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Single-centre comparison of a novel single-step balloon inflation device and Amplatz sheath dilatation during percutaneous nephrolithotomy: A pilot study

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Objective. A new second-generation balloon dilatation device for percutaneous nephrolithotomy (PCNL) has been launched, promising to challenge the traditional Amplatz serial dilators (ASDs). This device allows for the polyurethane sheath to be deployed on balloon inflation. Our primary objective in this pilot study was to determine whether the use of this new device impacted on overall patient outcome when compared with the traditional ASD system.

Design. Retrospective chart review.

Setting. Department of Urology, Inkosi Albert Luthuli Central Hospital, Durban.

Subject. Single-centre comparison of a novel single-step balloon inflation device and Amplatz sheath dilatation during percutaneous nephrolithotomy – a pilot study.

Outcome measures. Single procedure success rates, retreatment rates, hospital stay, haemoglobin concentration, calculi volume, calculi configuration, patient demographics.

Results. The stone-free rates after a single procedure were 30% (3/10) in the Amplatz sheath dilatation arm (series 1) and 80% (8/10) in the single-step balloon inflation device arm (series 2). Correspondingly, 11 individual repeat procedures in 7 patients (4 relook PCNLs, 5 ureteroscopies and 2 extracorporeal shockwave lithotripsies) were required in series 1 to render the remaining 70% stone free. Mean hospital stay was 5.2 days (range 3 - 10 days) in series 1 and 3.8 days in series 2. The mean fall in haemoglobin concentration after treatment was 1.79 g/dl in the whole group, 2.1 g/dl in series 1, and 1.5 g/dl in series 2.

Conclusion. The single-step balloon dilatation device is found to have an improved patient outcome compared with ASDs.

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Percutaneous nephrolithotomy (PCNL) has been the gold standard in the management of complex renal calculi ≥2 cm in diameter.[1,2]

Controversy exists regarding the optimal dilatation method in PCNL. There are several dilatation methods available, including Amplatz polyurethane serial dilators (ASDs), metallic telescopic dilators as described by Alken, and balloon dilators. Amplatz-assisted serial dilators have currently been shown to be superior to balloon dilators in a large multicentre international study.[2]

A new second-generation PCNL balloon dilatation device (SBD) has been launched, promising to challenge the traditional ASDs.[5] This device allows for the polyurethane sheath to be deployed on balloon inflation (Figs 1 and 2).

Our primary objective in this pilot study was to determine whether use of this new device impacted on overall patient outcome when compared with the traditional ASD system. We focused on peri-operative and postoperative variables including overall treatment success rates.

Materials and methods

A retrospective patient chart review was undertaken involving all patients receiving PCNL as a treatment modality during the period July 2009 - October 2010. All procedures were done in a single centre, Inkosi Albert Luthuli Central Hospital, by a surgical team comprising two surgeons with similar experience. Patients were grouped chronologically as they were treated with 10 patients in

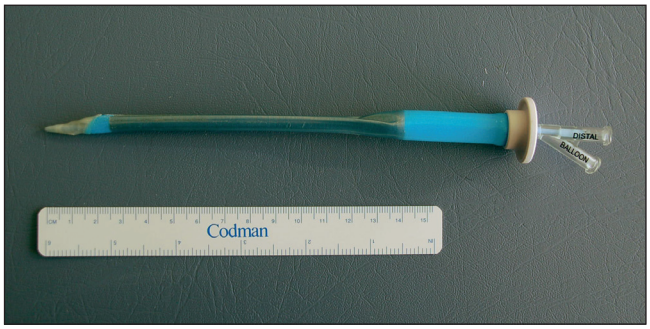

Fig. 1. Uninflated Pathway device.

Fig. 2. Inflated Pathway device.

Table 1. Combined results

Variables	Series 1	Series 2
Age (yrs) (mean (range))	55.9 (28 - 75)	48.8 (30 - 67)
Stone volume (mm^3) (mean (range))	456 (162 - 813)	440 (108 - 1 059)
Haemoglobin decrease (g/dl) (mean)	2.1	1.5
Single-procedure hospital stay (d) (mean)	5.2	3.8
Stone free (%)	33.3	80
Stone free after single procedure (*n*)	3	8
Repeat procedures (%)	70	20
Repeat procedures (*n*)		
PCNL	4	1
URS	5	1
ESWL	2	1
Stone position (*n*)		
Pelvis	4	5
Lower pole	2	1
Staghorn (*n*)	4	4
Complications (*n*)	1	0

each group, initially into the ASD group (series 1) and then into the more recent SBD group (series 2).

Parameters evaluated included patient demographic details, stone factors (position, volume), and operative and recovery variables. Single-procedure stone-free rate, fall in haemoglobin concentration, transfusion rate, hospital stay and complications were compared between the groups.

Pre-operative position and length and width of calculi were determined by a non-contrast computed tomography (CT) scan. Surface area of the calculus was calculated using the equation length × width × 0.25.[1] Subsequently the volume of the calculus was calculated by multiplying the surface area by the quotient of 0.6 and pi.[1]

Hospital stay was calculated by including the day of admission (which corresponded to the day prior to surgery) and the day of discharge. On admission, urine sterility was confirmed and prophylactic antibiotics commenced.

All patients were operated on using a standard technique, commencing with general anaesthesia, lithotomy positioning and rigid cystoscopy-assisted non-balloon 8F ureteric catheter placement to the level of the ipsilateral pelvi-ureteric junction. Subsequently, the patient was placed in a prone position and fluoroscopy-assisted puncture undertaken. The desired calyx was determined by the position of the calculus and anatomical factors, with the subcostal lower pole posterior calyx preferred.

A hydrophilic guidewire (0.98 mm) was inserted into the system with optimal placement down the ureter. A second guidewire was then passed with the aid of a 10F dilator (Boston Scientific).

In series 1, sequential ASDs (Boston Scientific) were used over the working guidewire and 8F introduction catheter, dilating the tract to the desired 30F. This required synchronised sequential insertion of dilators guided by tactile sensation of depth and multiple fluoroscopic exposures. The final 30F working sheath was then inserted over the final dilator in preparation for the nephroscope.

The SBD (Pathway, Endovision) was used in series 2. Following a second guidewire insertion, the uninflated device was passed into the system (6F proximal tip, 20F shaft),[3] guided by a distal radio-opaque marker. The balloon was inflated to 20 atmospheres for 60 seconds, expanding the polytetrafluoroethylene (PTFE) working sheath. On balloon deflation and retraction, the PTFE sheath (inner diameter 30F, outer diameter 33F) was separated from the balloon and in position for the nephroscope.

A rigid and occasionally flexible nephroscope (Karl Storz) was utilised with an ultrasonic lithotriptor (Calcusone) or holmium laser. Following fluoroscopic and direct visual evidence of calculi clearance, an antegrade ureteric JJ stent and a 24F Malecot nephrostomy catheter were inserted.

On postoperative day 1 the patient's haemoglobin concentration was measured and an abdominal radiograph done. The nephrostomy was removed and the patient discharged only when haematuria cleared and the abdominal radiograph did not show residual fragments. If a stone burden of ≥5 mm was identified on the immediate postoperative radiograph, a relook PCNL through the existing tract was undertaken on day 3.

Stone-free status was determined on repeat non-contrast CT evaluation several months after the procedure.

Fragments of ≤4 mm were considered insignificant and not treated, unless patient and anatomical factors precluded a conservative approach.

Results

The mean patient age was 52.3 years in the whole group of patients, 55.9 years in series 1 and 48.8 years in series 2 (Table 1). In series 1 and 2, 40% of patients had staghorn calculi, and all patients had posterior calyx subcostal access. The stone volume was similar in the two groups, with a mean of 448 mm^3.

The mean fall in haemoglobin concentration after treatment was 1.79 g/dl in the whole group, 2.1 g/dl in series 1 and 1.5 g/dl

in series 2. Two symptomatic patients in series 1 required blood transfusion following a 3.1 g/dl and 2.5 g/dl haemoglobin decrease.

One patient in series 1 had persistent tract haemorrhage following removal of the nephrostomy tube. Haemostasis was achieved with insertion of a 24F Foley catheter into the tract and tamponade balloon inflation. Angiography was normal and subsequent recovery unremarkable.

The stone-free rate after a single procedure was 30% (3/10) in series 1 and 80% (8/10) in series 2. Correspondingly, 11 individual repeat procedures in 7 patients (4 relook PCNLs, 5 ureteroscopies (URSs), 2 extracorporeal shockwave lithotripsies (ESWLs)) were required in series 1 to render the remaining 70% stone free.

Mean hospital stay was 5.2 days (range 3 - 10 days) in series 1 and 3.8 days in series 2.

Discussion

PCNL, like other minimally invasive procedures, is in a constant state of evolution. Since Goodwin and associates described the first nephrostomy placement in 1955, and Stables *et al.* popularised its use in the 1970s, the technique and equipment have changed considerably, improving patient outcome.[6-8]

Dilatation methods have been a key area in this evolution. Balloon dilatation methods have been shown to decrease operative time, the rate of haemorrhage and fluoroscopic exposure time.[10]

This has, however, been challenged.

The Clinical Research Office of the Endourology Society (CROES) has recently released the results of a global PCNL study involving 5 803 patients in 96 centres around the world.[2] The observational analysis found that ASD was associated with lower rates of haemorrhage (6.7% v. 9.4%) and a lower transfusion rate (4.9% v. 7%) when compared with balloon dilatation devices.[2] Furthermore, the procedure failure rate was higher in the balloon dilatation group (2% v. 1.5%).[2] A limitation of the study was that inter-centre indications for PCNL varied, with a larger number of staghorn calculi being treated in the balloon dilatation group. A second limitation was that only the first-generation 'two-step' balloon dilatation devices were analysed.

Recently several 'one-shot' SBD devices have been shown to decrease fluoroscopic exposure time and overall patient morbidity when compared with serial dilators.[9,10]

The aim of our pilot study was to document our experiences comparing a single-step balloon dilator (Pathway) with ASD. The study is considered an important role in evaluating our services and adding to the limited global body of evidence on single-step balloon dilatation devices.

Our findings were encouraging. Hospital stay, haemorrhage and transfusion rates were lower in the balloon dilatation group, with retreatment rates and complications higher in the ASD group. It has been proven that ASD is associated with haemorrhage, perforation of the collecting system and increased morbidity.[11,12] This trauma then results in impairment in intra-operative vision and a more substantial procedural failure rate. The simplicity of a single 'built-in' sheath allows for a reduction in the required shearing force to enter the collecting system.[3] Reduced haemorrhage translates to a greater single-procedure stone-free rate and reduction in hospital stay.[11] The Pathway single-step device is also cheaper (R2 300) than the least expensive Amplatz dilatation set on the market (R4 247 – Public, Boston Scientific).

The disadvantage is that owing to the balloon dynamics, the device is a single-use item. Although in our study all four staghorn calculi were successfully managed with a single puncture in the SBD group, multiple punctures that may be required in complex calculi may be better achieved with the ASDs.

Our study is in keeping with the body of evidence that balloon dilators are superior to ASDs[6,7,9,13,14] and by having similar indications and similar stone volumes, has reduced the bias of the CROES study. By using only two surgeons of similar experience and managing patients in a consecutive manner with series 1 treated first, inter-group bias was also reduced. This pilot study is also the first to directly compare the Pathway device with ASDs.

Limitations of the study are that it is a retrospective chart review of a small number of patients treated in a single centre. Moreover, the comparison groups were non-randomised and consecutively treated, so that the effect of increasing surgeon experience in series 2 cannot be excluded.

These issues will be addressed by a prospective multicentre study with a substantially larger study population. Further parameters to be addressed include dilatation time, operative time and patient pain scores, which owing to retrospective logistic limitations could not be included in this study. A 'three-way' comparison between ASDs, 'two-step' balloon dilatation and the new 'one-step' balloon dilatation systems is also necessary to settle the argument.

Conclusion

In this single-centre pilot study, hospital stay, haemorrhage and transfusion rates were lower in the SBD group with retreatment rates and complications higher in the ASD group. The single-step balloon dilatation device is found to have an improved patient outcome compared with ASDs.

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