One-step percutaneous nephrolithotomy sheath versus standard two-step technique
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The present study compared two procedures for large renal calculi removal, standard percutaneous nephrolithotomy (PCNL) versus PCNL using a pathway access sheath (PAS). In the standard PCNL, percutaneous access is achieved by a two-step process using a combination of either Amplatz dilators or placement of a high-pressure balloon catheter (HPBC) for tract dilation, followed by advancement of a sheath over the balloon. The novel PAS device allows for balloon tract dilation and percutaneous access sheath placement in one simple step.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with staghorn renal calculi.

Setting
The setting was tertiary care. The economic study was carried out in Los Angeles, California, USA (Kaiser Permanente Institution).

Dates to which data relate
The effectiveness evidence referred to May 2004 to October 2004. Resource use dates were not reported. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing method was not reported but only device costs were considered. It appears that the costing has been undertaken prospectively.

Study sample
Out of 21 patients with renal calculi, 10 patients underwent the standard two-step access using the HPBC or Amplatz dilators and 11 underwent PCNL using the novel PAS. The statistical rationale in selecting 20 patients to be involved in this study supported a 95% confidence interval and 90% power to detect a 1.5 minute difference between the groups. The mean age of the patients was 55 years in the PAS group and 36.5 years in the standard PCNL-HPBC group. There
were 6 women and 5 men in the PAS group and 7 women and 3 men in the PCNL-HPBC group.

**Study design**
This was a randomised prospective study that was conducted in a single centre. The authors did not report the methods of sample selection and randomisation. No blinded assessment of the outcomes or independent validation of the information recorded was reported. The duration of follow-up was not reported.

**Analysis of effectiveness**
The outcomes evaluated in the analysis were insertion time and blood loss. The insertion time was measured from the time that a guide-wire was placed into the collecting system to when the collecting system was visualised. Blood loss was measured by comparing the pre- and postoperative haemoglobin values. With the exception of age, the groups were comparable at baseline. No adjustments for confounding factors were reported. A statistical analysis was done using matched and independent t-tests.

**Effectiveness results**
The mean insertion time was 3 minutes (range: 2 to 4.75) in the PAS group and 5.75 minutes (range: 3 to 8) in the HPBC group. The difference in the mean and median insertion times was statistically significant, (p<0.01).

No patient required blood transfusions or other blood products. The mean decrease in haemoglobin was 1.49 g/dL in the PAS group and 2.02 g/dL in the HPBC group. This difference was not statistically significant, (p=0.21).

At the termination of one procedure in the PAS group, the patient developed brisk bleeding. The PAS device was easily reinserted and reinflated to successfully tamponade the bleeding nephrostomy tract.

**Clinical conclusions**
The shorter insertion time in the PAS group was statistically significant compared with that for the HPBC group. Blood loss was comparable in the PAS and HPBC groups. However, a trend demonstrated a chronologic decrease in blood loss that was approaching statistical significance.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was used in the economic evaluation. The costs and effects were left disaggregated and the study was therefore classified as a cost-consequences analysis.

**Direct costs**
The only direct medical costs included in the study were those for the new device, the Amplatz dilators, and the HPBC for standard PCNL. The costs were based on the Kaiser Permanente Cost Analysis system for the Amplatz dilators and HPBC, and compared with the manufacturer-s suggested price for the PAS. Discounting was not carried out, which was appropriate given the short-term horizon of the study. The quantities and the costs were not analysed separately. The cost estimation was based on actual data. The price year was not reported. Adjustments to correct for learning effects for the new technology were not made.

**Statistical analysis of costs**
The costs were treated deterministically (i.e. only point estimates were reported).

**Indirect Costs**
No indirect costs were reported.
Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
See the Effectiveness Results- section.

Cost results
No total costs of the interventions were reported.

The proposed cost of the PAS device was $280.

For standard PCNL, the Amplatz dilator costs were $230 and the HPBC costs were $260.

The authors stated that the difference in costs was not statistically significant, although only point estimates were reported.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The novel single-step renal access device is safe and efficacious and results in a shorter insertion time for percutaneous nephrolithotomy (PCNL). Blood loss was also less in the pathway access sheath (PAS) group, although the difference was not statistically significant. No conclusions pertaining to the cost results were discussed.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparators used. They reflected standard practice in the authors’ setting and a newer device. You should judge whether these procedures are relevant in your setting, or whether other comparators from other techniques and surgical procedures could have been relevant as well.

Validity of estimate of measure of effectiveness
The analysis was based on a prospective randomised study design that could be helpful to evaluate the effectiveness of the interventions, although details of its methodological design were only briefly reported. Also, there might be concerns about sample size and power calculations, which aimed to detect differences in duration and not a clinically significant patient outcome. Statistical analyses to account for potential biases and confounding factors, such as baseline differences, were not undertaken. These factors may introduce potential bias.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The reader is thus referred to the comments in the Validity of estimate of measure of effectiveness- field (above).

Validity of estimate of costs
The perspective of the study was not reported, but it appears to have been that of the hospital. There was too little detail on the cost estimation and only the device costs were considered. Although it was not stated, some relevant costs could
have been omitted from the analysis. The cost categories were not reported in detail and their omission might have affected the authors' conclusions. The costs and the quantities were not reported separately, which would not enable the analysis to be easily extrapolated to other settings. A statistical analysis of the costs was not reported. In addition, no sensitivity analyses were performed on the cost data to assess the robustness of the estimates used. All these factors could affect the robustness of the cost results. Discounting was not necessary as the study had a very short-term time horizon. The price year was not reported, which will make any future reflation exercises difficult.

Other issues
The authors compared their findings with those from similar studies. The issue of generalisability to other settings was not addressed. The conclusions reflected the scope of the analysis. The authors recognised the importance of having well-matched populations and also acknowledged some limitations of the study (e.g. small sample size). The number of patients in each arm was enough to achieve statistical significance for insertion time, but not for blood loss. A trend demonstrated a chronologic decrease in the blood loss that was approaching statistical significance. Whether this could be attributed to decreasing insertion times or patient variability was unclear. Finally, another limitation of the study was the measurement of blood loss, which is a controversial topic in endoscopic surgery. The authors believed that comparing preoperative versus postoperative haemoglobin was an objective method of estimating blood loss.

Implications of the study
Since its introduction, percutaneous renal surgery has continued to play an important role in the management of complex urinary tract calculi. The availability of novel devices and new technology warrants investigation to make percutaneous renal surgery safer and more efficacious. Additional studies would demonstrate whether the PAS might represent a new standard of obtaining renal access. Finally, reservations in the use of PAS in obese patients were addressed by the creation of a longer device.

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