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Clinical comparison of mini-percutaneous nephrolithotomy with vacuum cleaner effect or with a vacuum-assisted access sheath: a single center experience

Elena Lievore[a,#], Luca Boeri[a,#], Stefano Paolo Zanetti[a], Irene Fulgheri[b], Matteo Fontana[a], Matteo Turetti[a], Carolina Bebi[a], Francesco Botticelli[a], Andrea Gallioli[a], Fabrizio Longo[a], Roberto Brambilla[d], Mauro Campoleoni[d], Elisa De Lorenzis[a,c], Emanuele Montanari[a,c], Giancarlo Albo[a,c]

[a]Department of Urology, Foundation IRCCS Ca' Granda – Ospedale Maggiore Policlinico, University of Milan, Milan, Italy

[b]Department of Pharmacy, Foundation IRCCS Ca' Granda – Ospedale Maggiore Policlinico, Milan, Italy

[c]Department of Clinical Sciences and Community Health, University of Milan, Milan, Italy

[d]Health Physics Unit, Foundation IRCCS Ca' Granda – Ospedale Maggiore Policlinico, University of Milan, Milan, Italy

#The authors consider that the first two authors should be regarded as joint First Authors

CORRESPONDING AUTHOR

Elena Lievore, M.D.,

IRCCS Foundation Ca' Granda, Ospedale Maggiore Policlinico, Department of Urology

University of Milan

Via della Commenda 15, 20122 Milan, Italy

Tel. +39 02 55034501; Fax +39 02 50320584

Email: elena.lievore01@gmail.com

Abstract

Purpose: To compare outcomes of two different techniques in miniaturized percutaneous nephrolithotomy (PCNL): minimally invasive PCNL (MIP) with the vacuum-cleaner effect and vacuum-assisted mini-PCNL (vmPCNL).

Materials and methods: Data from 104 (66.7%) patients who underwent vmPCNL and 52 (33.3%) patients submitted to MIP at a single tertiary-referral academic center between 01/2016 and 12/2019 were analysed. Patients' demographics, peri and post-operative data were recorded, and propensity-score matching was performed. Descriptive statistics and linear regression models were used to identify variables associated with operative time (OT) and patient's effective dose. Logistic regression analyses were used to identify factors associated with infectious complications and stone free (SF) status.

Results: Patients' demographics and stone characteristics were comparable between groups. vmPCNL was associated with shorter OT ($p < 0.001$), fluoroscopy time and patient's effective dose (4.2 vs. 7.9 mSv; $p<0.001$). A higher rate of infectious complications was found in the MIP group (25.0% vs. 7.7%, $p<0.01$). Linear regression analysis showed that stone volume, multiple stone number and MIP procedure (all $p \leq 0.02$) were associated with longer OT. Similarly, OT and the MIP procedure ($p \leq 0.02$) were associated with higher patient's effective dose. Logistic regression analysis revealed that stone volume, preoperative positive bladder urine culture and the MIP procedure (all $p \leq 0.02$) were associated with postoperative infectious complications. vmPCNL was not associated with SF rate.

Conclusions: MiniPCNL performed with a continuous active suction is associated with lower rates of infectious complications, shorter OT and lower patient's effective dose than MIP.

Keywords: percutaneous nephrolithotomy, vacuum-assisted percutaneous nephrolithotomy, infectious complications, radiation exposure, stone free rate

Introduction

Renal stones are an increasingly common urological pathology, affecting 10% of the population of developed countries, and presenting an ascending trend in recent years[1]. The surgical treatment of kidney calculi varies according to the size of the stone and patient's characteristics. Current Guidelines suggest percutaneous nephrolithotomy (PCNL) as the gold standard surgical technique for large kidney stones in adult patients[2]. Several studies have shown that PCNL is a highly effective procedure[3], but it can be associated with serious complications, including post-operative fever (10.8%), major bleeding with the need of blood transfusion (7%), pneumothorax (1.5%) and sepsis (0.5%)[4].

Recently, the use of miniaturized instrumentations in PCNL has gained popularity with the promise of decreasing the treatment-related complications while maintaining good outcomes. Miniaturized PCNL was found to be equally effective as standard PCNL in terms of stone clearance[5] and associated with lower blood loss and transfusion rates [6]. However, limitations associated with the use of smaller tract sizes are longer operative time (OT), decreased visibility[7], difficulty in stone retrieval and increased intraoperative renal pressures (IRP), with consequent higher rates of infectious complications[8].

In order to overcome these drawbacks, new technologies have been introduced with the aim of permitting simultaneous irrigation flow under low pressure conditions. The minimally invasive PCNL system (MIP) (Karl Storz & Co. KG, Tuttlingen, Germany)[9] was designed to be an open low-pressure irrigation system and proposes the innovative method of stone clearance by the 'vacuum-cleaner' effect [10,11]. Several studies have confirmed the efficacy of MIP in terms of stone free (SF) rate, as well as its lower rate of major complications when compared to standard PCNL[12,13].

One of the most recent development in the miniaturized PCNL armamentarium is the vacuum-assisted access sheath (ClearPetra; Well Lead Medical, China). It consists of a 16 Ch sheath externally plugged and equipped with a lateral oblique arm connected to an aspiration system, that allows a continuous irrigation and lapaxy by aspirating the stone fragments together with the irrigation fluid during lithotripsy.

Overall, both the MIP and the vacuum-assisted PCNL (vmPCNL) have proved excellent safety and efficacy when compared to classic mini-PCNL[14], but no study has ever compared the two techniques. Therefore, the aim of this study was to compare the safety and efficacy of MIP with vmPCNL for the treatment of kidney stones.

Materials and methods

Study cohort

We conducted a retrospective analysis of all consecutive patients who underwent PCNL for renal stones in our tertiary-referral academic center between January 2016 and December 2019. Mini-PCNL represented the technique of choice when PCNL was planned, except in case of complete or almost complete staghorn stones, for which standard PCNL (24 Ch) was indicated. Between 01/2016 and 08/2017 all mini-PCNL were performed with the MIP Set, while from 09/2017 to 12/2019 all the procedures were performed with the ClearPetra Set by two experienced (>150 PCNL performed) endourologists (E.M; F.L.). A total of 206 mini-PCNL were included.

Collected data included patients' anthropometrics and medical history. Comorbidities were scored with the Charlson comorbidity index (CCI)[15]. The diagnosis of urolithiasis was based on a preoperative urographic computed tomography (CT) scan, which was used for the estimation of stone density (Hounsfield unit-HU) and stone location. The stone volume was calculated using the ellipsoid formula (length x width x height x π x 1/6)[16]. Preoperative bladder urine culture was required in each case. In case of negative culture, one-shot parenteral prophylaxis was administered. Patients with an asymptomatic bacteriuria started a targeted therapy 48-72 hour before intervention. In cases of leukocytosis, urinary symptoms or fever, the surgery was postponed after a full antibiotic course and a negative urine culture.

Surgical techniques

The surgical technique was standardized for both surgeons. All procedures were performed under general anesthesia with the patient in the supine Valdivia position. The surgical equipment included the MIP 16 Ch metallic sheath and dilator and the 16 Ch ClearPetra set (namely, vmPCNL), the 12 Ch MIP nephroscope and the holmium laser (VersaPulse PowerSuite 100W, Lumenis, Israel). The procedure started with a retrograde pyelography to assess the pelvicalyceal anatomy and the placement of a ureteral catheter in the renal pelvis to inject contrast medium. Renal puncture was performed under combined fluoroscopic/ultrasonographic control. Tract dilation was performed one-shot[17] with the MIP 16 Ch metallic dilator, or with the ClearPetra sheath assembled with its stylet. Irrigation was provided by a saline gravity bag allocated 1.5 m above kidney level. Stone fragmentation was performed with a 550 µm Holmium:YAG laser fiber, with fragmentation settings according to surgical needs. Stone fragments were evacuated using the “vacuum-cleaner effect” during MIP, or through the aspiration-assisted sheath during vmPCNL. The aspiration pressure could be regulated throughout the procedure. Flexible ureteroscope (7.9 Fr, Olympus URF-P6, Germany) and nitinol baskets were used through the percutaneous access when residual fragments could not be removed with the mentioned devices. An 8 Ch nephrostomy tube was used as exit strategy in all cases, while the ureteral catheter was either left in place or removed at the end of the procedure based on the surgeon’s preference.

Intraoperative and postoperative data

Number of the percutaneous tracts, litholapaxy modality, OT (defined as the time from the ureteral catheter placement to the exit strategy) and fluoroscopy time (FT) were recorded. Using the PCXMC software, patients’ effective doses and the equivalent dose rates of various organs were calculated, based on the International Commission on Radiological Protection Publication [18,19] Collimation was adapted for every single patient by the radiography technicians according to the As Low As Reasonably Achievable (ALARA) principles, and effective doses were calculated based on every patient body area exposed.

The evaluated postoperative data included hemoglobin drop and length of hospital stay. Postoperative complications were graded according to the PCNL-adjusted Clavien Score[20]. Patients were evaluated within 3 months after surgery with abdominal ultrasound (US) or CT scan to identify residual stones. US was the preferred choice in patients with simple stones and when the procedure had been carried out without complication and with an effective intraoperative evaluation of SF status, according to the surgeon's opinion. CT, instead, was indicated after more complex cases. The SF rate was defined as the absence of residual fragments >4 mm in diameter. Patients with residual fragments were offered, according to stone dimension, observation or auxiliary procedures including second-look PCNL, extracorporeal shockwave lithotripsy, or retrograde intrarenal surgery.

We excluded patients with congenital renal anomalies (N=10); scheduled staged procedures for large stone burden (N=23); concomitant additional procedures other than PCNL (N=11); endoscopic combined intrarenal surgery (ECIRS) procedures (N=2); stone fragmentation performed with ballistic, ultrasound or combined modality (N=21). A sample of 115 (65.7%) and 60 (34.3%) patients treated with vmPCNL and MIP with complete perioperative and follow-up data was considered for statistical analyses.

Data collection adhere to the principles of the Declaration of Helsinki. All patients signed an informed consent agreeing to share their own anonymous information for future studies. This study was conducted retrospectively collecting data obtained for clinical purposes and all the procedures were performed as part of the routine care. Consequently, our study did not need ethical approval.

Statistical methods

To control for measurable baseline differences among patients in the two groups, adjustment was performed using 1:2 propensity-score matching (nearest-neighbour analyses using a caliper width of 0.2 of the standard deviation of the logit of the propensity score). Matching is a common technique used in observational studies to select control subjects who are matched with treated subjects on controlled background covariates to reduce biases to a minimum[21]. Propensity scores were computed by modelling logistic regression with the dependent variable as the odds of being in the MIP group and the independent variables as age, Body Mass Index (BMI), CCI, stone volume, and stone location. After matching, 104 (66.7%) and 52 (33.3%) individuals in the vmPCNL and MIP group, respectively, were considered for the final analysis.

Distribution of data was tested with the Shapiro–Wilk test. Data are presented as medians (interquartile range; IQR) or frequencies (proportions). A 95% CI was estimated for the association of categorical parameters. The statistical significance of differences in medians and proportions were tested with the Mann-Whitney test and Fisher Exact Test, as indicated. After matching, descriptive statistics were used to assess potential differences in terms of clinical parameters and intraoperative and postoperative characteristics between the MIP and the vmPCNL group.

Univariable and multivariable linear regression models tested the association between clinical variables and OT and patient's effective dose in the whole cohort. Similarly, logistic regression analyses were used to identify factors associated with stone free status and infectious complications after PCNL. Statistical analyses were performed using SPSS v.26 (IBM Corp., Armonk, NY, USA). All tests were two sided, and statistical significance level was determined at $p < 0.05$.

Results

There was a significant difference in stone volume and stone location between the vmPCNL and MIP groups before matching (Table 1). After matching, patients and perioperative characteristics were evenly distributed.

Table 2 details intraoperative and postoperative characteristics among groups after matching. Overall, OT was shorter in the vmPCNL as compared to the MIP group ($p<0.001$). The use of flexible ureteroscopes and baskets to complete litholapaxy was more frequently reported during MIP than vmPCNL (all $p\leq0.02$). Postoperative haemoglobin drop and length of hospital stay were similar between groups. FT and patient's effective dose ($p<0.001$) were lower in the vmPCNL than the MIP group. The SF rate was higher for the vmPCNL than the MIP group (89.4% vs. 78.8%; $p=0.04$). Among those who were not SF, 2 (1.9%) patients in the vmPCNL group and 3 (5.7%) patients in the MIP group underwent second-look PCNL. RIRS was performed in 2 (1.9%) and 1 (1.9%) patients in the vmPCNL and MIP group, respectively (Table 2).

Table 3 details postoperative complications in the whole cohort. Overall, rates of postoperative complications were similar between groups (38.5% for the MIP vs. 24.0% for vmPCNL; p=0.09). Clavien-Dindo grade > II complications were found in 7 (6.7%) and 3 (5.8%) patients after vmPCNL and MIP (p=0.1), respectively. According to the modified Clavien-Dindo classification[20], a higher rate of infectious complications was found after MIP than vmPCNL (p<0.01) (Table 3).

Table 4 depicts linear regression models testing the association between clinical variables and either OT or patient's effective dose. Multivariable linear regression analysis revealed that stone volume, multiple stone location, and MIP surgery were significantly associated with longer OT, after adjusting for BMI and stone density (all p≤0.02). Similarly, OT, the use of multiple access tracts and MIP surgery were significantly associated with patient's effective dose (all p≤0.02), after adjusting for stone volume and BMI (Table 4).

Multivariable logistic regression analysis revealed that stone volume (OR 1.22, p<0.01), preoperative positive bladder urine culture (OR 3.66, p=0.02) and the MIP procedure (OR 3.57, p<0.01) were independently associated with postoperative infectious complications (Table 5). Smaller stone volume (OR 0.81; p≤0.001) and the absence of staghorn stones (OR 1.72; p≤0.001) were found to be predictors of SF rate, after accounting for BMI, stone density, the number of involved calyces and the type of access sheath (MIP vs. vmPCNL) (Table 5).

Discussion

The recent tendency towards miniaturization in PCNL has raised some questions about the prolonged OT and the increased chance of infectious complications related to higher IRP as compared to standard procedures with lager tracts[8]. Conversely, several studies have shown that miniaturized PCNL is a safe and effective treatment modality for large kidney stones[5].

In this study, we specifically compared two mini-PCNL procedures: i) the MIP, characterized by continuous low-pressure irrigation and the suction-like vacuum cleaner effect [9–11] for litholopaxy; and ii) the vmPCNL with its continuous irrigation-aspiration system (semi-closed circuit)[14,22]. To our knowledge, this is the first study that specifically compare clinical and procedural outcomes of the two techniques. We showed that PCNL performed with active aspiration were associated with lower rates of infectious complications, shorter OT and reduced patient's effective dose than MIP procedures.

Previous studies have shown the safety and efficacy of MIP. Nagele et al firstly described a series of 29 patients with lower pole stones treated with MIP, and reported a SF rate of 96% with excellent safety profile[23]. Similarly, Abdelhafez et al.[24] described a series of 197 MIP procedures comparing outcomes between small and large renal stones (cut-off 2 cm maximum diameter). Authors found that haemoglobin drop and OT were lower in patients with small renal stones, but the rate of postoperative complications was similar between groups. SF status was achieved in 83.8% of patients, and retreatment was needed in 13.1% of cases[24]. Outcomes from our series of MIP are similar to those from previous publications in terms of OT, mean hemoglobin drop and SF rate.[24] Of note, we reported a 25% rate of infectious complications in our MIP series, in line with the published literature from the general PCNL population (21-39.8%)[25].

Recently, patented negative pressure aspiration systems have been described in PCNL with promising results[22]. Lai et al. compared 75 patients treated with vmPCNL and 75 individuals who underwent PCNL with a peel-away access sheath[14]. Authors showed that vmPCNL was associated with higher SF rate but shorter OT and lower infectious complications than standard procedures.

In our study, the shorter OT of vmPCNL could be related to the efficacy of active negative-pressure suction in fragment retrieval when compared to the vacuum-cleaner effect. Moreover, the vmPCNL group was characterized by lower rates of flexible ureteroscopes and graspers/baskets employment to complete litholopaxy. These aspects are of primary clinical relevance in view of reducing OT and PCNL-related costs. In this study, the SF rate was higher for the vmPCNL than the MIP group (89.4% vs. 78.8%) and the aspiration-assisted sheath was univariably associated with SF status. However, this association was not confirmed in the multivariable logistic regression analyses. In multivariable analyses, the type of sheath may have lower magnitude of effects when compared to standard prognosticators (such as stone volume, location and staghorn stones).

The topic of radiation exposure has become increasingly important in the management of renal stones[26]. The reduction of FT and patient's effective dose observed in the vmPCNL group can be explained by several reasons. First, radiation exposure usually increases along with OT which in turn raises along with the use of flexible ureteroscope for fragments retrieval, all of which were advantageous for the vmPCNL, as compared to the MIP group. Second, patient's effective dose in vmPCNL might be reduced because the procedural radiation dose delivered by the beam source with a metallic set is likely to be higher compared to the one of a procedure performed with a plastic set. Indeed, a radiopaque object placed between the beam source and the automatic exposure control sensors attenuates the beam, causing an increase in the tube output to reach its air kerma threshold[27,28]. Haemoglobin drop and the rate of overall complications were similar between vmPCNL and MIP; which is consistent with other studies asserting the feasibility and safety of mini-PCNL[6]. Of clinical importance, infectious complications were lower in the vmPCNL than in the MIP group. Infectious complications during PCNL have been strictly connected to IRP fluctuation[29]. Nagele et al. described in vitro that MIP contributed to lower IRP compared to a conventional 18F sealed nephroscopic sheath[10] and the same group has later studied how an active suction of the irrigation fluid can further decrease IRP during miniaturized procedures with the MIP system[30].

Recently, Lai et al. [14] showed that vmPCNL were characterized by lower IRP than non-vacuum-assisted procedures, contributing to the lower rate of infectious complications observed in this group. We can similarly speculate that, in our study, the lower rate of infectious complications observed in the vmPCNL group might be related reduced IRP[14] together with shorter OT, that has been previously identified as an independent factor associated with infections after PCNL[31]. Furthermore, we should also consider the higher prevalence of calcium phosphate stones in the MIP group than the vmPCNL group one, which are usually associated with higher urine pH possibly favouring UTI and consequently infectious complications.

This study is innovative because it specifically compares mini-PCNL with a suction-like irrigation system (MIP) with vmPCNL, which are among the most innovative armamentarium of miniaturized PCNL. The second strength of the study is that we have analysed a homogenous cohort of patients with a thorough clinical and perioperative evaluation. In particular, most previous studies have used FT to report patient radiation exposure, which does not provide information on the actual amount of radiation exposure[32]. To address this limitation in the current literature, we analysed patient's effective dose to give more strengthen to our results and a greater collocation in the clinical scenario.

Our study is not devoid of limitations. Although propensity-score matching analysis is a valid method to reduce the selection bias of a retrospective study, the lack of randomization may limit the conclusions that can be drawn. Also, this was a single center-based study, which raises the possibility of selection biases; thereof, larger studies across different centers and cohorts are needed to externally validate our findings. In addition, MIP procedures were performed earlier in time than vmPCNL, therefore the surgeon's learning curve might favour the latter group. However, all PCNL were performed by surgeons that were expert (>150 PCNL performed) even before the beginning of this study. Lastly, the study lacks a standardized protocol for patients' follow-up. Although the CT scan is the preferred imaging for assessing the SF status, in our institution we usually weight the need to submit the patient to additional radiation dose after surgery if not strictly necessary.

Conclusions

In conclusion, the results of this study revealed that both the MIP and the vmPCNL system are valid alternatives for the surgical treatment of kidney stones. PCNL performed with an active suction was associated with lower rates of infectious complications, shorter OT and lower patient's effective dose than MIP procedures. In the future large, randomized studies are needed to validate our findings.

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References

1. Scales CD, Smith AC, Hanley JM, Saigal CS. Prevalence of Kidney Stones in the United States. *Eur Urol*. 2012;62(1):160-165. doi:10.1016/j.eururo.2012.03.052

2. Türk C (Chair), Neisus A, Petrik A, Seitz C, Skolarikos A (Vice-chair), Thomas K. *EAU Guidelines on Urolithiasis Available at Https://Uroweb.Org/Wp-Content/Uploads/EAU-Guidelines-on-Urolithiasis-2020.Pdf Assessed 31.3.20.*; 2020.

3. Chung DY, Kang DH, Cho KS, et al. Comparison of stone-free rates following shock wave lithotripsy, percutaneous nephrolithotomy, and retrograde intrarenal surgery for treatment of renal stones: A systematic review and network meta-analysis. Bhatt GC, ed. *PLoS One*. 2019;14(2):e0211316. doi:10.1371/journal.pone.0211316

4. Seitz C, Desai M, Häcker A, et al. Incidence, Prevention, and Management of Complications Following Percutaneous Nephrolitholapaxy. *Eur Urol*. 2012;61(1):146-158. doi:10.1016/j.eururo.2011.09.016

5. Ruhayel Y, Tepeler A, Dabestani S, et al. Tract Sizes in Miniaturized Percutaneous Nephrolithotomy: A Systematic Review from the European Association of Urology Urolithiasis Guidelines Panel. *Eur Urol*. 2017;72(2):220-235. doi:10.1016/j.eururo.2017.01.046

6. Yamaguchi A, Skolarikos A, Buchholz N-PN, et al. Operating Times and Bleeding Complications in Percutaneous Nephrolithotomy: A Comparison of Tract Dilation Methods in 5537 Patients in the Clinical Research Office of the Endourological Society Percutaneous Nephrolithotomy Global Study. *J Endourol*. 2011;25(6):933-939. doi:10.1089/end.2010.0606

7. Giusti G, Piccinelli A, Taverna G, et al. Miniperc? No, Thank You! *Eur Urol*. 2007;51(3):810-815. doi:10.1016/j.eururo.2006.07.047

8. Wu C, Hua L-X, Zhang J-Z, Zhou X-R, Zhong W, Ni H-D. Comparison of renal pelvic pressure and postoperative fever incidence between standard- and mini-tract percutaneous nephrolithotomy. *Kaohsiung J Med Sci*. 2017;33(1):36-43. doi:10.1016/j.kjms.2016.10.012

9. Zanetti SP, Boeri L, Gallioli A, Talso M, Montanari E. Minimally invasive PCNL - MIP. *Arch Esp Urol*. 2017;70(1):226-234.

10. Nagele U, Horstmann M, Sievert KD, et al. A newly designed Amplatz sheath decreases intrapelvic irrigation pressure during mini-percutaneous nephrolitholapaxy: An in-vitro pressure-measurement and microscopic study. *J Endourol*. 2007;21(9):1113-1116. doi:10.1089/end.2006.0230

11. Mager R, Balzereit C, Gust K, et al. The hydrodynamic basis of the vacuum cleaner effect in continuous-flow PCNL instruments: an empiric approach and mathematical model. *World J Urol*. 2016;34(5):717-724. doi:10.1007/s00345-015-1682-5

12. Abdelhafez MF, Bedke J, Amend B, et al. Minimally invasive percutaneous nephrolitholapaxy (PCNL) as an effective and safe procedure for large renal stones. *BJU Int*. 2012;110(11c):E1022-E1026. doi:10.1111/j.1464-410X.2012.11191.x

13. Abdelhafez MF, Wendt-Nordahl G, Kruck S, et al. Minimally invasive versus conventional large-bore percutaneous nephrolithotomy in the treatment of large-sized renal calculi: Surgeon's preference? *Scand J Urol*. 2016;50(3):212-215. doi:10.3109/21681805.2016.1155078

14. Lai D, Chen M, Sheng M, et al. Use of a Novel Vacuum-assisted Access Sheath in Minimally Invasive Percutaneous Nephrolithotomy: A Feasibility Study. *J Endourol*. 2020;34(3):339-344. doi:10.1089/end.2019.0652

15. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. *J Chronic Dis*. 1987;40(5):373-383. doi:10.1016/0021-9681(87)90171-8

16. Ito H, Kawahara T, Terao H, et al. The Most Reliable Preoperative Assessment of Renal Stone Burden as a Predictor of Stone-free Status After Flexible Ureteroscopy With Holmium Laser Lithotripsy: A Single-center Experience. *Urology*. 2012;80(3):524-528. doi:10.1016/j.urology.2012.04.001

17. Frattini A, Barbieri A, Salsi P, et al. One Shot: A Novel Method to Dilate the Nephrostomy Access for Percutaneous Lithotripsy. *J Endourol*. 2001;15(9):919-923. doi:10.1089/089277901753284143

18. Tapiovaara M, Siiskonen T. PCXMC—A PC-Based Monte Carlo program for calculating patient doses in medical X-Ray examinations. *J Int Comm Radiat Units Meas*. 2005;5(2):100-102. doi:10.1093/jicru/ndi034

19. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. *Ann ICRP*. 2007;37(2-4):9-34. doi:10.1016/j.icrp.2007.10.003

20. de la Rosette JJMCH, Opondo D, Daels FPJ, et al. Categorisation of Complications and Validation of the Clavien Score for Percutaneous Nephrolithotomy. *Eur Urol*. 2012;62(2):246-255. doi:10.1016/j.eururo.2012.03.055

21. D'Agostino RB. Propensity score methods for bias reduction in the comparison of a treatment to a non-randomized control group. *Stat Med*. 1998;17(19):2265-2281. doi:10.1002/(sici)1097-0258(19981015)17:19<2265::aid-sim918>3.0.co;2-b

22. Zeng G, Zhu W, Liu Y, Fan J, Zhao Z, Cai C. The new generation super-mini percutaneous nephrolithotomy (SMP) system: a step-by-step guide. *BJU Int*. 2017;120(5):735-738. doi:10.1111/bju.13955

23. Nagele U, Schilling D, Sievert KD, Stenzl A, Kuczyk M. Management of lower-pole stones of 0.8 to 1.5 cm maximal diameter by the minimally invasive percutaneous approach. *J Endourol*. 2008;22(9):1851-1853. doi:10.1089/end.2008.9791

24. Abdelhafez MF, Amend B, Bedke J, et al. Minimally invasive percutaneous nephrolithotomy: A comparative study of the management of small and large renal stones. *Urology*. 2013;81(2):241-245. doi:10.1016/j.urology.2012.09.030

25. Lojanapiwat B. Infective complication following percutaneous nephrolithotomy. *Urol Sci*. 2016;27(1):8-12. doi:10.1016/j.urols.2015.04.007

26. Baralo B, Samson P, Hoenig D, Smith A. Percutaneous kidney stone surgery and radiation exposure: A review. *Asian J Urol*. 2020;7(1):10-17. doi:10.1016/j.ajur.2019.03.007

27. Nguyen KK, Schlaifer AE, Smith DL, et al. In Automated Fluoroscopy Settings, Does Shielding Affect Radiation Exposure to Surrounding Unshielded Tissues? *J Endourol*. 2012;26(11):1489-1493. doi:10.1089/end.2012.0077

28. Kaplan SL, Magill D, Felice MA, Xiao R, Ali S, Zhu X. Female gonadal shielding with automatic exposure control increases radiation risks. *Pediatr Radiol*. 2018;48(2):227-234. doi:10.1007/s00247-017-3996-5

29. Tokas T, Herrmann TRW, Skolarikos A, Nagele U. Pressure matters: intrarenal pressures during normal and pathological conditions, and impact of increased values to renal physiology. *World J Urol*. 2019;37(1):125-131. doi:10.1007/s00345-018-2378-4

30. Nagele U, Walcher U, Bader M, Herrmann T, Kruck S, Schilling D. Flow matters 2: How to improve irrigation flow in small-calibre percutaneous procedures—the purging effect. *World J Urol*. 2015;33(10):1607-1611. doi:10.1007/s00345-015-1486-7

31. Chen D, Jiang C, Liang X, et al. Early and rapid prediction of postoperative infections following percutaneous nephrolithotomy in patients with complex kidney stones. *BJU Int*. 2019;123(6):1041-1047. doi:10.1111/bju.14484

32. Lipkin ME, Wang AJ, Toncheva G, Ferrandino MN, Yoshizumi TT, Preminger GM. Determination of Patient Radiation Dose During Ureteroscopic Treatment of Urolithiasis Using a Validated Model. *J Urol*. 2012;187(3):920-924. doi:10.1016/j.juro.2011.10.159

PCNL = Percutaneous nephrolithotomy

MIP = Minimally invasive percutaneous neohtolithotomy

vmPCNL = Vacuum-assisted mini percutaneous nephrolithotomy

OT = Operative time

IRP = Intraoperative renal pressure

SF = Stone free

CT = Computed tomography

FT = Fluoroscopy time

IQR = Interquartile range

Table 1: Demographic characteristics and descriptive statistics of patients according to the type of surgery

	Before propensity score matching			After propensity score matching		
	vmPCNL	**MIP**	**p-value***	**vmPCNL**	**MIP**	**p-value***
No. of individuals	115 (65.7%)	60 (34.3%)		104 (66.7%)	52 (33.3%)	
Age (years)			0.1			0.7
Median (IQR)	57.0 (49-76)	56.0 (48-76)		56.0 (49-75)	56.0 (50-75)	
Range	23 – 82	23 – 81		23 – 81	23 - 81	
Male Gender [No. (%)]	70 (60.8)	43 (71.6)	0.2	62 (59.6)	37 (71.2)	0.3
BMI (kg/m^2)			0.4			0.8
Median (IQR)	24.9 (22.1-27.9)	26.3 (24.1-29.7)		24.9 (22.5-27.7)	24.9 (23.2-28.0)	
Range	17.9 – 41.1	19.2 – 42.8		18.5 – 41.1	19.2 – 39.6	
CCI (score)			0.4			0.6
Median (IQR)	0.0 (0.0)	0.0 (0.0)		0.0 (0.0)	0.0 (0.0)	
Mean (SD)	0.5 (0.2)	0.7 (0.5)		0.5 (0.3)	0.6 (0.4)	
Range	0 – 5	0 – 5		0 - 5	0 - 5	

CCI ≥ 1 [No. (%)]	34 (29.5)	18 (30.0)	0.5	29 (27.9)	17 (32.7)	0.5
Laterality [No. (%)]			0.6			0.7
Right	53 (46.1)	26 (43.3)		47 (45.1)	22 (42.3)	
Left	62 (53.9)	34 (56.7)		57 (54.9)	30 (57.7)	
Stone volume (cm^3)			0.02			0.8
Median (IQR)	1.7 (1.3-3.6)	2.5 (1.8-3.1)		2.1 (1.0-3.5)	2.2 (1.0-3.5)	
Range	0.5 – 19.0	0.4 – 20.1		0.5– 19.0	0.4 – 18.9	
Stone Area (cm^2)			0.03			0.6
Median (IQR)	1.5 (1.1-2.8)	2.2 (1.5-2.8)		1.7 (1.4-3.1)	1.8 (1.4-3.2)	
Range	0.5 – 7.7	0.4 – 7.8		0.5 – 7.7	0.4 – 7.8	
Single stone [No. (%)]	44 (38.2)	29 (48.4)	0.04	41 (39.4)	21 (40.3)	0.8
Stone location			0.03			0.6
Upper pole calices	21 (18.2)	13 (21.6)		15 (14.4)	7 (13.4)	
Mid pole calices	36 (31.4)	21 (35.2)		34 (32.6)	17 (32.7)	
Lower pole calices	66 (57.7)	38 (63.4)		62 (59.6)	32 (61.5)	

Pelvis	47 (40.8)	24 (40.0)		42 (40.5)	21 (40.3)	
Staghorn stone [No. (%)]	33 (28.6)	20 (33.3)	0.03	33 (31.7)	16 (30.7)	0.5
Stone density (Hounsfield unit)			0.07			
Median (IQR)	1130 (876-1470)	1038 (754-1446)		1029 (869-1460)	1045 (743-1443)	
Range	122 – 2286	476 – 2065		122 – 2286	476 – 2065	
Positive urine culture [No. (%)]	21 (18.3)	13 (21.7)	0.6	19 (18.2)	11 (21.2)	0.6

Keys: vmPCNL = vacuum-assisted miniPCNL; MIP = Minimally invasive PCNL; BMI = body mass index; CCI = Charlson Comorbidity Index; PCNL = Percutaneous nephrolithotomy

* p value according to the Mann-Whitney test and Fisher Exact test, as indicated.

Table 2: Intraoperative and post-operative characteristics of the whole cohort after propensity score matching (No. = 156)

	vmPCNL (N = 104)	MIP (N = 52)	p-value*
Number of access tracts [No. (%)]			0.5
Single	97 (93.3)	47 (90.4)	
Multiple	7 (6.7)	5 (9.6)	
Operative time (min)			<0.001
Median (IQR)	90.0 (75-125)	120.0 (110-162)	
Range	36 – 210	60 – 257	
Litholapaxy with basket [No. (%)]	40 (38.5)	48 (94.1)	<0.001
Use of flexible ureteroscope [No. (%)]	42 (40.4)	31 (59.6)	0.02
Exit strategy [No. (%)]			0.07
Nephrostomy only	82 (78.8)	33 (63.4)	
Nephrostomy + Ureteral catheter	22 (21.2)	19 (36.6)	
Hospitalization time (days)			0.07
Median (IQR)	4.0 (3.0-5.0)	5.0 (4.0-7.5)	
Range	2.0 – 12.0	2.0 – 14.0	
Hemoglobin drop (g/dL)			0.1
Median (IQR)	-1.5 (-2.0 - -0.8)	-1.6 (-2.9 - -0.7)	
Range	-5.1 – -0.1	-6.0 – -0.2	
Fluoroscopy time (sec)			0.03
Median (IQR)	463.5 (303-664)	562.5 (360-836)	

Range	103 – 965	165 – 1723	
Patient's effective dose (mSv)			<0.001
Median (IQR)	4.2 (2.8-7.8)	7.9 (5.4-11.8)	
Range	1.1 – 21.3	1.1 – 28.5	
Dose area product (mGy x cm2)			<0.01
Median (IQR)	20298 (12213-31523)	30684 (18572-44160)	
Range	5699 – 85680	8337 – 101860	
Follow up imaging [No. (%)]			0.5
Ultrasound	63 (60.6)	34 (65.4)	
CT scan	41 (39.4)	18 (34.6)	
Stone free rate [No. (%)]	93 (89.4)	41 (78.8)	0.04
Auxiliary procedures [No. (%)]			0.09
No treatment	7 (6.7)	7 (13.4)	0.07
RIRS	2 (1.9)	1 (1.9)	0.9
Second look PCNL	2 (1.9)	3 (5.7)	0.1
Stone Composition			0.01
CaOx monohydrate	46 (44.2)	7 (13.5)	0.01
CaOx dihydrate	11 (10.6)	4 (7.6)	0.7
Ca Carbonate	14 (13.4)	0 (0.0)	0.1
Ca Phosphate	6 (5.7)	28 (53.8)	<0.001
Uric Acid	17 (16.3)	11 (21.1)	0.6
Cistine	10 (9.8)	2 (4.2)	0.5

Keys: vmPCNL = vacuum-assisted miniPCNL; MIP = Minimally invasive PCNL; CT = computed tomography

RIRS = Retrograde Intrarenal Surgery; PCNL = Percutaneous nephrolithotomy; CaOx = Calcium Oxalate; Ca = Calcium

* p value according to the Mann-Whitney test and Fisher Exact test, as indicated.

Table 3: Postoperative complications in the whole cohort after propensity score matching (No. = 156)

	vmPCNL (N = 104)	MIP (N = 52)	p-value*
Overall complications [No. (%)]	25 (24.0)	20 (38.5)	0.09
Highest Clavien-Dindo [No. (%)]			0.1
I - II	18 (17.3)	17 (32.7)	
IIIa - IIIb	7 (6.7)	3 (5.8)	
Type of complication (Highest Clavien-Dindo) [No. (%)]			0.02
Pain	7 (6.7)	3 (5.8)	0.81
Bleeding	5 (4.8)	5 (9.6)	0.31
Infectious	7 (6.7)	12 (23.1)	0.003
Drainage	5 (4.8)	0 (0.0)	0.19
Other	1 (1.0)	0 (0.0)	0.47
Infectious complications Any Clavien-Dindo [No. (%)]	8 (7.7)	13 (25.0)	<0.01

Keys: vmPCNL = vacuum-assisted miniPCNL; MIP = Minimally invasive PCNL; PCNL = Percutaneous nephrolithotomy

* p value according to the Fisher Exact test.

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Table 4: Linear regression models predicting operative time and patient's effective dose in the whole cohort after matching

	Operative time		Effective dose	
	UVA model	**MVA model**	**UVA model**	**MVA model**
	beta; p-value [95% CI]	**beta; p-value [95% CI]**	**beta; p-value [95% CI]**	**beta; p-value [95% CI]**
Age	0.4; 0.1 [-0.58 - 0.94]		0.11; 0.07 [-0.01 – 0.12]	
BMI	0.25; 0.75 [-1.34 - 1.84]	0.23; 0.9 [-1.77 - 1.75]	1.02; 0.12 [-0.7 – 2.12]	1.01; 0.21 [-0.2 - 1.45]
CCI ≥ 1	1.01; 0.47 [-0.96 - 1.07]		1.17; 0.21 [-0.66 - 3.05]	
Female Gender (vs. Male)	0.99; 0.87 [-0.98 – 1.05]		-0.43; 0.62 [-0.21 – 1.29]	
Stone Volume	2.76; 0.01 [1.21 – 5.34]	2.61; 0.02 [0.34 - 4.97]	0.13; 0.23 [-0.27 – 0.45]	0.13; 0.31 [-0.41 – 0.13]
Stone density (HU)	1.03; 0.11 [-0.1 - 1.76]	1.03; 0.2 [-0.01 - 1.45]	1.11; 0.19 [-0.96 – 1.43]	
Multiple stones (vs. Single)	1.65; 0.01 [1.03 - 3.45]	1.55; 0.01 [1.1 - 3.74]	1.17; 0.17 [-0.49 – 2.85]	
Operative time			1.37; <0.01 [1.01 – 4.45]	1.21; 0.01 [1.02 – 2.34]

Number of access tracts

4.92; <0.01 [1.75 – 8.25] 3.59; 0.02 [1.39 – 6.81]

Clear Petra vs. MIP -4.34; <0.001 [-8.72 - -1.12] -3.52; <0.001 [-5.72 - -1.24] -2.97; 0.001 [-4.77 – -1.23] -2.10; 0.01 [-3.96 – -0.26]

Keys: UVA = Univariate model; MVA = Multivariate model, BMI = body mass index; CCI = Charlson Comorbidity Index; HU = Hounsfield Unit;

MIP = Minimally invasive PCNL; PCNL = Percutaneous nephrolithotomy

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Table 5: Logistic regression models predicting postoperative infectious complications and stone free status in the whole cohort after matching

	Infectious complications		Stone free status	
	UVA model OR; p-value [95% CI]	MVA model OR; p-value [95% CI]	UVA model OR; p-value [95% CI]	MVA model OR; p-value [95% CI]
Age	1.1; 0.72 [0.97 - 1.04]		0.95; 0.87 [0.76 – 1.34]	
BMI	1.06; 0.28 [0.95 - 1.17]		0.96; 0.65 [0.72 - 2.45]	0.96; 0.76 [0.71 - 3.14]
CCI ≥ 1	1.23; 0.67 [0.46 - 3.28]			
Female Gender (vs. Male)	0.65; 0.41 [0.24 – 1.81]			
Stone Volume	1.24; <0.01 [1.06 - 1.48]	1.22; <0.01 [1.05 - 1.41]	0.86; <0.001 [0.81 - 0.89]	0.81; <0.001 [0.76 - 0.89]
Stone density (HU)	1.01; 0.75 [0.87 - 1.01]		0.87; 0.02 [0.79 - 0.91]	0.88; 0.31 [0.75 - 1.85]
N. of involved calyces (Single vs Multiple)			1.14; 0.07 [0.96 - 1.76]	1.12; 0.26 [0.91 - 1.27]
Staghorn stone (No vs Yes)			1.78; <0.001 [1.34 - 4.13]	1.72; <0.001 [1.15 - 5.01]
Preoperative Positive Urine culture	3.34; 0.01 [1.23 – 9.04]	3.66; 0.02 [1.24 - 7.83]		
Operative time	1.12; 0.01 [1.03 - 1.34]			

N. of access tracts	1.31; 0.12 [0.28 – 6.47]	
Clear Petra vs. MIP	0.25; <0.001 [0.09 - 0.65]	0.28; 0.01 [0.1 - 0.77]
1.13; 0.04 [1.02 - 2.13]	1.01; 0.23 [0.87 - 2.39]	

Keys: UVA = Univariate model; MVA = Multivariate model, BMI = body mass index; CCI = Charlson Comorbidity Index; HU = Hounsfield Unit;

MIP = Minimally invasive PCNL; PCNL = Percutaneous nephrolithotomy