Original Article

Mini access guide to simplify calyceal access during percutaneous nephrolithotomy: A novel device

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ABSTRACT

Introduction: A precise puncture of the renal collecting system is the most essential step for percutaneous nephrolithotomy (PCNL). There are many techniques describing this crucial first step in PCNL including the bull's eye technique, triangulation technique, free-hand technique, and gradual descensus technique. We describe a novel puncture guide to assist accurate percutaneous needle placement during bull's eye technique.

Methods: The mini access guide (MAG) stabilizes the initial puncture needle by mounting it on an adjustable multidirectional carrier fixed to the patient's skin, which aids in achieving the "bull's eye" puncture. It also avoids a direct fluoroscopic exposure of the urologist's hand during the puncture. Sixty consecutive patients with solitary renal calculus were randomized to traditional hand versus MAG puncture during bull's eye technique of puncture and the fluoroscopy time was assessed.

Results: The median fluoroscopy screening time for traditional free-hand bull's eye and MAG-guided bull's eye puncture (fluoroscopic screening time for puncture) was 55 versus 21 s ($P = 0.001$) and the median time to puncture was 80 versus 55 s ($P = 0.052$), respectively. Novice residents also learned puncture technique faster with MAG on simulator.

Conclusion: The MAG is a simple, portable, cheap, and novel assistant to achieve successful PCNL puncture. It would be of great help for novices to establish access during their learning phase of PCNL. It would also be an asset toward significantly decreasing the radiation dose during PCNL access.

INTRODUCTION

Large renal calculi (>2 cm) generally need removal by percutaneous nephrolithotomy (PCNL). An accurate initial puncture (IP) of the pelvicalyceal system (PCS) is perhaps the most important step of PCNL.[1] C-arm fluoroscopic-guided puncture is the most favored method of obtaining this initial access into the PCS.[2] Fluoroscopic-guided access can be obtained by the "bull's eye" puncture technique and the triangulation method. "Bull's eye" puncture technique is the most popular and easy technique for access.[3,4] However, it has the disadvantage of exposing the surgeon's hand directly to the fluoroscopic beam while steadying the needle in the bull's eye position before puncture. We aimed to design a simple, portable, mechanical apparatus that would aid the urologic surgeon by improving PCNL puncture efficacy, decrease time to successful puncture, reduce fluoroscopic screening time (FST), reduce puncture instability of the needle, and decrease the learning curve.

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METHODS

The mini access guide: Description of the apparatus

The essence of the mini access guide (MAG) is that it stabilizes the needle in desired direction on the patient's skin for PCNL puncture. The device consists of a radiolucent cylinder with a height of 2 cm, a circular base of 2.5 cm diameter on one side and open on other side [Figure 1a]. A 14 Fr radiolucent tube A is mounted on the cylinder transversely along the

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diameter close to the floor [Figure 1a]. Another needle carrier tube B of 14-gauge is inserted perpendicularly along a slit in the center of the tube A [Figure 1a]. By rotating tube A, tube B can be tilted from approximately 45° on either side of the vertical axis in the plane perpendicular to the long axis of tube-A which can correct the craniocaudal deviation [Figure 1b]. Tube B can also be tilted to +60° and –30° from the vertical axis in the plane formed by tube A and tube B, which corrects the mediolateral deviation of the puncture needle [Figure 1c]. Tube B allows an 18-gauge IP needle to be guided through its lumen along the direction in which tube B is oriented [Figure 1d].

The appropriate point of entry and direction for needle advancement is determined fluoroscopically by tilting the C-arm as per the orientation of desired calyx. The IP-needle tip is superimposed over the desired calyx on the fluoroscopic screen (Video can be viewed online at www.indianjurol.com). A small 2 mm incision is made on the skin at the tip of the IP-needle [Figure 2a]. The base of the device is securely fixed on the patient's skin with sterile adhesive ring with the eccentric hole in the base exactly placed over the skin nick at the puncture point [Figure 2b]. Orientation of the tube B can be maneuvered and the position checked intermittently with operator's hand outside the fluoroscopy beam [Figure 3a]. The fluoroscopic bull's eye is achieved by rotating tube A [Figure 3a] and tilting tube B [Figure 3b] keeping the IP-needle *in situ*. Once the bull's eye is achieved, the IP needle is advanced through the lumen of tube B approximately up to the estimated depth. All adjustments are done with the surgeon's hands off the needle, thereby reducing direct fluoroscopic exposure to the hands. The C-arm is rotated back to 0° position to estimate puncture depth and the IP needle is adjusted accordingly [Figures 4 and 5].

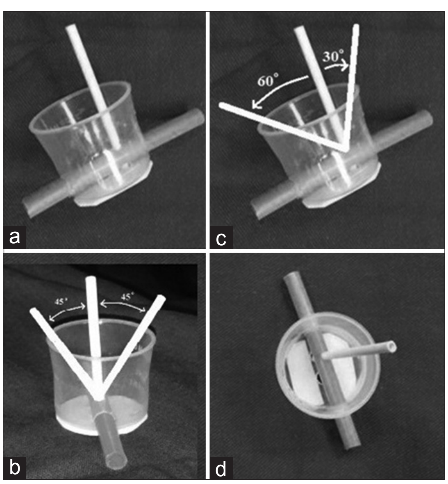

Figure 1: (a) The mini access guide for percutaneous nephrolithotomy consists of a radiolucent cap with base diameter of 2.5 cm and two aligned tubes for maneuvering the initial puncture needle. (b) Orange tube can be rotated to correct the craniocaudal tilt and (c) white tube can be tilted medially and laterally. (d) Top view of MAG

Objective assessment of the efficacy of the apparatus was obtained by *in vivo* and *ex vivo* testing using simulated PCNL puncture with and without use of the MAG. Sixty consecutive patients with single renal calculus, posted for PCNL, were randomized to undergo puncture by conventional hand maneuvered bull's eye technique (Group A) versus MAG technique (Group B) by two experienced surgeons PSC and PN. Two end points were assessed: time to successful puncture and FST for puncture (FSTP). In *in vivo* testing, time to successful puncture was calculated from the time of marking the skin puncture to the time of aspiration of fluid from PCS and FSTP was the fluoroscopic exposure time as recorded on C-arm in that period. Ten surgical trainees (who had observed PCNL but never done one) were recruited for the *ex vivo* testing. The *ex vivo* testing method involved fluoroscopic screening of a small (1 cm) hidden radioopaque metal coin under 10 cm polystyrene. The coin was connected to an electric circuit and a light illuminated when the coin was successfully touched by the IP-needle. Each trainee was allowed to try the puncture with and without using the MAG, ten times each, over a period of 1 week. Maximum permissible FSTP per puncture was fixed as 300 s. The number of successful attempts was assessed. Patients in Group A and B were comparable [Figure 5]. The independent *t*-test, Pearson Chi-square, and Mann–Whitney U-test were used to assess statistical significance, using IBM SPSS Statistics for Windows, Version 24.0. (IBM Corp., Armonk, NY). Ethical clearance was obtained from the hospital Ethics Committee.

RESULTS

In the *in vivo* series, patients in either group were comparable with respect to gender, calyx punctured, supracostal punctures, and puncture of nondilated PCS.

In vivo, the median FSTP for successful puncture in Group A versus B patients was 39 s (interquartile range [IQR] = 24–48) versus 21 s (IQR = 18–30) and was significantly more ($P = 0.001$). The median time to puncture was also more

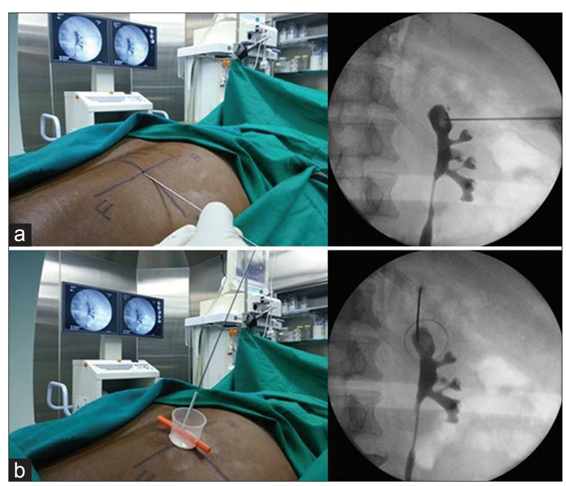

Figure 2: (a) Marking the puncture point. (b) Placement of the mini access guide superimposing on the desired calyx

in Group A compared to Group B, being 80 s (IQR = 60–95) versus 55 s (IQR = 40–80), respectively, but did not reach statistical significance ($P = 0.052$).

When MAG was used by the trainees for puncture on simulator, the number of successful punctures was significantly higher compared to the conventional hand-held puncture (92 times vs. 54 times). More number of students could achieve successful puncture in the initial attempts in the MAG group compared to the non-MAG group.

DISCUSSION

PCNL was first described more than three decades ago. Since then, technological advances have significantly improved the efficacy and the safety of this procedure.[5] However, a precise and secure access to PCS remain the most challenging and critical part of the procedure.[1-4]

The various techniques used to obtain access into PCS include the following: (1) Two-stage Radiology-Urology technique: initial access is obtained by a trained interventional radiologist and urologist performs the subsequent dilatation of tract, stone lithotripsy, and retrieval. However, the trend is changing and most practicing urologists have taken to obtaining their own access.[6] (2) Fluoroscopic-guided techniques: Bull's eye and "triangulation" techniques are the most used fluoroscopic-guided techniques.[1-4] (3) Ultrasonography-guided access with its advantage of avoiding or reducing the radiation exposure.[7,8] (4) Retrograde percutaneous access: [9,10] despite its feasibility, this method involves additional expertise and instrumentation, for example, flexible ureterorenoscopy and hence is not commonly utilized.[11] (5) Robotic-assisted access: From being a C-arm guided manually positioned robotic arm, the percutaneous access to the kidney (PAKY) system and the PAKY- remote center of motion system has advanced to being a fully automated robot which can perform the entire percutaneous access by remote control.[12-14] (6) A metal arm with 6° of freedom movement was developed by Stoianovici *et al*. This metal arm manipulated mechanically by the urologist, while attached to the side rail of the operating table.[15] Similar "locator" was described by Lazarus and Williams.[16]

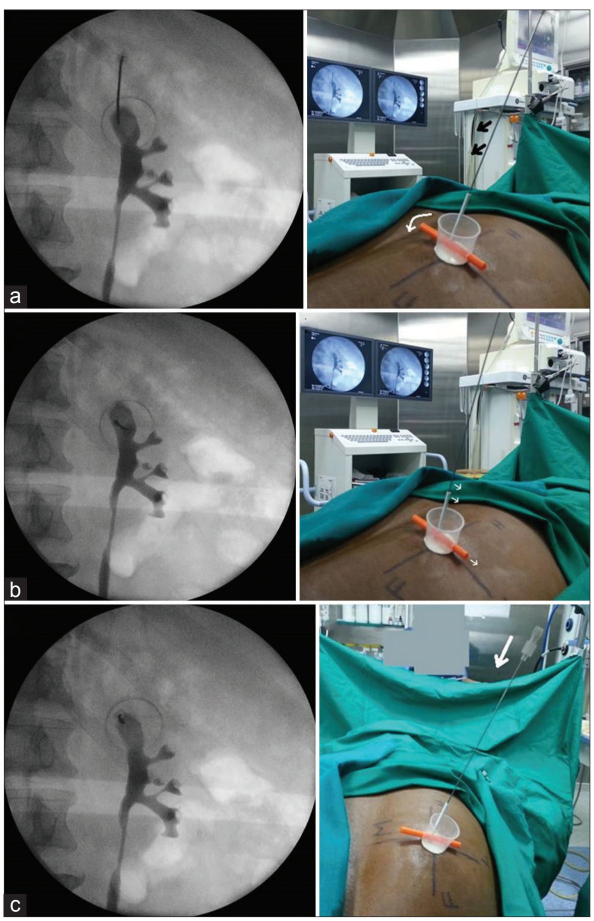

Figure 3: Adjusting mini access guide to attain bull's eye (C-arm and surface view). (a) Craniocaudal tilt being corrected. (b) Medio-Lateral tilt being corrected. (c) Bull's eye obtained and Needle introduced

In spite of the above options, fluoroscopic-guided puncture remains the mainstay for access during PCNL.[1] It often entails tentative needle punctures, which leads to a prolonged radiological screening. Access to PCS is critical and suboptimal access can lead to increased operative times, decreased stone-free rates, and increased complication rates.

The dangers of prolonged exposure to ionize radiation are well known, and a reduction of radiation dose adhering to the principle of as low as reasonably achievable is desirable.[17] The above-mentioned designs for obtaining access to PCS, with the exception of the fully automated robot, serve mainly to stabilize and in some cases advance the needle, thereby reducing direct radiation exposure to the surgeon's hands. However, these machines are complex and bulky and this has largely prevented their application in routine clinical practice.[12-15]

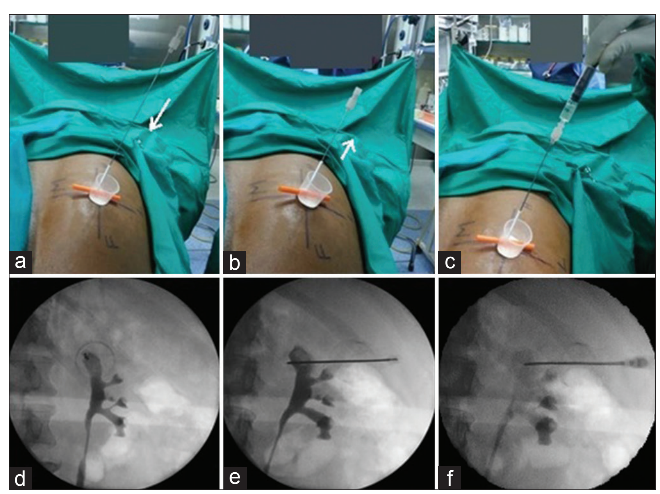

Figure 4: (a) Needle introduced at Bull's eye position (b) C-Arm rotated to 0 degree. (c) Adjusting initial puncture needle at 0° for depth correction

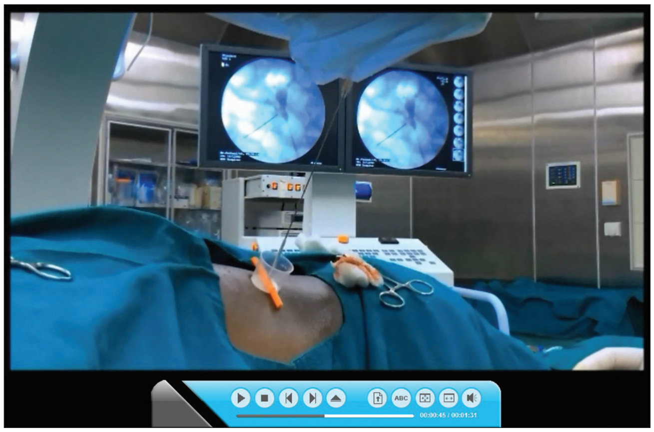

Figure 5: Technique of using mini access guide

The MAG uses the popular "bull's eye" puncture technique but removes human tremor and resultant needle misalignment, thereby reducing the need to periodically check for fluoroscopic alignment as in the manual technique.[3] MAG was designed ith the idea to develop a cost-effective, portable, and simple device that helps to achieve a quicker and more precise access to PCS than doing it manually.

After obtaining bull's eye sign under fluoroscopy, the MAG keeps the needle firm and secure, avoiding any drift in needle alignment as occurs commonly with a purely manual puncture. The MAG reduces the radiation exposure to the operating surgeon and the patient by eliminating the need for continuous exposure for checking needle position.[3] Surgeons hand can be totally kept out of the fluoroscopic beam while orienting the IP-needle. Although radioprotective gloves are available, they may hinder obtaining a fluoroscopic bull's eye by obscuring the image and affect the precision of puncture. MAG can simplify PCNL access and can probably lead to an easier mastering of PCNL by the trainees. Since MAG is fixed on the patient's skin, the relative motion of needle with respect to target along with the respiratory movements is grossly reduced.

This preliminary report of the MAG has indicated that it can reduce FST and reduce the time taken to gain access to the PCS. In spite of the differences between the *ex vivo* simulation and the *in vivo* testing, the results were replicated.

CONCLUSION

The MAG has the potential to make access to PCS easier during PCNL while reducing radiation exposure during access. Its novelty lies in it being a simple, portable, and economical alternative to its heavier and costlier predecessors. Novice urology trainees can benefit from MAG in simplifying the steep learning curve of PCNL. Further clinical evaluation to prove the efficacy of MAG is warranted.

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