

Is a dissection balloon beneficial in totally extraperitoneal endoscopic hernioplasty (TEP)?

A randomized prospective multicenter study

S. Bringman,¹ Å. Ek,² E. Haglund,³ T. Heikkinen,¹ A. Kald,⁴ F. Kylberg,² S. Ramel,¹ C. Wallon,⁴ B. Anderberg¹

¹ Department of Surgery, Karolinska Institute, Huddinge University Hospital, S-141 86 Stockholm, Sweden

² Department of Surgery, Karlskoga Hospital, Karlskoga, Sweden

³ Department of Surgery, Sahlgrenska University Hospital, Gothenburg, Sweden

⁴ Department of Surgery, University Hospital, Linköping, Sweden

Received: 17 May 2000/Accepted in final form: 28 September 2000/Online publication: 6 February 2001

Abstract

Background: Laparoscopic hernioplasty has been criticized because of its technical complexity and increased costs. Disposable dissection balloons can be used to facilitate the creation of the initial working space in totally extraperitoneal endoscopic hernioplasty (TEP), but their use adds to the cost of the operation.

Methods: A total of 322 men with unilateral, primary, or recurrent inguinal hernias were randomized to undergo TEP with or without a dissection balloon.

Results: In the group with the balloon, three of 161 patients (2.5%) required conversion to transabdominal preperitoneal hernioplasty (TAPP), or open herniorrhaphy, whereas 17 of 161 patients (10.6%) were converted to TAPP or open herniorrhaphy in the group without the balloon ($p = 0.002$). The mean operation time was 55 min in the group with the balloon and 63 min in the group without the balloon ($p = 0.004$). There was no difference between them in postoperative morbidity, and there were no major complications in either group. The recurrence rate was 3.1% in the group with the balloon and 3.7% in the group without the balloon ($p = 0.8$).

Conclusion: The use of a dissection balloon in TEP reduces the conversion rate and may be especially beneficial early in the learning curve.

Key words: Hernia — Inguinal hernia — Laparoscopic surgery — Dissection balloon — Totally extraperitoneal endoscopic hernioplasty — Conversion rate — Learning curve

(population nine million), an average of 18,000 inguinal hernia operations are performed annually, of which ~16% are for recurrent hernias [17]. Recent meta-analyses have concluded that patients who undergo totally extraperitoneal endoscopic (TEP) and transabdominal preperitoneal (TAPP) hernioplasties are able to return to their normal activities earlier and with less pain than after those submitted to the open suture or tension-free methods [12]. Prospective studies carried out after the learning curve found recurrence rates of 0.71% after TEP and 1.06% after TAPP [12].

Laparoscopic hernioplasty is still a controversial procedure. It has been criticized because of its technical complexity, the need for general anesthesia, the risk for serious complications, and its higher cost [1]. However, most serious complications, such as major vessel or bowel injury, have been laparoscopy related (TAPP) and can be avoided if the operation is done extraperitoneally (TEP) [7, 18]. There is an undisputed learning curve associated with the TEP approach [15], but once experience is gained, mean operation times can be expected to decline to levels comparable to those for open hernioplasties (30–40 min) [10, 11]. The operative costs of laparoscopic hernioplasties have been shown to be significantly higher than those of open anterior tension-free hernioplasties (i.e., Lichtenstein and mesh-plug). These higher costs are primarily due to the longer operation time, instrument capital costs, and the use of disposable instruments (trocar, hernia stapler, dissection balloon, etc.) [4, 22]. Although there may be significant indirect cost savings due to the earlier return to work [4, 5, 6, 14], the direct costs of the operation remain a key issue.

Disposable dissection balloons can be used in TEP hernioplasty to gain access to the initial preperitoneal working space. Despite their potential effectiveness, they also add a considerable sum—US\$142 in Sweden during the study period—to the costs of the operation. However, an alternative dissection technique that uses only a finger and the endo-

Inguinal hernia repair is the most common general surgical procedure in the Western world [19]. In Sweden alone

Table 1. Details of patients and types of hernias

	With balloon (n = 161)	Without balloon (n = 161)
Mean (SD) age (yr)	53 (12)	52 (11)
Mean (SD) follow-up (mo)	26 (10)	27 (11)
Day surgery patients	130 (81%)	132 (82%)
Admitted patients	31 (19%)	29 (18%)
Mean (SD) hospital stay, (for admitted patients)	1.2 (0.5)	1.4 (0.8)
Type of hernia		
Direct	55 (34%)	46 (28%)
Indirect	90 (56%)	104 (65%)
Combined	16 (10%)	9 (6%)
Femoral	0	2 (1)
No of hernias		
Primary	136	128
Recurrent		
First	22	28
Second	2	5
Third	1	0

scope to gain access to the preperitoneal space has also been described [10]. The aim of this study was to compare these two techniques for dissection in TEP hernioplasty in a randomized controlled trial.

Materials and methods

Between May 1994 and December 1997, a randomized multicenter study was carried out at four Swedish hospitals (Huddinge University Hospital, Karlskoga Hospital, Sahlgrenska University Hospital, and Linköping University Hospital). A total of 322 men aged 30–75 years with a unilateral primary or recurrent inguinal hernia who were scheduled for laparoscopic hernioplasty were randomized for TEP either with or without the use of dissection balloon. Before being included in the study, the patients were assessed to determine whether they were fit for general anesthesia. Patients with a history of major surgery in the lower abdomen other than appendectomy were excluded, as were those with an immune deficiency. Informed consent was obtained from all participants. The study was approved by the ethical committee.

Randomization was performed in the preoperative area immediately prior to surgery. In all, 161 patients were randomized for TEP with a balloon and 161 patients for TEP without a balloon. The comparative data for the two groups are shown in Table 1.

Ten surgeons participated in the study. In 1994, TAPP was the method usually used for laparoscopic hernia surgery in Sweden. To be eligible to participate in the study, each of the surgeons must have done at least 30 TAPP, thereby having some experience in laparoscopic hernia surgery, and 10 TEP prior to the study.

Surgical technique

All operations were performed under general anesthesia. An infraumbilical incision was made, and the ipsilateral anterior rectus sheath was opened.

TEP with the balloon

A dissection balloon (Endopath Balloon Dissector; Ethicon Endo-Surgery, Cincinnati, OH, USA) with a 30° laparoscope was introduced in the ipsilateral rectus sheath. The balloon was insufflated with air under direct visual control, thereby opening the preperitoneal space. The balloon was replaced by a blunt trocar with a 30° laparoscope, and CO₂ was insufflated preperitoneally.

Table 2. Mean (SD) follow-up

	With balloon		Without balloon	
	mo	n	mo	n
Total	26 (10)	161	27 (11)	161
Seen by an independent surgeon	33 (8)	14	30 (8)	21
Recurrence	36 (5)	5	35 (7)	6

TEP without the balloon

A blunt digital dissection was made in the preperitoneal space through the ipsilateral anterior rectus sheath. A blunt trocar with CO₂ insufflation and a 30° laparoscope was introduced in the preperitoneal space. The dissection was continued using the laparoscope under direct vision.

One or two trocars were then introduced in the preperitoneal space. Dissection of the preperitoneal space was done medially across the midline and laterally cranial to the anterior superior iliac spine. The hernia sac was reduced and the peritoneum retracted cranially. A large indirect hernia sac could be divided if the surgeon wanted to do so. A 10 × 15 cm polypropylene mesh (Prolene; Ethicon) was introduced into the preperitoneal space. A stapler (Endopath Endoscopic Multifed Stapler; Ethicon) was used at the surgeon's discretion to fix the mesh in Cooper's ligament, the symphysis, and the anterior abdominal wall. Stapling in the lower lateral quadrant was avoided. The CO₂ was exsufflated and the anterior rectus sheath was closed with 2/0 polyglactine (Vicryl; Ethicon).

If there were any technical problems, the operation was converted to TAPP, replacing the same trocars, or to open herniorrhaphy, with or without mesh, at the surgeon's discretion.

Long-term follow-up was done by questionnaires, which were sent to the patients in 1998. An independent surgeon in the hospital saw patients who presented with complaints, such as pain or a lump in the groin [8, 9]. In all, 143 patients (89%) in both groups answered the questionnaire. Fourteen patients (9%) in the balloon group and 21 patients (13%) in the group without the balloon were seen by the independent surgeon (Table 2). Recurrence was defined as a bulge or weakness in the operation area exacerbated by a Valsalva maneuver and necessitating further operation or provision of a truss [16].

Statistics

All data were analyzed using Statistica software (v 5.5 A; StatSoft., Tulsa, OK, USA). Student's *t*-test was used to compare data with normal distributions. The Mann-Whitney U test was used to assess nonparametric data sets. The chi-square and Fisher's exact test were used to assess the differences between categorical data. A *p* value of < 0.05 was considered statistically significant. All calculations were made on an intention-to-treat basis.

Results

The mean (SD) operation time in the balloon group was 55 (24) min; in the group without the balloon, it was 63 (26) min (*p* = 0.004). In the balloon group, 83 patients (52%) had a peritoneal lesion; in the group without the balloon, there were 93 (58%), (*p* = 0.26). There were three (2.5%) conversions to TAPP or open herniorrhaphy in the balloon group and 17 (10.6%) in the group without the balloon (*p* = 0.002). Whether the operation was performed on a primary hernia or a recurrence did not influence the rate of peritoneal lesions or conversions (Table 3). If the nonconverted operations are analyzed separately, the mean (SD) operation time was 54 (24) min in the balloon group and 61 (22) min in the group without the balloon (*p* = 0.02). The majority of the conversions (three of three, or 100%, in the balloon group and 12 of 17, or 70%, in the group without the bal-

Table 3. Peritoneal lesions and number of conversions (%)

	With balloon		Without balloon		<i>p</i> value
	Yes	No	Yes	No	
Peritoneal lesions					
Primary hernia	69 (51)	67 (49)	77 (60)	51 (40)	0.12
Recurrent hernia	14 (56)	11 (44)	16 (48)	17 (52)	0.57
Conversions					
Primary hernia	2 (2)	134 (98)	14 (11)	114 (89)	<0.002
Recurrent hernia	1 (4)	24 (96)	3 (9)	30 (91)	0.63

loon) occurred within each surgeon's first 15 operations included in the trial. The main reason given for conversion to TAPP was "difficult access," whereas the main reason given for conversion to open herniorrhaphy was "hemorrhage" (Table 4). All operations converted to TAPP due to difficult access also had a documented peritoneal lesion.

There was no significant difference in postoperative morbidity. In the balloon group, four (2.5%) early (<30 days) complications were recorded; in the group without the balloon, there were nine (5.6%) ($p = 0.26$). One complication in the balloon group and four in the group without the balloon occurred after a conversion to TAPP or open herniorrhaphy (Table 5). Late neuralgia occurred in one patient (0.6%) in the balloon group and four patients (2.5%) in the group without the balloon ($p = 0.37$). In all of the patients with neuralgia, the mesh had been fixed with staplers.

There was no statistically significant difference between the groups in terms of time to return to work. The balloon group enjoyed a significantly shorter recovery period (Table 6, Fig. 1). One patient took an extremely long period off work (500 days), but this was due to reasons other than the TEP operation.

There were four recurrences after a primary hernia and one after a recurrent hernia (3.1%) in the balloon group; in the group without the balloon, there were five recurrences after a primary hernia and one after a recurrent hernia (3.7%) ($p = 0.8$).

Discussion

The results of surgery for inguinal hernia vary. In non-specialized units, ~15% of the herniorrhaphies are performed on previously operated hernias [17]. New repairs with mesh, performed both by open surgery and laparoscopically, have been introduced in an effort to reduce the recurrence rate and the postoperative period of rehabilitation. However, the use of mesh increases the cost of the operation [1, 4, 6, 14]. In laparoscopic surgery, the use of disposable instruments is an option, but this also increases costs [4, 6, 14]. Hence, there is an economic incentive to reduce the use of disposable instruments such as dissection balloons if the results are the same whether or not a balloon is used.

TEP is a technically complex procedure that is performed in a space created during the operation. In order to obtain good results, the surgeon must be skilled in laparoscopic techniques and familiar with the anatomy of the abdominal wall [10, 15]. During the learning period, it may be problematical to find the correct plane in the preperitoneal space. If the dissection is done in the wrong surgical plane,

Table 4. Reasons for conversion

	Anatomy	Difficult access	Hemorrhage	Fixed hernia sac	Total
With balloon					
TAPP	1	1	0	0	2
Open	0	1	0	0	1
Total					3 ^a
Without balloon					
TAPP	0	8	0	2	10
Open	1	1	4	1	7
Total					17

^a $p = 0.002$

Table 5. Postoperative morbidity <30 days

	With balloon (<i>n</i> = 161)	Without balloon (<i>n</i> = 161)
Seroma	1	1 (TAPP)
Hematoma	2 (1 TAPP)	5 (1 Open)
Epididymitis	0	1
Urinary retention	1	1 (Open)
Infection	0	1 (TAPP)
Total	4	9

Table 6. Time to return to work and time to complete recovery

	With balloon	Without balloon	<i>p</i> value
Median days (range) away from work	4.5 (0–45)	5 (0–500)	0.12
Median no. of days (range) to complete recovery, total	14 (0–150)	14 (3–180)	0.01
Median no. of days (range) to complete recovery, converted	30 (30–30)	30 (14–120)	

there is an increased risk of hemorrhage and/or loss of the anatomical landmarks. A dissection balloon could make the dissection of the preperitoneal space easier and safer, thus reducing the operation time, the conversion rate, and the number of complications.

The mean operation time was slightly shorter in the balloon group, with almost no change if the converted operations were excluded. Although these differences are statistically significant, it is uncertain if they are clinically relevant. Other authors have reported a mean operation time between 35 and 70 min to perform a TEP procedure [4, 10, 11, 15], this is comparable to our respective times of 55 and 63 min.

Peritoneal lesions may influence the conversion rate, since an intraabdominal CO₂ leak could result in a narrowing of the operating field, making it difficult for the surgeon to continue the operation extraperitoneally with safety. However, there was no difference between the groups in terms of reported peritoneal lesions. We did find a significant difference in the conversion rates between the groups: the use of a dissection balloon resulted in fewer conversions. The conversions occurred early in the study, indicating that the conversion rate decreases with experience. Our conversion rate is similar to that reported in earlier series.

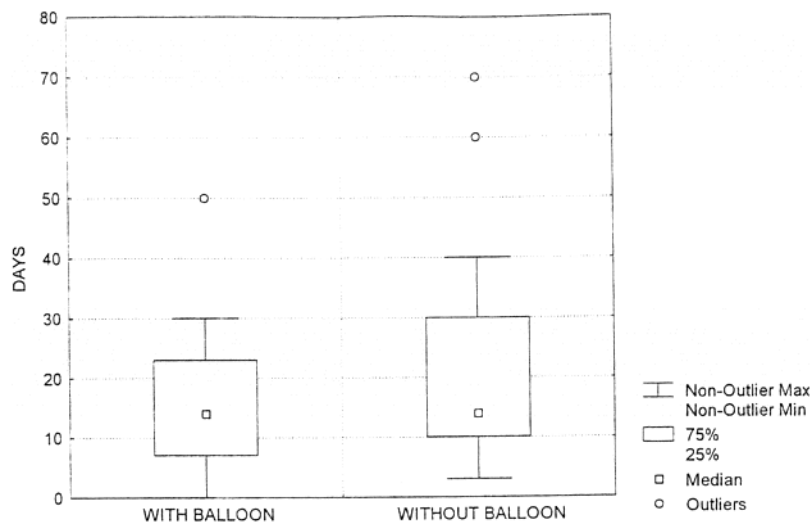


Fig. 1. Time to complete recovery.

where the conversion rate from TEP to TAPP or open herniorrhaphy was between 1% and 10% [7, 10, 15].

The length of the learning curve has been discussed by other authors [15, 23]. In our study, all of the surgeons had done at least 30 TAPP and 10 TEP prior to the study. Fifteen out of 20 of the conversions (75%) occurred within each surgeon's first 15 operations in the study (i.e., within the surgeon's first 25 TEP). This finding suggests that the learning curve for TEP requires ≥ 25 TEP operations (10 before the study plus 15 during the study) provided the surgeon has had previous experience in laparoscopic hernia surgery consisting of ≥ 30 TAPP before beginning to perform TEP procedures.

Neuralgia is a clinical problem after both open and laparoscopic hernia surgery [13, 21]. The use of a stapler to secure the mesh may cause nerve entrapment and neuralgia. Some authors found no difference in the occurrence of neuralgia whether stapled or nonstapled mesh was used in TAPP [20], but there have also been reports of severe neuralgia caused by staplers [7]. In our study, five patients developed neuralgia. It made no difference whether or not a balloon was used, but the mesh had been secured with staplers in all of the patients with neuralgia. The recurrence rate in tension-free herniorrhaphies has been reported to be $< 4\%$ [1, 5, 6, 11]. Our results are similar, with a recurrence rate of 3.1% in the group with the balloon and 3.7% in the group without the balloon.

The time to full recovery was shorter in the balloon group. This finding may be explained by the higher rate of conversions in the group without the balloon, who subsequently required more complicated operations and therefore a prolonged period of rehabilitation. However, there was no difference in the time to return to work; these results are similar to those reported in other studies [2, 3].

In conclusion, we found that the use of a dissection balloon in TEP reduced the conversion rate and that the conversion rate was higher if the surgeon was less experienced. It did not reduce the recurrence rate or postoperative morbidity. These results suggest that the use of a dissection balloon can be helpful during the learning period, but in experienced hands it merely increases the cost of the operation, without offering additional benefits.

References

- Amid PK, Shulman AG, Lichtenstein IL (1995) An analytic comparison of laparoscopic hernia repair with open "tension-free" hernioplasty. *Int Surg* 80: 9-17
- Cohen RV, Alvarez G, Roll S, Garcia ME, Kawahara N, Schiavon CA, Schaffa TD, Pereira PR, Margarido NF, Rodrigues AJ (1998) Transabdominal or totally extraperitoneal laparoscopic hernia repair? *Surg Laparosc Endosc* 8: 264-268
- Felix EL, Michas CA, Gonzalez MH Jr (1995) Laparoscopic hernioplasty: TAPP vs TEP. *Surg Endosc* 9: 984-989
- Heikkinen TJ, Haukipuro K, Koivukangas P, Hulkko A (1998) A prospective randomized outcome and cost comparison of totally extraperitoneal endoscopic hernioplasty versus Lichtenstein hernia operation among employed patients. *Surg Laparosc Endosc* 8: 338-344
- Johansson B, Hallerback B, Glise H, Anesten B, Smedberg S, Roman J (1999) Laparoscopic mesh versus open preperitoneal mesh versus conventional technique for inguinal hernia repair: a randomized multicenter trial. *SCUR Hernia Repair Study*. *Ann Surg* 230: 225-231
- Kald A, Anderberg B, Carlsson P, Park PO, Smedh K (1997) 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: 505-510
- Kald A, Anderberg B, Smedh K, Karlsson M (1997) Transperitoneal or totally extraperitoneal approach in laparoscopic hernia repair: results of 491 consecutive herniorrhaphies. *Surg Laparosc Endosc* 7: 86-89
- Kald A, Nilsson E (1991) Quality assessment in hernia surgery. *Qual Assur Health Care* 3: 205-210
- Kald A, Nilsson E, Anderberg B, Bragmark M, Engstrom P, Gunnarsson U, Haapaniemi S, Lindhagen J, Nilsson P, Sandblom G, Stubberod A (1998) Reoperation as surrogate endpoint in hernia surgery: a three year follow-up of 1565 herniorrhaphies. *Eur J Surg* 164: 45-50
- Kathouda N, Campos GM, Mavor E, Trussler A, Khalil M, Stoppa R (1999) Laparoscopic extraperitoneal inguinal hernia repair: a safe approach based on the understanding of rectus sheath anatomy. *Surg Endosc* 13: 1243-1246 DOI: 10.1007/s004649901237
- Knook MT, Weidema WF, Stassen LP, van Steensel CJ (1999) Endoscopic total extraperitoneal repair of primary and recurrent inguinal hernias. *Surg Endosc* 13: 507-511 DOI: 10.1007/s004649901023
- Leibl BJ, Schmedt CG, Ulrich M, Kraft K, Bittner R (1999) Laparoscopic hernia repair—the facts, but no fashion. *Langenbecks Arch Surg* 384: 302-311
- Lichtenstein IL, Shulman AG, Amid PK, Montllor MM (1988) Cause and prevention of postherniorrhaphy neuralgia: a proposed protocol for treatment. *Am J Surg* 155: 786-790
- Liem MS, Halsema JA, van der Graaf Y, Schrijvers AJ, van Vroonhoven TJ (1997) Cost-effectiveness of extraperitoneal laparoscopic inguinal hernia repair: a randomized comparison with conventional

- herniorrhaphy. Coala Trial Group. *Ann Surg* 226: 668–675 discussion 675–676
15. Liem MS, van Steensel CJ, Boelhouwer RU, Weidema WF, Clevers GJ, Meijer WS, Vente JP, de Vries LS, van Vroonhoven TJ (1996) The learning curve for totally extraperitoneal laparoscopic inguinal hernia repair. *Am J Surg* 171: 281–285
 16. Marsden A (1962) Inguinal hernia: a three-year review of two thousand cases. *Br J Surg* 49: 384–394
 17. Nilsson E, Kald A, Anderberg B, Bragmark M, Fordell R, Haapaniemi S, Heuman R, Lindhagen J, Stubberod A, Wickbom J (1997) Hernia surgery in a defined population: a prospective three year audit. *Eur J Surg* 163: 823–829
 18. Ramshaw BJ, Tucker JG, Conner T, Mason EM, Duncan TD, Lucas GW (1996) A comparison of the approaches to laparoscopic herniorrhaphy. *Surg Endosc* 10: 29–32 DOI: 10.1007/s004649910006
 19. Rutkow IM (1997) Surgical operations in the United States. Then (1983) and now (1994). *Arch Surg* 132: 983–990
 20. Smith AI, Royston CM, Sedman PC (1999) Stapled and nonstapled laparoscopic transabdominal preperitoneal (TAPP) inguinal hernia repair: a prospective randomized trial. *Surg Endosc* 13: 804–806 DOI: 10.1007/s004649901104
 21. Stark E, Oestreich K, Wendl K, Rumstadt B, Hagmuller E (1999) Nerve irritation after laparoscopic hernia repair. *Surg Endosc* 13: 878–881 DOI: 10.1007/s004649901124
 22. Wellwood J, Sculpher MJ, Stoker D, Nicholls GJ, Geddes C, Whitehead A, Singh R, Spiegelhalter D (1998) Randomised controlled trial of laparoscopic versus open mesh repair for inguinal hernia: outcome and cost. *Br Med J* 317: 103–110 erratum in *Br Med J* 1998; 317: 631].
 23. Voitk AJ (1998) The learning curve in laparoscopic inguinal hernia repair for the community general surgeon. *Can J Surg* 41: 446–450