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UROLOGY

SabreSource™: a novel percutaneous nephrolithotomy apparatus to aid collecting system puncture – a preliminary report

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Background: Successful percutaneous nephrolithotomy (PCNL) relies on a technically challenging, precise needle puncture of the renal collecting system. We aimed to compare, in an ex vivo model, the use of a real time image guidance system (the SabreSource™) and a mechanical stabilising device with conventional manual techniques for the accuracy of needle placement.
Methods: The SabreSource™ system (Minrad International Inc.; New York, USA) is a real time image guidance system. The system platform is mounted on a C-arm fluoroscope. It employs targeting cross hairs on the fluoroscopic image that can be easily positioned to target the desired renal calyx. The system directs a visible laser beam onto the patient which is precisely aligned with the cross hairs on the fluoroscopic image. This provides the correct "bull's-eye" angle of approach to the calyx, even after the x-ray source is turned off. The locator then stabilises the needle in the "bull's-eye" position so that only screening for depth is required. Objective assessment using a simulated PCNL puncture was performed by 7 urologic trainees on a kidney phantom with and without using the SabreSource™. Fluoroscopy screening time (FST) and amount of radiation (mGy) used to achieve successful puncture were compared.
Results: Simulated PCNL puncture was quicker and resulted in reduced radiation exposure when the apparatus was used. The mean FST for traditional "bull's-eye" vs SabreSource™ puncture was 17 vs 5 seconds ($p = 0.01$), and the mean radiation exposure to puncture was 0.7 vs 0.2 mGy ($p = 0.03$), respectively.
Conclusion: The SabreSource™ is a novel assistant to achieving successful PCNL puncture. In combination with "the locator" the preliminary in vitro testing suggests that the device reduces fluoroscopy exposure and is quicker. The device warrants further evaluation in the clinical setting.
Keywords: PCNL, SabreSource™, percutaneous nephrolithotomy, laser guidance, staghorn calculi, novel

Introduction

Percutaneous nephrolithotomy (PCNL) is the favoured endourologic procedure for large (> 20 mm) renal calculi, offering patients a low morbidity procedure with high stone clearance rates.[1] Precise percutaneous needle puncture of the desired calyx of the renal collecting system is the critical initial step to achieving operative success with PCNL. Obtaining a perfect puncture is technically challenging, making PCNL an advanced endourological procedure with surgical competence typically achieved only after 60 procedures and excellence after more than 100 cases.[2] As a result, only 27% of American urological surgeons trained in PCNL continue to perform it, while only 11% of American urologists performing PCNL routinely obtain percutaneous access themselves.[3]

Although there are a number of puncture techniques described, the traditional C-arm fluoroscopic guided puncture using the "bull's-eye" method is still the most commonly used.[1] One novel apparatus, "the locator" has been shown in vitro to decrease fluoroscopic screening time, radiation exposure and puncture time.[4] We aimed to test the use of a real time image guidance system, the SabreSource™, to assist with identification of a "bull's-eye" in combination with the locator to stabilise the needle and compare this with conventional manual techniques.

Materials and methods

The SabreSource™ system (Minrad International Inc.; New York, USA) is a real time image guidance system that is mounted on a C-arm fluoroscope (Figure 1). Once calibrated, it employs targeting cross hairs on the fluoroscopic image and can be easily positioned to target the desired renal calyx for PCNL puncture (Figure 2). A visible laser beam that shines onto the patient is precisely aligned with the cross hairs on the fluoroscopic image, providing the correct "bull's-eye" point of entry and angle of approach to the calyx. The puncture needle is fitted with a collimator which lights up when the needle is aligned with the beam, confirming that a perfect "bull's-eye" alignment has been achieved (Figure 3). The locator is a mechanical apparatus which stabilises the needle during puncture. The device consists of two articulated arms with two spherical joints that provide full positioning (six degrees of freedom) capabilities (Figure 4). It is securely fixed to the operating table via a

Figure 1: The SabreSource™

Figure 3: The puncture needle collimator lighting up

standard anaesthetic screen (metal right angle). The working head consists of a radiolucent extension arm, which is maneuvered by hand control outside the fluoroscopy beam. This maintains the needle in the exact "bull's-eye" position and thus, only screening for depth is required. The locator has been shown to be quicker and decrease radiation time and exposure.[4] The locator, however, only helps to stabilise the needle once it is correctly placed.

Assessment of puncture efficiency

Seven urologic trainees with little previous PCNL experience were recruited for the testing. A model phantom kidney supplied by Boston Scientific was filled with contrast and concealed. A coin representing a kidney stone was placed in a random calyx and each trainee was then asked to puncture a desired calyx first using the freehand "bull's-eye" technique and then using SabreSource™ in combination with the locator. The standard "bull's-eye" technique requires the C-arm to be rotated 20–30° towards the surgeon so the beam is aligned at right angles to the kidney. The puncture needle is then positioned perpendicular to the desired calyx

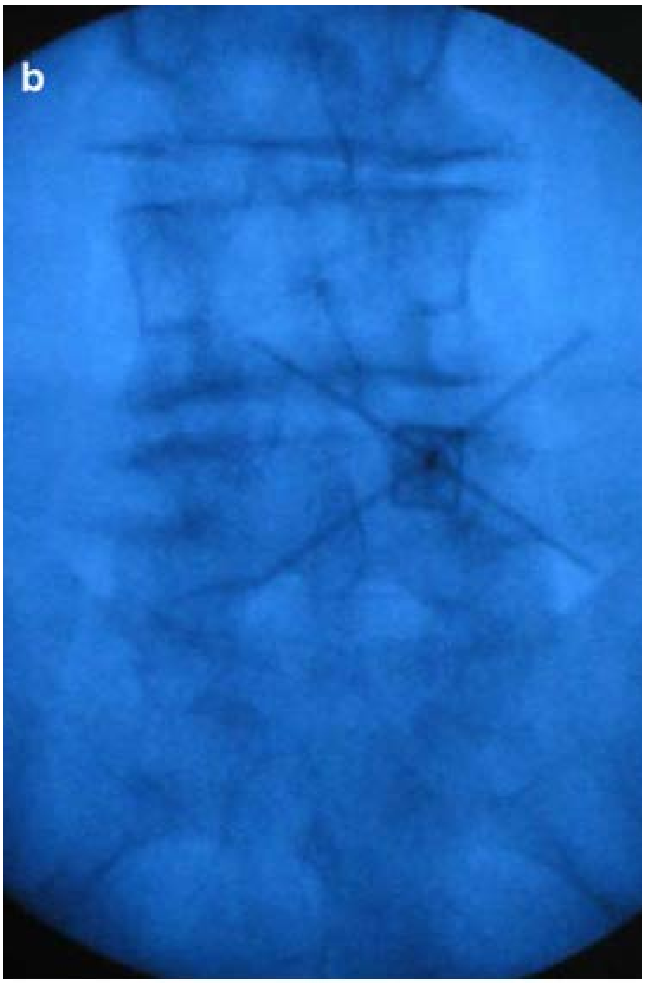

Figure 2: The SabreSource™ targeting crosshairs

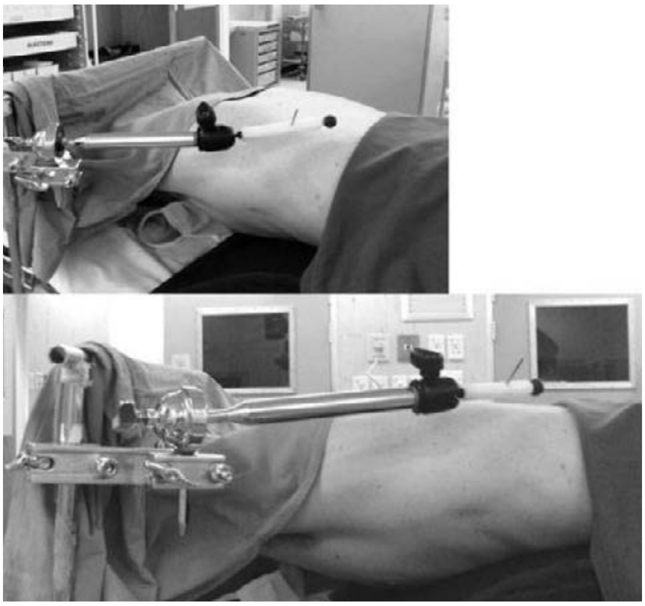

Figure 4: The locator

and advanced. The C-arm is then rotated 10–15° away from the surgeon to screen for depth whilst trying to maintain the same initial angle of puncture. Two end points were assessed; fluoroscopic screening time and total radiation dose required for successful puncture. Statistical analysis was performed using GraphPad Prism, version 5.03 (GraphPad Software, San Diego, California, USA).

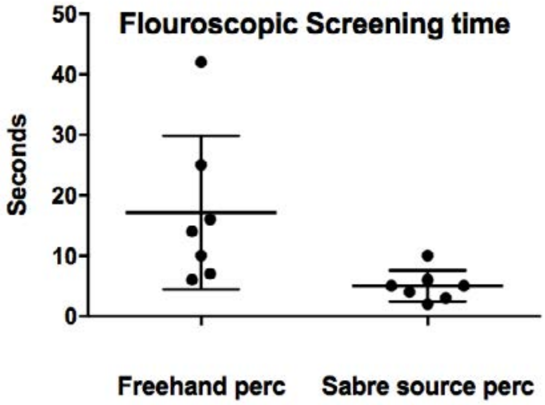

Table 1: Mean fluoroscopic screening time

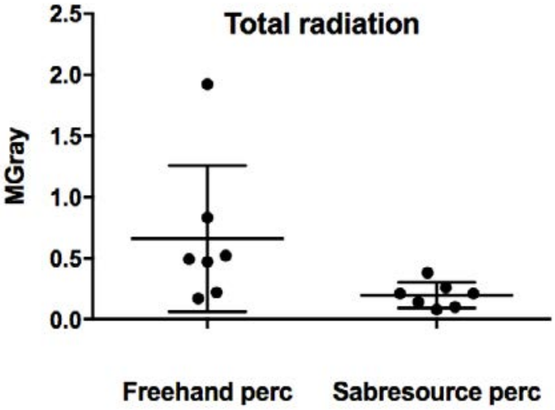

Table 2: Total radiation

Results

The mean fluoroscopic screening time was 17 seconds using the traditional freehand "bull's-eye" technique versus 5 seconds using the SabreSource™ and locator ($p = 0.01$) (Table 1). This equates to a 70.5% reduction in mean FST. The mean radiation exposure used for a successful puncture was 0.7 mGy using the traditional method versus 0.2 mGy using the SabreSource™ ($p = 0.03$) (Table 2).

Discussion

Our initial in vitro testing demonstrates reduction in radiation exposure and radiation dose when using the SabreSource™. These results are very similar to the only other laser guidance system tested in vitro for PCNL.[5] The direct alignment radiation reduction technique (DAART)[5] system similarly shines a laser beam from the C-arm fluoroscope but does not have moveable targeting cross hairs or a system of stabilising the needle once a "bull's-eye" is achieved. It was tested in a bench-top study and showed mean decrease in FST of 63% between the freehand and laser-guided techniques. The mean FST was 7.1 vs 18.5 in the attending group ($p = < 0.001$), 6.6 vs 13.9 in the resident physician ($p = 0.001$) and 6.7 vs 20.2 in the medical student group ($p = < 0.001$). This compares with the reduction in FST in our study of 5 vs 17 seconds ($p = 0.01$)

Our findings are also consistent with the only other in vivo published study where the SabreSource™ system has been shown to reduce radiation exposure and radiation dose in the denervation therapy of the lumbar facet joints.[6] Other laser-guided systems have been used in other settings showing improved accuracy and decreased time. Moser et al.[7] showed that laser guidance in the setting of CT-guided epidural and perineural injections decreased time and improved accuracy. Collins et al.[8] showed that laser guidance decreased ultrasound-guided puncture time of a phantom olive in a turkey breast.

Subjectively, the SabreSource™ improves ease of puncture. We believe the reduction in fluoroscopic screening time is a good surrogate marker for improved ease of puncture.

However, the limitations of the in vitro assessment of the device's efficacy need to be acknowledged. The number of trainees used was small. Concerns about unnecessary radiation exposure limited the number of puncture attempts the trainees were requested to perform. The phantom kidney model (Figure 4) does not accurately simulate the challenges of in vivo puncture, for example, there was no movement of the target due to respiration.

Despite these limitations, this device may have a role in decreasing radiation exposure for both the doctor and the patient. Radiation-induced cancer and genetic effects are stochastic (dose-related) in nature. Stochastic effects are believed to lack a threshold dose because injury to a few cells or even a single cell could theoretically result in production of the effect.[9] Yoshinaga et al.[10] demonstrated an increased risk of leukaemia, breast and skin cancer amongst radiologists and radiation technologists. Hence the importance of the principle of keeping radiation exposure as low as reasonably appropriate (ALARA principle).

A number of non-laser-guided methods of decreasing radiation exposure and improving ease of puncture have been described. Ultrasound, often in combination with fluoroscopy, is gaining in popularity, but traditional fluoroscopic-guided techniques remain the most commonly used.[1] Various simulators are available to aid PCNL apprenticeship. These range from phantom kidney models[11] to sophisticated virtual reality trainers such as the PERC Mentor.[12] These are useful adjuncts to clinical apprenticeship. Zarrabi et al. developed a computer-assisted gantry system which uses two C-arm derived images inputted into a computer to establish a computed angle of puncture using the triangulation technique.[13]

Computer-assisted navigation systems have, with the use of fiducial markers placed at CT and real time optical and electromagnetic tracking, been used to aid puncture.[14] Robotic puncture has also been shown to improve ease of puncture, however these products are expensive and not widely used in a clinical setting.[15] The advantage of the SabreSource ™ is that it is an intuitive and affordable device.

Conclusion

The SabreSource™ is a novel assistant to achieving successful PCNL puncture. Preliminary in vitro testing suggests that the device, used in combination with the locator, reduces fluoroscopy exposure and screening time. The device warrants further evaluation in the clinical setting.

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Conflict of interest

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