

Miniaturized percutaneous nephrolithotomy: Is smaller really better?

Gopal Sharma*

Department of Urology, PGIMER, Chandigarh, India

*E-mail: gopal.26669192@gmail.com

SUMMARY

Zeng *et al.* published a multicenter open-labeled randomized controlled trial (RCT) comparing mini percutaneous nephrolithotomy (mPNL) with standard PNL (sPNL).^[1] This was a noninferiority trial conducted across 20 centers in China.^[1] In this study, the authors aimed to prove their hypothesis that mPNL is not inferior to sPNL for managing renal stones between 2 and 4 cm in size. The primary outcome of the study was one-session stone-free rate (SFR), and the secondary outcomes included the duration of the surgery, length of stay (LOS), complication rates, and pain on visual analog scale (VAS) score at 24 h. All the procedures were performed by experienced surgeons and an 18F access sheath was used for mPNL and a 24F access sheath was used for sPNL. Stone-free status was determined with a X-ray of the kidney-ureter-bladder region and an ultrasound was performed before the discharge and again at follow-up. Noncontrast computed tomogram was performed in selected cases where there was a discrepancy between the plain radiograph and ultrasound. The noninferiority margin was set at -10% difference in the SFR between mPNL and sPNL.

Of the patients assessed for eligibility, 966 in the sPNL and 978 in the mPNL were analyzed in per-protocol (PP) analysis. On analysis, mPNL showed a noninferior single-session SFR in the PP and intention-to-treat (ITT) population. The duration of surgery was longer in the mPNL group (ITT: 2.2 min, $P = 0.008$; PP: 2.11–2.3 min, $P = 0.007$). The mean fall in hemoglobin level was higher with sPNL; however, the transfusion (PP: 1.1% vs. 1.1%, $P = 1$) and the angioembolization (PP: 0.93% vs. 0.82%, $P = 0.8$) rates were similar between the two groups. The need for analgesia and the VAS score at 24 h were significantly higher in the sPNL group. The need for auxiliary procedures (PP: 6.4% vs. 5.2%, $P = 0.3$) was similar in both the groups, whereas the numbers of procedures performed tubeless (PP: 19% vs. 35%, $P \leq 0.001$) were significantly higher in the mPNL group. LOS (differences 0.5 [0.3–0.8], $P < 0.001$) was

significantly longer in the sPNL group whereas the overall complication rate (PP: 49.3% vs. 41.9%, $P = 0.4$), fever (PP: 8.2% vs. 9.8%, $P = 0.2$), and septic shock rates (PP: 0.52% vs. 0.82%, $P = 0.4$) were similar in both the groups.

COMMENTS

Advancements in the technology and the development of smaller-sized scopes and lithotripsy devices have permitted the use of smaller-sized access sheaths for PNL. Theoretically, mPNL, due to the smaller diameter of the access sheath, should cause minimal damage, leading to a lower blood loss, reduced need for blood transfusions, lower post operative pain, and early convalescence. Despite the availability of multiple RCTs and meta-analyses, the current major guidelines do not recommend mPNL due to a lack of high-quality evidence.^[2,3] This study by Zeng *et al.* is the first well-conducted multi-center, open-labeled RCT comparing sPNL with mPNL.^[1] The previously RCTs published on this topic were small single-center studies and compared the two treatment modalities for variable stone sizes. Despite being a multi-center study enrolling a large number of patients, this study has certain limitations. First, this study focuses on a larger stone size, i.e. 2–4 cm. It would have been interesting if they would have included patients with smaller stone sizes (i.e., around 1–3 cm), for which mPNL is actually indicated; as for the larger stones, sPNL is still the standard of care. Another important limitation of this study is the use of a large size (18F) access sheath for the mPNL group as compared to the 24F access sheath for sPNL.^[1] The lithotripsy modalities in the two groups were different and this could be an important confounding factor in comparing the two groups. For the primary outcome, the authors noted a higher SFR with sPNL, but the difference could not reach the limit of noninferiority. Hence, both the techniques were labeled as equally efficacious. Similar to this study, Deng *et al.*^[3] and Jiao *et al.*^[2] noted a similar SFR in the two groups in their meta-analyses. Another clinically relevant safety parameter for the two techniques is blood loss. Estimation of blood loss during PNL is difficult due to the use of continuous irrigation. Other indirect parameters such as fall in hemoglobin and the need for blood transfusions are more clinically relevant. The mean difference of fall in hemoglobin by 4.6 g/dL is

both statistically and clinically relevant. However, the need for blood transfusion was similar between the two surgical techniques. These findings are in contrast with two previous meta-analyses,^[2,3] which reported a lower need for blood transfusion with mPNL. The plausible reasons for this could be that Zeng *et al.*^[1] have used a lower threshold for blood transfusion, i.e., <7 g/dL, and also, the study was not adequately powered to determine the difference in the rates of blood transfusion. The difference in the LOS and the duration of surgery between the two groups were 0.5 days and -2.3 min, respectively. Although statistically significant, this difference is clinically irrelevant because of its small effect size. Another critical finding noted by Zeng *et al.* is that the overall complications, fever, and sepsis rates were similar in both the groups.^[1] Results reported by Zeng *et al.* for SFR and overall complications are similar to the two previous RCTs conducted by Kandemir *et al.*^[4] and Güler *et al.*^[5] in patients with renal stone disease >2 cm comparing the two surgical techniques. Thus, mPNL, as compared to sPNL, can be considered noninferior for the management of renal stones of the size 2–4 cm. However, the theoretical advantage of lower tissue trauma, leading to a lower blood loss and transfusion rates, were not realized in this study, and both the surgical techniques were found to be equally safe.

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