

# Long-term results from a randomized comparison of open transinguinal preperitoneal hernia repair and the Lichtenstein method (TULIP trial)

W. J. V. Bökkerink<sup>1,2</sup> , G. G. Koning<sup>3</sup>, D. Malagic<sup>1</sup>, L. van Hout<sup>2</sup>, C. J. H. M. van Laarhoven<sup>1</sup> and P. W. H. E. Vriens<sup>2</sup>

Departments of Surgery, <sup>1</sup>Radboud University Medical Centre, Nijmegen, <sup>2</sup>Elisabeth TweeSteden Hospital, Tilburg, and <sup>3</sup>Bernhoven Hospital, Uden, the Netherlands

Correspondence to: Mr W. J. V. Bökkerink, Department of Surgery, Radboud University Medical Centre, Geert Grooteplein-Zuid 10, PO Box 9101, 6500 HB, Nijmegen, the Netherlands (e-mail: willembokkerink@gmail.com)

**Background:** The short-term results of the TULIP trial comparing transinguinal preperitoneal (TIPP) inguinal hernia repair with the Lichtenstein method have been reported with follow-up of 1 year. After TIPP repair, fewer patients had chronic postoperative inguinal pain (CPIP); they had better health status and lower costs. The present study reports the long-term outcomes of this trial.

**Methods:** All surviving patients initially randomized in the TULIP trial were contacted. Patients were interviewed by telephone and sent a questionnaire. Those reporting any complaints were invited for outpatient review. Chronic pain, hernia recurrence and reoperation were documented, along with any sensory change or disturbance of sexual activity.

**Results:** Of 302 patients initially randomized, 251 (83.1 per cent) were included in the analysis (119 TIPP, 132 Lichtenstein), with a median follow-up of 85 (range 74–117) months. Of 25 patients with chronic postoperative inguinal pain after 1 year, only one, who underwent Lichtenstein repair, still had groin pain at long-term follow-up. The overall hernia recurrence rate was 2.8 per cent (7 patients), with no difference between the groups.

**Conclusion:** Both TIPP and Lichtenstein hernia repairs are durable. Patients with chronic postoperative inguinal pain after 1 year can be reassured that the groin pain tends to fade over time.

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## Introduction

There are almost 30 000 inguinal hernia repairs in the Netherlands annually<sup>1</sup> and over 70 000 in the UK<sup>2</sup>. Since the introduction of the Lichtenstein technique, the recurrence rate has dropped to 2 per cent<sup>3,4</sup>. Chronic postoperative inguinal pain (CPIP) has become the main adverse outcome, with a mean incidence of 11 per cent<sup>3,5</sup>. With the introduction of endoscopic inguinal hernia repair, the preperitoneal space became the preferred position for the mesh, because of low pain and recurrence rates. Preperitoneal mesh can also be placed at open surgery, with a significant reduction in CPIP<sup>6,7</sup>. Endoscopic hernia repair has a long learning curve and is often more costly, whereas open preperitoneal techniques were developed as potentially the best of both worlds. One of these techniques, transinguinal

preperitoneal (TIPP) hernia repair<sup>8,9</sup>, has had promising results.

The Tilburg double-blind RCT TULIP was conducted between 2009 and 2011 (ISRCTN 93798494). The short-term results were published in 2012<sup>10</sup> and favoured the TIPP technique in terms of CPIP, health status and costs after 1 year. Rates of recurrence and other complications were low in both groups<sup>10–12</sup>. The tendency for CPIP to fade over time has been reported<sup>3,13–17</sup>. No long-term results on CPIP have been published for the TIPP technique. The present study investigated the long-term results of both techniques (TIPP and Lichtenstein) in the TULIP cohort. In line with the TULIP trial conclusion, it was hypothesized that there would be fewer patients with CPIP at long-term follow-up after TIPP than after Lichtenstein repair.

## Methods

The TULIP trial was a double-blind RCT in a high-volume hernia centre<sup>18</sup>. Patients with a unilateral, primary inguinal hernia, aged between 18 and 80 years, and with an ASA fitness grade of I, II or III were eligible for inclusion. There were standard procedures for all perioperative care from patient, surgical and anaesthetic perspectives. Each procedure was performed in exactly the same way by all participating surgeons after proctoring. Patients were checked in outpatients after 2 weeks, 3 months and 1 year. Outcomes were determined and published in the trial protocol before the start of the trial. Blinding was broken only in line with the protocol after 1 year at the patient's request or in an emergency. According to the risk-of-bias assessment<sup>19</sup>, TULIP was a trial with a low risk of bias with level of evidence 1b<sup>20</sup>.

## Present study design

This long-term follow-up study started by contacting all initially randomized patients by telephone. Contact numbers were retrieved from the case records forms of the initial TULIP trial, which have been stored in line with Good Clinical Practice (file numbers R95 and R96, external storage of Radboud University Medical Centre, Nijmegen, the Netherlands). Patients who had died were excluded. After obtaining oral consent for this study, the unblinded investigator asked whether the patient had any complaints in the groin (such as pain at rest and/or during activity, discomfort or other complaints). If yes, the patient was invited to visit the outpatient department of Elisabeth TweeSteden Hospital in Tilburg. Any other irregularities reported by the patient during the postoperative course since the inguinal hernia repair, such as a reoperation, were also reasons for inviting them for assessment. If the patient denied any complaints, a short series of standard questions was asked by telephone and a questionnaire sent by conventional mail. This method has been used in other large inguinal hernia studies<sup>16,21</sup>. To avoid missing asymptomatic recurrence, four questions were asked, including a self-test with Valsalva manoeuvre according to the PINQ-PHONE method (Table S1, supporting information)<sup>22</sup>. If the answer to any one of these questions was positive, or the investigator was in any doubt, the patient was invited to outpatients.

## Outcome measures

All patients, irrespective of type of follow-up, were asked to fill in the Short Form 36 questionnaire (SF-36<sup>®</sup> version 1<sup>23</sup>; Optum, Eden Prairie, Minnesota, USA). In

outpatients, the patient was interviewed by an experienced research physician and a standard physical examination performed to detect any hernia recurrence and/or sensory disturbances (pin-prick test). Pain was measured as a dichotomous outcome, and on visual analogue and verbal descriptor scales, at rest and during activity. CPIP was defined as any groin pain lasting for more than 3 months after surgery<sup>24</sup>. Additionally, if a patient suffered from any complaints, the Pain Disability Index<sup>25</sup> was completed to evaluate the functional consequences. Patients who experienced any complaints were asked to define these subjectively as discomfort or pain without interference from the research physician. All patients were asked if they had experienced any disturbance in sexual activities (in particular ejaculatory pain) since the operation. Similar to the initial study report, the results were scored according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE)<sup>26</sup>, which facilitates critical decision-making from a patient's perspective.

## Ethical aspects

The TULIP trial was approved by the Central Committee for Medical Scientific Research (reference number NL16781.008.07) and by the local medical ethical review board (METC Brabant; reference number 0737). The same board approved the protocol of the present long-term follow-up study (reference NW201835).

## Statistical analysis

The analysis was done using the intention-to-treat principle with guidance from an experienced biostatistician. The distribution of continuous variables was assessed by histogram plot and Kolmogorov–Smirnov test. Homogeneity of variances was tested with Levene's test. Continuous variables with a normal distribution are shown as mean(s.d.), with analysis by means of the *t* test. Variables with a skewed distribution are reported as median (i.q.r.). Qualitative or categorical variables are presented as frequencies and percentages, with analysis using  $\chi^2$  test or Fisher's exact test. Two-sided  $P < 0.050$  was considered significant. SF-36<sup>®</sup> data were analysed according to the original method described by Ware<sup>27</sup>. The linearly transformed scores ranged from 0 to 100, with a higher score indicating better health status. SPSS<sup>®</sup> for Windows<sup>®</sup> version 25 (IBM, Armonk, New York, USA) and SAS<sup>®</sup> Windows<sup>®</sup> version 9.4m5 (SAS Institute, Cary, North Carolina, USA) were used for statistical analysis. This cohort study was reported in accordance with the STROBE guidelines<sup>28</sup>.

	TIPP (n = 119)	Lichtenstein (n = 132)	P <sup>§</sup>
Age (years)*	57.0(11.4)	55.5(11.9)*	0.311¶
Sex ratio (M : F)	113 : 6	127 : 5	0.628
Side of hernia			0.570
Left	52 (43.7)	53 (40.2)	
Right	67 (56.3)	79 (59.8)	
ASA fitness grade†			0.447
I	67 (56.3)	84 (63.6)	
II	46 (38.7)	41 (31.1)	
III	6 (5.0)	7 (5.3)	
BMI (kg/m <sup>2</sup> )*	25.3(3.2)	25.5(2.7)	0.666¶
EHS hernia classification‡			0.776
Lateral	80 (67.2)	87 (65.9)	
1	19 (16.0)	30 (22.7)	
2	50 (42.0)	44 (33.3)	
3	11 (9.2)	13 (9.8)	
Medial	32 (26.9)	37 (28.0)	
1	11 (9.2)	10 (7.6)	
2	12 (10.1)	15 (11.4)	
3	9 (7.6)	12 (9.1)	
Combined (pantaloon)	7 (5.9)	7 (5.3)	
Not specified	0 (0)	1 (0.8)	

Values in parentheses are percentages unless indicated otherwise; \*values are mean(s.d.). †At the time of TULIP surgery. ‡All hernias were primary, in accordance with the trial protocol<sup>18</sup>. TIPP, transinguinal preperitoneal; EHS, European Hernia Society. § $\chi^2$  test, except ¶t test.

## Results

A total of 302 patients were randomized to TIPP or Lichtenstein hernia repair between 2009 and 2010 in the initial TULIP trial; 251 patients (83.1 per cent) were included in the long-term follow-up study. The median duration of follow-up was 85 (range 74–117) months. There were no significant differences in baseline characteristics between the two groups (Table 1).

After 1 year of follow-up, 25 patients experienced continuous CPIP, five (3.5 per cent) after TIPP and 20 (12.9 per cent) after Lichtenstein repair<sup>10</sup>. Of these 25 patients, 24 were available for long-term follow-up, and only one had persistent CPIP (Table 2). Few had any treatment in the interim. The single patient with continuous CPIP at long-term follow-up experienced unchanged pain since before the groin hernia operation. In previous years, no alternative diagnosis for his groin pain had been found. The chronic pain had disappeared in the other 23 patients.

A total of 19 patients reported some form of pain or discomfort in the groin since the hernia repair (Table 3). All these patients were examined. Besides the single patient with continuous CPIP, seven others (2.8 per cent) reported pain during certain activities such as sports, walking or

	Total	TIPP	Lichtenstein
CPIP 1 year after surgery	25	5	20
Lost to follow-up	1	1	0
CPIP at long-term follow-up	1	0	1
CPIP disappeared	23	4	19
Recurrence*	4	1	3
Infiltration with local anaesthetics	1	0	1
No treatment†	18	3	15

\*Repaired using the totally extraperitoneal procedure. †Patients were asked to comment on the fact that no treatment was started; all patients reported that their complaints were not severe enough to seek medical attention. TIPP, transinguinal preperitoneal; CPIP, chronic postoperative inguinal pain.

	TIPP (n = 119)	Lichtenstein (n = 132)	P‡
No complaints	110 (92.4)	122 (92.4)	0.997
Complaints			
Discomfort, no pain	6 (5.0)	6 (4.5)	0.854
CPIP, any	3 (2.5)	4 (3.0)	1.000
Activity-related	3 (2.5)	4 (3.0)	1.000
Mild intensity	3	1	
Moderate intensity	0	2	
Severe intensity	0	1	
At rest (continuous)	0 (0)	1 (0.8)	1.000
Mild intensity	n.a.	0	
Moderate intensity	n.a.	0	
Severe intensity	n.a.	1	
Hernia recurrence*	2 (1.7)	5 (3.8)	0.451
Interval recurrence†	0 (0)	2 (1.5)	0.499

Values in parentheses are percentages. \*Cumulative number of patients with a recurrent inguinal hernia. One patient with hernia recurrence in the Lichtenstein group was not available for long-term follow-up and not included in analyses of this group. †Recurrence developed between short- and long-term follow-up. TIPP, transinguinal preperitoneal; CPIP, chronic postoperative inguinal pain; n.a., not applicable. ‡Fisher's exact test.

gardening. These patients usually described the pain as mild, not influencing their daily life and/or work. These patients were distributed equally between the TIPP and Lichtenstein groups: three (2.5 per cent) versus four (3.0 per cent) respectively. Four patients reported sexual disturbances since the operation: two with erectile dysfunction and two with mild groin pain during intercourse. Sensory disturbance in the groin, mostly numbness, was found in six patients in the TIPP group and 25 in the Lichtenstein group (5.0 versus 18.9 per cent;  $P = 0.001$ ).

Seven patients (2.8 per cent) developed recurrent inguinal hernia, two (1.7 per cent) after TIPP and five (3.8 per cent) after Lichtenstein repair. Five recurrences were

early, and two occurred between short- and long-term follow-up. All seven patients with recurrent inguinal hernia had reoperation. Two patients gave a positive response to one of the PINQ-PHONE questions; both reported a bulge in the groin (without inguinal complaints). Patients were examined by an experienced physician and no recurrent hernia was diagnosed.

Health-related quality of life measured using SF-36<sup>®</sup> showed a significant decrease in all dimensions except physical pain (Lichtenstein group), mental health (TIPP group) and role – emotional (Lichtenstein group) (Table S2, supporting information). No significant differences were found between the two repair techniques.

## Discussion

The present study investigated the long-term results of the TULIP trial cohort, comparing patients after the TIPP and Lichtenstein methods for open inguinal hernia repair. The short-term results favoured TIPP repair, with fewer patients reporting chronic groin pain<sup>10</sup>. The long-term results showed that this difference disappeared, and rates of CPIP were similar after TIPP and Lichtenstein methods. All but one of the 25 patients with CPIP at 1 year after surgery had relief of symptoms by long-term follow-up. Even those with activity-related pain found that it diminished over time. The overall hernia recurrence rate was low, and health status did not differ between the intervention groups.

The short-term results of TULIP<sup>10</sup> were in line with the outcomes of a systematic review<sup>6</sup> comparing TIPP *versus* Lichtenstein hernia repair. Only three of the studies included in the review reported a minimum of 5 years of follow-up; however, these cannot be compared with the present cohort because two articles<sup>29,30</sup> described variants of the TIPP method (Kugel and Nyhus techniques) and the other RCT<sup>31</sup> reported only on incarcerated inguinal hernias. Comparing the findings of the present study with others on inguinal hernia repair, the percentage of patients with long-term CPIP was well below the reported range of 14–20 per cent<sup>16,17,32</sup>. CPIP rates 5 years or more after Lichtenstein repair are generally between 3.5 and 20.1 per cent<sup>15,16,33–35</sup>. The CPIP rate of 0.8 per cent in the present study is well below this range, possibly because the trial was done in a high-volume hernia centre.

The improvement in CPIP in the TULIP cohort is consistent with the literature<sup>16,32,33,36</sup>. Most patients in the present study had no specific treatment, usually because the pain was not severe enough to seek medical attention. Eklund and colleagues<sup>33</sup> reported a similar series of patients with resolving CPIP and described this as

potentially its natural course. Another possible explanation is the effect of ageing, although that was not assessed in the present study.

The rate of hernia recurrence was low after both procedures (2.8 per cent overall) and similar to that in other studies<sup>6,16,32,35</sup>, ranging from 1.7 to 5.6 per cent. Just like the well established Lichtenstein technique, the TIPP method also seems to stand the test of time. The present study was not large enough to compare recurrence rates directly, and is limited by the baseline being a telephone questionnaire. The PINQ-PHONE method is considered an adequate tool to minimize the risk of missing a recurrent hernia<sup>22</sup>.

Late hyperaesthesia or hypoaesthesia was more common in patients who underwent Lichtenstein repair, similar to the findings of Pierides and Vironen<sup>32</sup>. Sexual dysfunction after hernia repair is deemed of more importance; Aasvang *et al.*<sup>37</sup> and Kehlet and Bay-Nielsen<sup>38</sup> reported that 22.1 per cent of patients had pain during sexual activity and 2.7 per cent had pain-related sexual dysfunction. Only four patients in the present cohort (1.6 per cent) reported significant negative effects on sexual activities.

The short-term results of the TULIP trial suggested that the TIPP technique is a safe and efficient method for inguinal hernia repair, with less groin pain after 1 year compared with the Lichtenstein method. The long-term results in the present study have confirmed that TIPP is as durable as the Lichtenstein repair. Patients with CPIP in the first year after open inguinal hernia repair can be reassured that the pain is likely to fade away over time.

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### Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.

### Editor's comments

This hernia issue of *BJS* has a recurring theme: compared with open hernia repair, there are short-term gains in recovery and less early pain after endoscopic hernia repair, but equivalence in long-term quality of life and hernia recurrence. The main difference between endoscopic repair and open methods is that general anaesthesia is required for the former, whereas open repair can be done under local anaesthesia with, or without intravenous sedation. So the message for patients is that if you are fit for a general anaesthetic, and speed of recovery is important to you, endoscopic repair will be an advantage. For the typical patient with a hernia (elderly, co-morbid man) avoiding a general anaesthetic may be better, in which case open repair may be appropriate. Finally, it is also clear that the best results are obtained by surgeons who do a lot of hernia repairs, and/or work in hernia services, operating to a standard protocol. As in so many branches of surgery, choosing your surgeon wisely is more important than the method they use.

J. J. Earnshaw  
*Editor-in-Chief, BJS*