



Comparative study between a new screwed Amplatz sheath and the ordinary one in percutaneous nephrolithotomy

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Abstract

Objective The objective of the article is to compare the results of using new screwed Amplatz sheath with results of the conventional Amplatz sheath regarding success and complications during percutaneous nephrolithotomy.

Methods 100 patients aged more than 18 years with renal calculi more than 2 cm with guy's score 1 from December 2018 till July 2020 were randomly stratified by closed envelope in group A (50 patients) with using conventional sheath and group B (50 patients) with new screwed sheath. We exclude morbid obese patients and patients with contraindication for PNL.

Results There were no significant differences between both groups regarding patients demographic and stone demographic. Operative time and fluoroscopy time were significantly lower in group B rather than group A. Tract stability was in favor of group B as no tract loss recorded while in group A, 5 cases were recorded. In overall complications there were no significant differences between both groups. Bleeding was higher in group A (14%) than in group B (4%), but it was not statistically significant. Success rates were 78% for group A and 88% for group B but it was not statistically significant.

Conclusion The screwed Amplatz sheath had showed less operative and fluoroscopy time. Also it enables urologists to have stable PNL tract. So it may be a promising tool to make PNL easier with higher success rate and lower complications.

Keywords Screwed sheath · Percutaneous nephrolithotomy (PNL) · PNL complications and PNL outcomes

Abbreviations

PNL	Percutaneous nephrolithotomy
SWL	Shock wave lithotripsy
IRB	Institutional board reviewing
CBC	Complete blood picture
FBS	Fasting blood sugar
KUB	Kidney, ureter, and bladder plain X-ray
CT	Computed tomography
NCCT	Non-contrast spiral CT
ECG	Electrocardio Myography
HB	Hemoglobin
SWL	Shock wave lithotripsy
IRB	Institutional board reviewing

Introduction

In the forties of the last century, Rupel and Brown were the beginners to launch stone removal through nephrostomy tube [1]. In the seventies of the same century, Fernstrom and Johansson described the detailed method in dealing with renal calculi and its extraction [2].

SWL utilisation led to a decline in PNL procedures [3]. PNL uses were reloaded again due to better understanding of PNL indications, refinement of its instruments and also its higher success rate than SWL [4, 5]. PNL now is the mainstay in treatment algorithm of renal calculi larger than 2 cm or SWL refractory calculi [6].

Percutaneous management of renal calculi is safe and tolerable, however, it has its own complications as any surgery [7]. On available literatures, PNL showed a wide range of complication rates up to 30%. However, most of these complications are minors [8–11].

Creation and maintenance of a stable tract is the main step of a successful PNL procedure with least operative morbidity [12]. Unstable tract may lead to increase of operative time, need for second look (redo) or even failure to achieve treatment goal [13].

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The goal of our research is to compare tract stability of our new screwed Amplatz sheath with ordinary one in PNL and its role in improving outcome and decreasing complications as primary end point. Also the radiation time and operative time were considered the secondary end point.

Patients and methods

Preliminary protocol was validated from our department scientific committee then approved by institutional reviewing board (IRB). Our team started data collection from our consented patients. This prospective comparative randomized (closed envelop) study was done in our urology center from December 2018 to till July 2020.

Patients stratified into two groups, group A patients in whom we used the ordinary Amplatz sheath and group B where we used the new screwed Amplatz sheath.

Our study included adult patients (more than 18 years old) with kidney calculi more than 2 cm (greatest dimension on NCSCT) with grade 1 according to Guy's stone score [14] (single stone in lower pole or renal pelvis with normal anatomy). We excluded recurrent cases, morbid obese cases more than 40 kg/m², uncontrolled bleeding disorders, congenital anomaly of kidney, skeletal deformities, and pregnant ladies.

Detailed patient's history, clinical assessment also routine pre-operative laboratory investigations (e.g., urine analysis and culture FBS, CBP, bleeding profile, renal function tests and liver function tests) and ECG (if required) were requested.

Scout X-ray for kidney, ureter, and bladder (KUB), ultrasonography for patient's abdomen and pelvis, non-contrast spiral CT and the contrast CT studies (for selected cases) were done.

Operative time was calculated from induction of anesthesia till fixation of nephrostomy tube, also radiation exposure (exposure time of the C arm) was recorded for each group.

In our current study, we listed intraoperative difficulties (at any step) or requirement of non-classic operative maneuvers and any intraoperative drawbacks, e.g., blood loss, collecting system perforation, tract wasting, re-puncture, sheath migration, any other complications (e.g., colonic, vascular or pleural injuries) or even abortion of the procedure for both groups and we gave special attention for the following:

- The need for another needle puncture.
- Over shooting of Alken dilators with fat visualization or extravasation of contrast.
- Amplatz sheath malposition as sheath inward over migration or slipping out of collecting system that required repositioning.

- Difficulties of visualization due to bleeding or perforation.
- Bleeding needs transfusion [15].
- Needs for auxiliary maneuvers

Screwed sheath description: (Fig. 1)

Inspired by laparoscopic instruments which are established tools in introduction of fitting sheaths and trocars through musculoaponeurotic tissues, we designed our device. The screwed Amplatz sheath was designed and developed by Khaled A E and realized locally in our hospitals' medical engineering unit, with a registration code (international application NO PCT / EG2020/000014). All devices dimensions and specifications were assured and revised with our medical engineers and operating staff.

- Made of PTFE (polytetrafluoroethylene)
- Radio-opaque
- Semi-lucent
- From the base till bevel end the sheath has 17 cm length
- The sheath composed of two parts, entry part with a beveled end of 3 cm length and 14 cm surgeon part
- The surgeon part description:
 - its length is 14 cm
 - inner sheath diameter is 30 French
 - outer sheath diameter (including) the screw is 36 French
 - sheath thickness with its crests is 2 mm
 - the crests edges are blunt and smooth
 - Each pitch has a thickness of 1.5 mm (wide blunt crests)
 - Inter-pitches distance is 3 mm
 - Each crest has a height of 1 mm
 - Screw outer surface fit nut

Patient part:

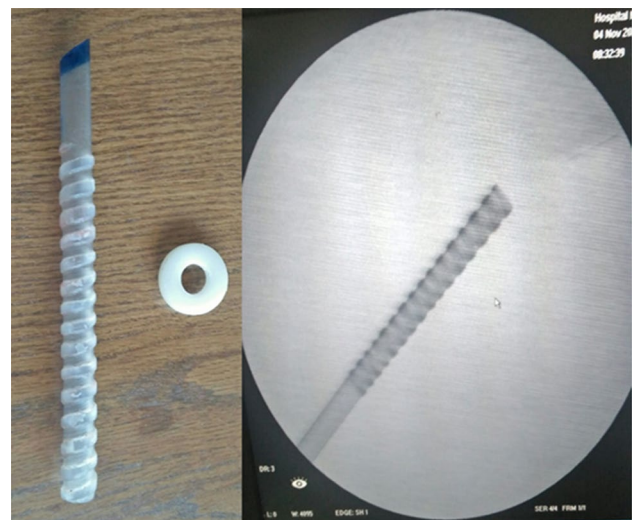


Fig. 1 The new screwed sheath with external nut

- o smooth surface (harmless contact to renal parenchyma)
- o beveled end with distal colored ring mark, (after which free instrument handling is achieved)
- o It is 3 cm length
- o sheath diameter is 30 French

External nut was used as extra compression force when there was bleeding from sheath entry, also it added more stabilization to sheath.

Operative data:

Operations were done by the same operative team. Preoperative antibiotic prophylaxis and general anesthesia were used for all patients for both groups, open tip ureteric catheter was inserted in lithotomy position then patient adopted prone position. The preferred calyceal puncture site was at posterior auxiliary line using free hand technique targeting posterior lower calyx. Contrast was injected with fluoroscope guide then insertion of 18 gauge puncture needle in collecting system using free hand technique, through which J-tip (0.035) guide wire was fixed then fascial dilator was applied, followed with (Alken) central metallic core dilator inserted into collecting system then single shot acute dilation with 30 F Amplatz dilator was done and finally with the screwed new sheath (30/36 F—described before) with clock wise controlled rotation (supplementary Fig. 1) through musculoaponeurotic tissue was applied, till the tip reach the collecting system in group (A), and with conventional 30 F sheath (Boston scientific 30F) and in group (B) Then calculus disintegration was done by the use of pneumatic lithotripsy as it is still used frequently in most urologic centers in Egypt. Nephrostomy tube and ureteral catheter or double J stent were inserted at the end of procedure (according to the final stone free situation at the end of the operation).

Statistical analysis

All data were collected, tabulated, and statistically analyzed using SPSS 22.0 for windows (SPSS Inc., Chicago, IL, USA).

Data were tested for normal distribution using the Shapiro–Wilk test. Qualitative data were represented as frequencies and relative percentages. Chi-squared test (χ^2) and Fisher exact were used to calculate difference between qualitative variables as indicated. Quantitative data were expressed as mean \pm SD (standard deviation) for parametric and median and range for non-parametric data.

Independent *T* test and Mann–Whitney test were used to calculate difference between quantitative variables in

two groups for parametric and non-parametric variables, respectively.

All statistical comparisons were two tailed with significance level of *P* value ≤ 0.05 indicates significant, $p < 0.001$ indicates highly significant difference while, $P > 0.05$ indicates non-significant difference.

Sample size.

Based on fluoroscopy time in multiple dilators 3.7 ± 2.8 and that for Amplatz dilators 5.9 ± 4 (Arslan et al. 2017) [16]. Using OpenEpi software, sample size was calculated to be 52 in each group at confidence level 95% and power of study 90%. In group A, two cases were dropped as there were suspected Covid 19. While in group B one case refuse PNL and ask for SWL and another case was dropped from our study due to Covid 19 infection.

Results

Patient characteristics

As shown in supplementary table 1, 100 patients divide equally into two groups A and B, ($n = 50$) for each one representing 50% of total sample size, group A utilized conventional PNL sheath and group B utilized the new screwed sheath in the current study. The patients' mean age was 45.14 ± 8.21 years for group A and 45.0 ± 10.01 years for group B. In both groups, there were no significant differences regarding gender and BMI.

Stone characteristics

As shown in supplementary table 2, the mean stone size for group A was 27.54 ± 5.05 mm and for group B was 28.0 ± 4.85 mm. Lower calyceal stones present in 48% of group A patients and 56% for group B patients. Renal pelvic stone represent 52% and 44% for group A and B receptively. Mean stone density for group A was 1022.44 ± 336 while group B was 1071 ± 388 . There were no significant differences between both groups regarding stone demographics.

Intraoperative data

As shown in Table 1, there were no statistically significant differences between both groups regarding puncture number and sites. However, the operative time revealed statistically significant lower incidence in group B (59.36 ± 8.44) than group A (82.32 ± 4.26). Fluoroscopy time revealed statistically significant lower incidence in group B (1.49 ± 0.478) than group A (3.31 ± 0.941). In access failure issue, although group B was lower but with no statistically significant difference between both groups. As it was (4%) and (8%) in group B and A, respectively. According to track loss and

Table 1 Intraoperative data and complications

	Group A (n=50)	Group B (n=50)	T	P
Number of punctures	1.10±0.303	1.04±0.198	1.17	0.060
Mean ± SD	1–2	1–2		
Range				
Puncture site				
Lower	33 (66%)	39 (78%)	2.214	0.331
Lower & middle	5 (10%)	2 (4%)		
Middle	12 (24%)	9 (18%)		
Operative time (min)	82.32±4.26	59.36±8.44	17.17	0.000
Mean ± SD	74–89	45–80		
Range				
Fluoroscopy time (min)	3.31±0.941	1.49±0.478	12.17	0.000
Mean ± SD	2–6.5	1–3		
Range				
Aborted procedure due to failed access				
No	44 (88%)	48 (96%)	2.84	0.242
Yes	4 (8%)	2 (4%)		
Track loss				
No	45 (90%)	50 (100%)	5.26	0.022
Yes	5 (10%)	0		
Sheath reposition				
No	45 (90%)	50 (100%)	5.26	0.022
Complications of percutaneous nephrolithotomy	Group A (n=50)	Group B (n=50)	χ^2	P
Intraoperative bleeding managed by nephrostomy tube and premature termination of procedure				
No	43 (86%)	48 (96%)	3.05	0.081
Yes	7 (14%)	2 (4%)		
Perioperative bleeding needs transfusion (15)				
No	46 (92%)	49 (98%)	1.89	0.169
Yes	4 (8%)	1 (2%)		
Pelvicalyceal system perforation				
No	44 (88%)	49 (98%)	3.84	0.050
Yes	6 (12%)	1 (2%)		
Postoperative complication grade 1–2 (fever and stent related)				
No	40 (80%)	39 (78%)	0.060	0.806
Yes	10 (20%)	11 (22%)		

sheath reposition, group B (0%) was significantly lower than group A (10%).

Pneumatic lithotripsy was the standard method in our center due to cost issues. The frequent stone extractions increase the percent of sheath malposition, track loss and also bleeding. Although we use safety guide wires but the presence of safety wire does not prevent sheath slippage but facilitate tract regain and or decrease of another puncture. Track loss and sheath reposition was occurred in five cases of group A and thus explain the increased time for fluoroscopy and operative time. The presence of external nut in screwed sheath group fix the sheath in position prevented sheath malposition.

Complications

Table 1 shows intraoperative complications.

Intraoperative bleeding managed by premature procedure termination and nephrostomy tube was higher in group A (14%) than group B only 4%. Bleeding needs transfusion [in patients with hemodynamic instability or hemoglobin (Hb) levels were below 10 g/dl (15)] high in group A (8%) than group B (2%). Pelvicalyceal perforations were 12% for group A versus 2% for group B. Although there was no statistically significant difference between both groups but group B had fewer complications than group A. Sheath width has no relation to parenchymal bleeding as the parenchymal part

was similar to conventional sheath. Also the screwed part was designed to fade away gradually from outside to inside.

Operative outcome

Supplementary table 3 shows that there was no significant difference between the groups. However, success rate was higher in group B as it was (78%) and (88%) in groups A and B. It was also notable that there was lower need for auxiliary maneuvers but with non-statistically significant values. The success percentage can be explained as shown in results tables:

We have failed to obtain access to the kidney in four patients in group A and in two cases in group B, also we have intraoperative bleeding which push us to terminate the operation early and thus was in the early cases.

Discussion

PNL is the mainstay in management of kidney calculi more than 2 cm. Stable track is necessary for high stone free rate, shorter radiation, and operative time. Also it helps to lower complication rates [12, 13, 17].

So the idea of our new screwed Amplatz sheath is creation of a more tenacious tract between skin, dorso-lumbar fascia and the kidney. This minimizes the possibility of tract loss, repositioning of the sheath and repeating collecting system puncturing. That all give an added value in improvement of PNL outcome and decreasing complications [18].

Similar to De Sio and his colleagues, we excluded morbid obese patients more than 40 kg/m to avoid the need of extra length sheath [19].

Track loss and the need for sheath repositioning were significantly lower in group (B) with screwed sheath. In group A with conventional sheath, track loss with sheath reposition occurred in 10% of patients. This could be explained by the mechanically fixed sheath with its less over migration or withdrawal. So the vicious circle of consequently instability (over migration/withdrawal), collecting system violation and bleeding was cut [18].

Collecting system perforation was lower in group B (2%) than group A (12%). It was not statically significant, but it was clinically evident the wide range of difference between both groups. Also group B results show lower percent of collecting system violation when compared with Taylor et al. [20] and Mousavi-Bahar SH et al. [8]; collecting system injuries were 8% and 5.2%, respectively. This could be explained by the stability of the screwed sheath and lower rates of advancement during manipulations. External nuts keep PNL sheath in place.

Intraoperative bleeding which was managed by termination of the procedure and nephrostomy tube fixation was

higher in group A than group B; it was 14% versus 4%, respectively. Although the wide clinical difference between both groups but it was not statically different. Mousavi-Bahar SH et al. [8] reported 6% incidence of intraoperative bleeding. Nikie P et al. [21] also reported 7.9% of intraoperative bleeding. Both studies had higher incidence of bleeding than screwed sheath group.

Blood transfusion was indicated if the patient was hemodynamic instable or HB was less than 10 gm/dl [15]. Blood transfusion was needed in 2% of group B patients versus 8% of group A patients. Although the wide clinical difference between both groups but it was not statically different. In literature blood transfusion due to PNL bleeding showed wide range (5–18%) [8, 22]. Also Turna et al. [23] reported blood transfusion in 23.8% of patients, while Nikić P et al. [21] reported blood transfusion in 3.17%. All mentioned studies showed higher rates of blood transfusion than screwed sheath group.

Tract stability beside tract numbers affect bleeding control. This issue is still controversial. Hegarty and Desai [24] proposed similarity between hemoglobin drop in single and multiple tracts. On other hand, Turna and his associates blamed other factors rather than stability as puncture number, dilation size, and site especially in large stones [23]. Also the external nut had hemostatic effect due to its compression force which control cutaneous bleeding from the entry site.

Other complications were minor with Clavien grade 1–2 for both groups. No significant difference between group A 20% and group B 22%. Nikić P et al. [21], Tzeng et al. [25], and Wang et al. [26] showed similar results.

PNL procedure was terminated in (4%) in group (B) while the percent was (8%) in group (A) with no significant difference between both groups. The cause of failure in both groups was related to failure to gain access. Borofsky et al. [27] stated that access failure was the main cause for aborted PNL.

Screwed sheath group operative time (59.36 ± 8.44 min) was significantly lower than group A (82.32 ± 4.26 min). It was also lower than operative time reported by Akman et al. [28] (64.9 ± 27.6 in 1897 patients) and Rahul Gupta et al. [29] (78.24 ± 17.6 min).

It is noteworthy that, definition of operative time is variable between different studies. While De sio et al. [25] calculate it from ureteral catheterization to the placement of the nephrostomy tube, Rana et al. [30] recorded it from the anesthesia sheet. Other studies not mention the operative time at all, but in our work, we calculate it as Basiri et al. [31] as they calculate from intubation till nephrostomy tube fixation.

Fluoroscopy time in group B showed significant lower mean value of (1.49 ± 0.478 min) than group A (3.31 ± 0.941 min). Also screwed sheath group had lower

fluoroscopic time than reported by than Basiri and Karami and their colleagues whom reported (5.5 ± 1.7 min) and (9.4 ± 2.3 min), respectively [32, 33]. Time shortage in our screwed sheath group could be explained with the lower indices of tract loss with a less need for sheath reposition. As sheath reposition consumes more radiation to put the PNL procedure in its right tract.

Stone free state is considered if residual stone less than 4 mm [34]. According to this, no statistically significant difference in success rate between both groups, (78%) in group A and (88%) in group B. Our results is comparable as reported in many literatures [9, 10, 35].

Finally, it worth mentioning that, we did not need extra hand of assistant in sheath securing during stone fragments removal. It may add more space for the surgeon to manipulate his stone.

Limitations

We think that our study should be extended in a larger number of patients and utilized in more stones demographic varieties. The difference in size (stone volume), site, and its composition, and this aspect surely affect calculus free outcome state and also affect intraoperative complications. Also tract size was big and related intraoperative morbidity is undeniable but large sheathes still have indication in large burden stone. Also, our idea proved that our screw sheath was stable so we can use lower sheath size and for this issue further studies can be done comparing different sizes of the smooth and screwed sheathes.

Conclusion

The sub-totally screwed Amplatz sheath enabled us to achieve stable PNL tract. So it minimizes PNL complications and makes it easier, with shorter operative time and less radiation exposure. As it enables urologists to have more tenacious tract in comparison with the original sheath.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s00345-021-03806-2>.

Author contributions AK: protocol development, data collection, and manuscript writing; MEI: manuscript writing and data analysis; MMM: data collection; SEM: protocol development, data collection, and manuscript writing.

Declarations

Conflict of interest In this study, no conflict of interest is present. It includes human patients with renal stones. Every patient was consented after detailed information about the study.

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