

**Daria Kuliś¹, Jakub Łomnicki¹, Agnieszka Leszko¹, Marcin Chajec¹,
Paweł Bogacki², Mirosław Szura²**

1 Department of General, Oncological and Minimally Invasive Surgery, Żeromski Hospital, Kraków

2 Physiotherapy Institute, Department of Experimental and Clinical Surgery, Jagiellonian University Collegium Medicum, Kraków

Long term outcome of totally extraperitoneal hernia repair without mesh fixation

Wyniki odległe operacji przepuklin pachwinowych metodą TEP

ABSTRACT

Introduction: Hernia repair using the TEP method without mesh fixation is an effective way of treatment with low recurrence rate and small number of patients with chronic pain post surgery. This study aims to asses the quality of life and the number of recurrent hernia in patients treated with the TEP method without mesh fixation with a mean follow-up of 61 months (5 years)

Materials and methods: A retrospective analysis of 278 patients operated with the TEP method between 2008 and 2014 was performed. Factors such as: demographic data, type of hernia, length of surgery, peri-operative complications and length of hospital stay were subject to analysis. In a telephone survey, the number of hernia recurrence as well as quality of life assessed by the Carolinas Comfort Scale (CCS) and the polish version of the Short Form 36 (SF-36) were gathered.

Results: Between 2008 and 2014 278 patients underwent hernioplasty using the TEP method. In 243 (87.4%) patients, an unilateral hernioplasty was performed, whereas in 35 (12.6%) a bilateral operation was done. Mean operation time for the unilateral surgery was 48minutes, and 5 minutes longer for the bilateral procedure. Mean hospital stay (from the day of surgery) was 2.5 days. 13 (4.5%) conversions were recorded: 10 to Lichtenstein method and 3 to TAPP method. No significant perioperative complications were noted, and the post-surgical complication rate was 2.5%. Mean follow-up period was 61 months. The number of patients that were subject to long term post-surgical was 98 (35.2%). In this subgroup, the number of recurrent hernias was 2 (2.04%). Mean CCS and SF-36 scores were 3.4 and 38.9 points respectively.

Conclusions: Hernioplasty with the TEP method without mesh fixation is an effective and safe method with low recurrence rate and high quality of life levels post-surgery

Adres do korespondencji / Address for correspondence: miroslaw.szura@uj.edu.pl. **ORCID:** Daria Kuliś – 0000-0001-9522-4629; Jakub Łomnicki – 0000-0002-7392-2941; Agnieszka Leszko – 0000-0001-8471-3195; Marcin Chajec – 0000-0002-9596-8983; Paweł Bogacki – 0000-0001-6100-2462; Mirosław Szura – 0000-0002-9993-7471

STRESZCZENIE

Wstęp: Plastyka przepukliny pachwinowej metodą TEP bez mocowania siatki jest skuteczną metodą leczenia obarczoną niskim odsetkiem nawrotów i niskim odsetkiem pacjentów z bólem przewlekłym. Niniejsze badanie ma na celu ocenę jakości życia i odsetka nawrotów u pacjentów poddanych plastyce metodą TEP bez mocowania siatki ze średnim pooperacyjnym czasem obserwacji wynoszącym 61 miesięcy (5 lat).

Metody: Przeprowadzono retrospektywną analizę 278 pacjentów poddanych operacji metodą TEP w latach 2008–2014. Przy pomocy elektronicznej bazy danych u operowanych pacjentów przeanalizowano takie dane jak: czynniki demograficzne, rodzaj przepukliny, długość zabiegu, powikłania około- i pooperacyjne, długość hospitalizacji po zabiegu. W przeprowadzonej ankcie telefonicznej analizowano odsetek nawrotów oraz jakość życia za pomocą kwestionariuszy Carolinas Comfort Scale (CCS) oraz polskiej wersji Short Form 36 (SF-36).

Wyniki: W latach 2008–2014 278 pacjentów poddano zabiegowi plastyki przepukliny pachwinowej metodą TEP. U 243 (87,4%) pacjentów wykonano jednostronną plastykę przepukliny pachwinowej, u 35 (12,6%) przeprowadzono zabieg obustronny. Średni czas zabiegu dla operacji jednostronnej wynosił 48 min, dla operacji obustronnej był dłuższy średnio o 5 minut. Średni czas hospitalizacji (licząc od dnia zabiegu) wynosił 2,5 dnia. W badanej grupie było 13 konwersji (4,5%) – 10 do metody Lichtensteina, 3 do metody TAPP. Nie zanotowano istotnych powikłań okołooperacyjnych, a odsetek powikłań pooperacyjnych wynosił 2,5%. Średni czas obserwacji wynosił 61 miesięcy. Liczba pacjentów objętych długookresową obserwacją pooperacyjną wyniosła 98 (35,2%). W tej grupie liczba nawrotów dotyczyła 2 pacjentów (2,04%). Średnie wyniki w skali CCS i SF-36 były niskie i wynosiły odpowiednio dla CCS – 3,4 oraz SF-36 – 38,9 punktów.

Wnioski: Plastyka przepukliny pachwinowej metodą TEP bez mocowania siatki jest skutecną i bezpieczną metodą operacyjną zapewniającą niski odsetek nawrotów oraz wysoki poziom jakości życia u operowanych chorych.

Key words: totally extraperitoneal (TEP) hernia repair, recurrence rate, long term follow up, quality of life

Introduction

Inguinal hernia repair is one of the most common surgical procedures. It is estimated that around 20 million hernia repairs are performed each year worldwide (Sugita FY, 2017). Since the introduction of tension-free methods of hernia repair, with the Lichtenstein method being the most common one, the recurrence rate decreased by 50–57% in comparison to tension techniques (Schjøth-Iversen L, 2017). Laparoscopic approach to hernia repair was the next big improvement in this field of surgery. Totally extraperitoneal patch plasty (TEP) was first performed in

1992 by Dulucqa and, alongside the Lichtenstein method and the TAPP (transabdominal patch plasty) method, is one of the main three techniques of modern inguinal hernia repair. In the last 20 years this technique was gathering more and more attention. According to a Swedish national registry and a German Herniamed registry the TEP method accounts for 25% of all hernia repairs performed in those two countries (Sharma A, 2017). The main advantage of this method is the access path that does not include the opening of the peritoneum, thus limiting the risk of damaging the abdominal organs (Simons MP, 2009), shorter time to full activity, lesser pain and shorter

hospital stay (Garofalo F, 2017). According to the European Hernia Society (EHS) guidelines, tension-free methods with synthetic mesh implantation are the recommended method of treatment, and these include the Lichtenstein method, TAPP and TEP. The two latter are recommended in bilateral hernias and in recurrent hernias after an open procedure. (Simons MP, 2009; T.H. Group, 2018).

The most controversial aspect of the TEP method is mesh fixation. Many hospitals do not perform any fixation of the mesh – its proper landing is ensured by the dissipation of the preperitoneal space. The peritoneum presses against the mesh from the bottom side, and the abdominal rectus muscles press against the mesh from the top, ensuring its stable fixation by the ‘sandwich effect’ (Garg P, 2011). Many studies have shown that mesh fixation does not affect the rate of recurrence but can cause more post-surgical pain as well as chronic pain (Simons MP, 2009; Buyukasik K, 2017; Aliyazicioglu T 2017). The TEP method without mesh fixation is now considered to be an effective and safe method of hernia treatment. According to the EHS 2018 guidelines, mesh fixation is only effective in reducing the recurrence rate in grade III hernias, especially the medial ones (T.H. Group, 2018). In this study we are presenting our own experience in the TEP method without mesh fixation in inguinal hernia repair.

Aim of the study

The aim of the study was to assess the long-term recurrence rate and the quality of life of patients undergoing inguinal hernia repair using the TEP method without mesh fixation. Additional data such as demographic data, type of hernia, length of surgery, length of hospital stay, conversion rate and complication rate were gathered and analysed.

Materials and methods

A retrospective analysis of all 278 patients operated for inguinal hernia using the TEP

method without mesh fixation between 2008 and 2014 in the Department of General, Oncological and Minimally Invasive Surgery in the Zeromski Hospital in Krakow was performed. Demographic data (age, gender), type of hernia, length of surgery, peri-operative and post-operative complications and length of hospital stay were analysed. In 2018, a telephone survey was performed and the quality of life of the patients and the rate of recurrence were noted. The quality of life was assessed by the Carolinas Comfort Scale and the polish version of the Short Form 36 (SF-36) (T.J.P.R., 2009). CCS is a short form consisting of 8 questions designed to assess the comfort of patients after surgical hernia repair with mesh implantation. CCS implements a scale of 0 points (no symptoms) to 5 points (symptoms compromising normal activity), and assesses the conscious feeling of the mesh by the patient, level of pain and impairment of movement. The maximum score is 115 and means the most severe pain. The polish version of the SF-36 is an adopted to polish conditions American scale meant for general quality of life assessment. It consists of 36 statements focusing on physical and mental aspect of life (0 to 171 points). The higher the score, the worse the quality of life. Using the SF-36, one can also assess the physical (0-103) and the mental (0-68) aspect of life separately. Again, the higher the score, the worse the quality of life. The data was gathered in the MS Excel, and statistical analysis was performed with the StatSoft Statistica 13.3.

The operation technique was standardised and repetitive in all procedures. The procedures were performed by general surgery specialists only. The patients were instructed to empty the urinary bladder before surgery, Foley catheters were not used. All procedures were performed under general anaesthesia in the Trendelenburg position. 1.2-2cm incision underneath the belly button was performed, then the frontal rectus sheath was cut. After preparing the rectus muscles, a pre-peritoneal space was created using the Herloon balloon (B-Braun Aesculap). Two working

ports were installed: one in the middle of the line connecting the belly button and the pubis and the other over the anterior superior iliac spine on the operating side (Figure 1).

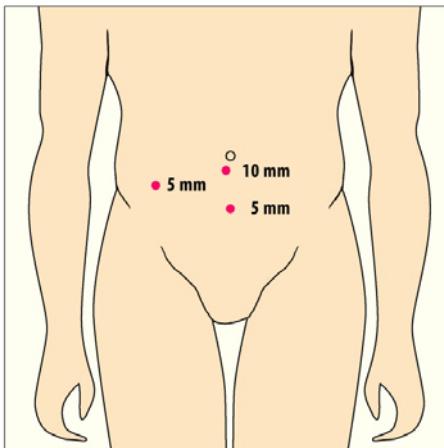


Fig. 1. Port placement during the TEP procedure

After identifying the landmarks (inferior epigastric vessels, pubic bone and the spermatic cord) the space aside the spermatic cord and above the ilio-lumbar muscle was prepared and the hernia sack was then separated and escorted back into the abdomen. 0.25% solution of Bupivacain was injected in the periperitoneal space. The meshes implanted were no bigger than 10×15 cm (Bard 3D Max, Optilene Aesculap, TEC Medtronic). Meshes were not fixated to surrounding tissues. The CO₂ was evacuated from the pre-peritoneal space under visual control to avoid sliding of the peritoneum under the mesh.

Results:

278 patients between 2008 and 2014 were qualified for hernioplasty using the TEP method. In 13 (4.5%) cases a conversion to a different method was recorded. In 10 cases (3.5%) the Lichtenstein operation was performed, and in 3 (1%) the TAPP surgery was performed. The total of 313 hernioplasties were performed: in 243 (87%) of the patients

a unilateral procedure was performed and in 35 (13%) patients a bilateral hernioplasty was performed. 296 hernias were primary hernias (no surgical procedure in the past) and 17 were recurrent hernias. All patients with recurrent hernias had previously had a classical open hernioplasty with or without mesh implantation. The mean age of the patients was 48 years. In the study group there were 16 (5.7%) women and 262 (94.3%) men. 79% percent of the patients had direct hernias, 19% indirect hernias and 2% had femoral hernias. The shortest length of surgery was 20 minutes and the longest was 135 minutes. The mean length of surgery in unilateral hernias was 48 minutes and did not change over the years. The mean length of surgery in bilateral hernias was 5 minutes longer. The mean hospital stay was 2.5 days (the day of surgery was considered as day 1) and was reduced over the years. Currently most of the patients are discharged from the hospital on day 1 post surgery (table 1 and 2).

Table 1. Demographic data

		n	Min	Max	Mean	±SD
Age	Female	16	27	69	47,2	7,21
	Male	262	19	78	48,3	6,26
	Together	278	19	78	48,2	6,32
BMI	Female	16	18	36	27,4	9,12
	Male	262	18	40	28,1	8,13
	Together	278	18	40	29,9	8,20
Length of stay	Female	16	1	3	2,3	1,73
	Male	262	1	5	2,2	1,42
	Together	278	1	5	2,2	1,31

Table 2. Type of hernia

Ethiology		Localization		Anatomy		
Primary	Recurrent	Unilateral	Bilateral	Indirect	Direct	Femoral
296 (93,9%)	17 (6,1%)	243 (87,4%)	35 (12,6%)	86 (30,9%)	190 (68,3%)	2 (0,8%)

In the study group no significant perioperative complications were noted. In 14 (5.03%)

cases post-surgical complications were noted. The most common were seromas/heamatomas, oedema and pain in the early postoperative period (table 3). All patients had a check-up visit on day 7 post-surgery. The level of pain, ability to get back to work and wound healing were assessed.

Table 3. Postoperative complications

Complication	n	%
Wound infection	2	0.72%
Urinary retention	4	1.44%
Seroma	4	1.44%
Heamatoma	2	0.72%
Pain on day 7 post surgery	12	4.32%
Subcutaneous oedema	6	2.16%
Pleural oedema	3	1.08%

In June 2018 a telephone survey was performed among the study participants. The answers were gathered from 98 (35.2%) patients, which accounted for 112 (35.7%) hernioplasties. All patients were assessed using the standardised questionnaire for the recurrence of the hernia as well as the SF-36 and CCS scales.

The mean follow-up time was 61 months (5 years and 1 month). The longest was 111 month (9 years and 3 months) and the shortest was 42 months (3 years and 6 months). In the study group, 2 (2%) out of 98 patients reported a recurrence of the hernia on telephone check-up. In both cases the original procedure was for primary direct hernia. In one patient the recurrence appeared 6 months post surgery and in the other one it occurred 8 years after surgery.

The mean score in the CCS scale was 3.4 points. 57 (58%) reported the CCS score at 0, that is no pain, no movement impairment and no discomfort from the mesh. In another 32 (33%), the score was below 10. Only 8 (8%) patients scored between 10 and 30 points. In 1 patient the CCS score was 80. Most patients (34) reported pain during physical activity, the least patients (4) reported pain while seating. The pain was mostly mild, with scores of 1 and

2 points in 94 and 62 patients respectively. No patient reported pain at the level of 5 points. 87 patients complained of discomfort from the mesh, 78 of pain in the groin, 31 reported movement impairment.

Table 4. Quality of life of patients on follow-up

CCS (mean)	3.4
SF-36 (mean)	38.9
SF-36 mental (mean)	9.5
SF-36 physical (mean)	7.0

The mean SF-36 score was 38.9, which is 23% of the maximum score. In the mental aspect the mean score was 9.5 points (14%) and in the physical aspect it was 7 (7%). 75 patients recorded the mean SF-36 score between 0 and 50 points. Only 20 patients reported the mean score between 50 and 100 points. 3 patients scored more than 101 points (table 4).

Discussion

In our study we showed that patients undergoing the TEP procedure without mesh fixation are at low risk of hernia recurrence and report good quality of life post-surgery. Our results correspond with the available literature.

As already mentioned, the most controversial aspect of the TEP method is the mesh fixation. In many hospitals no fixation is used, in others mesh fixation is a routine procedure. In a metaanalysis performed by Tam in 2010, no statistical difference was shown between fixating and not fixating the mesh in terms of recurrence rate, as well as sharp and chronic postoperative pain (Tam KW, 2010). Buyukasik reported higher complication rate after mesh fixation (pain, need for opioids) with no benefit in terms of recurrence rate (Buyukasik K, 2017). Moreover, Sajid showed in a metaanalysis that not fixating the mesh reduces the risk of nerve damage (genital branch of the ilio-genital nerve and the femoral lateral cutaneus nerve) (Sajid MS, 2010). In a randomised clinical trial Taylor showed that mesh fixation is associated with bigger risk of post-operative pain (Taylor C, 2008). In our study, pain

or discomfort in the surgical site are present in a very low number of patients, and those symptoms are rather mild (1–2 points in CCS). More than 50% of our patients remain symptom free after surgery. The most popular indicator in assessing the hernia repair techniques is the recurrence rate. Not fixating the mesh does not increase the recurrence rate in those patients. According to available literature, it is between 0.3 and 3% (Lien MS, 1997; Toma H, 2015; Tolga Aliyazicioglu 2017; Golani S, 2016).

In our study the recurrence rate was 2%. It appeared in 2 patients, both with direct hernias. One was noted 6 months post surgery and the other one 8 years post surgery. Lack of proper preparation of the preperitoneal space, insufficient experience, improper size of the mesh may lead to increase in recurrence rate. Currently, according to EHS, fixation of the mesh is only recommended in large medial hernias.

Quality of life remains one of the most important parameters to be assessed after surgery. There are many tools for that; in our study we decided to use the SF-36 and the CCS scales. The laparoscopic procedure (TEP or TAPP) offers better QoL in comparison to open techniques. Patients suffer from less acute pain and less chronic pain, are discharged home earlier (Simons MP, 2009; Bittner R, 2005). Our study showed good lever of QoL of our patients in terms of surgical site discomfort and general QoL. Bansal and Meyers also showed better QoL in patients after laparoscopic hernia repair (Bansal VK, 2017; Tam KW, 2010).

A strong side of our study is a long follow-up period of up to 9 years post surgery and the assessment of QoL using standardised tools allowing inter-research comparison. The limitation of the study is a low number of patients that completed the telephone survey. More accurate data collection is needed in future studies.

Conclusions

Hernia repair using the TEP method without mesh fixation is a safe and effective method of treatment of inguinal hernia, with low recurrence rate and good quality of life post surgery.

References

- Aliyazicioglu T, Laparoscopic total extraperitoneal (TEP) inguinal hernia repair using 3-dimensional mesh without mesh fixation, *Surg Laparosc Endosc Percutan Tech*, 27: 282–284, 2017.
- Bansal VK, A prospective randomized comparison of testicular functions, sexual functions and quality of life following laparoscopic totally extra-peritoneal (TEP) and trans-abdominal pre-peritoneal (TAPP) inguinal hernia repairs, *Surg Endosc*, 31: 1478–1486, 2017.
- Bittner R, Comparison of endoscopic techniques vs Schouldice and other open non-mesh techniques for inguinal hernia repair: a meta-analysis of randomized controlled trials, *Surg Endosc*, 19: 605–615, 2005.
- Buyukasik K, Comparison of mesh fixation and non-fixation in laparoscopic totally extraperitoneal inguinal hernia repair, *Hernia*, 21: 543–548, 2017.
- Garg P, Mesh fixation comparing to non-fixation in total extraperitoneal inguinal hernia repair: a randomized controlled trial in a rural center in India, *Surg Endosc*, 25: 3300–3306, 2011.
- Garofalo F, Total extraperitoneal hernia repair: residency teaching program and outcome evaluation, *World J Surg*, 41: 100–105, 2017.
- Golani S, Long-term follow up of laparoscopic total extraperitoneal (TEP) repair in inguinal hernia without mesh fixation, *Hernia*, DOI 10.1007/s10029-016-1558-7, 2016.
- Lien MS, Comparison of conventional anterior surgery and laparoscopic surgery for inguinal hernia repair, *N Eng J Med*, 336:1541–1547, 1997.
- Meyers E, Laparoscopic (TEP) versus Lichtenstein inguinal hernia repair: a comparison of quality of life outcomes, *World J Surg*, 34: 3059–3064, 2010.
- Sajid MS, A meta-analysis examining the use of tacker fixation versus non-fixation of mesh in laparoscopic inguinal hernia repair, *Int J Surg*, 10: 224–231, 2010.
- Schjøth-Lversen L, Factors associated with hernia recurrence after laparoscopic total extraperitoneal

- repair for inguinal hernia: a 2 year prospective cohort study, *Hernia*, 21: 729:735, 2017.
- Sharma A, Endo-laparoscopic inguinal hernia repair: What is the role?, *Asian J Endosc Surg*, 10: 111–118, 2017.
- Simons MP, European Hernia Society guidelines on the treatment of inguinal hernia in adult patients, *Hernia*, 13: 343–403, 2009.
- Suguita FY, Learning curve takes 65 repetition of totally extraperitoneal laparoscopy on inguinal hernias for reduction of operating time and complications, *Surg. Endosc.*, 31: 3939–3945, 2017.
- T.H. Group, International guidelines for groin hernia management, *Hernia*, 22: 1–165, 2018.
- T.J.P.R., Kwestionariusz oceny jakości życia SF-36 – wersja polska, *Kardiologia Polska*, 67:10, 2009.
- Tam KW, Outcomes of staple fixation of mesh vs. non-fixation in laparoscopic total extraperitoneal inguinal repair: a meta-analysis of randomized controlled trials, *World J Surg*, 34: 3065–3074, 2010.
- Taylor C, Laparoscopic inguinal hernia repair without mesh fixation, early results of large randomized clinical trial, *Surg Endosc*, 22: 757–762, 2008.
- Tolga Aliyazicioglu, Laparoscopic total extraperitoneal (TEP) inguinal hernia repair using 3-dimensional mesh without mesh fixation, *Surg Laparosc Endosc Percutan Tech*, 27: 282–284, 2017.
- Toma H, A 10 year experience of totally extraperitoneal endoscopic repair for adult inguinal hernia, *Surg Today*, 45:1417–1420, 2015.