Journal of Current and Advance Medical Research
January 2023, Vol. 10, No. 1, pp. 19-24
http://www.banglajol.info/index.php/JCAMR
ISSN (Print) 2313-447X
ISSN (Online) 2413-323X
NLM Catalog ID 101673828
DOI: https://doi.org/10.3329/jcamr.v10i1.69783

ORIGINAL ARTICLE

Comparison of Miniperc and Standard Percutaneous Nephrolithotomy in the Treatment of Renal Stone: An Open Level Parallel Arm Randomized Control Trial

SM Syeed-Ul-Alam[1], Ayesha Rahman[2], Md. Rassell[3], Abul Hasanat Muhammad Afzalul Haque[4], Abdur Rabban Talukder[5]

[1]Assistant Professor, Department of Surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; [2]Junior Consultant (Surgery), Officer on Special Duty (OSD), Directorate General of Health Services, Ministry of Health and Family Welfare, Dhaka, Bangladesh; [3]Associate Professor of Surgical Oncology, Department of Surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; [4]Assistant Professor, Department of Urology, Dhaka Medical College, Dhaka, Bangladesh; [5]Associate Professor, Department of Surgery, Sir Salimullah Medical College Mitford Hospital, Dhaka, Bangladesh

Abstract

Background: Treatment of renal stone is very crucial for the outcomes of the patients. **Objective:** The purpose of the present study was to compare the Miniperc and standard percutaneous nephrolithotomy in the Treatment of Renal Stone. **Methodology:** This randomized control trial was conducted in the Department of Urology at National Institute of Kidney Diseases and Urology, Dhaka and some private hospitals in Dhaka city of Bangladesh from July 2016 to November 2017 for a period of one and half year. Patients from 18 to 65 years of age with renal calculi ($\leq$ 2cm) were selected on the basis of plain X-ray and ultra-sonogram of KUB region, from Urology outpatient Department (OPD) in National Institute of Kidney Diseases and Urology (NIKDU), Dhaka and some private hospitals in Dhaka city. Patients were selected in every alternate sequence (odd numbers for Miniperc in Intervention group and even numbers for Standard PCNL, control group). All patients underwent PCNL of both the procedures under general anesthesia and received intravenous broad spectrum antibiotics. **Results:** A total number of 60 patients were selected for study of which 30 patients were underwent miniperc and 30 patients were undergoing standard PCNL. The mean age of miniperc group and PCNL group were 34.43±11.09 and 36.70 ± 12.27 years respectively. An overall stone clearance rates was 93.33 (28) in intervention group and 6.67 % (2) was not cleared. Among the control group an overall stone clearance rates were 96.67% (29) and 3.33% (1) was not cleared. Stone clearance rates were not significant. The mean operative time (min) of intervention group was 97.47±15.03 and the mean operative time (min) of control was 86.37±17.73 Operative time was significant between the groups ($p<0.05$). **Conclusion:** In conclusion the rate of clearance of intervention group is not statistically significant. [*Journal of Current and Advance Medical Research, January 2023;10(1):19-24*]

Keywords: Miniperc nephrolithotomy; Standard percutaneous nephrolithotomy; Renal Stone; RCT

Correspondence: Dr. SM Syeed-Ul-Alam, Assistant Professor, Department of Surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh; **Email:** syeedulalam96@gmail.com; **Cell No.:** +8801911896884; **ORCID:** https://orcid.org/0009-0003-8639-6033

Introduction

Urolithiasis is a common disease with globally increasing incidence and significant socio-economic implications[1]. The management of renal calculi has evolved considerably in the last four decades. The ideal treatment would be complete stone clearance in a single session without any trauma to the patient and prevention of any new stone formation. Though this is not yet achieved, the available treatment modalities are continuously being modified to improve efficacy while minimizing complications[2]. Percutaneous nephrolithotomy (PCNL), retrograde intrarenal surgery (RIRS) and shockwave lithotripsy (SWL) are the current management options for small renal calculi[3].

Percutaneous nephrolithotomy (PCNL), which was first described in 1976 (Fernstrom and Johansson 1976) has become the procedure of choice for large burden renal calculi and a management option for small renal calculi[4]. Though PCNL has a good stone clearance rate, it is associated with significant risk of complications[5]. Over the years, many modifications have occurred in the technique and instrumentation to reduce its morbidity and improve its efficacy. Most of the complications associated with PCNL including bleeding, calyceal and infundibular tear, persistent urine leak and nephron loss can be attributed to the size of the tract[6]. While most bleeding associated with PCNL can be managed conservatively, approximately 0.6 to 1.4% of patients require angioembolization to control intractable bleeding[7]. Traditionally, nephrostomy tract from 24F to 34F is used for the PCNL procedure and this procedure is called standard percutaneous nephrolithotomy (sPCNL) and if PCNL procedure is performed with an access sheath of 12-20 F diameter, this procedure is called miniaturized percutaneous nephrolithotomy[8].

Miniperc is safe and effective for managing renal calculi in adult patients. Miniperc has significantly lower incidence of bleeding necessitating transfusion and higher stone free rate for multiple calyceal stone in comparison with the standard PCNL[4]. MPCNL (Mini PCNL) is a safe and effective procedure with stone free rate comparable to that of standard PCNL. Miniperc also resulted in less bleeding, fewer transfusion, less pain and shorter hospitalization[10]. With the intent of reducing hemoglobin drop, less postoperative discomfort, less pain and shorter hospital stay miniperc procedure has gained popularity in recent years. Currently, many urologists in Bangladesh are practicing miniperc routinely. But few articles are available in this regard. Therefore, this study may be done to compare the outcome of miniperc and standard PCNL in treating renal stone.

Methodology

Study Design and Population: This was a randomized single center parallel arm open level clinical trial. This study was conducted in the Department of Urology at National Institute of Kidney Diseases and Urology, Dhaka and some private hospitals in Dhaka city. This study was carried out from July 2016 to November 2017 for a period of one and half year. Patients from 18 to 65 years of age with renal calculi ($\leq$ 2cm) were selected on the basis of plain X-ray and ultra-sonogram of KUB region, from Urology outpatient Department (OPD) in National Institute of Kidney Diseases & Urology (NIKDU), Dhaka and some private hospitals in Dhaka city. Patients age between 18 to 65 years, patients having renal calculi $\leq$ 2 cm, patient with single puncture during PCNL, patients with normal renal function and sterile urine were included as study population. Patient with age bellow 18 year and above 65 years, patient with anomalous renal anatomy or radiolucent stone were excluded from this study. All patients were evaluated by detailed history, thorough physical examinations and relevant investigations. The investigations included plain X-ray KUB, abdominopelvic ultrasound, serum creatinine, intravenous urograpy (IVU), urine analysis and culture, full blood count, hepatitis B and C screening, chest X-ray, ECG, 2D echocardiogram, coagulation profile. If urine culture showed any growth, sensitive antibiotics was administered and repeat urine culture was done following completion of antibiotic course and thereby negative urine culture was ensured before surgical intervention. Co-morbidities like hypertension, diabetes mellitus, and bronchial asthma was addressed and controlled preoperatively.

Allocation and Blinding: The current prospective study was conducted in 60 patients. Patients were selected according to inclusion and exclusion criteria. Patients were selected in every alternate sequence (odd numbers for Miniperc in Intervention group and even numbers for Standard PCNL, control group). All patients underwent PCNL of both the procedures under general anesthesia and received intravenous broad spectrum antibiotics.

Randomization: All patients were divided into two groups. Intervention group (Odd number serial) for

the Miniperc and control group (Even number serial) for standard PCNL.

Operative Procedure: Initially, on lithotomy position, a 5/6 Fr ureteric catheter placed transurethrally. Percutaneous access was created using an 18 G access needle into the selected calyx under fluoroscopic guidance keeping the patient in prone position. A straight-tipped guidewire was placed into the collecting system. The nephrostomy tract was dilated by serial dilatation technique with metallic dilators. In case of Miniperc a (12-20) Fr Amplatz sheath and in Standard PCNL a 26/28 Fr Amplatz sheath positioned into the renal collecting system. The stone was fragmented using pneumatic lithotripsy or ultrasonic lithotripsy. Nephroscopy with forceps was used to retrieve stones from calyx. Once complete clearance was confirmed fluoroscopically and endoscopically, a 5/6 F double J stent was placed antegradely. On completing the procedure, the Amplatz sheath was removed after keeping a nephrostomy tube in situ, 24 Fr in Standard PCNL and 12/16 Fr in miniperc. All the patients of both group was evaluated accordingly in the post-operative period.

Follow up and Outcomes Measures: Operation time was derived from the operation note and defined as the time elapsed in minutes from getting access by needle to nephrostomy tube placement. Hospitalization time was defined as the number of days the patient spent at the hospital starting from the day of surgery. Stone clearance can be ensured during operation by C-arm and post operatively by plain X-ray KUB. A successful outcome was defined when the patients were rendered stone free or had residual fragments smaller than 4 mm after PCNL. A Visual Analogue Scale (VAS) for measuring pain was directed to the patients at 6 and 24 h after the procedure. Patients were asked to rate their pain by moving the marker on the VAS with 0 equivalent to no pain and 10 to very severe pain. Narcotic analgesic (Inj. Pethedine) was given to all patients intramuscularly according to body weight at the postoperative ward according to patient's demand.

Pain was quantified indirectly according to the amount of analgesic injections needed in 24 hours after both the procedure. On postoperative day 1, nephrostomy tube was removed if the urine was not hemorrhagic and stone clearance was successful. Patients were observed for the duration of haematuria and urinary leak after nephrostomy tube removal. Wound dressing at the nephrostomy tract were checked every twelve hourly to see urinary leakage so that we can assess the duration of urinary leak. The Foleys catheter was removed on 2nd postoperative day. All patients were seen with Hb% on 1st POD and Hb%, urine R/M/E & C/S, serum creatinine, plain X-ray KUB and USG of KUB at 1 month after the operation. Plain X-ray KUB was performed in all patients prior to discharge from hospital to exclude any significant residual stone & to council the patients for D-J stent removal. Patient was discharged when he was pain free & there was no urinary leak. Emergency contact number was supplied to all patients or his/her attendants. The double J stent was removed after 6 weeks.

Quality Control Measures: During this study utmost quality was been assured in every step. Patients were selected based upon the inclusion and exclusion criteria. Operative procedures were done by a specialist urologist (at least an Asst. professor level). Before proceeding to operative procedure proper counseling was done with patients regarding the operative procedure, possible complication and their management. Proper data were collected by using a questionnaire. Collected data were analyzed properly.

Statistical Analysis: After meticulous checking and rechecking, data was compiled and statistical analysis – measures of dispersion (mean, standard deviation) and the tests of significance (Unpaired Student's T test and x^2 test) were done using computer, based on statistical software (SPSS-statistical package for social science, Version- 21). 'P' value <0.05 was considered as significant.

Ethical Measures: Informed written consent was taken from each patient. Prior to consent they were explained in local language about the aim and purpose of the study. All participants were informed about the advantages and disadvantages of both procedures.

Results

A total number of 60 patients were selected for study according to the selection criteria. Of the 60 subjects, 30 patients, those who underwent miniperc were labeled as intervention group and 30 patients, those who underwent standard PCNL, were labeled with control group. Majority of the renal stones was found in the age range 18-40 years. The mean age of intervention group and control group were 34.43±11.09 and 36.70 ± 12.27 years respectively. The lowest and highest age in intervention group was 18 and 63 years respectively and those in control group were 19 and 65 years respectively.

Age categories were almost homogenously distributed in both age groups (Table 1).

Table 1: Comparison of Age Groups between Two Groups

Age Group	Intervention Group	Control Group
18 to 30 Years	12(40.00%)	10(33.33%)
31 to 40 Years	13(43.3%)	12(40.0%)
41 to 50 Years	2(6.7%)	3(10.0%)
51 to 60 Years	2(6.7%)	3(10.0%)
More Than 60 Years	1(3.3%)	2(6.7%)
Total	**30(100.0%)**	**30(100.0%)**
Mean± SD	34.43±11.09	36.70±12.27

Student's T-test (Unpaired) was done; SD= Standard deviation; P value was 0.46 between the mean with SD of 2 groups

Size of the stone was within 2 cm in both the groups. Mean size of the stones were 1.47±0.42 cm in group A and the size of the stones were 1.63±0.30 cm in group B. Calculated p value was 0.09 which is not significant.

Table 2: Comparison of Stone Size between Groups

Stone Size	Intervention Group	Control Group
Less Than 1.0 cm	3(10.0%	1(3.3%
1.1 to 1.5 cm	16(53.3.%	15(50.0%
1.6 to 2.0 cm	11(36.7%)	14(46.7%)
Total	**30(100.0%)**	**30(100.0%)**
Mean± SD	1.47±0.42	1.63±0.30

Student's T-test (Unpaired) was done; SD= Standard deviation; P value was 0.09 between the mean with SD of 2 groups

An overall stone clearance rates was 28(93.3%) in intervention group and 2(6.67%) was not cleared. Among the control group an overall stone clearance rates were 96.67 % (29) and 3.33% (1) was not cleared. Stone clearance rates were not significant (Table 3).

Table 3: Comparison of Stone Clearance between Groups

Stone Clearance	Intervention Group	Control Group
Successful	28(93.33%)	29(96.67%)
Failed	2(6.67%)	1(3.33%)
Total	**30(100.0%)**	**30(100.0%)**

Chi-square (x^2) test done to analyze the data; P value was 0.09 between proportion of 2 groups

The mean operative time (min) of group A was 97.47±15.03 and the mean operative time (min) of group B was 86.37±17.73 Operative time was significant between the groups ($p<0.05$) (Table 4).

Table 4: Comparison of Total Operative Time between Groups

Operative Time	Intervention Group	Control Group
55 to 75 Minutes	2(6.7%)	6(20.0%)
76 to 95 Minutes	11(36.7%)	17(56.7%)
96 to 115 Minutes	14(46.7)	4(13.3%)
116 to 135 Minutes	3(10.0%)	3(10.0%)
Total	**30(100.0%)**	**30(100.0%)**
Mean± SD	97.47±15.03	86.37±17.3

Student's T-test (Unpaired) was done; SD= Standard deviation; P value was 0.01between the mean with SD of 2 groups

Discussion

Incidence and prevalence of renal stone is increasing worldwide facilitating the upgrading of related diagnostic and therapeutic procedure with more advancement in the last 10 years[11]. In recent decades, endoscopic technology and operative techniques including endoscopic technology have consistently advanced which have increased the success rate more than 90.0% of PCNL and decreased the associated complications and morbidity[12]. Thus, PCNL gained popularity to manage renal stone with some indications.

In the early years, PCNL was done for large volume stone such as complex multiple calyceal stones, staghorn stones. Various studies in the past have confirmed that reducing the tract size potentially also reduces the complications of percutaneous surgery. This lead to the concept to reduce the tract size and miniaturization. These miniaturized instruments and accessories obviated the need to dilate the tract beyond 20 Fr[13]. Many studies[7,11] have been done in the different part of the world to compare the outcome of Miniperc with standard PCNL. Keeping this idea in mind this prospective comparative study had been designed to observe the outcome of miniperc and standard PCNL for the treatment of renal stone.

Percutaneous nephrolithotomy (PCNL) is a procedure to remove a kidney stone or stones through the skin. Percutaneous means 'through the skin' and nephrolithotomy means 'taking stones out of the kidney'. Standard Percutaneous nephrolithotomy is the term used for PCNL with tract size from 24Fr to 34 Fr. Miniperc is the term used for PCNL with tract size from 12 Fr to 20 Fr. Total operative time means time started from getting access by needle to nephrostomy tube

placement. Days remained in hospital in post-operative period up to the discharge of the patient from hospital was regarded as postoperative hospital stay.

Patients with renal stone admitted for PCNL were divided into 2 groups. After informed consent and random allocation, group A included miniperc and group B undergone standard PCNL. Total 60 patients were included in the study according to inclusion and exclusion criteria. Results of treatment of both groups were compiled and compared. Preoperative baseline variables like age, gender, size of stone were compared between groups. Outcome variables such as stone clearance, postoperative pain score, analgesics requirement, operation time, postoperative complications like haematuria and urinary leakage and hospital stay were compared between groups.

The age of the patients in both groups of the present study ranged between 18 and 65 years and the majority between 18 to 40 years, of which 25 and 22 patients belong to intervention group and control group respectively. Mean age ± SD of intervention group was 34.43±11.09 (range 18 to 62) and that of control group was 36.70 ± 12.27 (range 19-65) years. The age range of present study is comparable with the study done by Mishra et al[7] in 55 patients who underwent miniperc or standard PCNL. Mean age of their study was 42.2±19.8 and 48.2±16.8 years in miniperc and standard PCNL respectively. Giusti et al[14] evaluate the results of miniperc with standard PCNL in 134 patients and found that average age was 48.0 (29 to 70) years for the patients underwent miniperc and 48.5 (22 to 77) for standard PCNL. Sarilar et al[9] have similar age group in their study.

The mean stone size in intervention group was 1.47±0.42 cm and that was in control group 1.63±0.30 cm, statistically not significant (P value >0.05). Mishra et al[7] in 55 patients with miniperc and standard PCNL, mean stone size of their study was 1.47± 0.3 cm in intervention group and that was 1.49±0.6 cm in control group. A retrospective study by Giusti et al[14] found that the mean stone size was 1.67±0.5 in miniperc and 1.83±0.8 for standard PCNL. Sarilar et al[9] showed that size did not correlate significantly with miniperc and standard PCNL (P=0.730).

In the present study, stone free rate was 93.3% in intervention group with miniperc procedure and that was 96.7% in group B with standard PCNL procedure. The success rate of stone clearance in a study conducted by Mishra et al[7] was 96.0% with miniperc and 100.0% standard PCNL respectively. Gupta et al[15] in a retrospective study, found that overall stone free rate was 77.5% of patients in miniperc and was 94.0% of patient in standard PCNL respectively. Sarilar et al[9] observed in their study that the success rate of stone clearance was 92.0% in miniperc group and 92.5% in standard PCNL group respectively. Zhu et al[10] in a meta-analysis showed no difference between the miniperc and standard PCNL (P=0.23). Thus, present study is similar to that of previous studies.

In our study, mean operation time was 97.47±15.03 (75 to 135) min in miniperc and that was 86.37±17.73 (48 to 120) min in standard PCNL. Both the differences are statistically significant (p value <0.05). Gupta et al[15] in 134 patients found the mean operation time was 155.5±32.9 min in miniperc and that was 106±24.4 min in standard PCNL. Mishra et al[7] presented data where they found that mean operation time 45.2±12.6 min for miniperc and 31.0±16.6 min for standard PCNL (*p* <0.05). Sarilar et al[9] found that the mean operative time of miniperc 100.1±35.0 min and in standard PCNL 56.1±28.6 min (p<0.001). Zhu et al[10] in a meta-analysis study showed mean operative time was shorter in standard PCNL (p =0.002).

There are some limitations of this study. Sample size was relatively small. Operation done in different hospital. Operation done by multiple surgeons. Follow up period was short. Pain is a subjective phenomenon. Even the VAS score might have some subjective variations.

Conclusion

In conclusion miniperc has better outcome than standard PCNL in the treatment of renal stone with potential advantages in terms good outcomes. An overall stone clearance rates in intervention group and control group has differed and this rate is not significant. The mean operative time (min) of intervention group and control group is significant. Further large scale study should be conducted to get the real scenario.

Acknowledgements
None

Conflict of Interest
The authors have no conflicts of interest to disclose

Financial Disclosure and Funding Sources
This study has been performed without any funding from outside else.

Contributions to authors: Syeed-Ul-Alam SM, Rahman A, Rassell M prepared the manuscript from protocol

preparation upto report writing. Haque AHMA, Talukder AR have revised the manuscript. Syeed-Ul-Alam SM has prepared the manuscript. All the authors have involved from protocol preparation up to manuscript writing & revision.

Data Availability
Any inquiries regarding supporting data availability of this study should be directed to the corresponding author and are available from the corresponding author on reasonable request.

Ethics Approval and Consent to Participate
Ethical approval for the study was obtained from the Institutional Review Board. As this was a prospective study the written informed consent was obtained from all study participants. All methods were performed in accordance with the relevant guidelines and regulations.

Cite this article as: Syeed-Ul-Alam SM, Rahman A, Rassell M, Haque AHMA, Talukder AR. Comparison of Miniperc and Standard Percutaneous Nephrolithotomy in the Treatment of Renal Stone: An Open Level Parallel Arm Randomized Control Trial. J Curr Adv Med Res 2023;10(1):19-24

ORCID
SM Syeed-Ul-Alam: https://orcid.org/0009-0003-8639-6033
Ayesha Rahman: https://orcid.org/0009-0000-5742-5091
Md. Rassell: https://orcid.org/0000-0003-0844-3802
Abul Hasanat Muhammad Afzalul Haque: https://orcid.org/0009-0003-0737-2341
Abdur Rabban Talukder https://orcid.org/0009-0007-3786-4872

Article Info
Received: 2 October 2022
Accepted: 12 December 2022
Published: 1 January 2023

References

1. Romero V, Akpinar H, Assimos DG. Kidney stones: a global picture of prevalence, incidence, and associated risk factors. Reviews in Urology. 2010;12(2-3):e86-96
2. Abdelhafez MF, Wendt-Nordahl G, Kruck S, Mager R, Stenzl A, Knoll T, Schilling D. Minimally invasive versus conventional large-bore percutaneous nephrolithotomy in the treatment of large-sized renal calculi: surgeon's preference?. Scandinavian Journal of Urology. 2016;50(3):212-5
3. Türk C, Knoll T, Petrik A, Sarica K, Skolarikos A, Straub M. Guidelines on Urolithiasis. Uroweb. Last accessed on 2013 Apr 15th Available from: http://www.uroweb.org/gls/pdf/21_Urolithiasis_LR
4. Cheng F, Yu W, Zhang X, Yang S, Xia Y, Ruan Y. Minimally invasive tract in percutaneous nephrolithotomy for renal stones. Journal of endourology. 2010;24(10):1579-82
5. Rosette JD, Assimos D, Desai M, Gutierrez J, Lingeman J, Scarpa R, Tefekli A. The clinical research office of the endourological society percutaneous nephrolithotomy global study: indications, complications, and outcomes in 5803 patients. Journal of Endourology. 2011;25(1):11-7
6. Choi SW, Kim KS, Kim JH, Park YH, Bae WJ, Hong SH, Lee JY, Kim SW, Hwang TK, Cho HJ. Totally tubeless versus standard percutaneous nephrolithotomy for renal stones: analysis of clinical outcomes and cost. Journal of endourology. 2014;28(12):1487-94
7. Mishra S, Sharma R, Garg C, Kurien A, Sabnis R, Desai M. Prospective comparative study of miniperc and standard PNL for treatment of 1 to 2 cm size renal stone. BJU international. 2011;108(6):896-9
8. Michel MS, Trojan L, Rassweiler JJ. Complications in percutaneous nephrolithotomy. European Urology. 2007;51(4):899-906
9. Sarılar Ö, Özgör F, Küçüktopçu O, Uçpınar B, Akbulut MF, Savun M, Gürbüz ZG, Binbay M. Is standard percutaneous nephrolithotomy still the standard treatment modality for renal stones less than three centimeters?. Turkish Journal of Urology. 2017;43(2):165-170
10. Zhu W, Liu Y, Liu L, Lei M, Yuan J, Wan SP, Zeng G. Minimally invasive versus standard percutaneous nephrolithotomy: a meta-analysis. Urolithiasis. 2015;43:563-70
11. Turney BW, Reynard JM, Noble JG, Keoghane SR. Trends in urological stone disease. BJU international. 2012;109(7):1082-7
12. Margaret S, Jodi A, Yair L. Urinary Lithiasis: Etiology, Epidemiology, and Pathogenesis. (11th) Campbell-Walsh Urology, Philadelphia, Elsevier, 2016;1170-1199
13. Ganpule AP, Bhattu AS, Desai M. PCNL in the twenty-first century: role of Microperc, Miniperc, and Ultraminiperc. World journal of urology. 2015;33:235-40
14. Giusti G, Piccinelli A, Taverna G, Benetti A, Pasini L, Corinti M, Teppa A, de Zorzi SZ, Graziotti P. Miniperc? No, thank you!. European urology. 2007;51(3):810-5
15. Gupta NP, Mishra S, Nayyar R, Seth A, Anand A. Comparative analysis of percutaneous nephrolithotomy in patients with and without a history of open stone surgery: single center experience. Journal of Endourology. 2009;23(6):913-6