Proactive monitoring of pediatric haemodialysis vascular access: effects of ultrasound dilution on thrombosis rates

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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 use of ultrasound dilution (UD), a simple, non-invasive bedside test for monitoring vascular access flow (QA), for children receiving haemodialysis.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children with permanent vascular access for haemodialysis, in the form of arteriovenous fistula or graft, who received chronic haemodialysis.

Setting
The setting was a hospital. The economic study was carried out at the Texas Children's Hospital Renal Dialysis Unit, Houston (TX), USA.

Dates to which data relate
The effectiveness evidence and resource use data were gathered from April 1999 to April 2001. The price year was 2001.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively from April 1999 to April 2001 on the same patient sample as that used in the effectiveness analysis. The costing appears to have been carried out retrospectively for a different group of patients selected as the comparison group.

Study sample
Power calculations to determine the sample size were not performed. All eligible children who received chronic haemodialysis for at least two months at the study hospital during the study period (April 1999 to April 2001) were included in the analysis. These were divided into two study groups, pre-UD era (from April 1999 to March 2000) and UD era (from April 2000 to April 2001). The overall group of children developing VAT in the two-year period was
then compared with a size-matched patient group who did not develop VAT. The former group comprised 9 patients experiencing 18 VAT episodes, with a mean weight of 47.8 (+/- 14.6). The latter group comprised 7 patients with a mean weight of 45.5 (+/- 10) kg). The number of children in the pre-UD and UD eras was not reported.

**Study design**
This was a case-control study that was carried out in a single centre. The comparison was performed between children who developed VAT and those who did not. A further longitudinal comparison was carried out between the pre-UD era and the UD era. The same nurse performed all UD measurements during the first 60 minutes of the dialysis session. The length of follow-up was not reported.

**Analysis of effectiveness**
All patients included in the study were taken into account in the analysis (in effect, intention to treat). The primary health outcomes were the values of QAcorr, double-pool Kt/V (measured using the logarithmic extrapolation method of Goldstein and Brewer), and the number of surgical procedures. The comparability of the study groups at baseline was not reported, other than the weight of the children was similar.

**Effectiveness results**
The mean QAcorr (mL/minute per 1.73 m2) was 562 (+/- 290) in the VAT group and 1,005 (+/- 372) in the no VAT group, (p=0.02), meaning that it was significantly lower for patients with subsequent VAT.

The VAT rate was significantly lower in the UD era than in the pre-UD era. There were 4.1 VAT/patient-months in the UD era versus 11 VAT/patient-months in the pre-RD era, (p=0.03).

The VAT rate in the rapid referral period (from November 2000: 0.96 per 100 patient-months) was significantly lower than the rates observed in both the pre-UD era, (p=0.001), and the pre-rapid referral period of the UD era, (p=0.02).

No difference was noted in the mean double-pool Kt/V between the pre-UD era (1.20 +/- 0.16) and the UD-era (1.22 +/- 0.16), (non significant). There was also no difference in the mean double-pool Kt/V between patients with VAT (1.22 +/- 0.18) and those without VAT (1.22 +/- 0.14), (non significant).

The mean percentage change double-pool Kt/V from the two months prior to VAT (measured to assess whether there was a decrease in double-pool Kt/V prior to VAT) was -2.3% +/- 9.8% (range: -27.6 - 22.9).

In terms of the number of surgical procedures, 13 patients received 28 surveillance venograms in the pre-UD era, during which 13 angioplasty procedures were performed. Seven patients received 8 angioplasty procedures in the UD era.

Angioplasty resulted in significant improvements in QAcorr in the UD era, from 393 (+/- 155) to 850 (+/- 215) mL/minute per 1.73 m2, (p<0.001).

No patient in the UD era developed a VAT in the month after angioplasty.

**Clinical conclusions**
The effectiveness analysis demonstrated that UD monitoring was associated with significant decreases in VAT episodes, mainly due to the combination of UD with rapid referral for angioplasty.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore carried out.
Direct costs
Discounting was not carried out as the costs were incurred over two years. The unit costs and the quantities of resources used were not given. The cost items included in the analysis were thrombectomy/access revision costs (operating room and hospital stay) and balloon angioplasty costs (radiologist and radiology suite). A one-time charge for the purchase of UD equipment was not included in the analysis. No disposable costs were associated with UD. The cost/resource boundary adopted in the analysis appears to have been that of the hospital. The source of the cost data was not reported, but was presumably the finance department of the study hospital. The resource use data were derived from the study and were measured from April 1999 to April 2001. All of the costs were adjusted for inflation and were reported in 2001 prices.

Statistical analysis of costs
Statistical analyses of the costs were not carried out.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
Overall, the total costs were $137,674 in the pre-UD era and $112,493 in the UD era. This resulted in a cost per patient-month of $1,264 in the pre-UD era and $765 in the UD era.

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
The results of the study indicated that monthly vascular access monitoring by ultrasound dilution (UD) should be recommended, with prompt referral for angioplasty when the corrected vascular access flow (QAcorr) is less than 650 mL/minute per 1.73 m2. This practice led to decreased morbidity and paediatric dialysis costs.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. The use of monthly UD monitoring (UD era) was compared with the standard practice of no monthly monitoring (pre-UD era). In a further comparison, children developing VAT were compared with children who did not develop VAT. The comparator of surveillance venography is invasive, more expensive, and requires repeated exposure to contrast agents. You should assess which kind of UD monitoring system is implemented in your own setting.

Validity of estimate of measure of effectiveness
The data used in the effectiveness analysis were derived from a small sample of patients and power calculations were not performed. In addition, bias and confounding cannot be ruled out due to the lack of randomisation. The comparability of the study groups was reported only in terms of the patients’ weight, and patient demographics were not given. These issues tend to limit the internal validity of the analysis. Few statistical analyses were carried out to assess the impact of potential associations across the health outcomes.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis, and thus a cost-consequences analysis was carried out. It would have been interesting had the authors estimated the quality of life in the two eras assessed in the analysis, although correspondence with the authors indicates that there are no currently-available pediatric ESRD quality of life instruments. The decreased hospitalisations associated with decreased thrombosis surgeries implies improved quality of life.

**Validity of estimate of costs**
It appears that all the categories of costs relevant to the perspective adopted in the study were included in the analysis. The cost of purchasing the UD monitor was not included in the analysis, but it was far below the total cost-savings realised in the UD era. The price year was reported. The unit costs and the quantities of resources were not reported. The costs were treated deterministically as statistical analyses were not carried out.

**Other issues**
The authors did not compare their findings with those of other studies, as they stated that their study was the first of its kind in the paediatric setting. The external validity of the study was quite low, as sensitivity analyses were not carried out and both the cost and effectiveness data were fairly specific to the study setting. A sample of children with permanent vascular access for haemodialysis was enrolled in the study, and this was reflected in the conclusions of the analysis. The study results were reported in detail.

**Implications of the study**
The implications for clinical practice are that monthly non-invasive UD is superior to a much more invasive and costly method with respect to associated thrombosis rates. The authors state that further long-term studies should be performed to "determine if such a proactive vascular access management program will result in prolonged AVG (arteriovenous graft) and AVG (arteriovenous fistula) survival in children receiving haemodialysis". There appears to be a need to develop a suitable quality of life instrument for this patient domain.

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