

Minipercutaneous Nephrolithotomy Under Mixture of Local Anesthesia: A Randomized Controlled Study

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Abstract

Objective: To evaluate the safety, efficacy, and feasibility of minipercutaneous nephrolithotomy (MPCNL) under mixture of local anesthetics (MLA) vs spinal anesthesia (SA) for management of large renal stones.

Patients and Methods: This study was a prospective randomized controlled study and approved by IRB (REC-FOMBU). A total of 120 consecutive patients who met the inclusion criteria of the study and agreed to sign the informed consent form were randomized to undergo MPCNL under MLA (60 patients) or SA (60 patients). Intra- and postoperative findings including visual pain analogue scale (VAS), operative time, hospital stay, adverse events (AEs), stone-free rate, and related data were recorded.

Results: Baseline characteristics and demography included age and gender; stone's site, size, and density were comparable for both groups ($p > 0.05$). The average VAS scores in the MLA group at 0, 2, 6, 12, and 24 hours were 2.5, 0, 1, 1, and 0, respectively. The corresponding values in the SA group were 2, 1, 2, 2, and 1, respectively, ($p < 0.05$). The average operation time was ~1 hour for both groups and the length of hospital stay was 1.5 days for both groups ($p > 0.05$). Whereas the mean hemoglobin deficit was $1.04\% \pm 0.54\%$ vs 1.27 ± 0.46 ($p = 0.013$) and the primary postoperative stone clearance was 93.4% vs 88.3% ($p > 0.05$), for MLA and SA groups, respectively. Postoperative analgesic consumption and complications were similar in the MLA and SA groups.

Conclusion: Single tract MPCNL is feasible under either MLA or SA with comparable stone clearance and AEs. Perioperative VAS was similar and acceptable for both modalities.

Keywords: MPCNL, local anesthesia, SFR, spinal anesthesia, VAS

Introduction

UP TILL NOW, the standard procedure of choice for management of larger renal stones (≥ 2 cm) is percutaneous nephrolithotomy (PCNL).¹ Traditionally, the majority of PCNLs are usually performed under general anesthesia (GA) or regional anesthesia,² which convey many challenges such as uncomely for some patients, long recovery from anesthesia, higher anesthesia, and hospital costs.³ Spinal anesthesia (SA) has many advantages such as less bleeding, less blood transfusion rate, and lower postoperative analgesia requirements than GA.⁴

It is known that pain that may be experienced during PCNL is because of dilation of the tract (skin and muscle), renal capsular stretch, or increase in intrapelvic pressure rather than intrarenal manipulation or stone retrieval.^{3,5}

Furthermore, some patients, especially those who have chronic pulmonary or cardiac diseases and complain of

stones that may compromise their renal function didn't tolerate GA or SA.⁵ In addition, with the continuous increase in surgical experience of urologists and the improvement of technology and equipment in the lack of anesthesiologists, PCNL under local anesthesia (LA) infiltration may be a viable alternative.³

In addition, urologists should make every effort to minimize the invasiveness of PCNL to minimize adverse events (AEs), postoperative analgesia, and shorten hospitalization period.⁶ So, minipercutaneous nephrolithotomy (MPCNL) was developed to lessen complications while maintaining the efficacy of conventional PCNL.⁷

Published studies about performing MPCNL under LA are limited and there is no study comparing the use of LA and SA during MPCNL. So, we designed this randomized prospective study to investigate and compare the feasibility, efficacy, and safety of carrying PCNL with assistance of mixture of local anesthetics (MLA) or SA.

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Patients and Methods

This is a prospective randomized study that was performed at the urology department, Banha University Hospital, Egypt. Recruitment of patients started from February 2017 through January 2021 after local research ethics committee (REC-FOMBU [IDIRB2017122601]) approved the study protocol according to the international guidelines.

The primary endpoint of this study was the measurement of perioperative visual pain analogue scale (VAS). Hence, the power analysis calculated by G*Power 3.1 (Heinrich-Heine, Germany), applying the two-sample non-inferiority test formula. The sampling ratio was 1:1, the power was 80%, 5% α error, and 95% confidence interval. The total calculated minimum sample size was 102 (51 per group). This number was raised to 60 patients in each group to account for possible attrition rate (20%).

After obtaining informed consent from each patient, the recruited patients were assigned into either one of the treatment groups using the 1:1 block randomization allocation method. The blocks were randomly varied from two to four patients.

All procedures were performed in accordance with the Helsinki Declaration by an experienced surgeon in attendance of an experienced responsible anesthesiologist. The preoperative data of the patients, including age, gender, body mass index (BMI), American Society of Anesthesiology (ASA) score, affected side, presence of hydronephrosis, stone burden, type, and density were recorded.

Inclusion criteria

Adult patients (age 18–70 years), motivated and able to complete a VAS independently, and with renal stones diameter ≥ 2 cm and ASA score ≤ 2 , were included.

Exclusion criteria

Patients with renal anomalies, transplanted kidney, uncorrected coagulopathy, complete staghorn stone, or multiple stones requiring multiple tracts for its clearance, morbid obesity, and/or active urinary infection were excluded.

Preoperative evaluation

Preoperative evaluation included complete medical history, physical examination, laboratory investigations (urine analysis, culture and sensitivity test, coagulation profile, complete blood count, serum urea, and creatinine), and imaging studies (including abdominal–pelvic ultrasonography (US), kidney, ureter, and bladder radiograph [KUB], and noncontrast spiral CT [NCCT] for all patients).

Patients were randomly allocated (1:1) into one of two groups (Fig. 1):

Group I: patients were subjected to MPCNL under MLA (MLA group)

Group II: patients were subjected to MPCNL under SA (SA group).

Procedures

All patients in both groups received 2 mg of midazolam hydrochloride plus pethidine hydrochloride [50 mg; Intra-

muscularly (IM)] as a potent analgesic (sedation and analgesia), ceftriaxone (1 gm; IM) as a prophylactic antibiotic, and 10:20 mL/kg warmed normal saline. Patients in the MLA group were positioned in lithotomy position and 5F open tip ureteral catheter was fixed by short 7.5F/9.5F semirigid ureteroscope (Karl Storz, Tuttlingen, Germany) after application of 2% of lidocaine jelly to the urethra. The patient was then positioned in Valdivia supine position. Then, the suitable trajectory for puncture was virtually predetermined under both US (free hand technique) and fluoroscopic guidance. The skin of the entry point was infiltrated by ~ 2 mL of lidocaine HCL. Then, under the guidance of both US and fluoroscopy during pyelography, a 20-gauge Chiba needle was introduced toward the desired calix till the renal capsule. Thereafter, a few milliliters of freshly prepared MLA (2% lidocaine with 1:100,000 epinephrine [9 mL], 0.5% bupivacaine with 1:200,000 epinephrine [9 mL], and 0.8 mL of 8.4% NaHCO₃) was injected into the renal subcapsular space. The needle was left in place to precisely mark the tract. Then, another needle was introduced alongside the previous needle that was used for infiltration of the whole tract by the MLA while retracting the second needle. The rest of the procedure was performed according to the standard protocol as we previously reported.⁸ In brief, dual-guided percutaneous puncture with an 18-G coaxial needle was made into the intended calix that was marked by the first needle. After efflux of fluid was seen, a 0.038" guidewire was inserted into the collecting system. A skin incision was made, and the tract was dilated over the guidewire by 15 F one-shot metal dilator, then an Amplatz (15F/16F) suction–irrigation sheath was inserted finally (Fig. 2).

Either 12F mininephroscope (RZ Medizintechnik GmbH, Tuttlingen, Germany) or ureteroscope was used for disintegration of stones by pneumatic lithotripter (Richard Wolf GmbH, Knittlingen, Germany). Fragments were washed out or removed by forceps. All used fluids (intravenous or irrigates) were warmed to body temperature. A 12 F nephrostomy tube was inserted at the conclusion of the procedure (Fig. 2).

For the SA group, patients received premedication as mentioned previously. Then, intrathecal bupivacaine 0.5% was injected through the L2 or L3 intervertebral space that was expected to achieve anesthetic level between thr₄ and thr₆. Thereafter, the rest of the procedure was performed as described for the MLA group.

Heart rate, blood pressure, and oxygen saturation were continuously monitored during the procedure. Also, the primary outcome (VAS score) was evaluated intraoperatively (0 time) and at 2, 6, 12, and 24 hours, postoperatively. The secondary outcomes including operative time, analgesic requirements (both nonsteroidal anti-inflammatory drugs [NSAIDs] and/or opioids), perioperative AEs, hemoglobin deficit, Likert scale of satisfaction, and stone-free rate (SFR) were recorded based on finding of low dose NCCT. At first postoperative day, 1, and 3 months postoperatively, patients were evaluated by US, KUB, and/or NCCT when appropriate. Auxiliary procedures were decided accordingly.

Statistical analysis

The statistical analysis of the data was performed by SPSS 26 (IBM, Armonk, NY, USA). Continuous nonparametric data are expressed as median and interquartile range, whereas

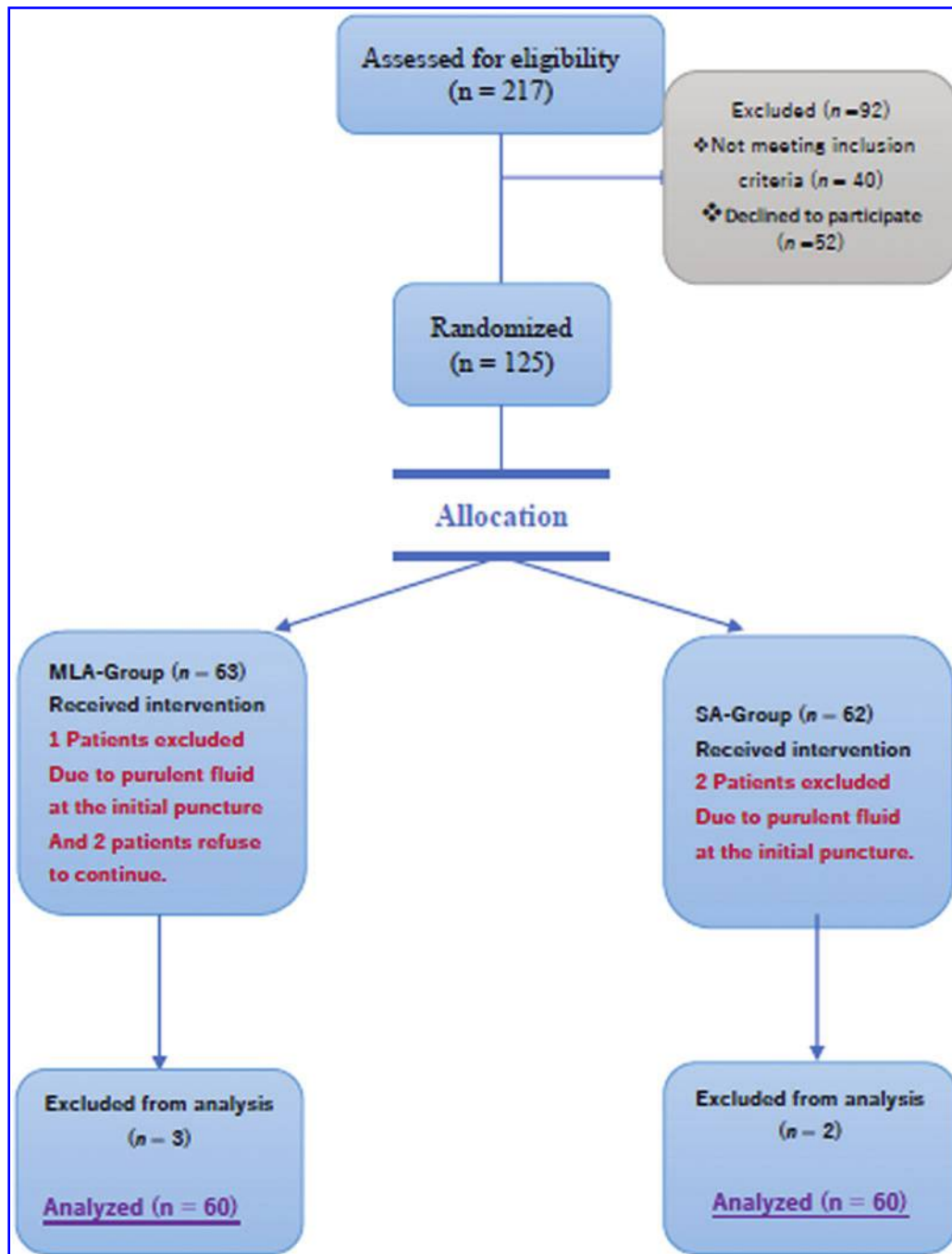


FIG. 1. Flow diagram illustrating the study design. Color images are available online.

parametric data are expressed by mean \pm SD and were analyzed by Mann–Whitney U test or independent Student's *t* test, respectively. Categorical data are expressed as number and percentage and were analyzed using χ^2 or Fisher's exact tests when appropriate. The statistical significance was approved when $p < 0.05$.

Results

A total of 217 patients were assessed for eligibility, but only 120 patients (who met the inclusion criteria and agreed to sign the informed consent) were recruited and subjected to

the final statistical analysis (Fig. 1). These patients were randomly allocated to one of the two treatment arms as already mentioned.

As indicated in Table 1, patients in the two study groups had similar baseline characteristics regarding age, gender, laterality, BMI, comorbidities, hydronephrosis, and stone type ($p > 0.05$).

In addition, patients in both groups had comparable median stone burden (25 mm vs 26 mm for the MLA group and SA group, respectively), and average stone densities that were 800 (650–1000) and 850 (692–1050), respectively ($p > 0.05$) (Table 1).

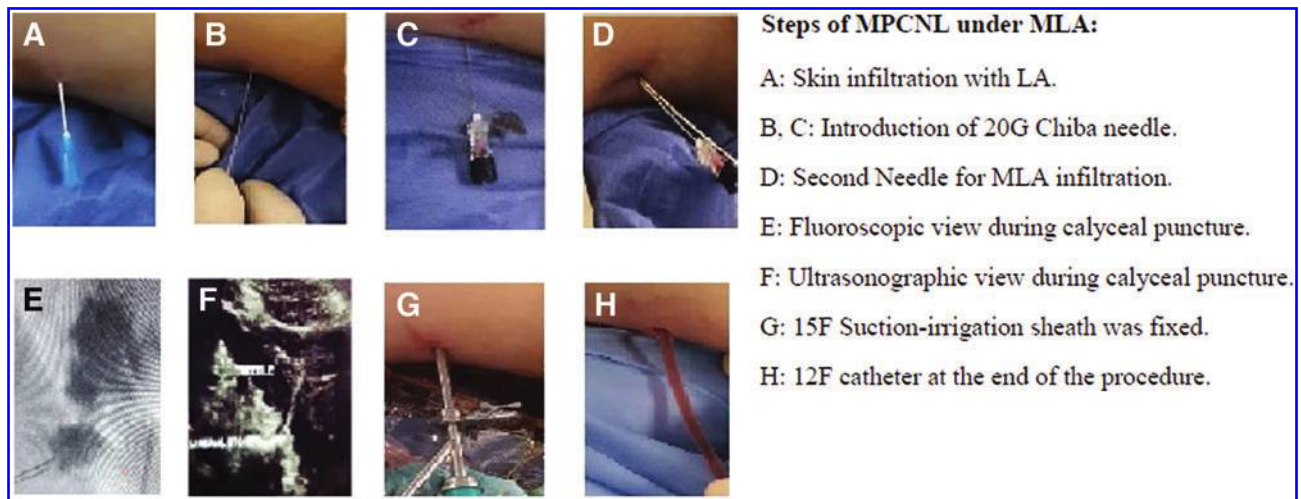


FIG. 2. Steps of minipercutaneous nephrolithotomy under mixture of local anesthesia. Color images are available online.

With regard to the VAS score, which is the primary endpoint of this study, the results indicated that median intraoperative score was higher in the MLA group than in the SA group (2.5 vs 2, respectively, $p=0.021$). Conversely, the median VAS score at 6- and 12-hour postoperation was lower in the MLA group than in the SA group (1.1 vs 2.2, respectively, $p<0.05$). Whereas the VAS score at 2 and 24 hours postoperation was comparable between the two groups ($p>0.05$) (Table 2).

Regarding the other endpoints, the median operative time was 60 minutes in both treatment groups. Similarly, the

median nephrostomy time was 1 day, and hospital stay time was similar in the two groups and was 1.5 days, ($p>0.05$) (Table 2). The primary SFR was 93.4% in MLA groups as compared with 88.3% in the SA group (Table 2). At 3 months postoperatively, SFR in the MLA group and SA group was 100% and 98.3%, respectively.

Table 2 indicated that the postoperative analgesic consumption was comparable in both groups ($p>0.05$). In the MLA group, 20 of 60 patients required NSAIDs, out of them 15 required 1 ampule (75 mg diclofenac sodium) and 5 patients required 2 ampules, whereas in the SA

TABLE 1. DEMOGRAPHIC AND PREOPERATIVE CLINICAL CHARACTERISTICS OF THE ENROLLED PATIENTS

Parameters	MLA group (n=60)	SA group (n=60)	p
Age, years; median (IQR)	39.5 (30.25–46)	40 (32–47)	0.592
Gender (male/female)	42/18	43/17	0.841
Laterality (Right/Left)	35/25	32/28	0.581
BMI, kg/m ² , median (IQR)	27 (25–30)	28 (26–30)	0.127
Comorbidities, n (%)	12 (20)	14 (23.3)	0.486
Hypertension	6 (10)	10 (16.7)	
Diabetes mellitus	6 (10)	4 (6.6)	
Hydronephrosis, n (%)			0.725
None	8 (13.3)	11 (18.3)	
Mild	20 (33.3)	20 (33.3)	
Moderate	27 (45)	22 (36.7)	
Severe	5 (8.3)	7 (11.7)	
Stone size, mm; median (IQR) ^a	25 (23.25–28)	26 (25–28)	0.324
Stone burden, mm ² ; median (IQR) ^a	429 (352–543)	485 (365–616)	0.239
Stone density, HU; median (IQR)	800 (650–1000)	850 (692.5–1050)	0.333
Stone type, n (%)			
Single	39 (65)	37 (61.7)	
Multiple	21 (35)	23 (38.3)	
Stone location, n (%) ^b			0.705
Renal pelvis	28 (47)	30 (50)	
Lower calix	35 (58)	33 (55)	
Middle calix	15 (25)	17 (28)	
Upper calix	4 (7)	3 (5)	

^aIn case of multiple stones, the size was calculated as the sum of sizes of all stones.

^bSome patients had multiple stones in the same location.

BMI=body mass index; IQR=interquartile range; MLA=mixture of local anesthetics; SA=spinal anesthesia.

TABLE 2. INTRAOPERATIVE AND POSTOPERATIVE PARAMETERS

	MLA group (n=60)	SA group (n=60)	p
Targeted calix, N (%)			0.282
Lower	40 (66.7)	46 (76.7)	
Middle	16 (26.7)	13 (21.7)	
Upper	4 (6.7)	1 (0.8)	
Operative time, minute; median (IQR)	60 (50–76)	60 (55–80)	0.096
VAS score			
Intraoperative	2.5 (2–4)	2 (1–3)	0.021 ^a
2-hour postoperative	1 (0–1)	0 (0–1)	0.219
6-hour postoperative	1 (0–2)	2 (1–2)	0.001 ^a
12-hour postoperative	1 (1–1.25)	2 (0.5–3)	0.031 ^a
24-hour postoperative	0 (0–1)	0 (0–1)	0.148
Hemoglobin drop (g/dL, mean ± SD)	1.04 ± 0.54	1.27 ± 0.46	0.013 ^a
Nephrostomy time; days, median (IQR)	1 (1–1)	1 (1–1)	0.505
Hospital stay; days, median (IQR)	1.5 (1.5–2)	1.5 (1–2)	0.158
Primary Stone Free Status, N (%) ^b			0.590
No residual fragments	49 (81.7)	45 (75)	
Insignificant fragments	7 (11.7)	8 (13.3)	
Significant fragments	4 (6.7)	7 (11.7)	
Auxiliary procedures, N (%)			0.713
Second look PCNL	2 (3.3)	1 (1.7)	
Extracorporeal shockwave lithotripsy	1 (1.7)	0 (0)	
Ureteroscopy	1 (1.7)	1 (1.7)	
Analgesic consumption, N (%)			
Nonsteroidal anti-inflammatory drugs	20 (33.3)	19 (31.7)	0.064
Opioid	7 (11.7)	9 (15)	0.591
Likert-like satisfaction, N (%)			0.083
Very satisfied	29 (48.3)	23 (38.3)	
Satisfied	16 (26.7)	28 (46.7)	
Neutral	7 (11.7)	7 (11.7)	
Dissatisfied	5 (8.3)	2 (3.3)	
Very dissatisfied	3 (5)	0 (0)	

^a $p < 0.05$.

^bAfter primary surgery (1ry MPCNL); stone-free status is defined as no visible stones (no residual fragments), insignificant fragments: presence of residual fragments <4 mm, whereas the presence of fragments ≥4 mm is considered as “significant fragments.”

MPCNL = minipercutaneous nephrolithotomy; NSAID = nonsteroidal anti-inflammatory drug; PCNL = percutaneous nephrolithotomy; VAS = visual pain analogue scale.

group, 19 patients required only 1 ampule of 75 mg diclofenac sodium. While, 16 out of 120 patients required more potent analgesic (50 mg pethidine HCL) to control their pain (Table 2).

During the hospital discharge, every patient was requested to express his satisfaction on the Likert-like 5 points scale (Table 2). There was no statistically significant difference between the two groups ($p = 0.083$).

AEs are reported and listed according to the modified Clavien classification of complications (Table 3). There was no statistically significant difference in overall reported AEs among the two groups ($p = 0.345$). Interestingly, one patient from the MLA group experienced severe pain just on introduction of the nephroscope that revealed pelvicaliceal perforation. Thus, re-entry catheter was introduced, and the maneuver was postponed; a second look was performed 4 days later under MLA and the stone was removed effectively. Six patients (10%) of the SA group had postoperative headache, whereas no patient from the MLA group did complain of headache ($p = 0.027$).

TABLE 3. THIRTY DAYS POSTOPERATIVE ADVERSE EVENTS ACCORDING TO MODIFIED CLAVIEN CLASSIFICATION OF COMPLICATIONS, N (%)

Complication	MLA group (n=60)	SA group (n=60)	MC grade	p
Overall	13 (21.7)	9 (15)	I:IIIB	0.345 ^a
Tube displacement	0 (0)	2 (3.3)	I	0.248
Postoperative fever	6 (10)	5 (8.3)	I	0.500
Bleeding required transfusion	0 (0)	1 (1.7)	II	0.500
Urinary tract infection	6 (10)	3 (5)	II	0.245
Double-J stenting	3 (5)	1 (1.7)	IIIA	0.309
Bleeding required quitting the operation	0 (0)	1 (1.7)	IIIB	0.500

Some patients had simultaneous complications. And Fisher's exact test was used (all p -values except chi-square test).

^aChi-square test.

MC = Modified Clavien.

Discussion

Recently, hospital admissions are increasing because of urinary calculi and its related complications.⁹ Moreover, during the COVID-19 crisis, there is deficiency in hospital beds, equipment, and health care givers, especially anesthesiologists.⁹ So, it is recommended to perform urologic intervention without GA to spare ventilators whenever possible.¹⁰

PCNL can be performed under general or regional anesthesia, or LA.^{5,11} In modern urologic practice, performing this procedure under SA is gaining much popularity as it confers less operative time, shorter hospital stay, and less postoperative pain, and analgesic requirement.^{4,12} Moreover, there is rising concern about performing PCNL under assistance of LA in high anesthetic risk patients.^{13,14}

In this study, the results revealed that the median VAS score was 2.5 vs 2 for the MLA group and SA group, respectively. Although intraoperative VAS score was slightly higher in the MLA group than in the SA group ($p=0.021$), there was no great clinical impact of this statistical difference. Indeed, none of the patients required conversion to another anesthesia modality except one in the MLA group. In addition, none of the patients required additional analgesia. Moreover, overall satisfaction on Likert-like 5 points scale was similar between the two groups. Earlier pilot study reported by Dalela and coworkers stated that PCNL is feasible under LA.⁵ Other studies reported that two-stage PCNL was performed under LA.⁶ Furthermore, a recent study that recruited 2000 participants concluded that PCNL can be effectively performed under LA with satisfactory results.² A newly published study that included large number of patients who underwent MPCNL under lidocaine LA reported an average intraoperative VAS score of 3.6.¹⁵ Our results confirmed these results; however, the intraoperative VAS score is lower in our study, which might be attributed to different tract sizes, as we used 15F tract while others used 18F to 30F tract. Second, we used buffered MLA, unlike the aforementioned studies that used plain lidocaine only. Third, in these three studies, patients were laid in prone position, whereas in our study patients were positioned supine, which is more comfortable for alert patients. In addition, the irrigates in our study were warmed to body temperature to decrease pain sensation and irritability.¹⁶ Lastly, different cultural background of recruited patients may play a role. At the 6th- and 12th-hour postoperatively, VAS scores were better in the MLA group than in the SA group, reflecting the longer duration of the used buffered mixture of lidocaine and bupivacaine.¹⁷

An experienced anesthesiologist attended all procedures for provision of premedication (sedation/analgesia) and SA and continuous patient monitoring of vital signs, pain control as per VAS score, or conversion to another modality of anesthesia if indicated. During monitored anesthesia care, ASA recommended that local infiltration anesthesia is given mainly by surgeons, whereas sedation and analgesia should be provided by a responsible anesthesiologist.¹⁸ Moreover, many patients expressed fear of performing the procedures under MLA during preoperative counseling so, they were reassured by informing them that an anesthesiologist will be readily available for conversion to another modality.

In this study, the average operative time was ~1 hour for both groups, resulting in one-session SFR 93.4% vs 88.3% for the MLA group and the SA group. This is similar to the recently

reported results of MPCNLs.^{19–21} In contrast, an earlier study reported that the mean operative time was 72.4 minutes and initial SFR was 77.6% after MPCNL for simple renal stones.²² These differences may be because of the different armamentarium used, and/or patients' positioning (supine in our study).

Regarding hemoglobin drop, our results revealed that there was a statistically significant difference in hemoglobin deficit between the two groups (1.04 ± 0.54 in the MLA group vs 1.27 ± 0.46 , in the SA group; $p=0.013$). Yet, this difference is of no clinical significance as none of the patients in the two groups had intraoperative bleeding, necessitating quitting the procedure or required transfusion, except one patient in the SA group ($p=0.5$). This lower hemoglobin drop in the MLA group may be because of the effect of epinephrine, which is a component of the mixture of anesthesia used.²³ Another possible cause is hypothermia caused by SA, which may lead to increased blood loss in the SA group.²⁴

Headache is one of the most known complication after SA²⁵ and its prevalence is ~1% to 36%.²⁶ In this study, the incidence of postdural puncture headache was 10% for the SA group. Cicek et al. compared PCNL under GA and SA and they noted headache in 0.2% and 8% for GA and SA groups, respectively.⁴

A published meta-analysis stated that postoperative analgesic requirements were lower for SA than for GA for PCNL.¹² In our study, the analgesic consumption showed no statistically significant difference between the study groups.

This study is not devoid of limitations. Different cohorts of patients (such as high anesthetic risk patients) may be included. Further multicentric trials with larger study groups are warranted to confirm our results. Finally, MLA could be applied in selected cases and cannot be generalizable for all PCNL procedures.

Conclusion

MPCNL is feasible under mixture of buffered local anesthetic agents (lidocaine, epinephrine, bupivacaine, and NaHCO_3) with providence of relatively long-term postoperative analgesia in well-counseled, motivated, and cooperative patients. It is a well-tolerated alternative anesthesia technique for SA. And suitable for stone removal requiring single access in experienced hands. Such an anesthesia may not be the primary choice for rookies.

Author Disclosure Statement

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Abbreviations Used

AEs = adverse events
ASA = American Society of Anesthesiology
BMI = body mass index
GA = general anesthesia
HU = Hounsfield units
IM = Intramuscularly
IQR = interquartile range
KUB = kidney, ureter, and bladder radiograph
LA = local anesthesia
MLA = mixture of local anesthetics
MPCNL = minipercutaneous nephrolithotomy
NCCT = noncontrast spiral computed tomography
NSAIDs = nonsteroidal anti-inflammatory drugs
PCNL = percutaneous nephrolithotomy
SA = spinal anesthesia
SFR = stone-free rate
US = ultrasonography
VAS = visual pain analogue scale