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Postoperative Outcomes and Patients' Satisfaction after Hybrid TIPP with UHS and TEP Repair for Inguinal Hernias: A Single-Centre Retrospective Comparative Study

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Rezumat

Rezultate postoperatorii și satisfacția pacienților după TIPP hibrid cu UHS și tehnica TEP pentru hernii inghinale: studiu retrospectiv comparativ a unui singur centru

Generalități: Cura herniilor inghinale prin procedeele transabdominal preperitoneal (TAPP) şi total extraperitoneal (TEP) sunt recunoscute pentru scăderea riscului de durere cronică postoperatorie şi cu rate de recidivă acceptabile. Totuşi procedeele hibrid/combinate încă sunt o opțiune semnificativă în rândul chirurgilor. Scopul este de a compara tehnicile hibrid TIPP (hTIPP) folosind sistemul Ultrapro Hernia® (UHS) şi TEP privind rezultatele şi satisfacția pacienților şi de a analiza siguranța şi eficiența celor două procedee.
Materiale şi Metode: Nouăzeci de pacienți care au fost operați între anii 2013-2017 pentru hernie inghinală prin procedeele hTIPP sau TEP la spitalul Naas General Hospital, Irlanda au fost incluşi într-o bază de date şi analizați într-un studiu retrospectiv.
Rezultate: Internarea postoperatorie neplanificată a fost comparabilă între cele două grupuri (3 pacienți pentru hTIPP şi 3 pacienți pentru TEP). Nu a fost nicio diferență statistică între complicațiile imediat şi tardiv postoperatorii. Rata de recidivă a fost nulă în grupul hTIPP comparativ cu TEP unde a existat o recidivă. Pe baza chestionarului PROM şi scalei Likert, nu există diferențe statistic semnificative privind satisfacția pacienților între hTIPP şi TEP.

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Concluzii: Nu există diferență statistic semnificativă privind rata de complicații şi satisfacția pacienților între hTIPP şi TEP. hTIPP este un procedeu sigur şi o alternativă validă.

Cuvinte cheie: UHS, TIPP, TEP, hernii, chirurgie laparoscopică

Abstract

Background: Transabdominal Preperitoneal (TAPP) and Totally Extraperitoneal (TEP) inguinal hernia repairs are largely acclaimed for their lower risk of chronic postoperative pain and acceptable recurrence rates. However, hybrid/combined open procedures are still a reliable option among surgeons. Our aim is to compare the outcomes and patients' satisfaction of hybrid TIPP (hTIPP) procedure using the Ultrapro Hernia System® with laparoscopic pre-peritoneal mesh repair approaches (TEP) to assess its safety and effectiveness.

Patients and Methods: The study design is a single center, retrospective comparative study on 90 patients who had hTIPP and TEP inguinal hernia repair in the NAAS General Hospital, over a four-year period (2013-2017).

Results: Unplanned postoperative hospital admission was comparable both groups, the figures were 3 patients for hTIPP and 3 patients for TEP. There was no statistically significant difference in the immediate, early and late postoperative pain and complications in both groups. The recurrence rate was nil in hTIPP group compared to one recurrent case in TEP. There is no statistical difference in the five outcomes of the PROM questionnaire and satisfaction rate between hTIPP and TEP.

Conclusions: There is no significant difference between hTIPP and TEP in terms of postoperative outcomes and patient satisfaction. hTIPP approach is a safe and feasible alternative to TEP.

Key words: UHS, TIPP, TEP, hernia; laparoscopic surgery

Introduction

Hernia Repair is one of the fields that profited the most from the technological advancement in surgery (1,2). Ever since Wallace Carothers introduced synthetic polymers (3-5), the use of mesh repair has been adopted by many as the gold-standard technique.

Once the "Era of laparoscopic surgery" was ushered in, many laparoscopic surgical techniques were described and used in hernia repair. The most popular are the transabdominal preperitoneal [TAPP] or the totally extraperitoneal [TEP] procedures. When compared to Lichtenstein procedure, studies showed that laparoscopic approaches are associated with fewer complications, less postoperative neuropathic pain and fewer recurrences (6-16).

Even though laparoscopic approach is increasingly embraced by surgeons worldwide, open and hybrid techniques are still frequently used, especially in low-income countries. One of them, the Gilbert technique, is used as a standard open procedure in our department. First developed and assessed by Gilbert, the Ultrapro Hernia System® (UHS) from Ethicon® is a bilayer mesh capable of reinforcing the inguinal canal on both sides, anteriorly and posteriorly, through an open approach, thus reducing the risk of recurrence. This technique merges the advantages of classic TIPP repair (17,18), with placement of one layer of the mesh in the preperitoneal space, and of Lichtenstein repair as the other layer of the mesh is applied anteriorly after being fashioned with a slit to accommodate the spermatic cord. By using the UHS, we will describe this technique as hybrid TIPP (hTIPP) due to the dissection similarity with the TIPP technique, however using this mesh the stability of the repair is improved by

an anterior fixation of the second layer of the mesh and through this anterior approach this technique is modified (hybrid) in comparison to classic TIPP or Lichtenstein. It is basically a merge between the two.

The aim of the study is to compare the hTIPP and TEP techniques in terms of post-operative complications and the overall patients' satisfaction rates. The secondary endpoints are to compare operative time and other postoperative outcomes such as the need for post-operative admission, and time to return to daily activities.

Patients and Methods

The study design is a single center, retrospective comparative study. It adopted a retrospective survey methodology to compare the post-operative outcomes of hTIPP and TEP inguinal hernia repair in NAAS General Hospital, over a four-year period (2013-2017) (*Fig. 1*).

Inclusion criteria:

- Adult patients with an inguinal hernia who had TEP or hTIPP repair for unilateral inguinal hernia.
- Willing to be involved in the study .
- ASA less than 4.

Exclusion criteria:

- Bilateral repair.
- High ASA grade (4,5).
- Previous preperitoneal dissection or pelvic radiotherapy.

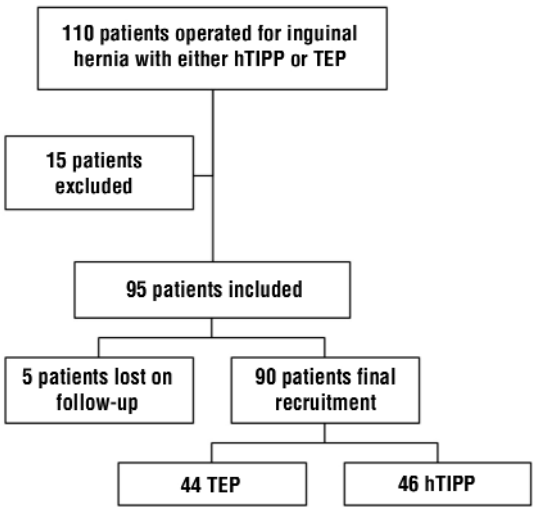

Figure 1. Flow chart showing the patients selection process

- Pediatric age group (< 16 years).
- Unwilling to participate in the study.

Patients were not randomly assigned to these procedures. Each patient was selected for the appropriate procedure based on hernia size, body mass index and the patient's/consultants' preference. Thus, in advanced hernias, mostly in scrotal hernias, the procedure of choice was hTIPP as these cases are more difficult to manage laparoscopically. From this point of view the two groups are not homogenous.

The authors modified Bendavid classification (TSD) (*Table 1*) to fit our research purpose. In the original Bendavid classification, which consist of three variables TSD, the letter T and

Table 1. Modified BENDAVID Classification. Diameter size was omitted because it was not measured during the procedures

BENDAVID Classification	Modified BENDAVID Classification
(T) TYPE	**(T) TYPE**
• Type I: Indirect	Type I: Indirect
• Type II: Direct	Type II: Direct
• Type III: Femoral	Type III: Femoral
• Type IV: Posterolateral (Prevascular)	Type IV: Posterolateral (Prevascular)
• Type V: Anteroposterior (Inguinofemoral)	Type V: Anteroposterior (Inguinofemoral)
(S) STAGE	**(S) STAGE**
• Stage I: From DR* to SR**	Stage I: From DR to SR
• Stage II: Beyond SR	Stage II: Beyond SR
• Stage III: Reaches into scrotum	Stage III: Reaches into scrotum
(D) DEFECT SIZE	**Primary versus Recurrent**
• D: Diameter of hernia defect in millimetre	P: Primary Hernia
	R: Recurrent hernia

*DR – deep ring, **SR – superficial ring

S indicate the type and stage of hernia respectively. However, the letter P/R has been added to the TSD classification which indicates primary repair or recurrent hernia. The defect size (D) parameter was omitted. The rationale is to facilitate comparing the hernia stage between the two groups. Also, as the study is a retrospective one and as the defect size was not used at the initial classification, D could not be included in this study. The diameter of the defect was not measured during the open procedures and measurement would have been difficult in the TEP cases. We opted for the Bendavid classification after analyzing the clinical notes of all patients. The data acquired was easily used in Bendavid classification. We did not have enough clinical data (hernia size in centimeters or fingerbreadths) to use other classifications.

Data Collection

A standardized form was used for data collection. To maintain the anonymity and confidentiality, patients' MRN (medical record numbers) and names were coded during data collection and analysis. Patients' demographics, hernia type and stage based on modified Bendavid classification and postoperative variables were collected retrospectively from the patients' records such as admission note and operative report.

The median follow-up period was 32 months (range 6-56) for hTIPP and 19 months (range 9-24) for TEP. The immediate and early post-operative pain was assessed based on reviewing the patients' record such as day-ward discharge note and follow-up clinic note. In our institute, Verbal Rating Scale (VRS) is used for all postoperative patients to assess level of pain before discharge and on follow-up. Patients were asked to scale their pain from one (least) to ten (unbearable pain)

Patient satisfaction was assessed via Patient Reported Outcome Measures (PROMs) questionnaire (*Table 2*) and by using Likert scale to provide quantitative data which was further analyzed via Chi square test and Mann-Whitney Test *(Table 2)* (19-27). The patients were evaluated using the PROMs questionnaire at their clinic follow-up, once the study was implemented. The questionnaire was applied at least 6 months after the surgery (minimum follow-up period). As it is a retrospective study, the questionnaire was applied depending on the moment of follow-up, starting from 6 months to 56 months.

Table 2. Patient reported outcome measures

The Five Variables of the PROM questionnaire		hTIPP	TEP	p value*
		No.	No.	
PAIN Discomfort	I have a lot of pain/discomfort	3	4	
	I have some discomfort	7	3	0.425
	I have no pain/discomfort	36	37	
Mobility	I have a lot of problems walking	1	3	
	I have some problems walking	7	7	0.555
	I have no problems walking	38	34	
Looking after myself	I have a lot of problems	0	0	
	I have some problems	3	2	0.682
	I have no problems	43	42	
Doing daily activities	I have a lot of problems	1	0	
	I have some problems	5	3	0.480
	I have no problems	40	41	
Feeling worried	I am very worried	1	1	
	I am a bit worried	1	4	0.357
	I am not worried	44	39	

*Chi-square test. Each variable from each of the five outcomes was scored from 1 to 3.
The resulting numerical data for each outcome was analyzed using order to compare the two techniques, hTIPP and TEP.

Hybrid TIPP Surgical Technique

The procedure can be performed under spinal or general anaesthesia based on the patients, general condition and the pre-assessment teams' decision. The procedure was performed as described by Gilbert et al (28,29). A 3-4 cm skin incision is usually performed parallel to inguinal ligament, 3 cm above the deep inguinal ring. Access of the inguinal canal is achieved by sharp dissection of Scarpa's facia and the anterior wall of the inguinal canal. Minimal dissection to mobilize the spermatic cord is performed with identification of the hernia sac(direct/indirect). The indirect hernia sac is dissected of the spermatic cord and resected; however, the direct hernia sac can be reduced without resection as in classical Lichtenstein repair. The preperitoneal space then entered through the deep inguinal ring using atraumatic dissection and different size of retractors. The authors suggested that the diathermy dissection is not necessary and highly unrecommended during preperitoneal dissection. Sweeping of the index finger just underneath the floor of inguinal canal toward the pubic tubercle can be used for this purpose. Continue this dissection laterally toward Cooper ligament over the iliac vessels and toward the lateral triangle. Next, the index finger started at the pubic tubercle sweep under the aponeurotic arch and epigastric vessels, separating the preperitoneal fat from the muscle layer and transversalis facia. Once the dissection is complete, a 10 cm *10 cm gauze can be inserted completely into the space through the deep inguinal ring to maintain the dissected space.

Identification and careful retraction of superior epigastric vessel is essential. Medial dissection of preperitoneal space up to Retropubic space (Retzius' space) and down to femoral and obturator orifices is essential for complete evaluation of preperitoneal space and exclude another hernia sac. Bogros' space can also be dissected to utilize the preperitoneal space to accommodate the lateral part of the mesh.

Direct visualization of preperitoneal space can be achieved by gentle retraction of transversalis abdomens muscle. However, digital examination of the retroperitoneal area can also be used for full assessment.

The UHS is pre-shaped, three-dimensional system consisting of an on-lay patch, a mesh cylinder and an underlay patch. The underlay part of the mesh was folded before insertion of the mesh into preperitoneal space through the internal ring. Surgical manipulation was used for proper deployment of the underlay part of the mesh and for confirming the proper expansion and the entire covering of the myopectineal orifice (MPO). The onlay part of the mesh was used to cover and reinforce the floor of the inguinal canal. Modification of the onlay mesh is essential to accommodate the cord structure which is achieved by creating a small slit in the mesh. The onlay part of the mesh was fixed with interrupted absorbable sutures with the longer side of the onlay being positioned parallel to the inguinal ligament.

TEP Surgical Technique

A preperitoneal access was achieved through a small sub umbilical incision. A space was created using a balloon spacer with 30-degree camera lens. Two 5 mm ports are inserted in the midline under direct vision. Tunnelling technique of retroperitoneal dissection was adopted in our centre. The hernia sac (direct or indirect) is identified and reduced. A 3D max mesh was then applied and fixed using 3-5 tacks. The mesh size was dependent on surgeon preference.

Statistical Analysis

The statistical analysis was performed with the IBM-SPSS 22.0. Categorical data were compared using the Chi-square test; however, the continue variables and scale were compared using Mann–Whitney U test since most of the data was not normally distributed.

Ethical Approval

The study was conducted in Naas General

Hospital, Department of General Surgery, Ireland. The study was approved by the local ethical committee. The patients were informed about the nature and the purpose of the study and all provided verbal informed consent before being involved in the study.

Results

After applying pre-set criteria, 90 patients were recruited for the study: 46 patients had hTIPP repair and 44 got TEP repair (*Fig. 1*).

Statistical tests such as Mann-Whitney test and Chi-square test were used to compare preoperative patients' characteristics. Preoperative patient characteristics were assessed via Mann-Whitney and Chi-square tests. Mann-Whitney test showed a statistically significant difference in the median age between hTIPP and TEP [median = 63 (range 32-87) and. 46 range (34-86) respectively, p<0.001]. No difference existed in gender distribution and the incidence of previous surgery.

There is significant difference in type of anaesthesia between the two groups. In hTIPP group 37 patients had general anaesthesia (GA), and 9 had a spinal/epidural block. However, all the patients in the TEP arm had the surgery under GA (p=0.008).

Considering hernia type, In the hTIPP group 27 suffered from indirect hernia (T1) and 19 patients from direct inguinal hernia (T2) with 6 patients being treated for recurrence after previous repair (R). However, in TEP group, the figures were 33 patients for indirect hernia (T1) compared to 11 patients for direct inguinal hernia (T2) with 4 patients being treated for recurrent hernia (R) (*Table 3*). Statistically, there is no difference in hernia type and in rate of repair for recurrent hernia p=0.101 and p=0.551 respectively.

In terms of hernia size (S), the overwhelming majority of hTIPP group had S2 or S3 size of inguinal hernia, 28 patients and 12 patients respectively. In contrast, in TEP group, only 12 patients had S2 and merely 2 patients were complaining of S3 hernia. As a result, the number of patients with S2 and S3 were significantly higher in hTIPP group than for TEP repair (p<0.001) (*Table 3*).

The median of operative time for the hTIPP group was 45 min (range 30-48) and 40 min (range 35-43) for TEP but the difference was not statistically significant.

In the hTIPP group, 29 patients were treated as a day case compared to 39 patients in TEP group. Nine patients in the hTIPP group and 2 of TEP patients were treated as Day-Of-Surgery Admission (DOSA). Unplanned postoperative hospital admission was similar in TEP and hTIPP group, the figures were 3 patients in hTIPP arm and 3 patients in TEP arm (p=0.12).

There was no statistical significant difference in the median of the postoperative stay length of both arms. The median was 12 (range 8-28) hours for hTIPP and 14 (range 9-21) hours for TEP (p=0.069).

The median follow-up period for hTIPP was 32 (6-56) months while in TEP group was 19 (9-24) months. The median of immediate

Table 3. Comparison of hernia stages in the two groups

		hTIPP	TEP	p value*
		No.	No.	
Hernia type	T1: Indirect	27	33	
	T2: Direct	19	11	0.101
	T3: Femoral	0	0	
Hernia Size	S1: From DR to SR	6	30	
	S2: Beyond SR	28	12	<0.001
	S3: Reaches into scrotum	12	2	
P/R	Recurrence	6	4	0.551
	Primary	40	40	

*Chi-Square was used to compare different hernia types, according to Bendavid classification, between the two techniques

postoperative pain (VRS score within 24 hours post-operatively) of hTIPP and TEP groups were 3 (range 1-7) and 3 (range 1-7) (p=0.785).

The immediate complications rate was minimal in both groups: 8.7% after hTIPP compared to 6.8% after TEP. The early complications rate was 10.5% and 9.1% respectively. Late complications were 8.7% for hTIPP versus 6.8% for TEP.

In the immediate complications of hTIPP, two patients had urine retention requiring urinary catheter insertion for about 12 hours. One of them is a known case of BPH on regular treatment, the other had a pelvic ultrasound confirmed prostate hypertrophy. Both had the surgery under spinal anaesthesia which can explain the cause of urine retention beside the BPH. The third patient developed bronchospasm during the recovery, while the fourth patient had severe postoperative pain required admission for PCA.

For TEP group, during the immediate period, 2 patients had severe pain required postoperative admission and the third had urine retention.

During the early period, 2 patients of the hTIPP group had testicular pain on the ipsilateral side of the surgery, ultrasound was normal, and the patient were treated conservatively without significant sequelae. The other 2 patients had pain on the surgery site demanding analgesia for longer duration. The fifth patient developed subcutaneous wound seroma confirmed by ultrasound without any evidence of wound infection.

However, for the TEP group, 2 patients had groin pain requiring analgesia for longer duration. One had ipsilateral testicular pain with normal ultrasound study. The fourth had ipsilateral testicular swelling with mild hydrocele confirmed by ultrasound that resolved without surgical intervention. The late complication for hTIPP patients is mainly inguinal discomfort/ chronic pain that did not required long-term treatment and without significant impact on the daily activities. The figures were 3 patients for the hTIPP and 4 patients for TEP and there are no significant differences between the groups (p=0.740).

The recurrence rate was nil in hTIPP group and one recurrent case in TEP group.

Based on the PROM questionnaire, there is no significant difference in the five outcomes of the PROM questionnaire between hTIPP and TEP based on Chi Square Test (*Table 2*). Based on Likert Scale, there is no significant difference in the satisfaction rate. The median of the overall satisfaction rate was 10 (range 4-10) for the former and 10 (range 4-10) for the later.

Discussion

Both procedures have the same principle which is to repair the hernia defect via placing a mesh into the preperitoneal space. However, the hTIPP uses the open anterior approach while the TEP is adopting the laparoscopic total extra-peritoneal approach (posterior approach).

Our study is significant in current literature as it compares the results of two techniques adopting the same principles yet using two completely different approaches. Based on our literature review, there is no previously reported comparison between these two techniques.

By adopting the principles of patient-centered care, patient satisfaction is an essential indicator for measuring the clinical outcomes. However, it has been completely ignored in the previous studies. If it is properly evaluated for both techniques, it could influence the surgeons' future decision for hernia repair approach.

Although the author agreed that non-inferiority RCT is more significant to evaluate the two techniques, this retrospective single-center study can form the basis for such a future trial.

The immediate complications rate was minimal in both groups with a low VRS pain score during this period. As a result, the need for overall postoperative admission was low. The overwhelming majority of patients were treated as a day case procedure and discharged within 4-12 hours after the surgery. A small percentage of patients were

kept in overnight due to underlying comorbidities not for surgical related complications. The unplanned postoperative hospital admission rates were comparable and reasonably low. Frederik and colleagues showed approximately similar rates of postoperative admission mainly because patients developed acute urinary retention (12).

Interestingly postoperative urinary retention was low in both groups in comparison to previous trials (12,27). On reflection, this can be explained by rise in awareness of urine retention after hernia repair. No patient was assessed preoperatively by urologist and alpha 2 blockers weren`t given prophylactically.

The immediate postoperative VRS pain score was significantly low and similar in both groups. This finding contradicts Gunnel (31) and Hamza (32) RCTs findings. Both confirmed that postoperative pain was statistically lower in laparoscopic approach compared to open technique. However, a recent meta-analysis showed there was no difference between the two techniques (33).

The early and late complications were statistically similar. They consist mainly of postoperative discomfort which does not cause a significant impact on the daily activities and none of those patients required long-term treatment.

Theoretically, local early complications such as wound seroma, haematoma, and testicular swelling are supposed to be more common in open procedure such as hTIPP compared to laparoscopic approach such as TEP (34). However, in our retrospective study, the incidence of these local complications in the open procedure was not significantly different from the TEP repair. This finding is coherent with Sajid's recent meta-analysis study (33) and X. Feliu's prospective trial (30).

Patient Reported Outcome Measures (PROM) analysis shows that patients from both groups reported significant gains in the outcomes. This finding was validated by high patients' satisfaction rate after both operations (*Tables 2, 3*). Our finding emphasizes the need for further research on patient satisfaction following hernia surgery as currently there are no trials analysing this.

Patients were not randomized. Each patient was selected for the appropriate procedure based on hernia size, body mass index and the patient's/consultants' preference. Although it can be argued that this is a kind of selection bias which may eventually affect the study's results; the author suggests that the fundamental notion in daily practice is to select the appropriate procedure for specific patients. It can be considered as an indication rather than selection bias.

Despite the hTIPP group had elder patients with more advanced hernias, compared to TEP group, the outcomes were comparable. Based on these findings we cannot assume the hTIPP is superior or non-inferior to TEP procedure since the study was not designed to admit this. However, we can suggest outcomes are comparable and as safe as TEP technique.

The retrospective assessment of post-surgical pain can be a source of recall bias. However, for this reason a retrospective reviewing of the patients' record such as day-ward discharge summary and follow-up clinics notes was done. Degree of postoperative pain was primarily collected from the record; however, it was revalidated with patients on outpatient follow-up.

Conclusions

There is no significant difference between hybrid TIPP using UHS and TEP approaches in terms of immediate postoperative pain, satisfaction rate (PROM score) and the recovery time. As a result, we can conclude that hTIPP open approach may be a safe and feasible alternative to TEP procedure with comparable postoperative complications and high patients' satisfaction rate.

Authors Contribution

Muthana Haroon, Stefan Morarasu:

- Surgical team;
- Study design;
- Statistical analysis;

- Manuscript preparation.

Osama Al Sahaf, Emmanuel Eguare:

- Consultant surgeons;
- Supervision of study design and manuscript;

Pedro Wagner, Rushi Batt, Kasi Subramanian, Chinenye Santina Anike-Nweze, Revathy Ponniah, Fiona O'Riordan:

- Surgical team;
- Data collection;
- Follow-up of patients.

Conflict of Interest

We declare no conflict of interest.

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