Peripherally inserted central catheters: a randomized, controlled, prospective trial in pediatric surgical patients

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 use of peripherally inserted central catheters (PICCs) in paediatric patients.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included paediatric patients ranging from neonates to those aged 14 years. Patients were included if they were scheduled for an anticipated postoperative stay of at least 4 days. Patients were excluded if their parents or guardians could not speak English, could not provide consent, or could not complete the satisfaction survey. They were also excluded if they required central venous access during their hospital stay, or they were enrolled in a conflicting investigational trial. Patients could withdraw at any time. The target population appears to have been that of the study population.

Setting
The setting was secondary care. The economic study was carried out in the USA.

Dates to which data relate
The dates of the effectiveness analysis were not provided, nor were the dates relating to the resources and prices.

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

Link between effectiveness and cost data
It would appear that the costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
The sample size was determined in the planning stages of the study. All paediatric patients, neonates to 14-year-olds, who were scheduled for an anticipated postoperative stay of at least 4 to 7 days, were included in the study. The authors did not justify the choice of the patient sample in terms of the characteristics of the treatment under investigation. No patients refused to participate in the study. Of the 96 patients initially included in the study, 4 were excluded on account
of being discharged, while 8 PICC patients had failed PICC placement and were analysed in their treatment group. A further 6 patients did not return their satisfaction survey and were therefore not included in the analysis of satisfaction, although they were included in the analysis of complications.

Study design
This was a randomised controlled trial that was carried out in a single centre. The patients were randomised using opaque envelopes. Randomisation occurred before the induction of anaesthesia for the proposed procedure. The use of blinding was not reported. The duration of follow-up was not reported.

Analysis of effectiveness
The primary health outcomes were:

the number of needle punctures;
postoperative intravenous (IV) restarts;
the number of venipunctures;
the number of major complications; and
the insertion time.

The instruments used to evaluate the outcomes were not reported. It would appear that the basis of the analysis was treatment completers only. The groups were comparable at analysis.

Effectiveness results
There was a significantly different number of needle punctures between the two groups. There were 0.27 (standard deviation, SD=1.07) postoperative IV restarts in the PICC group and 1.5 (SD=2.68) in the PIV group. There were 0.3 (SD=1.0) venipunctures in the PICC group and 1.4 (SD=1.9) PIV group.

A smaller proportion of PICC patients had delayed fluid or medication administration in comparison with PIV patients (2.6% versus 28.9%).

A smaller proportion of PICC patients had red or indurated sites in comparison with PIV patients (2.6% versus 33.3%).

Positive blood cultures were found in 2.6% of PICC patients compared with 2.2% of PIV patients.

In 56.4% of PICC patients, old blood was present at the insertion site.

In 7.7% of PICC patients, staff were unable to draw blood from the catheter.

The median insertion time was 19 minutes (interquartile range, IQR: 15 - 25) for the PICC patients and 5 minutes (IQR: 3 - 12) for the PIV patients.

Clinical conclusions
The clinical conclusions were that PICC is more effective and safe than PIV in infants and children with anticipated postoperative hospitals stays of 4 to 7 days.

Measure of benefits used in the economic analysis
The measure of benefit used was satisfaction with IV care, as measured by a questionnaire with eight questions.
Direct costs
Provider costs were included in the analysis. The costs included were labour costs (anaesthesiologists and phlebotomists), equipment costs (PICC trays and IV catheters) and operating room costs. The resource quantities and the costs were not reported separately. Discounting was not relevant and was not carried out. The dates to which the price data referred were not reported.

Statistical analysis of costs
The data were deterministic. No statistical analysis was conducted.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
A sensitivity analysis was carried out to determine whether the results would change when the failed PICC patients were removed from the analysis.

Estimated benefits used in the economic analysis
The results of the satisfaction scores are as follows:

- 75% of PICC parents and 24% of PIV parents reported "my child's IV experience had been better this time" (mean difference 0.51, 95% confidence interval, CI: 0.20 - 0.72);
- 0% of PICC patients and 18% of PIV patients reported "too many needle sticks during hospitalisation" (mean difference 0.18, 95% CI: 0.07 - 0.29);
- 84% of PICC parents and 50% of PIV parents reported that they were "satisfied with the way my child had received IV fluid and medications" (mean difference 0.36, 95% CI: 0.18 - 0.54);
- 72% of PICC patients and 28% of PIV patients reported that "IV has been trouble free" (mean difference 0.44, 95% CI: 0.25 - 0.63);
- 14% of PICC patients and 26% of PIV patients reported that "IV had caused discomfort" (mean difference 0.12, 95% CI: -0.04 - 0.29);
- 86% of PICC parents and 54% of PIV parents reported that "everything possible had been done to ensure my child's comfort" (mean difference 0.21, 95% CI: 0.04 - 0.39);
- 66% of PICC parents and 41% of PIV parents reported that they were "satisfied with the way my child has had blood drawn" (mean difference 0.25, 95% CI: 0.03 - 0.46);
- 81% of PICC patients and 44% of PIV patients reported "no problems from the IV or blood draws" (mean difference 0.37, 95% CI: 0.18 - 0.55).

Cost results
The cost for the PICC group was higher than the cost for the PIV group.

The total estimated cost for the PICC group was $178 when insertion took place after the start of the operation and...
$440.70 when insertion took place before the start of the operation. The total estimated cost for the PIV group was $108.49.

**Synthesis of costs and benefits**
The authors reported the cost-effectiveness results as the total costs divided by the satisfaction scores for the two groups.

When inserting the study catheter after the start of surgery, the cost-effectiveness (total cost/satisfaction) was 28.69 (SD=13.55) for the PICC group and 27.08 (SD=15.94) for the PIV group (mean difference -1.612, 95% CI: -8.766 - 5.541).

When inserting the study catheter before the start of surgery, the cost-effectiveness (total cost/satisfaction) was 86.09 (SD=88.61) for the PICC group and 33.33 (SD=41.65) for the PIV group (mean difference -52.77, 95% CI: -86.65 - -18.88).

**Authors’ conclusions**
Peripherally inserted central catheters (PICCs) are safe and effective for infants and children with anticipated postoperative hospital stays of 4 to 7 days.

**CRD COMMENTARY - Selection of comparators**
Although no explicit justification was given for the comparator used, it would appear to represent current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. The patient groups were shown to be comparable at analysis.

**Validity of estimate of measure of benefit**
Whilst satisfaction was used to measure health benefit, to allow a meaningful comparison with other disease areas some measure of quality of life should be used. The authors recognised that the satisfaction survey they used was not a validated tool.

**Validity of estimate of costs**
It appears that all the categories of cost relevant to the perspective adopted have been included in the analysis. The costs and the quantities were not reported separately. No statistical analysis of the quantities or prices was performed.

**Other issues**
The authors made appropriate comparisons of their findings with those from other studies. They also addressed the issue of the generalisability of the results to other settings. The authors appear to have presented their results selectively. The study enrolled paediatric patients who were scheduled for anticipated postoperative hospital stay of at least 4 to 7 days and this was reflected in the authors' conclusions.

**Implications of the study**
The authors did not state any implications.

**Source of funding**