Translational Research Urology

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Original Article

Evaluation of "UNDER VISION TOTAL TUBELESS PCNL" as a Novel Technique in Comparison to TOTAL TUBELESS PCNL

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HIGHLIGHTS

- Minimizing the access tract to the kidneys and skin incision helps to reduce surgical complications such as pain, scarring, wound infection, recovery, and hospitalization.
- Today, less invasive methods are considered for most surgeries.
- Stone surgery is no exception to this rule.

ARTICLE INFO

Receive Date: 05 August 2022
Accept Date: 09 November 2022
Avaliable online: 13 November 2022
DOI: 10.22034/TRU.2022.368587.1133

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ABSTRACT

Introduction
This study aims to evaluate Under Vision Total Tubeless PCNL (TT-PCNL) as a novel technique in reducing surgeon exposure to X-rays compared to the standard Total Tubeless PCNL. Percutaneous nephrolithotomy (PCNL) has been widely welcomed as a less-invasive medication for kidney stones. However, because it is usually performed using fluoroscopy, the endourologist is at risk of chronic X-ray exposure.

Methods
The number of 76 consecutive patients who were candidates for PCNL surgery was randomized into two groups: 38 patients experienced TT-PCNL, and 38 patients underwent Under Vision TT-PCNL. The results were compared with fluoroscopy time and surgeon satisfaction.

Results
The fluoroscopy time in the Under Vision TT-PCNL group was lower than in the Total Tubeless PCNL group (0.02). Surgeon satisfaction was higher in the Under Vision Total Tubeless PCNL group than in the TT-PCNL group (P-value=0.001). The mean total duration of surgery in the TT-PCNL under the Vision group was lower than the Total Tubeless PCNL group (P-value=0.04). There was no significant difference between the two groups' complications.

Conclusions
The Under Vision TT-PCNL is compared to the normal PCNL in safety and effectiveness, but also it can significantly reduce the use of a fluoroscope. Moreover, surgeon satisfaction is better compared to the standard technique.

Keywords: Renal Stone; PCNL; Fluoroscopy; Under Vision; Stone Free Rate; Kidney Stones

Introduction

Percutaneous nephrostomy (PCN) was first described in. 1865 by Dr. Thomas Hillier in London (1, 2). Although this modality is a minimally invasive procedure, several complications, such as postoperative pain, bleeding, renal pelvis perforation, and adjacent organ injury, may occur (3). In a prospective international multi-Center study of more than 5,000 patients, approximately 15% experienced

significant complications after PCNL (3, 4). In addition, to better visualize the pyelocaliceal system, PCNL is usually performed under fluoroscopic guidance, which puts the patient, endourologist, and surgical staff to ionizing radiation exposure (5). Since radiation exposure can lead to an increased risk of lifetime cancer development (6, 7), exploring the methods to improve the surgical technique and reduce radiation exposure during PCNL is of utmost importance.

In the past two decades, numerous studies have been conducted addressing the modification of the PCNL procedure to augment its effectiveness, diminish complications, and reduce adverse effects (8-10). After stone removal, a PCN tube and a ureteric stent named double J (DJ) were placed. However, nephrostomy was connected to increased postoperative pain, the need for analgesia, and prolonged hospital stay (11, 12). On the other hand, the insertion of ureteric stents was correlated with an increased risk of hematuria, pain, and irritative lower urinary symptoms (13, 14). In this regard, the tubeless method was introduced as an alternative to the conventional procedure to refine the PCNL technique and reduce its morbidity (11, 12, 14-16). Although the tubeless approach has resulted in lower complications, excessive radiation due to fluoroscopy during PCNL still must be addressed.

Recently, we have proposed the "under-vision" approach as a novel PCNL technique in which access to the pyelocaliceal system is performed using the one-shot technique under a direct vision (17, 18). In this miniaturized technique, an ureteroscope equipped with amplatz and amplats sheath is guided into the access calyx targeted by a previously inserted safety guidewire. So, the access to the target calyx and visualization of the stone performs without the need for fluoroscopy.

Herein, we aimed to compare the tubeless PCNL using the under-vision approach with the conventional PCNL regarding safety, efficacy, and radiation exposure.

Methods

Trial design and participants

This randomized controlled clinical trial was conducted at Sina hospital, Tehran, Iran, from January 2019 to September 2020. The ethics committee of Tehran University of Medical Sciences approved the study, and the trial was registered at the Iranian Registry of Clinical Trials (IRCT20190624043991N1).

Among 105 eligible patients scheduled for PCNL, 76 patients were eventually registered in this randomized clinical trial study. Patients were included according to the following criteria: 1) age>18 and 2) candidate for PCNL. Exclusion criteria were multiple stones in multiple calyxes, staghorn stones, previous renal surgery, urinary tract anomalies, single kidney, urinary tract infection, coagulation abnormalities, anemia, spinal deformities, morbid obesity, and renal, pulmonary, or heart failure. Written informed consent was signed by all patients (Figure 1).

Intervention

The indications of PCNL were considered the proposals of the American Urological Association (AUA) and European Association of Urology (EAU) guidelines. Laboratory examinations were noted. A non-contrast computed tomography (NCCT) exam was performed for each patient, with a slice thickness of 5.0 mm, reconstruction at 1.25 mm, and field of view of 50 cm.

Under general anesthesia, the procedure started with cystoscopic insertion of a 5 French ureteral stent in the stone side in the lithotomy position. Then the patient was repositioned into the prone position. After access direction, angle, and depth estimation, access to the pyelocalyceal system was performed by fluoroscopy guidance. Then, a retrograde injection of contrast media solution through the previously inserted ureteral catheter was performed to visualize the renal pelvis and calyces. Targeted renal calyceal fornix access with an 18G needle was performed and confirmed, a guidewire was included, the skin at the access site was cut to 1 cm, and a fascial dilator was applied for gradual dilation. After successfully co-axial dilatation on the guidewire, in a tubeless group, the "one-shot" technique was used to access stone, and a tract was established with an indwelling of the 28-French sheath; whereas, in the under-vision tubeless group, after adequate dilatation, an amplatz and 28-French sheath placed on an 8-French ureteroscope, then, ureteroscope was placed on the guidewire through the tract, so, the access to the stone was performed under a direct vision (Figure 2). A 1.6-mm ballistic probe was used to fragment the stone. The energy settings did not differ between procedures. Stone fragments were removed with both forceps and irrigation.

Outcome

The demographic characteristics of patients (age, gender, weight, height, BMI, GFR, serum creatinine, hemoglobin, and stone burden) were recorded. The perioperative and postoperative information, such as fluoroscopy time, anaesthesia time, hemoglobin change, changes in GFR, complications, and length of stay (LOS) were additionally recorded.

Fluoroscopy time was described as the total time for which fluoroscopy was used. Anesthesia time was defined as the time between induction of anesthesia and transfer of the patient to the recovery room. The surgery time was defined as the time between the entrance of the needle to the targeted calyx and the wound closure, In contrast, the access time was characterized as the time between the needle's entry to the targeted calyx and the entrance of the nephroscope and initiation of Lithoclast. Hemoglobin

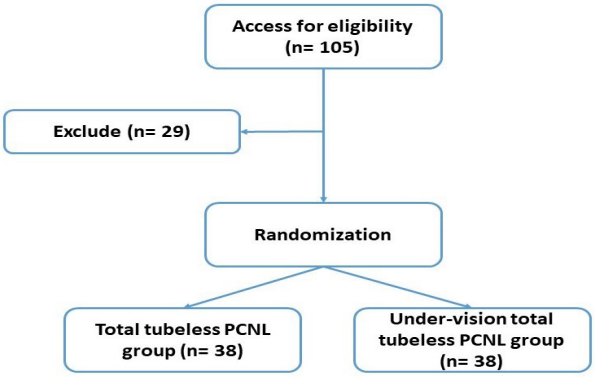

Figure 1. Consort flowchart

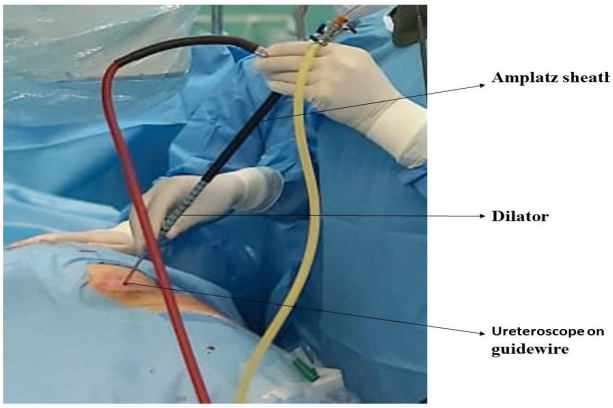

Figure 2. Ureteroscope with amplatz and sheath was placed on the guidewire through the tract, so the access to the stone was performed under a direct vision

change was defined as the contrast between hemoglobin concentration before operation and 24 and 48 hours after the operation. The modified Clavin classification system and the Comprehensive Complication Index (CCI) were used to describe complications after PCNL. Surgeon satisfaction was evaluated with a visual analogue scale where 0 points were extraordinarily dissatisfied, and 10 points were very satisfied.

The primary outcome variables were fluoroscopy time and surgeon satisfaction scores. Secondary outcome variables were anaesthesia time, access time, changes in hemoglobin and GFR, and complication rate.

Sample size

To achieve a power of 80%, α of 0.05, and a confidence level of 95%, the minimum number of participants in each intervention and control group was calculated to be 38 (Figure 1).

Randomization

Patients were randomly allocated into two groups; 38 underwent total tubeless PCNL (control group), whereas 38 underwent under-vision total tubeless PCNL as a novel technique (intervention group). Randomization was performed using block randomization.

Statistical analysis

Statistical analyses were completed using SPSS16 software. Values were reported by mean±standard deviation (SD). Surgeon satisfaction on the Visual Analogue Scale (VAS) was reported as mean rank and mean and standard deviation. The normality of distribution for continuous variables was confirmed with the Shapiro–Wilk test. The student's t-test or the Mann-Whitney U-test compared continuous variables between two groups, depending on whether the statistical hypotheses were fulfilled. ANCOVA was used to remove the effect of baseline values during comparison. The chi-squared test or Fisher's exact test was used for categorical variables. The values are statistically significant when the P-value is <0.05.

Results

For the last analysis, 76 patients were included. There was no significant difference between both groups concerning height, weight, gender, age, and body mass index (BMI). The location of stones (P-value=0.67) and stone burden (P-value=0.12) did not differ between the two groups. None of the lab findings measured on separate days differed among the groups. ANCOVA for day two creatinine, GFR, and hemoglobin using preoperative values as a baseline was insignificant (P-value=0.93, P-value=0.36, and P-value=0.52, respectively). Compared to the tubeless PCNL group, the mean fluoroscopy time was shorter for under–vision tubeless group (8.42±2.06 vs. 10.03±3.37; P-value=0.02). Furthermore, the novel under-vision PCNL reduced the surgery time from 70.29 minutes to 64.16 minutes; P-value=0.04). Despite decreased surgery time, anaesthesia and access time did not differ significantly (P-value=0.80 and 0.67, respectively). Finally, surgeon satisfaction was considerably higher in under-vision PCNL. Detailed demographics and measured outcomes are presented in Table 1.

Clavin's score after surgery was not more than 2 points in both groups. Fever occurred in 12 patients who underwent total tubeless PCNL and 10 patients who underwent tubeless total PCNL under vision (P-value> 0.05, data not shown). Blood transfusion was required in eight and seven patients in the two groups (P-value>0.05fp, data not shown). Pneumothorax, intraoperative bleeding ends to termination of surgery, damage to adjoining organs, nephrectomy, sepsis, and death did not take place in either group. The comprehensive complication index was lower in the under-vision whole tubeless PCNL group, but the difference was insignificant.

Discussion

PCNL is an established technique used to treat large renal calculi. AUA (19) and EAU (20) have recommended

Table 1. Characteristics of cases in each group and measured variable for each intervention group.

Variables	Standard (N=38)	Under vision (N=38)	P-value
Age (Mean±SD)	43.63±11.84	44.32±16.65	0·84
Sex (male%)	28 (73.7%)	25 (65.8%)	0.45
Weight (Mean±SD)	79.97±11.63	79.63±9.85	0.89
Height (Mean±SD)	175.55±8.26	174.37±7.27	0.51
BMI (Mean±SD)	25.83±2.43	26.15±2.50	0.57
Creatinine			
Pre-operation	1.25±0.49	1.16±0.36	0.38
Day 1	1.25±0.49	1.19±0.32	0.52
Day 2	1.39±0.45	1.26±0.33	0.16
Day 3	1.24±0.40	1.18±0.30	0.49
GFR			
Pre-operation	89.56±27.78	92.22±28.50	0.68
Day 1	88.66±24.75	89.22±26.89	0.93
Day 2	78.89±24.23	85.57±32.76	0.32
Hemoglobin			
Pre-operation	14.23±1.53	14.35±1.80	0.76
Day 1	13.42±1.65	13.21±1.93	0.61
Day 2	12.67±1.79	12.67±1.79	0.65
Day 3	12.35±1.54	12.22±1.75	0.74
Stone burden	43.45±10.20	39.97±8.87	0.12
Anesthesia time	112.29±17.24	113.18±13.01	0.80
Surgery time	70.29±14.13	64.16±11.55	0.04
Fluoroscopy time	10.03±3.37	8.42±2.06	0.02
Time to access	28.66±3.86	28.26±3.90	0.67
Surgeon satisfaction	7.76±1.08(30.17)	8.58±0.89(46.83)	0.00
Comprehensive complication index (CCI)	13.25±1.12	11.36±0.94	0.10

PCNL as first-line treatment for staghorn calculi, kidney stones greater than 20 mm in diameter, and lower calyceal stones in their latest guidelines on the management of renal calculi. Traditionally PCNL is performed in a prone position under the guidance of a fluoroscope, at the end of which the pyelocalyceal system drainage was provided by a nephrostomy tube and a DJ ureteral stent or ureteral catheter. Recently, tubeless (ureteral stent is placed, but nephrostomy tube is omitted) and even total tubeless (no ureteral stent and nephrostomy) PCNL have been introduced and gradually popularized (19, 20).

A trial study comparing "totally tubeless" PCNL to conventional PCNL with a post-procedure nephrostomy tube illustrated a significant reduction in hospital stay, analgesic requirement, and time to return to regular tasks with no increasing complications in the "totally tubeless" approach (21). These outcomes have also been mirrored in a single, small randomized controlled trial conducted in the pediatric population (22). In the case of a tubeless method, total healthcare costs are also reduced (23).

The initial stage in the percutaneous methods is to get to collecting system, which is usually achieved with fluoroscopy guidance. Many surgical methods have been proposed aiming at reducing radiation exposure. For example, according to some studies, PCNL under ultrasound guidance is highly successful and few complications can be a safe and effective alternative to fluoroscopy for experts (24). Despite its advantages, this technique has not become popular since endourologists are less familiar with ultrasonographic images, and the used equipment, such as the Amplatz dilator and sheath, have poor echogenicity (25, 26).

This study introduced a new approach using a ureteroscope to provide a direct vision into the access

tract to decrease fluoroscopy time and radiation exposure. Our study showed that getting under-vision access to the stone can reduce the need for fluoroscope use and reduce radiation exposure. The time to access the stone was not statistically different between the two groups. It is considered because time for equipping ureteroscope with amplatz and amplatz sheath was considered in access to stone time. The surgeon's satisfaction was better in the under-vision tubeless PCNL group, while the surgeon's satisfaction was not assessed in other studies focusing on reducing fluoroscopy time. Higher satisfaction may be attributed to better vision and direct visualization of the stone. The complication rate was close to other similar studies. Although the CCI was lower in the under-vision PCNL group, it was not statistically significant. The changes in hemoglobin, creatinine, and GFR were not different between the two groups. Additionally, the length of hospital stay was similar in the two groups. These all showed that the new technique is comparable to the standard technique in safety.

Our study was limited due to the one-center nature of the study. Also, the study could not be double-blinded, causing potential bias toward under-vision PCNL when assessing surgeon satisfaction.

Conclusions

The new technique of under-vision total tubeless PCNL is safe and can be a rational option to reduce radiation exposure.

Authors' contributions

FG designed, reviewed and edited the manuscript, MMR and AM wrote the manuscript, AFY and MAP analysed the data, SFM and.

Acknowledgments

Special thanks to the Persian Registry for Stones of Urinary System (PERSUS) to provide data and patients.

Conflict of interest

All authors declare that there is no potential competing or conflict of interest.

Funding

There was no funding.

Ethics statement

Written informed consent was taken from patients, and the ethical review committee approved the study at Tehran University of Medical Science, and the trial was registered at the Iranian Registry of Clinical Trials) (IRCT20190624043991N1).

Data availability

Data will be provided on request.

Abbreviations

BMI	Body mass index
CCI	Comprehensive complication index
DJ	Double J
LOS	Length of stay
NCCT	Non-contrast computed tomography
PCN	Percutaneous nephrostomy
PCNL	Percutaneous nephrolithotomy
SD	Standard deviation
TT-PCNL	Total Tubeless PCNL
VAS	Visual Analogue Scale

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How to cite this article

Rakebi MM, Mohammadi A, Fakhr Yasseri A, Ahmadi Pishkuhi M, Maroufi SF, Guitynavard F. Evaluation of "UNDER VISION TOTAL TUBELESS PCNL" as a Novel Technique in Comparison to TOTAL TUBELESS PCNL. Translational Research in Urology. 2022 Nov;4(4):173-179.
DOI:10.22034/TRU.2022.368587.1133
URL:https://www.transresurology.com/article_160216.html