the intensity of pain. Each reported a significantly lower level of pain in the laparoscopy group. No significant differences were seen in the studies of Barkun et al. [3], Maddern et al. [5], or Horeysek et al. [24]. Liem and van Vroonhoven [25] employed an "activity of life" scale, comprising everyday activities. The laparoscopically operated patients returned to normal everyday life significantly faster. Another test was applied by Leibl et al. [4]. They measured how long a patient went for a walk each day postoperatively. The laparoscopy group again showed significant better results. It is of note that so far no study has reported higher pain levels in the laparoscopy group than in the conventional group.

In our study analgesic requirements in both groups were significantly less after unilateral TAPP on postoperative day 3 ( $p = 0.04$ ). Afterward no analgesics were needed in the laparoscopy group. The total amount of tramadol utilized from day 1 to day 5 was clearly less after TAPP, even though statistically only a trend could be shown. Again it can be stated that in all trials so far [3–5, 7, 8, 22, 25] analgesic intake was lower in the laparoscopy group.

In general it is difficult to determine how expectations about a new method influence patients' pain levels, as we have not used identical opaque dressings irrespective of the operation done, as Majeed et al. [26] had done with patients after laparoscopic and open cholecystectomy. The advantage of the laparoscopic procedure is less than that of a tension-free conventional herniotomy (i.e., according to Lichtenstein), as postoperative pain seems also to be less recognizable with the Lichtenstein technique [1].

There was no difference between the groups regarding inguinal or scrotal swellings or hematomas. No further operative revision was required. Leibl et al. [4] and Maddern et al. [5] reported the same rate, and Stoker et al. [8] noted that hematomas were three times more frequent in the conventional group. Wound infections were seen rarely; of the above-mentioned authors, only Stoker et al. [8] reported a local wound infection rate four times higher than in the conventional group.

In our pilot study the rate of nerve irritations was high, at 4%. The nerve irritation frequency decreased considerably when we avoided using clips in the region below the iliopubic tract.

Although Schrenk et al. [7] and Stoker et al. [8] reported a higher rate of nerve irritations in the conventional group (12% vs. 8% and 8% vs. 4%, respectively), in the trials of Barkun et al. [3] and Maddern et al. [5] patients after laparoscopic hernia repair complained of nerve irritation more often than in the conventional group (2% vs. 0% and 10% vs. 5%, respectively). These authors also thought a learning curve might be responsible for their results.

With respect to recurrences in our groups, the somewhat higher rate in the laparoscopy group (2% vs. 1%) did not prove significant at the 2-year follow-up. There is no doubt that a technical

**Table 7.** Randomized trials comparing TAPP ( $n = 585$ ) and open herniotomy ( $n = 569$ ).

Trial	No. of patients (lap/conv)	Operating time (min) (lap/conv)	Postop. pain (lap/conv)	Duration of hospital stay (days) (lap/conv)	Return to work (days) (lap/conv)	Recurrence rate (%) (lap/conv)	Follow-up (months) (lap/conv)	Cost (lap/conv)
Barkun [3]	43/49	72/32*	lap < conv* (analgesics)	1/1	9.6/10.9	0/2.05	14 (median)	lap > conv
Leibl [4]	54/48	65/47.5	lap < conv*	?	21/28	0/0	16 (median)	?
Maddern [5]	57/44	60/30.5*	lap = conv	3.75/2.24	17.5/30.0	3.5/0	8 (median)	?
Stoker [8]	75/75	50/35*	lap < conv*	10/10	14/28*	0/0	7 (mean)	lap > conv
Vogt [9]	30/31	62.5/80.9*	lap < conv*	<1/<1	7.5/18.5*	3.3/6.45	8 (mean)	?
Lawrence [10]	58/66	72/32*	lap < conv*	<1/<1	22/28	1.7/0	3 (median)	lap > conv (operating costs only)
Tschudi [12]	44/43	87/59*	lap < conv*	4.9/6.3*	25/48	1.8/3.6	7 (mean)	?
Schrenk [7]	28/34	46/38*	lap = conv	3.7/3.7	34/34	2.9/25 (suspected)	3 (median)	?
Kald [13]	110/89	72/62*	?	<1/<1	10/23*	0/3	12	lap < conv
Mannheim (this study)	86/90	60/60	lap < conv	4/6	27/34	2/1	17/15 (median)	lap > conv

\*Significant.

lap: laparoscopic; conv: conventional; ?: not known.

failure caused the only early recurrence in the laparoscopy group. Findings of other authors have ranged from nil in both groups [4, 8] to 3% in the laparoscopy group and 6% in the conventional group [9]. The shortest follow-up in the randomized studies (Table 7) was 3 months and the longest 16 months. It will be of interest to see the results after a period of 5 or 10 years.

There was a marked difference in the hospital stay depending on the operative procedure. Shouldice patients on average stayed 2 days longer, 6 days altogether, compared to patients in the TAPP group. In Europe only Schrenk et al. from Austria [7] reported a similar hospital stay. In their trial both groups spent 4 days in hospital. In the United States and Great Britain most patients underwent day-surgery [5, 27]. The maximum stay usually was 2 days for inpatients [22]. It should be mentioned that in Germany conventional hernioplasty, especially under local anesthesia, is also carried out as a day-surgery [1, 28]. Hence in the future the advantage of a shorter hospital stay for laparoscopically treated patients will no longer exist. The change to a shorter hospital stay in Germany is occurring slowly. In our study the patient could choose the day of discharge.

The duration of sick leave, a considerable economic factor, ranges from 9 days [6] for the laparoscopic procedure to 38 days for the open repair [4]. This wide range reflects the obvious regional and subjective influence on this parameter. A more objective means for evaluating the ability to absorb stress was described recently [29]. The authors subjectively assessed postoperative convalescence using a questionnaire and objective standardized exercises. The result showed a significantly faster convalescence in the laparoscopy group ( $p < 0.0001$ ). Lawrence et al., though, did not see an improvement in quality of life after laparoscopic hernioplasty compared to open surgery [30].

Our own results were in the upper third: 27 days (mean, unilateral TAPP) and 34 days (mean, unilateral Shouldice) off work for the laparoscopy and conventional groups, respectively. Surprisingly, we found that the difference after bilateral herniotomy in both groups became less distinct, and that the bilateral TAPP group also had a relatively long convalescence of 38 days (mean) versus 42 days (mean) for the bilateral Shouldice group.

The traditional attitude toward hernia repair in German-speaking countries becomes obvious here. Usually patients after hernia

repair do not return to work postoperatively before 4 to 6 weeks. Although patients with laparoscopic hernia repair were instructed to avoid physical work based only on their subjective discomfort, on average they first returned to work 3 weeks after the operation (unilateral TAPP).

There is little to be found in literature concerning the cost of the various procedures. Some consider only the cost of the operation, whereas others include the cost of the hospital stay. In our study the hospital costs (costs for operation plus hospital stay) account for 42% of the total amount (DM 2145 of DM 5115) in the laparoscopic group and for 33% (DM 1863 of DM 5589) in the conventional group. The major costs are those attributable to the postoperative inability to work in both groups.

In all the reviewed trials, laparoscopic hernia repair, as far as operation costs themselves are concerned, was more expensive than the conventional method. In respect to direct operative costs, the difference between laparoscopic and conventional operations ranged from 1.2-fold [6; own results] to 1.4-fold [3] to 1.6-fold [31]. Considering costs due to prolonged unfitness for work in the conventional group, which in Germany is considered to amount up to DM 108 per day per working person [20], the laparoscopically operated patients are less cost-intensive [13, 31; own results]. In our study, the difference from the Shouldice group was DM 474 less per patient.

Our results and the results of other authors (Table 7) are comparable as far as these two procedures (TAPP versus Shouldice operation) are concerned. To sum up, for 585 laparoscopic and 569 conventional randomized hernia repairs, the operating time more often was shorter in the Shouldice group (8 of 10). In 6 of 10 studies significantly less pain or analgesic intake was seen in the TAPP group; and in nine studies the duration of postoperative sick leave could be lowered (in three studies even significantly).

Meaningful statements concerning recurrence rates are not available because of the effect of the learning curve and the short period of follow-up of the trials, although lower recurrence rates were seen after TAPP in five of the reviewed studies. A recently reported series of 2700 nonrandomized TAPP procedures, by Leibl et al. [32], showed a recurrence rate of 1.03% for all patients after a 20-month median follow-up.

The studies in Table 7 mentioned follow-up periods of only 3 to 17 months. Before acceptance, the laparoscopic procedure must prove it can give excellent long-term results similar to those already known for the Shouldice procedure [1]. Such results are not easy to obtain in full spectrum, as was reported by a Dutch multicenter study comparing the conventional procedure to the laparoscopic extraperitoneal method (TEP) [33]. Those authors claimed advantages for the laparoscopic procedure, mainly the faster reconvalescence (return to daily activities, work, sports), fewer wound infections, and fewer recurrences. The latter, though, amounted to 6% in the conventional group after a 2-year follow-up.

Operative and hospital costs are unequivocally lower in the conventional surgery group. Considering nonhospital costs and hospital costs, reports [4, 31; own results] have presented the laparoscopic procedure as less expensive and more cost-effective, especially in terms of the duration of postoperative sick leave.

### Conclusions

Considering all aspects, at present the TAPP technique seems to have a slight advantage, in terms of patients' comfort and length of postoperative sick leave. Negative aspects include higher hospital costs and, at least theoretically, a higher risk of intraabdominal injury, even though long-term results are awaited.

Based on our study, laparoscopic hernioplasty (TAPP) does not seem to be the one and only choice for the treatment of primary, unilateral hernias. It may, though, be valuable for treating special hernia subtypes. At present, we recommend the laparoscopic method for recurrent hernias because there is the advantage of operating in a previously untouched area using a tension-free mesh for reconstruction. It is especially advantageous if the patient, after intensive explanation of the various options, explicitly asks for the laparoscopic procedure.

### Résumé

Notre étude randomisée de 176 patients, comparant la cure de hernie primitive par la technique de Shouldice versus la voie transabdominale préperitonéale (TAPP), n'a mis en évidence que quelques avantages modestes en faveur de la technique laparoscopique en comparaison avec les techniques conventionnelles: moins de douleur subjective (significative seulement au cinquième jour postopératoire,  $p < 0.05$ ), besoin de moins d'analgésiques (significative seulement au 3<sup>e</sup> jour postopératoire,  $p < 0.05$ ), séjour hospitalier significativement plus court (quatre vs. six jours,  $p < 0.05$ ) et retour plus rapide au travail (27 vs. 34 jours, n.s.). En ce qui concerne l'incidence des récurrences, il n'y avait aucune différence significative entre les deux groupes (2 vs. 1) dans la période de suivi de deux ans. La morbidité postopératoire a été similaire et les coûts au total étaient moindres pour la technique TAPP.

### Resumen

Los resultados de nuestro ensayo randomizado para comparar la reparación de Shouldice con el procedimiento laparoscópico transabdominal preperitoneal en 176 pacientes con hernias primarias mostraron apenas ligeras ventajas del procedimiento laparoscópico: menos dolor subjetivo (significante sólo en el 5<sup>o</sup> día

postoperatorio,  $p < 0.05$ ), menor requerimiento analgésico (significante sólo en el 3<sup>er</sup> día postoperatorio,  $p < 0.05$ ), hospitalización significativamente más breve (4 vs. 6 días,  $p < 0.05$ ) y más pronto retorno al trabajo (27 vs. 34 días, n.s.). En cuanto a la tasa de recurrencia, no se encontró diferencia significativa entre los dos grupos (2 vs. 1) en un seguimiento de dos años. La morbilidad postoperatoria fue similar y el costo total fue más bajo en el grupo de reparación trasabdominal preperitoneal.

### Acknowledgments

Dedicated to Michael Trede, M.D., Hon.F.A.C.S., Hon.F.R.C.S., for his 70th birthday.

### References

1. Schumpelick, V., Töns, C.H., and Kupczyk-Joeris, D.: Operation der Leistenhernie: Klassifikation, Verfahrenswahl, Technik und Ergebnisse. *Chirurg* 62:641, 1991
2. Amid, P.K., Shulman, A.G., and Lichtenstein, I.L.: Die Herniotomie nach Lichtenstein. *Chirurg* 65:54, 1994
3. Barkun, J.S., Wexler, M.J., Hinchey, E.J., Thibeault, D., and Meakins, J.L.: Laparoscopic versus open inguinal herniorrhaphy: preliminary results of a randomized controlled trial. *Surgery* 118:703, 1995
4. Leibl, B., Dèubler, P., Schwarz, J., Ulrich, M., and Bittner, R.: Standardisierte laparoskopische Hernioplastik vs. Shouldice-Reparation. *Chirurg* 66:895, 1995
5. Maddern, G.J., Rudkin, G., Bessell, R., Devitt, P., and Ponte, L.: A comparison of laparoscopic and open hernia repair as a day surgical procedure. *Surg. Endosc.* 8:1404, 1994
6. Payne, J.H., Grininger, L.M., Izawa, M.T., Podoll, E.F., Lindahl, P.J., and Balfour, J.: Laparoscopic or open inguinal herniorrhaphy? A randomized prospective trial. *Arch. Surg.* 129:973, 1994
7. Schrenk, P., Woisetschlager, R., Rieger, R., and Wayand, W.: Prospective randomized trial comparing postoperative pain and return to physical activity after transabdominal preperitoneal, total preperitoneal or Shouldice technique for inguinal hernia repair. *Br. J. Surg.* 83:1563, 1996
8. Stoker, D.L., Spiegelhalter, D.J., Singh, R., and Wellwood, J.M.: Laparoscopic versus open inguinal hernia repair: randomised prospective trial. *Lancet* 343:1243, 1994
9. Vogt, D.M., Curet, M.J.C., Pitcher, D.E., Martin, D.T., and Zucker, K.A.: Preliminary results of a prospective randomized trial of laparoscopic onlay versus conventional inguinal herniorrhaphy. *Am. J. Surg.* 169:84, 1995
10. Lawrence, K., McWhinnie, D., Goodwin, A., Doll, H., Doll, H., Gordon, A., Gray, A., Britton, J., and Collin, J.: Randomized controlled trial of laparoscopic versus open repair of inguinal hernia: early results. *B.M.J.* 311:981, 1995
11. Champault, G., Benoit, J., Lauroy, J., and Rizk, P.: Hernies de l'aine de l'adulte: chirurgie laparoscopique vs opération de Shouldice; étude randomisée contrôlée; 181 patients; résultats préliminaires. *Ann. Chir.* 48:1003, 1994
12. Tschudi, J., Wagner, M., Klaiber, C., Brugger, J.J., Frei, E., Krähenbühl, L., Inderbitzi, R., Hüsler, J., and Hsu Schmitz, S.: Controlled multicenter trial of laparoscopic transabdominal preperitoneal hernioplasty vs Shouldice herniorrhaphy. *Surg. Endosc.* 10:845, 1996
13. Kald, A., Anderberg, B., Carlsson, P., Park, P.O., and Smedh, K.: Surgical outcome and cost-minimisation-analyses of laparoscopic and open hernia repair: a randomised prospective trial with one year follow up. *Eur. J. Surg.* 163:505, 1997
14. Brown, R.B.: Laparoscopic hernia repair: a rural perspective. *Surg. Laparosc. Endosc.* 4:106, 1994
15. Campos, L., and Sipes, E.: Laparoscopic hernia repair: use of a fenestrated PTFE graft with endo-clips. *Surg. Laparosc. Endosc.* 3:35, 1993
16. Corbitt, J.D.: Laparoscopic herniorrhaphy: a preperitoneal tension-free approach. *Surg. Endosc.* 7:550, 1993

17. Felix, E.L., Michas, C.A., and McKnight, R.L.: Laparoscopic herniorrhaphy: transabdominal preperitoneal floor repair. *Surg. Endosc.* 8:100, 1994
18. Johanet, H., Cossa, J.P., Roussel, J.Y., and Le Goff, J.Y.: Cures de hernies de l'aîne par coelioscopie: résultats préliminaires à propos de 162 cas. *Ann. Chir.* 48:507, 1994
19. Bittner, R., Leibl, B., Kraft, K., Däubler, P., and Schwarz, J.: Die laparoskopische Hernioplastik (TAPP): Komplikationen und Rezidive bei 900 Operationen. *Zentralbl. Chir.* 121:313, 1996
20. Lefering, R., Troidl, H., and Ure, B.M.: Entscheiden die Kosten? *Chirurg* 65:317, 1994
21. Schumpelick, V., and Arlt, G.: Transinguinal preperitoneal mesh prosthesis (TIPP) for repair of inguinal hernia under local anesthesia. *Chirurg* 67:419, 1996
22. Wright, D.M., Kennedy, A., Baxter, J.N., Fullarton, G.M., Fife, L.M., Sunderland, G.T., and O'Dwyer, P.J.: Early outcome after open versus extraperitoneal endoscopic tension-free hernioplasty: a randomized clinical trial. *Surgery* 119:552, 1996
23. Bessell, J.R., Baxter, P., Riddell, P., Watkin, S., and Maddern, G.J.: A randomized controlled trial of laparoscopic extraperitoneal hernia repair as a day surgical procedure. *Surg. Endosc.* 10:495, 1996
24. Horeyseck, G., Roland, F., and Rolfes, N.: Tension-free inguinal hernia repair: laparoscopic (TAPP) vs open (Lichtenstein). *Chirurg* 67:1036, 1996
25. Liem, M.S.L., and van Vroonhoven, J.M.V.: Laparoscopic inguinal hernia repair. *Br. J. Surg.* 83:1197, 1996
26. Majeed, A.W., Troy, G., Nicholl, J.P., Smythe, A., Reed, M.W.R., Stoddard, C.J., Peacock, J., and Johnson, A.G.: Randomised prospective, single-blind comparison of laparoscopic versus small-incision cholecystectomy. *Lancet* 347:989, 1996
27. Wilson, M.S., Deans, G.T., and Brough, W.A.: Prospective trial comparing Lichtenstein with laparoscopic tension-free mesh repair of inguinal hernia. *Br. J. Surg.* 82:274, 1995
28. Lehr, L., Muschaweck, P., and Siewert, J.R.: Das Konzept der Tageschirurgie am Beispiel der Leistenhernienoperation. *Chirurg* 62:587, 1991
29. Liem, M.S.L., Graaf, Y., Zwart, R.C., Geurts, I., and Vroonhoven, T.L.M.V.: A randomized comparison of physical performance following laparoscopic and open inguinal hernia repair. *Br. J. Surg.* 84:64, 1997
30. Lawrence, K., McWhinnie, D., Jenkinson, C., and Coulter, A.: Quality of life in patients undergoing inguinal hernia repair. *Ann. R. Coll. Surg. Engl.* 79:40, 1997
31. Heikkinen, T., Haukipuro, K., Leppèlè, J., and Hulkko, A.: Total costs of laparoscopic and Lichtenstein inguinal hernia repairs: a randomized prospective study. *Surg. Laparosc. Endosc.* 7:1, 1997
32. Leibl, B.J., Schmedt, C-G., Schwarz, J., Däubler, P., Kraft, K., Schlossnickel, B., and Bittner, R.: A single institutions' experience with transperitoneal laparoscopic hernia repair. *Am. J. Surg.* 175:446, 1998
33. Liem, M.S.L., Graaf, Y., Steensel, C.J., Boelhouwer, R.U., Clevers, G.J., Meijer, W.S., Strassen, L.P.S., Vente, J.P., Weidema, W.F., Schrijvers, A.J.P., and Vroonhoven, T.L.M.V.: Comparison of conventional anterior surgery and laparoscopic surgery for inguinal hernia repair. *N. Engl. J. Med.* 336:1541, 1997

## Invited Commentary

Edward L. Felix, M.D.

Department of Surgery, Fresno Community Hospital, Fresno, California, USA

I must applaud Lorenz and his associates for attempting to evaluate objectively the always controversial topic of laparoscopic hernia repair. Over the last 9 years there have been numerous studies comparing laparoscopic hernioplasty to open or conventional repairs, but many of these controlled studies of laparoscopic hernioplasty have fallen short of the mark [1]. The current study may be different. It clearly documents the operating surgeons' competence as laparoscopists. They completed more than 100 laparoscopic repairs before beginning their study. Although their mean operating time was slightly longer than reported by some surgeons with extensive experience [2], it is definitely acceptable and demonstrates a significant level of expertise. This is in contrast to many earlier controlled studies reporting significantly higher mean surgical times and therefore a lack of experience with the laparoscopic approach.

The authors' effort also points out how difficult it is to carry out a truly unbiased controlled study. More than 50% of their patients opted out of the study, choosing either a laparoscopic or Shouldice approach rather than be randomized. How much this influenced their findings is difficult to determine, but it may have had a significant effect. One also wonders why so many patients declined to be randomized. Was there some underlying bias in the surgeons that caused the patients to refuse to be part of the study? If so, how did it influence the results?

An additional 20% of patients were excluded from the study.

Some of these patients had recurrent hernias and might have benefited most from a laparoscopic approach. It would be interesting for the authors to analyze this subgroup in the future, as the results after laparoscopic repair of recurrent hernias has varied widely in the literature. McKernan, Ramming, and our own laparoscopic hernia center have all demonstrated the efficacy of the laparoscopic approach for recurrent hernias [2-5], whereas Beets and others have failed to achieve the same success [6]. The difference in results remains to be fully explained but may be related to the ever-present learning curve, or possibly the latter studies lack fixation of the mesh.

Lorenz and colleagues looked at several parameters—pain scales, amount of analgesic used, time in the hospital, and time to return to work—to determine the morbidity associated with each approach. They showed a definite trend favoring the laparoscopic approach and even some isolated significant differences. The authors, however, pointed out how different their population of patients was from those seen in the United States, where hernioplasty is an outpatient procedure, and return to work may be as short as 1 to 2 weeks [7]. To evaluate the true difference between open and laparoscopic approaches, one might consider questioning patients who have had both repairs. In our experience with more than 300 such patients, it is rare that they do not report a marked difference in recovery and pain in favor of the laparoscopic approach.

Is it still necessary for surgeons to randomize patients between approaches? Should we not be analyzing which approach should be chosen for a particular hernia and patient according to our own personal expertise? I suggest the latter. There are several approaches, including the laparoscopic approach, which have proven trustworthy [8]. There is no universal repair for all patients, hernias, or surgeons; rather, it is up to the patient and surgeon to *select the most appropriate repair for both surgeon and patient.*

**References**

1. Go, P.: Overview of randomized trials in laparoscopic inguinal hernia repair. *Semin Laparosc. Surg.* 5:238, 1998
2. Ramshaw, B., Frankum, C., Young, D., Mason, E., Duncan, T., Miller, J., Tucker, J., Lucas, G., and Promes, J.: 1000 Total extraperitoneal herniorrhaphies: after the learning curve. *Surg. Endosc.* (in press)
3. Felix, E.L., Michas, C.A., and Gonzalez, M.: Recurrent hernioplasty. *Am. J. Surg.* 172:580, 1996
4. McKernan, J.B., and Laws, H.L.: Laparoscopic repair of inguinal hernias using a totally extraperitoneal prosthetic approach. *Surg. Endosc.* 7:26, 1993
5. Felix, E., Scott, S., Crafton, B., Geis, P., Duncan, T., Sewell, R., and McKernan, B.: Causes of recurrence after laparoscopic hernioplasty: A multicenter study. *Surg. Endosc.* 12:226, 1998
6. Beets, G.I., Dirksen, C.D., Go, P., Geister, F., Baeten, C., and Kootstra, G.: Open or laparoscopic preperitoneal mesh repair for recurrent inguinal hernia repair? A randomized controlled trial. *Surg. Endosc.* 13:323, 1999
7. Felix, E.L., Michas, C., and McKnight, R.L.: Laparoscopic herniorrhaphy-transabdominal preperitoneal repair. *J. Surg. Endosc.* 8:100, 1994
8. Brooks, D.: Laparoscopic herniorrhaphy: where are we now? *Surg. Endosc.* 13:321, 1999