



# Laparoscopic transabdominal preperitoneal technique versus open surgery with the ULTRAPRO Hernia System for the repair of female primary femoral hernias—an observational retrospective study

Dongfeng Chen, MD, Nana Su, MD, Weijia Wang, MD, Zhaoyong Zhang, MD, Mingxiao Guo, MD, Chunlei Lu, MD, Haifeng Zhang, MD\*

#### Abstract

Femoral hernias (FHs), predominantly seen in females, require surgery for cure. To date, surgical repair of primary FHs in female patients with either open surgery or laparoscopic operation has been poorly documented. We retrospectively investigated the treatment of female primary FHs with open surgery using the ULTRAPRO Hernia System (UHS procedure) or the laparoscopic procedure, namely, the transabdominal preperitoneal (TAPP) technique. A total of 41 female patients with primary FHs who had undergone UHS or TAPP were included in this study. The procedural parameters, post-surgical complications, treatment expense, and follow-up results were analyzed. The vast majority of patients (39/41) underwent elective operations: 15 received UHS (including 2 emergency cases) and 26 had TAPP (P=.08). The UHS group had a greater average age, due to the fact that FHs occur often in people with advanced age who tend to have systemic disease, limiting the use of general anesthesia required for TAPP. Compared with UHS, TAPP took a significantly shorter time to complete and patients undergoing TAPP had a dramatically shorter hospital stay. While no recurrence was observed in both groups, post-procedure pain and foreign body sensation were reported by significantly more patients in UHS group. The cost was greater with TAPP. Taken together, we concluded that both UHS and TAPP are effective in the management of female FHs. In view of the advantages and disadvantages between the open and the laparoscopic operation, surgeons can select a procedure according to their skills and patients' situation.

Abbreviations: FH = femoral hernia, TAPP = transabdominal preperitoneal, UHS = ULTRAPRO Hernia System.

Keywords: femoral hernia, surgical repair, transabdominal preperitoneal technique, ULTRAPRO Hernia System

## 1. Introduction

Groin hernias occur in approximately 4% of the population aged over 45 years and require surgery for cure.<sup>[1,2]</sup> There are 2 surgical procedures for the repair of hernia defects, namely the

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Department of General Surgery, Linyi People's Hospital, Linyi, Shandong Province, China.

\* Correspondence: Haifeng Zhang, Department of General Surgery, Linyi People's Hospital, No 27 Jiefang Road, Linyi 276000, Shandong Province, China (e-mail: zhanghaifenglinyi@yahoo.com).

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Received: 25 August 2018 / Accepted: 16 November 2018 http://dx.doi.org/10.1097/MD.000000000013575 open surgery and the laparoscopic technique.<sup>[2,3]</sup> The ULTRA-PRO Hernia System (UHS, Ethicon Inc., Somerville, NJ), a new generation of mesh for open repair surgery, consists of an onlay patch that is connected to an underlay patch by a mesh cylinder. This double layer property lends fewer sutures for fixation of the device during deployment, shortening time of the UHS procedure, reducing postoperative pain and/or discomfort, and decreasing recurrence rates compared with the Lichtenstein patch.<sup>[4–6]</sup> The laparoscopic procedure is mini-invasive, leading to faster recovery. To date, 2 frequently used laparoscopic procedures are the totally extra peritoneal (TEP) and the transabdominal preperitoneal (TAPP) techniques.<sup>[3,7]</sup>

There are 2 types of groin hernias, i.e, inguinal and femoral hernias (FHs) with inguinal hernias being the predominant ones seen in patients. FHs account for only 2% to 4% of all groin hernias,<sup>[8,9]</sup> and occur in both sexes but with the majority in females.<sup>[10–12]</sup> FHs are associated with a high risk of complications, and an elective surgical repair, rather than a watch-andwait approach, for newly diagnosed FHs has been recommended, regardless of the patient's sex and symptoms.<sup>[13–15]</sup> As FHs are uncommon, few studies have specifically compared the open surgery and the laparoscopic procedure in FH repair in the last decade.<sup>[16]</sup> Investigations focusing on female FH repair, in particular, have only been documented in case reports.<sup>[15,17,18]</sup> In this article, we present our experience in FH repair in 41 female patients with the UHS procedure or the TAPP operation. Specifically, we investigated determining factors for procedure

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selection, compared perioperative parameters and post-operative complications between these 2 methods.

## 2. Methods

#### 2.1. Ethical statement

This study was approved by the Medical Ethics Committee, Linyi People's Hospital with the waiver of informed written consent in view of the retrospective nature of the study.

#### 2.2. Study subjects

All female patients aged over 18 years with primary FHs who underwent surgery repair at our department during May 2012 to December 2016 were included in this study. All operations were performed by Dr D Chen, an author of this article who had over 5 years of experience in both open and laparoscopic procedures. Demographics, clinical outcomes including operative and postoperative/recovery data, and short- and medium-term outcomes of all patients were recorded.

#### 2.3. The UHS procedure

The UHS procedure was performed as described elsewhere.<sup>[19]</sup> Briefly, under continuous epidural block, an incision from a point 2 cm above the midpoint of the inguinal ligament to the pubic tubercle was made. After incision of the external oblique muscle aponeurosis, the inguinal ligament was dissected and the femoral ring was explored. The transversalis fascia was divided to gain access to the preperitoneal space. After identification of the hernia sac, it was separated, the contents in the sac were then reduced and the sac was ligated. Subsequently, sufficient space was created in the preperitoneal space by blunt dissection for the deployment of the USH mesh. The underlay patch of the device was spread to cover the entire myopectineal orifice; the onlay patch was placed over the transversalis fascia and fixed to the conjoint tendon and the inguinal ligament with single sutures. Closure of the peritoneum, aponeurosis, and skin was completed in a routine manner as with an open surgery.

#### 2.4. The TAPP procedure

General anesthesia was administered and tracheal intubation was performed. A small incision above the upper rim of the umbilicus was made, and the Verres needle was inserted to create pneumoperitoneum by CO<sub>2</sub> with an insufflation pressure set at 13 mm Hg. Afterward, the Verres needle was removed and a 10mm optical trocar was placed through the supra umbilical incision. A 30° telescope attached to the camera was introduced. Through the telescope, all anatomical landmarks were visualized and the hernia identified. After the FH was confirmed, a 5-mm operating trocar was placed 0.5 cm below the umbilicus at the lateral edge of the rectus abdominis on each side of the abdomen. The peritoneal incision was performed 2 cm above the inner ring of the femoral canal from anterior superior iliac spine to the medial umbilical ligament followed by dissection to separate the Retzius and Bogros (retroinguinal) spaces. The hernia sac was then identified, dissected using traction and contra-traction maneuvers, and reduced. If repeated attempts to reduce the hernia sac failed, the lacuna ligament was divided to release compression, and the hernia sac was then reduced. Afterward, the round ligament of uterus was lifted, a wide dissection was performed to create a space between the inner ring and the triangle of doom, where a  $10 \times 15$  cm polypropylene hernia patch was placed, cut and positioned to cover the entire myopectineal orifice, and the patch part overlapping the round ligament of the uterus was fixed to the ligament with fibrin glue. For fixation, the patch was also stapled to the pectineal ligament, rectus abdominis, and conjoint tendon. The peritoneum, aponeurosis, and skin were closed with absorbable sutures. Same procedure was performed if the FH was found on the other side.

#### 2.5. Follow-ups

A physical examination was performed 1 week and 1 month after patients were discharged. Telephone interviews were then conducted every 6 months in the first year and yearly thereafter.

### 2.6. Statistical analysis

Normality of continuous data was validated using the Shapiro–Wilk test and expressed as mean $\pm$ standard deviation (SD). The Student 2-tailed *t* test was used to determine the significant difference between means of 2 groups. Categorical data were analyzed with the Chi-square test. All statistical analysis was performed using the SPSS version 19.0 software (IBM, Armonk, NY). A *P* value <.05 was considered statistically significant.

## 3. Results

Toble 1

A total of 41 patients, aged 18–81 years, who had newly diagnosed FHs and underwent the UHS or TAPP procedures were included in this study. The vast majority of patients (39/41) underwent an elective operation. Of all patients, 15 received the UHS (including 2 emergency cases) and 26 took the TAPP procedure (P=.08). The UHS group had a greater average age compared to the TAPP group (P<.05), mainly because older patients had a significantly higher prevalence of cardiovascular disease, hypertension, and lung disease (Table 1), who were unsuitable for general anesthesia required for TAPP. All patients were classified as physical status II or III according to the American Society of Anesthesiologists Physical Status Classification System. The demographics and baseline clinical characteristics of all patients and follow-ups are summarized in Table 1.

Comparison of operative parameters between the 2 groups showed that there was no significant difference in bleeding during surgery between the 2 groups. However, the TAPP procedure was

Demographics,	clinical	characteristics	and	follow-ups	of	all
patients.						

UHS	TAPP	P value
15 (36.6%)	26 (63.4%)	.086
66.5±15.6	50.7±15.9	.037
$25 \pm 1.1$	24±1.8	.059
10 (66.7%)	15 (57.7%)	.570
10 (66.7%)	7 (26.9%)	.013
11 (73.3%)	9 (34.6%)	.017
3 (20%)	9 (34.6)	.526
10 (66.7%)	2 (7.7%)	.001
2 (13.3%)	1 (3.8%)	.616
2 (13.3%)	0	.248
0	0	
2.1 ± 0.8 (range 1-4)	2.4±1.1 (range 1-4)	.362
	$\begin{array}{c} 15 \ (36.6\%) \\ 66.5 \pm 15.6 \\ 25 \pm 1.1 \\ 10 \ (66.7\%) \\ 10 \ (66.7\%) \\ 11 \ (73.3\%) \\ 3 \ (20\%) \\ 10 \ (66.7\%) \\ 2 \ (13.3\%) \\ 2 \ (13.3\%) \\ 0 \end{array}$	$\begin{array}{ccccc} 15 & (36.6\%) & 26 & (63.4\%) \\ 66.5 \pm 15.6 & 50.7 \pm 15.9 \\ 25 \pm 1.1 & 24 \pm 1.8 \\ 10 & (66.7\%) & 15 & (57.7\%) \\ 10 & (66.7\%) & 7 & (26.9\%) \\ 11 & (73.3\%) & 9 & (34.6\%) \\ 3 & (20\%) & 9 & (34.6) \\ 10 & (66.7\%) & 2 & (7.7\%) \\ 2 & (13.3\%) & 1 & (3.8\%) \\ 2 & (13.3\%) & 0 \\ 0 & 0 \end{array}$

BMI = body mass index, CD = cardiovascular disease, DM = diabetes mellitus, IH = incarcerated hernia, PLAS = pelvic and lower abdominal surgery, SD = standard deviation.

Table 2

compansion of operative parameters between the 2 groups.						
	UHS (n=15)	TAPP (n = 26)	P value			
Procedure time, min	$60 \pm 5$	40±5	.001			
Length of hospital stay, days	5.5 ± 2.1	2.5±1.8	.008			
Bleeding, mL	12±2.5	11 ± 2.0	.168			
Cost, Chinese Yuan	$8945 \pm 550$	$11015 \pm 650$	.006			

completed significantly faster than the UHS operation, and the length of hospital stay for patients with TAPP was dramatically shorter (Table 2). The expense in TAPP group was higher compared to the UHS group.

Table 3 shows postoperative complications classified by the Clavin Dindo scales.<sup>[20]</sup> There were no significant complications that needed surgical re-intervention. No recurrence or wound infection was found in both groups. Seroma formation was observed in 4 patients in TAPP group while none in UHS group. Post-procedure pain and foreign body sensation were reported by significantly more patients in UHS group.

## 4. Discussion

In this study, we compared the open surgery and the laparoscopic procedure for the treatment of female primary FHs in a total of 41 patients. All patients we treated had advanced ages, which aligns well with the previous finding that FHs occurs mostly in elderly people.<sup>[8–10]</sup> It is thought that the size of lacuna vasorum increases as a person ages, allowing the protrusion of abdominal viscera through the femoral canal.<sup>[21]</sup>

There was no recurrence in both groups. Compared with the UHS procedure, the TAPP operation was shown to have a number of advantages, for example, less operational time, shorter hospital stay, less pain, and foreign body sensation. While these factors make TAPP a more attractive option, the cost of TAPP is higher and the laparoscopic approach requires general anesthesia that could influence patients' selection of procedure. We had patients who were suitable for TAPP but chose the open surgery because of higher cost or/and general anesthesia encountered in TAPP (data not shown). Although increasingly gaining popularity, laparoscopic surgery is still not the standard of care for hernia due mainly to the fact that this method requires specialized laparoscopic skills that takes long for surgeons to acquire. Bracale et al reported that it took 65 individual procedures for trainees to fully complete the learning curve for the TAPP.<sup>[22]</sup> Bittner and colleagues found that the recurrence rate in the first 300 TAPP repairs significantly varied even among different senior surgeons; similarly, trainees needed to perform about 300 TAPP to achieve similar results as senior surgeons in terms of operating time, morbidity rate and recurrent rate.<sup>[23]</sup>

## Table 3

Comparison of post-procedure complications between the 2 groups.

	UHS (n=15)	TAPP (n = 26)	P value
Seroma formation (Grade 1)*, n (%)	0	4 (15.4%)	.044
Pain (Grade 2) <sup>*</sup> , n (%)	4 (26.7%)	1 (3.8%)	.031
Hernia recurrence, n (%)	0	0	
Foreign body sensation, n (%)	6 (40%)	3 (11.5%)	.034
Wound infection	0	0	

<sup>\*</sup> Grades were determined following the Clavien-Dindo classification.

Complete dissection of distal sac with TAPP is challenging, which might leave small cavities, leading to seroma. This is probably the reason for higher incidence of seroma (15.4%, Table 3) seen in the TAPP group. Kapiris et al reported that 8% of over 3000 patients who underwent TAPP for the repair of inguinal hernias had postoperative seroma.<sup>[24]</sup> In another study, 32 out of 73 patients have been shown to develop seroma after TAPP treatment of inguinal hernias.<sup>[25]</sup> These data are in line with our findings.

FHs are often associated with a high incidence of incarceration or strangulation because the outer orifice of the femoral canal is rigid.<sup>[21]</sup> TAPP, which has been used successfully for the management of incarcerated inguinal hernias,<sup>[25]</sup> was also safely and effectively applied in this study for the repair of incarcerated FHs. However, once strangulation takes place, emergency open surgery is warranted. In the present study, 2 cases of strangulation were emergently treated with the open UHS procedure. Incidence of strangulation is high among FH patients undergoing emergent surgery.<sup>[9,10]</sup> A study from Sweden that analyzed the data from the Swedish Hernia Register revealed that bowel resection was performed in 22.7% (325/1430) of emergent femoral repairs.<sup>[9]</sup> Using healthcare records from the Clinical Practice Research Datalink linked to Hospital Episode Statistics data from 1997 to 2007 in England, Humes et al reported that 293 out of 406 patients (72.2%) undergoing FH emergent repair had strangulation or small bowel obstruction.<sup>[10]</sup>

The open and laparoscopic approaches use different anesthesia methods, namely, local anesthesia for the open surgery and general anesthesia for the laparoscopic procedure. The majority of patients with FHs are elderly people who tend to have systemic diseases that can affect the options of surgery. In the present study, patients in the UHS group had a higher prevalence of cardiovascular disease, hypertension, and lung disease, unsuitable for general anesthesia and TAPP. Therefore, the UHS procedure using local anesthesia was performed for these patients. We felt that it is important that the surgeon closely consults the anesthetist before the selection of a surgical procedure. When the medical conditions of patients make general anesthesia risky, an open surgery using local anesthesia should be the first choice of treatment. In our practice, we routinely consult with the anesthesiologist concerning the physical status of the patient before selecting a repair procedure.

Perioperative use of antibiotics for the prevention of infection in hernia surgery is controversial. Bittner et al summarized data of 8050 groin hernia repairs by TAPP and reported a 0.1% infection rate in all patients who received a single perioperative dose of prophylactic antibiotic. The authors attributed the low rate of infection to the use of prophylactic antibiotic.<sup>[23]</sup> Another study by Mazaki et al also indicates that antibiotic prophylaxis is effective for the prevention of surgical-site infection after open mesh-plug hernia repair.<sup>[26]</sup> In contrast, in a meta-analysis of antibiotic prophylaxis in patients who had elective open inguinal hernia repair, Sanchez-Manuel found that the prophylaxis group of 4703 patients had an infection rate of 3.1%, which was not significantly different than 4.5% of the control group consisting of 3140 patients.<sup>[27]</sup> An alarming rise in bacterial antibiotic resistance due to increased and often unrestricted antibiotic use in humans and animals has been a health crisis in China.<sup>[28]</sup> Against this setting, we generally give no antibiotic anaphylaxis to patients, and in this study, no post-surgery infection was observed. A protocol without antibiotic anaphylaxis has also been adopted in hernia repair by other groups. [29,30]

This study has several limitations. First, it is a retrospective study that can introduce sample selection bias, misclassification bias and recall bias, which may lead to overestimated results. We included all female patients who underwent FH repair at our department during May 2012 to December 2016 by not setting exclusion criteria, which could avoid sample selection bias. All outcomes we assessed are clearly defined ones that are not difficult for us to recognize, which might minimize the misclassification bias. Information of all patients used in this study was recorded on site before and after surgery, which might minimize the recall bias. Other limitations of this study include small sample size and a-single-center experience. Because of the low incidence of FHs, it will be a great challenge to conduct multicenter prospective studies in a large series to compare superiority of different repair methods. Therefore, this retrospective study is important, and the information garnered is valuable. Lastly, we did not analyze quality of life following hernia repair. Of note, while laparoscopic operation for inguinal hernia repair appears to result in less pain and faster recovery than open surgery, [31-33] the impact of different procedures on quality of life in femoral repair is rarely documented. We searched the literature and found that only a recent study addressed this issue, and it revealed no difference in quality of life between laparoscopic and open surgery in the repair of FHs.<sup>[34]</sup>

#### 5. Conclusions

Both the UHS and the TAPP procedures are safe and effective in the repair of female primary FH. If strangulation occurs, emergent treatment with an open surgery is warranted. In view of the advantages and disadvantages between the open and the laparoscopic operation, surgeons can select a procedure according to their skills and patients' situation.

## **Author contributions**

Conceptualization: Haifeng Zhang.

- Data curation: Dongfeng Chen, Nana Su, Weijia Wang, Mingxiao Guo.
- Formal analysis: Dongfeng Chen, Nana Su, Weijia Wang, Zhaoyong Zhang, Chunlei Lu, Haifeng Zhang.
- Investigation: Dongfeng Chen, Nana Su.

Methodology: Dongfeng Chen.

Software: Mingxiao Guo.

Validation: Zhaoyong Zhang.

Writing – original draft: Dongfeng Chen.

Writing - review & editing: Chunlei Lu, Haifeng Zhang.

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