Minerva Urologica e Nefrologica
EDIZIONI MINERVA MEDICA

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Minerva Urologica e Nefrologica 2021 Jan 13
DOI: 10.23736/S0393-2249.20.04107-7

Article type: Original article

Article first published online: January 13, 2021
Manuscript accepted: November 24, 2020
Manuscript revised: November 11, 2020
Manuscript received: August 16, 2020

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Abstract

BACKGROUND:

To reach a consensus in the classification and standardized reporting for the different types of PCNLs.

METHODS:

The RAND/UCLA appropriateness methodology was used to reach a consensus. Thirty-two statements were formulated reviewing the literature on guidelines and consensus on PCNLs, and included procedure specific details, outcome measurements and a classification for PCNLs. Experts were invited to two rounds of input, the first enabled independent modifications of the proposed statements and provided the option to add statements. The second round facilitated scoring of all statements. Each statement was discussed in the third round to decide which statements to include. Any suggestion or disagreement was debated and discussed to reach a consensual agreement.

RESULTS:

Twenty-five recommendations were identified to provide standardised reporting of procedure and outcomes. Consensual scoring above 80% were strongly agreed upon by the panel. The top treatment related outcomes were size of sheath used (99.1%) and position for PCNL (93.5%). The highest ranked Outcome Measures included definition of post-operative hospital length of stay (94.4%) and estimated blood loss (93.5%).

CONCLUSIONS:

The consensus statements will be useful to clarify operative technique, in the design of clinical trials and standardized reporting, and presentation of results to compare outcomes of different types of PCNLs.

Key words: Classification, standardization, percutaneous nephrolithotomy, miniaturization, consensus, sheath size

Introduction

Currently, there is no consensus on the classification and standardized reporting of percutaneous nephrolithotomies (PCNL). An increasing number of publications and presentations on PCNL are received by journals and conferences and a consensus on classification and standardized reporting of PCNL should be reached to facilitate design of clinical trials, and for readers of clinical papers and delegates at conferences to clarify operative technique, results and compare outcomes for the different types of PCNLs.

In addition, miniaturization of PCNL is gaining popularity in many regions of the world in an attempt to treat a rising incidence of paediatric stones and to reduce morbidity (blood loss and complications) and improve quality of life (reduced pain and shorter hospital stay) for adult stones [1]. However, there are variations of miniaturised PCNL, and new miniaturised techniques continue to evolve.

The definition of mini-PCNL is still variable and new clinical trials are designed to study the efficacy of different types of mini-PCNLs, which are still unclear for many readers and reviewers. There is no agreement on definition of stone free status and size of insignificant stone fragments, making it difficult to compare results from different studies. In the design of clinical trials, it is important to clarify the important features of the new surgical technique and include the necessary information to facilitate comparison of outcomes.

This consensus was conducted to identify areas of agreement and key features in PCNLs that ought to be specified. This will help reviewers and readers to understand and differentiate the different types of PCNLs, aid in clarification during presentations and allow comparison of outcomes.

Materials and Methods

The consensus was carried out as per the RAND/UCLA appropriateness methodology[2]. As per this approach, a core group of clinicians prepared a set of 32 statements concerning procedure specific details such as positioning, imaging used, outcome measurements and a classification for conventional versus mini PCNLs. In the first round, the identified experts with combined experience of more than 40,000 PCNLs reviewed these statements and were allowed to modify existing statements or add additional statements. In round 2, a revised set of 37 statements was resent to the same group and they were asked to rank the acceptance of the statement from 1 (do not accept) to 9 (accept completely). These scores were collated and the statements were grouped into three groups formed on agreement (good agreement: 7-9, equivocal: 4-6 or disagreement: 1-3) reached from the median score calculated for each statement based on the RAND/UCLA classical criteria. Percentage of agreement was calculated for each statement and statements that had more than 80% agreement were deemed to need minimal discussion in round 3. Those that gained less than 80% were included for discussion and modification in round 3. The panel met on 21 September 2019 at the International Alliance of Urolithiasis annual conference to discuss each statement ranking and to decide which statements to include. During this meeting, the ranking and scores of the statements were projected and each statement was discussed. Any

disagreement or suggestion was noted, debated and discussed until resolution was obtained. The primary author in this paper navigated the final round and maintained an impartial view to the statements to be included and did not provide scoring for the statements. The panel included one member with prior experience with RAND/UCLA methodology [3] who provided guidance in this process.
The authors were selected based on their experience in endourology and PCNL. Half of the authors are from the IAU core group and the other half are not.

Setting and participants:
An international panel was selected based on their expertise and experience in both conventional and miniaturized PCNLs. The same questionnaires were sent to an international panel of 16 members. Members who participated in all three sections were automatically included as authors and acknowledgment was given where an opinion was sought.

Results

The consensus process identified 25 recommendations that are useful to allow standardised reporting of procedure and outcomes, and to allow for comparison among various techniques. Every statement was discussed [Table 1]. The statements scoring above 80% were strongly agreed upon by the panel. Statements scoring less than 80% were discussed in great detail. The consensus scoring shows that the size of the sheath used (in Fr) should be stated. Conventional PCNL is defined as sheath size of greater than 22 Fr and mini-PCNL is defined as sheath size of less than or equal to 22 Fr.

The position for PCNL include the position on table (prone, supine or lateral) and the position and level of puncture for PCNL. The access position including upper pole (supracostal versus subcostal), inter-pole or lower pole should be stated. The number of tracts, the use of flexible nephroscope and/or flexible ureteroscope should be registered. Endoscopic combined intrarenal surgery (ECIRS) and the operative positioning need to be specified.

The name of the procedure should be mentioned. Super-mini PCNL imply the use of a 12-14 Fr access sheath and the presence of continuous low pressure and intermittent high-pressure suction to remove stone fragments [4] Ultra-mini PCNL imply using a 6 Fr mini nephroscope through an 11-13 Fr metal sheath to perform holmium: YAG laser lithotripsy. It uses a vacuum cleaner (vortex) effect to remove stone fragments[5]. Access and nephroscopy times should be included. Modality of imaging used to perform access should have a minimum of fluoroscopy time and radiation dose. The size and name of drainage tubes should be stated. Energy source used for stone breakage should be delineated.

In terms of outcome measures, the top five outcomes included post-operative hospital length of stay, blood loss estimated by drop in haemoglobin and/or requirement for blood transfusion, imaging modality to determine treatment success, complications classified using Clavien-Dindo classification [6, 7] and that pain post op should be measured using a Visual Analogue Scale, 12, 24, 48 hours after the procedure [Table 1].

Treatment success will be defined as the absence of clinically significant residual fragments of more than or equal to 2mm by a non-contrast CT KUB rather than absence of any stone fragment. The ideal modality of imaging before and after a PCNL is a non-contrast CT KUB and the ideal period for both is within 3 months of the PCNL. Important consensual features of the surgical technique and outcome measures which need to be stated for clarification purposes are listed in Table 2.

One member felt that the nephroscope size should be stated as it may affect the intra-renal pressure. The consensus was that a size difference of a minimum of 4 Fr between the sheath and the nephroscope is more important than the actual nephroscope size. In addition, the presence of continuous low pressure and active high-pressure suction (such as in Super-mini PCNL) will influence the intra-renal pressure.

It was felt that the irrigation and suction pressure used during PCNLs are optional as it may differ from case to case.

Two members did not complete the first two rounds and did not attend the third-round meeting and were not included in the paper.

Discussion:

The RAND/UCLA Appropriateness Method was developed in the mid 1980s, as part of the RAND (Research and Development) Corporation/University of California Los Angeles (UCLA) Health Services Utilization Study, primarily as a method that combined the best available scientific evidence with the collective judgment of experts to yield a statement regarding the appropriateness of performing a procedure at the level of patient-specific symptoms, medical history, and test results[2].

A systemic review and meta-analysis of clinical effectiveness of kidney stone treatments have concluded that well-designed, prospective, comparative studies that measure PCNL technique and outcomes using standardised definitions are required [8]. Establishing a PCNL-specific classification system for reporting outcomes and complications could set the basis for further improvement of the PCNL technique and outcomes [9].

A number of treatment guidelines and consensus of standardization of patient outcomes reporting in percutaneous nephrolithotomy have been described [10-12]. Several authors in this article were involved in these guidelines and consensus of standardization reporting. Since the last consensus paper [12] was published 6 years ago, a number of changes in surgical technique including miniaturization of PCNL and outcome measures of PCNL have evolved and will be discussed below.

It comes to no surprise that the statement related to the size of sheath used was ranked highest closely followed by the statement related to the position for PCNL since both have dominated the discussion on treatment related outcomes during the past decade. Since conventional PCNLs began in its current form in 1980s, a variety of modifications have taken place in an attempt to retain good outcomes while minimizing bleeding, complications and to enhance recovery[13].

While an increasing number of urologists are practising miniaturized PCNLs, there are many who are continuing with conventional PCNLs. Conventional PCNL is defined as sheath size of greater than 22Fr as the typical sheath sizes are 26, 28 and 30 Fr. Mini-PCNL is defined as sheath size of less than or equal to 22Fr. Common mini-PCNL sheath sizes range from 14-18 Fr and usually rely on vacuum cleaner effect to remove stone fragments. Super-mini PCNL uses 14 Fr suction sheath with continuous low pressure and controllable intermittent high-pressure suction for stone fragment removal. A disposable Super-mini PCNL suction sheath is available (ClearPetra®), which uses a 12 to

22 Fr plastic suction sheath that also allows the passage of a flexible nephroscope to access the ureter and different calyces. The continuous low pressure and controllable intermittent high-pressure suction of Super-mini PCNL keep the intrarenal pressure low [4] and may be useful to preserve renal function. Ultra-mini PCNL uses 13 or 11 Fr with vacuum cleaner effect to remove stone fragments [14]. Micro-percutaneous nephrolithotomy (Microperc) uses a 4.85 Fr (16-gauge) sheath and holmium laser to disintegrate small stones. Stone retrieval is not possible [15]. Mini-Microperc is a modification of Microperc and employs an 8 Fr metallic sheath, which permits holmium laser, an ultrasonic/ballistic probe with suction to remove renal stones[16].

Whereas many urologists who carry out miniaturized PCNLs are convinced of their benefits, urologists who do not perform miniaturized PCNLs would like to see more evidence of its advantages, especially from prospective randomized controlled trials, before adding miniaturized PCNLs onto their armamentarium. There may be particular situations where a smaller tract may be advantageous, such as stones in anterior calyceal diverticula, infundibular stenosis, transplant, horseshoe kidneys and paediatric cases. In the comparison of miniaturized and conventional PCNL or among the different types of miniaturized PCNLs, or in the comparison of a PCNL to RIRS or SWL, it is important to clarify the important operative features in order to compare surgical outcome [Table 2].

The positioning of PCNL has different surgical and anaesthetic implications. Prone and supine PCNL each has its pros and cons [17-22]. Supine PCNL is associated with an easier cardiovascular and airway control; shorter operation time in some cases due to lack of the need for repositioning and the possibility for a combined retrograde approach in selected cases. However, the prone position provides a bigger surface area for percutaneous access and a broader space for manipulating the nephroscope and lithotripters; a shorter skin to kidney tract distance and opportunity for a single session bilateral PCNL[23]. To optimize operative factors and overcome their respective limitations, there have been various modifications of supine positioning [24-31].

A popular position for supine PCNL is the Galdakao modified supine Valdivia position, described by Ibarluzea et al[32]. This position has pros and cons, main advantages include greater versatility of stone manipulation, most of the cardiovascular and pulmonary problems during anaesthesia related to prone position are also reduced. Furthermore, this position reduces risks of compression of brachial plexus, possible cause of postoperative visual problems and neurological defects. On the other hand, authors mention possible lesions of knee ligaments, ulnar or radial nerves in case lower/upper limbs are not correctly placed and protected.

An additional advantage of the Galdakao modified supine position is the possibility of performing easily a combined retrograde/antegrade intrarenal approach, allowing enough room for two separate surgeons to operate simultaneously in the upper urinary tract[33].

However, there is a lack of randomized controlled studies to compare these modified positions with standard and miniaturized PCNLs and the suitability of miniaturized PCNLs in various supine positions. Currently, a superiority of a position over the others is not clearly demonstrated[34]. In the design of these studies, it is crucial to use the right nomenclature to be able to compare outcomes accordingly.

We therefore welcome the increasing number of studies comparing different approaches to PCNL [5, 14, 35-38]. It is of utmost importance, however, to also use the right nomenclature to be able to compare outcomes accordingly.

In parallel to miniaturization of PCNL instruments, the urological community has also witnessed the development and benefits of different energy sources for stone disintegration. Miniaturized PCNLs with smaller sheath sizes of 14 Fr or smaller are relying on laser energy to fragment and dust stones. Larger sheaths can accommodate ballistic lithoclast, ultrasonic probe or laser. Newer and high-powered laser machines with a number of novel features and thulium fiber laser (TFL) have become available to fragment and dust stones to reduce

operative times. In vitro studies comparing thulium fiber laser with Holmium:YAG laser have shown a four-fold higher absorption coefficient in water, allowing the use of smaller operating laser fibers (50–150 µm core diameter) with lower energy per pulse (as low as 0.025 J), and higher maximal pulse repetition rate (up to 2000 Hz) in favour of TFL [39]. Multiple comparative in vitro studies of high power holmium:YAG versus thulium fiber laser treatment of kidney stones in dusting mode suggest a 1.5–4 times faster stone ablation rate in favour of the Thulium fiber laser. TFL appears to be a promising alternative laser for lithotripsy when operated in dusting mode, producing higher stone ablation rates and smaller stone fragments than the Holmium laser. The achievement of a higher stone ablation rates and the production of smaller stone fragments may be particularly advantageous for miniaturized PCNL, especially those with a continuous low pressure and active high-pressure suction such as the Super-mini PCNL. Clinical studies with the right standardized nomenclature are necessary to demonstrate the efficacy of newer energy sources for stone disintegration.

When we consider outcome measures for different variations of PCNL, important clinical outcomes include length of hospital stay, blood loss and blood transfusion, imaging modality to determine stone free rate, definition of stone free, classification of complications and assessment of post op pain. The consensus statements included post-operative hospital length of stay, which is defined as length of stay (LOS) between end of procedure and clinical decision to discharge. Hospital stay less than 24 hours after surgery = 0 day/day case. Blood loss is estimated by drop in haemoglobin or requirement for blood transfusion due solely to the procedure at a pre-set cut off Hb level. Imaging modality to determine treatment success and the timing post procedure (ideally within 3 months) should be mentioned. Currently, a low dose non-contrast CT KUB has the best sensitivity and specificity and is less operator and machine dependent when compared to ultrasound localisation. A CT is more likely to be able to differentiate pre-existing Randall's plaques compared to residual fragments. Complications should be classified using Clavien-Dindo classification [40-44]. Pain post op should be measured using a Visual Analogue Scale, 12, 24, 48 hours after the procedure. Additionally, the utilization of validated questionnaires should be considered to evaluate post-operative quality of life such as the Wisconsin Stone Quality of life Questionnaire (WISQOL) [45].

A limited number of examples of comparative studies are available where standardization of reporting is emphasized in being important to be able to compare outcomes [35]. In a review of patient outcomes in 83 RCTs, the quality of reporting of outcomes was variable, only 24/53 (45.3%) studies had a formal definition of stone-free status and the imaging modality varied considerably among studies [12]. Many studies in the past had relied on ultrasound or X-ray as imaging modalities to determine stone-free status, which had their challenges picking up residual stone fragments smaller than 4mm. Patients with fragments >4 mm had higher rates of stone-related events and shorter time to occurrence of stone-related events [46]. Residual stone fragments following PCNL have been associated with dramatic increase in stone formation [47]. The definition of residual stone fragments is still under debate. Hence the panel has decided to come together to agree on a suitable cut-off for stone-free status. Recently, it has become possible to carry out low dose CT KUB with a radiation dose similar to a plain KUB X-ray with increased sensitivity. We propose to utilize a 2 mm cut-off as it seems to be associated with less stone-related events post-operatively as suggested by Osman et al in a multivariate analysis [48]. We also believe that a 2 mm cut-off may exclude the commonly found Randall's plaques and prefer a 2 mm to 0 mm cut-off. Treatment success as stone-free status will be defined as the absence of clinically significant residual fragment of more than or equal to 2mm rather than absence of any stone fragment. The modality of imaging must be stated and ideally should be carried out within 3 months of the operation.

Many of the developments in treatment related factors go hand in hand with outcome measures. It is therefore obvious that a standardized nomenclature is critical and mandatory.

Following a PCNL operation, length of stay can be affected by patient and stone factors as well as surgical techniques, and these include patient comorbidities, stone size and complexity, access sheath sizes and operator experience. Data derived from a UK multicentre hospital episode statistics database consisting of 5750 index PCNL procedures performed in 165 hospitals showed a median hospital stay of 4 (3-6) days and a mean of 5.2 days [49]. The PCNL procedures took place between 2006 and 2011, prior to the introduction of miniaturized PCNLs in the UK. Since the introduction of miniaturized PCNL, a number of papers have shown that miniaturized PCNL were associated with a short hospital stay. Desai who started 13 Fr Ultra-mini PCNLs (UMP) reported hospital stay of 1.2 days in the treatment of calculi less than 2cm [5, 14]. The 'mini-perc' technique was suggested as a less invasive alternative to conventional percutaneous nephrolithotomy with a reported hospital stay of 1.7 days [36]. A randomised clinical trial comparing ultra-mini and standard PCNL in stones up to 20 mm showed a statistically significant difference in the duration of hospitalisation of 2.32 (0.84) in the UMP versus 3.60 (0.80) in the standard PCNL groups [37]. In a randomized prospective study comparing miniaturized 16 Fr and standard PCNL with kidney stones greater or equal to 2 cm, hospitalization was longer in the standard PCNL group (p=0.005) [38].

Important factors influencing bleeding include accurate puncture of the calyceal fornix and avoiding excessive torque of the kidney. Although a papillary puncture is generally preferrable, a non-papillary access is also described[50]. In this case, authors did not report a higher risk of complication and this Consensus believe it is a good option in experienced hands when an access to the renal papilla is not feasible.

In terms of sheath size, blood loss has been shown to be associated with PCNL sheath size in children. A sheath size of >20 Fr was found to be an independent predictor of complications and bleeding requiring blood transfusion in a retrospective multi-institutional cohort involving 1,205 paediatric renal units [51]. Other studies of paediatric PCNLs have also shown that a larger PCNL access tract were associated with greater blood loss [52, 53]. In agreement, a smaller PCNL access tract of <24 Fr resulted in less blood loss with equivalent success rate [54]. Another large paediatric study of 1,135 renal units demonstrated significantly less blood transfusion in all age groups when a smaller tract <20 Fr was used [55].

As for the influence of sheath size and bleeding in the adult population, a randomised prospective comparison of miniaturized (16 Fr mPNL) and standard (30 Fr sPNL) PCNL with kidney stones equal or larger than 2 cm, the haemoglobin drop was less in mPNL (0.7 *vs* 1.4 g/dL, $p = 0.011$). This study consisted of a total of 148 (76 mPNL, 72 sPNL) patients with a history of PNL and/or open surgery. The tubeless procedure was higher in the mPNL (21.1% *vs* 2.8%, $p = 0.001$). Duration of nephrostomy and hospitalization was longer in sPNL ($p = 0.001$ and $p = 0.005$, respectively). The mean duration of operation was longer in mPNL (106.9 *vs* 91.2 minutes, $p = 0.016$). The mean duration of fluoroscopy in mPNL was shorter (4.4 *vs* 5.3 minutes, $p = 0.021$). The success rate in the mPNL group was higher compared with the sPNL group; however, this difference was statistically insignificant (75.0% *vs* 72.2%, $p = 0.558$) [38]. A smaller tract in miniaturized PCNL may allow more torque to be exerted on the tract and less bleeding when compared to a conventional larger tract.

There are a number of limitations of this consensus document. It was not possible for this consensus document to cover every important issue and every factor of PCNL, especially when there are regional differences in clinical practice and the need to individualize treatment plans. This is reflected in the use of antibiotic prophylaxis and its effect on sepsis rate. Any change in renal function following kidney access by different tract sizes with variable intra-renal pressures with or without suction and following removal of kidney stone has not been measured. It may be interesting to study whether a small tract size with continuous suction to maintain a low intra-renal pressure preserves

renal function. The costs of different treatments have also not been included. The cost incurred in one hospital or country may not be comparable to another institution and can be difficult to measure accurately, especially when other factors such as nursing and theatre costs are included. We have tried to select experienced experts who perform large numbers of PCNLs using different methods and positions. Even though some experts we approached have not responded to the questionnaires, we acknowledge that there are presently simply too many great endourology experts to include all of them. This consensus has focused on some important features of PCNL as it is not feasible to cover every detail in a single consensus or one paper and a future consensus will be helpful to go into further details. The strength of this document is that it is supported by the International Alliance of Urolithiasis (IAU) and covers a global representation.

In summary, different types of PCNL are currently undertaken worldwide and miniaturized PCNL has shown to be safe and efficacious. Newer varieties of PCNL will become available to minimize complications and enhance recovery, especially in challenging renal units. Further studies are necessary to compare and contrast between the different types of PCNLs. Hence a standard of classification and reporting is required to enable this to be carried out.

Conflict of interests

Authors have nothing to disclose

Table 1 Agreement rates on proposed statements

Score	Rank	Treatment Related Statements
99.1%	1	The size of sheath used (in Fr) should be stated.
93.5%	2	Position for PCNL must be mentioned (prone/supine/lateral).
92.6%	3	Access time includes the time from the first attempt of needle puncture to the beginning of nephroscopy.
92.6%	3	Total nephroscopy time should be calculated as the time spent on both fragmentation and retrieval of fragments.
92.6%	3	The end point of the procedure is the time of closure of the nephrostomy site or when the nephrostomy tube is secured.
91.7%	4	Size and name of drainage tubes (nephrostomy or stents), or whether the procedure was tubeless should be mentioned.
90.7%	5	The name of the procedure should be mentioned (standard, super-mini PCNL etc).
90.7%	5	Radiation exposure is obtained from the dose summary noted in the fluoroscopy machine at the end of each procedure.
88.8%	6	Modality of imaging used to perform access should be mentioned i.e., fluoroscopy only, ultrasound only or combination.
88.8%	6	Access time should be included in the overall operating time.
87.9%	7	Energy source used for stone breakage should be stated.
82.4%	8	Standard PCNL is defined as sheath size of greater than 22Fr.

82.4%	8	Mini PCNL is defined as sheath size of less than or equal to 22Fr.
82.4%	8	Beginning of PCNL should be measured from the moment of initiating access into the collecting system using a nephrostomy needle.
78.7%	9	Nephroscope size and name should be stated.
78.7%	9	Feasibility of stone retrieval for analysis should be mentioned.
77.8%	10	Method of stone removal should be mentioned. e.g. grasping forceps, suction of fragments through ultrasound probe channel, active suction, vortex etc.
67.6%	11	Irrigation pressure (in cm H_2O) of normal saline used should be stated
61.1%	12	Suction pressure (in cm H_2O) used during PCNL should be stated.
Score	**Rank**	**Outcome Measures**
94.4%	1	Post-operative hospital length of stay must be defined as LOS between end of procedure and clinical decision to discharge.
93.5%	2	Blood loss estimated by drop in haemoglobin (Hb) or requirement for blood transfusion (due solely to the procedure at a pre-set cut off) must be stated.
92.6%	3	The imaging modality used to investigate this and the timing of this post procedure must be mentioned.
92.6%	3	Complications should be classified using the Clavien Dindo classification specified for PCNL.
87.9%	4	Pain post op should be measured using a Visual Analogue Scale. This should be assessed at 12 hours, 24 hours and 48 hours after end of procedure.
87.9%	4	Urine leakage should be defined as the presence of urine draining from the flank incision more than 48 hours after removal of all tubes (nephrostomy/drain) from the kidney.
86.1%	5	Haemoglobin should be measured pre-operatively and 24 hour post-operatively
86.1%	5	Analgesic requirement can be used as a surrogate only if there is a standardized post op pain escalation pathway. The dose and duration of analgesia used should be mentioned.

83.3%	6	Hospital stay less than 24 hours after surgery = 0 day/day case.
82.4%	7	Treatment success will be defined as the absence of clinically significant residual fragment of > 2mm.
81.5%	8	QOL assessment using EQ-5D-5L value set before, one day post op and 6 weeks after surgery must be used.
78.7%	9	Change in renal function due to PCNL should be measured by the difference in estimated GFR before and one month after PCNL.
63.9%	10	Treatment success will be defined as the absence of any stone fragment irrespective of size.

Table 2 Summary of Panel Consensus recommendations to allow standardised reporting of procedure and outcomes

Surgical Technique
1. Name of procedure
2. Size of sheath
3. Position of PCNL
4. Modality of imaging used to perform access, i.e., fluoroscopy only, ultrasound only or combination.
5. Operating time
6. Drainage tube
7. Radiation time
8. Energy source for lithotripsy
Outcome measures
1. Length of stay
2. Blood loss and blood transfusion with at a preset cut off value
3. Imaging modality and timing post-op
4. Complications according to Clavien-Dindo classification

5. Urine leakage
6. Analgesic requirement
7. Treatment success will be defined as the absence of clinically significant residual fragment equal or > of 2mm.
8. QOL assessment using WISCOL value set before, one day post op and 6 weeks after surgery must be used.

Authors contribution

Study design: SC, AS

data collection: all authors

Statistical analysis: SC, AS

article writing: SC, JD, JDR, GM

supervision of the study: SC, AS, GZ, JD, JDR

All authors read and approved the final version of the manuscript

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