

# Initial experiences with preoperative three-dimensional image reconstruction technology in laparoscopic pyeloplasty for ureteropelvic junction obstruction

# Weijie Zhu<sup>1#</sup>^, Shengwei Xiong<sup>1#</sup>, Chunru Xu<sup>1#</sup>, Zhenpeng Zhu<sup>1</sup>, Zhihua Li<sup>1</sup>, Lei Zhang<sup>1</sup>, Hua Guan<sup>1</sup>, Yanbo Huang<sup>1</sup>, Peng Zhang<sup>2</sup>, Hongjian Zhu<sup>3</sup>, Jian Lin<sup>1</sup>, Xuesong Li<sup>1</sup>, Liqun Zhou<sup>1</sup>

<sup>1</sup>Department of Urology, Peking University First Hospital, Institute of Urology, Peking University, National Urological Cancer Centre, Beijing, China; <sup>2</sup>Department of Urology, Emergency General Hospital, Beijing, China; <sup>3</sup>Department of Urology, Beijing Jiangong Hospital, Beijing, China *Contributions:* (I) Conception and design: W Zhu, J Lin, X Li; (II) Administrative support: L Zhou, S Xiong, C Xu; (III) Provision of study materials or patients: Z Li, Z Zhu; (IV) Collection and assembly of data: H Guan, Y Huang; (V) Data analysis and interpretation: P Zhang, H Zhu; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

"These authors contributed equally to this work.

*Correspondence to:* Jian Lin; Xuesong Li. Department of Urology, Peking University First Hospital, Institute of Urology, Peking University, National Urological Cancer Centre, No. 8 Xishiku St., Xicheng District, Beijing 100034, China. Email: pineneedle@sina.com.

**Background:** To explore the clinical value of three-dimensional image reconstruction technology (3DIT) on preoperative surgical planning and perioperative outcomes in laparoscopic pyeloplasty (LP).

**Methods:** Data of 25 patients with ureteropelvic junction obstruction (UPJO) admitted to our hospital from January 2018 to January 2019 was analyzed retrospectively. All patients underwent preoperative enhanced computed tomography (CT) scanning. In the 12 cases in the 3DIT group, preoperative planning involved the use of virtual operation and morphometry based on reconstruction of the CT data into three-dimensional (3D) images. Surgery in the other 13 cases was performed with traditional CT examination. Demographic, surgical outcome, and postoperative parameters were compared between these two groups.

**Results:** Reconstructed 3D images clearly showed the spatial structural relationships between the UPJO and surrounding blood vessels. In all 25 cases surgery was completed with no conversion to open surgery. Preoperative 3DIT analyses resulted in significant improvements to mean operation time (107.76 vs. 141.58 min, P=0.024), mean time of dissociating ureteropelvic junction (UPJ) (11.26 vs. 19.40 min, P=0.020), and mean estimated blood loss volume (23.84 vs. 49.16 mL, P=0.028). There were no statistically significant differences in perioperative complications, postoperative hospital stays or postoperative drainage time.

**Conclusions:** 3DIT based on enhanced CT scans is of clinical value in the treatment of UPJO, as it can provide accurate anatomical information and reliable guidance for preoperative operation planning, and it facilitates image-guided LP.

**Keywords:** Three-dimensional image reconstruction technology (3DIT); surgical plan; laparoscopic pyeloplasty; ureteropelvic junction dissection

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#### ^ ORCID: 0000-0003-2699-8377.

#### Introduction

Ureteropelvic junction obstruction (UPJO) is a urinary tract obstruction disease that is characterized by blockage or obstruction of urine flow from the renal pelvis into the proximal upper ureter (1). The overall incidence of UPJO is approximately 67 cases per 100,000 adults per year, and it is considered to be a common cause of hydronephrosis (2). The etiologic factors of UPJO can be categorized as congenital and acquired, which can be further divided into intrinsic and extrinsic. Intrinsic factors of UPIO include congenital impaired ureteric peristalsis, ureteric kinking and scarring of the ureteric valve, urothelial neoplasm and acquired renal calculi. Extrinsic factors include congenital crossing of the lower pole vessels, horseshoe kidney and duplex kidney, acquired iatrogenic strictures and fibroepithelial polyps (3-5). Crossing vessels that distort the configuration of the ureteropelvic junction (UPJ) are often regarded as the main extrinsic cause of UPJO (6-8). These vessels include aberrant, accessory, and early branching renal arteries and veins.

Without early and effective treatment, UPJO can cause hydronephrosis, leading to interstitial fibrosis and nephron loss and can eventually lead to renal failure. Therefore, it is important to take timely and appropriate measures. In recent decades, surgical techniques for management of UPJO have made great progress. In the 1990s, open approaches began to be replaced by laparoscopic Anderson-Hynes pyeloplasty and then endopyelotomy, and robotassisted approaches were introduced in 2002 (9,10).

A reflection of this trend is the development of laparoscopic pyeloplasty (LP), which is now the preferred treatment method, as it is accompanied by improved intraoperative visualization, reduced blood loss, lower postoperative morbidity, faster recovery and better cosmetic effects (11). However, LP has been proven to be a challenging procedure with a steep learning curve for surgeons, who must have strong experience with laparoscopic procedures and must have advanced laparoscopic skills including the ability to perform intracorporeal suturing and knotting (12). Because of the challenges presented by this technique, accurate preoperative assessment is essential to improve surgical planning, decrease intraoperative surgical risk and difficulty, and to reduce the incidence of postoperative complications.

Accurate preoperative evaluation requires the utilization of modern imaging technology. Recently, a

novel technology based on computed tomography (CT) or magnetic resonance imaging (MRI), three-dimensional image reconstruction (3DIT), has emerged as a useful tool for making a targeted region visible and tangible. The use of this technique allows simulated manipulations to be conducted to assess operative features preoperatively. In a similar way, previous studies have reported that helical CT with vascular reconstruction can assist the surgeon to observe the relationship between the UPJ and peripheral structures, to detect of crossing vessels before surgery and to perform virtual manipulation (13). To this point, however, no research has investigated the superiority of three-dimensional (3D) techniques over conventional twodimensional (2D) CT as applied to LP procedures. Here, then, we provide a comparative evaluation of perioperative outcomes upon the application of 3DIT to LP. We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/ tau-21-590).

#### **Methods**

#### Study population

From January 2018 to January 2019, a total data of 25 patients from our hospital who were diagnosed with UPJO and who received standardized dismembered LP by a single experienced surgeon were analyzed retrospectively (14). Of this cohort, 12 patients underwent LP combined with three-dimensional visualization surgical planning (3DIT group), while 13 patients underwent LP under conventional two-dimensional CT assessment (non-3DIT group).

Patients were selected according to the following criteria: (I) anatomic abnormalities of the urinary tract as determined by preoperative CT; (II) functioning kidneys that responded appropriately to attempted ureter repairs; and (III) availability of follow-up data of at least 6 months. Patients with missing perioperative or postoperative data were excluded from the analysis.

Patients were classified according to their willingness to submit to the preoperative 3D visualization technique. All patients were informed of the treatment strategy and potential risks and complications. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Peking University First Hospital (approval number: 2020-283) and individual consent for this



**Figure 1** Three-dimensional (3D) imaging reconstruction model of urinary system based on computerized tomography (CT). (A) Bilateral kidneys and collecting systems shown by the transaxial CT scan; (B) bilateral kidneys and collecting systems shown by the coronary CT scan; (C) 3D imaging reconstruction model of urinary system and vessels.

retrospective analysis was waived.

## 3D image reconstruction technology

Enhanced CT scans were performed on all 25 patients using a 64-slice CT system with a slice thickness of 0.625 mm (Philips, Best, The Netherlands). The original CT data for subsequent analysis was set to the best image quality and stored in Digital Imaging and Communications in Medicine format. Different phases of the CT data were segmented and reconstructed to create 3D digital images with a Medical Imaging Three Divisional Visualization System (Yorktal, Inc., Shenzhen, Guangdong, China). A 3D model of the retroperitoneal anatomical structures, including renal parenchyma, upper urinary tract, renal vessels, abdominal aorta and inferior vena cava, was reconstructed simultaneously using the region-growing method based on arterial and parenchymal phase data (Figure 1). Information regarding the collecting system was obtained based on secretory phase data (15).

# Morphometry and preoperative planning

The reconstructed 3D model was observed by 360° rotation along all axes. Each part of the reconstructed anatomical structure allowed the user to zoom in and zoom out at selected angles. The surgeon was able to rotate, amplify or delete areas or to make certain areas transparent in order to better visualize the anatomy of the involved surgical area. Important retroperitoneal structures were tinted with different colors for distinguishing prior to the surgery. This system created a virtual reality environment of the surgical field and allowed the surgeon to perform virtual manipulation on the screen. After the simulated surgery was performed, potential intraoperative events were predicted, which helped the surgeon to make appropriate surgical plans.

# Statistical analysis

Standard variables were retrospectively collected from our Reconstruction of Urinary Tract: Technology, Epidemiology and Result (RECUTTER) database (https:// pkufh.yorktal.com). Data on age, gender, side of UPJO, and the presence of a crossing vessel were gathered for comparison between the groups. The efficiency of 3DIT was assessed by operating time and recorded as the total operating time, from skin incision to wound closure, and the UPJ dissection time, from the opening of Gerota's fascia to the completion of the exposure immediately before the pelvic incision.

Postoperative follow-up occurred at 3 and 6 months and then once per year. Follow-up examinations included clinical evaluation, serological examination of creatinine levels and estimated glomerular filtration rate, renal ultrasound examination, diuretic nephropathy, and CT imaging. The criteria for success were relief of subjective pain, improvement of hydronephrosis, and stabilization or improvement of renal function.

Statistical analysis was performed using SPSS software

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Table 1 Chinical data analysis of patients diagnosed with CPJO with ectopic vessels in 5D11 group									
Case	Type of ectopic vessels	Number of branches	Spatial relationship between UPJ	Spatial distance between UPJ	Operation procedures				
1	Artery	1	In front of UPJ	Near	Retained				
2	Artery	1	In front of UPJ	Far	Retained				
3	Artery	2	Behind the UPJ	Far	Retained				
4	Artery	1	In front of UPJ	Far	Cut off				
5	Arteries and veins	A: 4/V: 1	Behind the UPJ	Far	Retained				
6	Arteries and veins	A: 4/V: 3	In front of the renal pelvis	Near	Cut off				
7	Vein	1	Crossed the UPJ	Near	Retained				
8	Vein	1	Surrounded the renal pelvis and ureter	Near	Cut off				

<b>Table 1</b> Chillear data analysis of patients diagnosed with OT TO with ectopic vessels in JDT1 g	group
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3DIT, three-dimensional images reconstruction technology; UPJ, ureteropelvic junction; UPJO, ureteropelvic junction obstruction; A, artery; V, vein.



Figure 2 Ureteropelvic junction obstruction with left renal crossing artery (arrows). (A) Anterior aspect in three-dimensional (3D) imaging model; (B) posterior aspect in in 3D imaging model; (C) crossing artery located at the lower pole of the left kidney, behind the ureter, intraoperatively.

version 23.0 (SPSS, Inc., IBM Corp., Somers, NY, USA). Descriptive data are expressed in terms of frequency and percentage. Fisher exact tests or chi square tests were used to compare percentages between the two groups. Nonparametric two sample median tests were used to compare median values. Differences with bilateral P<0.05 were considered statistically significant.

#### **Results**

#### 3D reconstruction of renal crossing vessels

Of the 12 patients without preoperative 3D reconstruction,

5 were determined to have renal crossing vessels, but it should be noted that ordinary CT imaging does not allow for conclusive distinguishing of veins from arteries.

Of the 13 patients with preoperative 3D reconstruction, eight patients with UPJO in the 3DIT group showed the presence of ectopic blood vessels (Table 1). The ectopic blood vessels of 4 patients were arteries, including 3 ectopic arteries in front of the renal pelvis and ureter and 1 ectopic artery behind the renal pelvis and ureter (Figure 2). The ectopic blood vessels of 2 patients were both arteries and veins: in 1 case, the vessel was in front of the renal pelvis and ureters, and in the other case, the vessel was behind the



**Figure 3** Ureteropelvic junction obstruction with left renal ectopic vein (arrows). (A) Anterior aspect in three-dimensional (3D) imaging model; (B) posterior aspect in 3D imaging model; (C) renal ectopic vein made a circuit around the left renal pelvis, intraoperatively.

Table 2 Properative characteristics of patient					
Parameter	Non-3D reconstruction	3D reconstruction	P value		
No. of patients	12	13			
Gender (M/F)	8/4	7/6	0.533		
Age (year), mean ± SD [range]	33.33±15.08 [18-73]	27.30±14.70 [8-69]	0.318		
BMI (kg/m²), mean ± SD	20.2±4.5	21.4±3.5	0.260		
Laterality (left/right)	6/6	8/5	0.580		
History of urological surgery	4	5	0.800		
Crossing vessels	5	8	0.420		
Presentation			0.915		
Osphyalgia	6	9			
Hematuresis	3	1			
Vascular variation	5	8	0.341		

Table 2 Preoperative characteristics of patient

3D, three-dimensional; No., number; M, male; F, female; BMI, body mass index; SD, standard deviation.

renal pelvis and ureters. Only 2 patients had ectopic blood veins. Here, in 1 case, the vein crossed the UPJ, while in the other case, the vein surrounded the renal pelvis and ureter (*Figure 3*).

#### LP without preoperative 3D reconstruction

Preoperative characteristics of patients are presented in *Table 2*. Twelve patients underwent LP without preoperative 3D imaging reconstruction, including 7 males and 6 females. The mean age of the patients was 33.33±15.08 years (range, 18–73 years). Six patients had pyeloplasty performed on the

left side, and six patients had pyeloplasty performed on the right side. Three patients visited the hospital complaining of hematuria, and six patients complained of osphyalgia. The mean surgery time, time of dissociating UPJ and blood loss during operation were 141.58±46.90 min (range, 77–253 min), 19.40±9.13 min (range, 7.9–41.5 min) and 49.16±36.54 mL (range, 20–160 mL), respectively. There was no conversion to open surgery. The mean time of drain removal was 3.41±0.99 days (range, 2–6 days), and the average time of hospitalization was 4.16±2.55 days (range, 3–12 days). Five patients experienced postoperative fever (Clavien-Dindo grade I). The mean postoperative follow-

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Table 3 Perioperative and postoperative data of patients

Parameter	Non-3D reconstruction	3D reconstruction	P value
Operative time (min), mean ± SD [range]	141.58±46.90 [77–253]	107.76±18.18 [75–137]	0.024
Time of dissociating UPJ (min), mean $\pm$ SD [range]	19.40±9.13 [7.9–41.5]	11.26±5.01 [4.3–23.4]	0.020
Conversion to open surgery	0	0	-
Intraoperative blood loss (mL), mean ± SD [range]	49.16±36.54 [20–160]	23.84±13.25 [10-60]	0.028
Hospital stay (day), mean $\pm$ SD [range]	4.16±2.55 [3–12]	3.76±0.72 [3–5]	0.595
Drain removal (day), mean ± SD [range]	3.41±0.99 [2-6]	3.15±0.89 [2–5]	0.495
Early complications	Fever after operation in 5 patients	Fever after operation in 5 patients	0.877
Later complications	0	0	-
Follow-up (months), mean $\pm$ SD [range]	19.33±3.02 [15–24]	18.15±3.36 [15–24]	0.368
Success rate	91.70%	100.0%	0.339
Waist pain, n (%)	1 (8.3)	0 (0)	
Improved hydronephrosis, n (%)	11 (91.7)	13 (100.0)	
Improved renal function, n (%)	11 (91.7)	13 (100.0)	

SD, standard deviation; UPJ, ureteropelvic junction.

up was 19.33 months (range, 15–24 months), and 11 of the 12 patients had reduced hydronephrosis and improved renal function.

#### LP with preoperative 3D reconstruction

LP with preoperative 3D imaging reconstruction was successfully performed in 13 cases, including 7 males and 6 females (Table 2). The mean age of patients was 27.30±14.70 years (range, 8-69 years). Eight patients received surgery on the left side, and five patients on the right side. Six patients were admitted to hospital with complaints of loin pain, and three patients were admitted with hematuresis. The mean operative time, time of dissociating UPJ and intraoperative blood loss were 107.76±18.18 min (range, 75-137 min), 11.26±5.01 min (range, 4.3-23.4 min) and 23.84±13.25 mL (range, 10-60 mL), respectively. All patients were treated successfully without any conversion to open surgery. The mean time of drain removal was 3.15±0.89 days (range, 2-5 days), and the mean hospitalization time was 3.76±0.72 days (range, 3-5 days). Five patients complained of postoperative fever (Clavien-Dindo grade I). The symptoms of preoperative discomfort disappeared,

hydronephrosis decreased and the renal function was stabilized or improved at a mean follow-up of 18.15 months (range, 15–24 months).

As shown in *Table 3*, preoperative 3DIT analyses resulted in significant improvements to mean operation time (107.76 vs. 141.58 min, P=0.024), mean time of dissociating UPJ (11.26 vs. 19.40 min, P=0.020), and mean estimated blood loss volume (23.84 vs. 49.16 mL, P=0.028). There were no statistically significant differences in perioperative complications, postoperative hospital stays or postoperative drainage time.

## Discussion

Over the past two decades, minimally invasive treatment of UPJO has developed and is becoming increasingly popular. LP, in particular, has been used successfully to correct all possible causes of UPJ obstruction, including kinks or compression associated with crossing vessels or inherent narrowing of the UPJ (16). LP is a difficult surgical technique that demands superior surgeon expertise, including superior dexterity and intracorporeal suturing skills, and it especially challenges novice urological surgeons. Variance of both venous and arterial crossing

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vessels and the complexity of features of UPJO make exposure of the dilated pelvis and UPJO difficult (17).

The need to reduce the difficulty of surgery and to improve intraoperative safety drives the improvement of appropriate auxiliary equipment and technology. In fact, in order to obtain high-resolution anatomical information in LP, the application of medical imaging tools such as CT, MRI and intraoperative ultrasound has become essential.

Previously, traditional 2D CT and image reconstruction by traditional CT have been used preoperatively to assess factors that may complicate surgery, including relationships to the surrounding viscera, distribution of the vasculature, and degree of the UPJO-dependent hydronephrosis. However, due to its relatively weak ability to represent anatomical structures, including vasculature and collecting system, intuitively and stereoscopically, these traditional techniques are frequently unable to meet surgeons' demands for accurate anatomical information of targeted region. Consequently, well-established 3D image technologies based on original image data files and application of computer-aided technology have been developed to provide reliable assistance to surgeons while shortening the learning curve required for these procedures (18,19).

The technology that 3D imaging relies upon has been improved through application to multiple fields such as 3D CT, 3D printing, 3D computed simulation surgery and 3D assisted navigations (20-22). Spiral CT (HCT) with 3D imaging, in particular, has been found to be an accurate tool to determine whether there are crossed blood vessels at the level of the UPJO. Khaira *et al.* (17) reported in their study that the positive predictive value for detecting crossed blood vessels with HCT is 100%. The negative predictive value is 88%, and the specificity and sensitivity are 100% and 91%, respectively, which demonstrates that HCT with 3D imaging can serve as an effective noninvasive preoperative screening tool in the treatment of UPJO.

In the present study, we introduced a novel 3D visualization analysis tool to provide intuitive and omnidirectional information about the regional anatomy of the surgical area. This technology can accurately identify the position of UPJO, the structure of the surrounding vasculature and relationships with the renal parenchyma by the tinting of anatomical structures with different colors and by allowing observation with various degrees of transparency and axial rotations. In addition, this system can provide a platform for the preoperative performing of realistic surgical simulations that resemble the actual surgical procedures, which provide surgeons

with unparalleled guidance and understanding leading to optimization of the surgical strategy. Preoperative planning helps the surgeon to determine the feasibility of LP in a specific situation and to design the optimal surgical plan. If the surgeon observes potential risks of intraoperative accidents during simulation process, the surgical plan may be modified and reconsidered.

According to our results, 3DIT promoted operative success, as evidenced by the facts that the 3DIT group had reduced blood loss volume and shorter time of operation and of dissection of Gerota's fascia. These improvements correlate with the understanding of the required surgical anatomy and improved anatomical orientation. In laparoscopic procedures, key information about the anatomy of the region of interest is always below the surface of the organ. In this specific case, the irregularly shaped peri-renal adipose tissue tends to blur the image, making it difficult to distinguish the anatomical structures to be targeted, including UPJ and crossing vessels. As we found in our study, in-depth surgical planning and virtual simulation can provide an improved understanding of the patient's local anatomy prior to surgery. These factors may increase the surgeon's self-confidence, which would then be expected to lead to the noted results. We also found that 3DIT can improve the efficiency of UPJ exposure. The dissection time of UPJ in 3DIT group was about one third less than that in the non-3DIT group (P=0.020).

The extra renal vessels that do not enter the kidney through the renal portal, called accessory renal arteries or veins, or heterotopic renal vessels (23), are of particular interest with regard to UPJO. Ectopic vessels exist in 38% to 71% of UPJO cases and in 20% of normal kidneys, and the treatment of UPJO that is complicated by ectopic vessels is difficult and controversial. Vascular variation will affect the safety of surgery, while accidental injury to the vessels may cause bleeding. Keeping the existence and distribution of ectopic vessels in mind before operation is therefore of great significance for the choice of surgical methods, reducing intraoperative bleeding, and shortening the operation time (7,24-26). The 3D reconstruction model based on CT can directly reflect the anatomical variation in the renal collecting system and peripheral vessels, and can help the operator to determine the location, type and direction of ectopic vessels before operation.

An ectopic artery, which maintains the blood supply to part of the kidney, is usually preserved in treatment and can be severed only when the following conditions are met: the ectopic artery clearly compresses the renal pelvis and causes UPJO and is thus difficult to avoid in the operation field; the ectopic artery is suspended, the tension is high. When UPJO is caused by ectopic vein compression, the non-main renal vein trunk is usually ligated and removed.

This study demonstrated the utility of 3DIT in cases involving an ectopic artery. In one case (Figure 2), the preoperative 3D imaging model clearly showed the position of the ectopic artery behind the ureter. The proposed operation plan was to fully free the ectopic artery and preserve the artery after UPJ, and then to perform pyeloureterostomy in front of the artery. In another case of UPJO (Figure 3), the preoperative 3D reconstruction model showed that there were annular ectopic veins in front of the renal pelvis, which were difficult to avoid in the operation area. When performing pyeloplasty, surgeons thus understood that specific attention should be paid to free the ectopic veins in the posterior segment of the UPJ. Thus, these cases demonstrate that clinicians can make accurate preoperative planning for different vascular variations of UPJO patients based on preoperative 3D reconstruction model information, and make targeted positioning, ligation and disconnection of vessels during operation, so as to avoid unnecessary vascular damage and to improve the accuracy and efficiency of operation.

In the group that underwent traditional CT examination, although CT images were able to provide detailed information, it might be difficult for the surgeon to observe the number and distribution of ectopic vessels and the adjacent relationship with the UPJ clearly and intuitively. The difficulty in processing this vital information may have led to the observed increases in the difficulty of the operation and the chances of bleeding due to the presence of vascular variation, as well as longer operation times and times of Gerota's fascia dissection the non-3DIT group compared with the 3DIT group.

Previous reports have similarly suggested that 3D reconstructions of preoperative imaging led to better surgical performance in urological laparoscopic surgery. Porpiglia *et al.* (27) showed that, according to nephrology scores, 3D visual models are more accurate than 2D standard imaging in assessing the surgical complexity of kidney masses, because they can provide urologists with a better understanding of tumor location, relationships and depth with intrarenal structures, leading to a better likelihood of consensus among evaluators and simplifying preoperative planning. Wake *et al.* (28) emphasized the workflow and new application of 3D printing and AR kidney

model, which can provide preoperative guidance for robotic partial nephrectomy, and the insights gained by advanced visualization techniques can influence the decision-making of surgical planning. Porpiglia et al. (29) identified a hyperaccuracy 3D virtual navigation technique that can faithfully represent the renal artery vascular system and can thus maximize the effect of selective clamping in robot assisted partial nephrectomy. Rabah et al. (30) highlighted the use of 3D reconstructed images with helical CT angiography, which provides valuable preoperative information for UPJO patients who plan to undergo surgical intervention. Their research shows that this technique can be used to select the appropriate surgical treatment according to the anatomy of the cross vessels, so as to obtain a higher success rate. Khaira et al. (17) agreed that 3D reconstruction image is an accurate predictor of the presence of cross vessels in UPJO.

While these results demonstrate the utility of 3D technology in assisting renal surgeons, 3DIT has seldom been used in upper urinary tract reconstruction. As far as we know, ours was the first study of LP for UPJO comparing 3DIT with the use of traditional 2D images. Some limitations of this study, though, must be recognized. First, the lack of randomization and the retrospective basis of the evaluation are the main limiting factors of our research, as they may lead to selection bias. In addition, clinical data were collected from a small patient group in a single center, and a larger population study involving multi-institution prospective, randomized and controlled trials is needed to improve confidence in the results of the research. Moreover, long-term follow-up should be conducted in further studies to better assess outcomes. Finally, all operations were performed by an experienced surgeon in our study, and inexperienced beginners should be further evaluated. 3DIT is still not available routinely in clinical practice and requires the support and cooperation of biomedical engineers.

Despite these limitations, this study shows that the assessment of the anatomical complexity of UPJO depends strictly on the imaging tools used to evaluate it. The emergence of 3DIT opens a new chapter for the surgical planning of LP, makes the classification of cross vessels more accurate and reliable, and ultimately improves the indications of surgery.

#### Conclusions

In summary, this study shows that in assessing the collection system, 3DIT is more accurate than standard 2D CT

images, because they it provides urologists with a better understanding of the location and relationship of the UPJ to the structures surrounding the kidney, so as to better reach an assessment, simplify preoperative planning, and promote dissection around the UPJ during LP, leading to more accurate and safe dissections of UPJ.

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of Peking University First Hospital (approval number: 2020-283) and individual consent for this retrospective analysis was waived.

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