A prospective randomized trial demonstrating valved implantable ports have fewer complications and lower overall cost than nonvalved implantable ports

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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 a valved subcutaneous port system for long-term venous access in the treatment of patients who require chemotherapy, prolonged antibiotic therapy, parenteral nutrition and frequent blood draws was assessed.

Type of intervention
Other: Management care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were 18 years or older and who required long-term venous access for chemotherapy, blood draws, or total parenteral nutrition. Patients were excluded if they had had a central venous access port within the preceding 6 months, or if they were fully anticoagulated for any reason.

Setting
The setting was secondary care. The economic study was carried out in Dallas (TX), USA.

Dates to which data relate
The dates when the effectiveness and resource use data were collected 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 same patients provided the effectiveness data and the cost data. It would appear that the costing was carried out prospectively.

Study sample
Power calculations were not reported. A total of 73 burn patients were included in the analysis. These patients were randomly assigned to two groups. Thirty-seven patients (89.2% female) were implanted with a valved port (PAVS group) and the remaining 36 (80.6% female) with a nonvalved port (control group). The patients had a mean age of 54 years (range: 23 - 83) in the PAVS group and 54.6 years (range: 25 - 76) in the control group.
Study design
The study was a prospective, randomised clinical trial that was conducted in a single institution. The method for randomisation was not reported. The follow-up period to assess the clinical outcomes was 180 days, or until port removal, for both groups.

Analysis of effectiveness
The basis of the analysis was intention to treat. The primary health outcomes assessed were:

- the difficulty with blood return,
- the excess time spent assessing the port,
- the major complication rate, and
- required interventions (e.g. chest radiography, duplex ultrasonography, or contrast studies).

The inability to withdraw blood was defined as not being able to withdraw at least 5 mL of blood on initial access. The use of thrombolytics to re-establish catheter patency was also recorded. Interviews with the patients and nursing records were used to evaluate adequacy of port function. There were no statistically significant differences in the general characteristics of the two groups at baseline.

Effectiveness results
There were no significant differences in major complications between the two groups.

One patient in each group was hospitalised for catheter-related sepsis and their ports were removed.

Valved ports were associated with significantly fewer difficulties in drawing blood than nonvalved ports (5.8% versus 11%; p=0.02).

Valved ports had fewer reported access difficulties that required additional access time (≥ 30 minutes nurse infusion time) than nonvalved ports (3.0% versus 6.1%; p=0.05).

The additional time spent assessing and treating inadequate blood draw in the nonvalved port group was twice that found in the valved port group (750 versus 1,545 minutes; p<0.03).

There was also a trend toward less use of tissue plasminogen activator (t-PA) in the valved port group, although this did not reach statistical significance.

Clinical conclusions
The PASV valved port was associated with significantly fewer instances of poor blood return and less nursing access time in comparison with the nonvalved port.

Measure of benefits used in the economic analysis
No summary measure of benefit was used. The study was, in effect, a cost-consequences analysis.

Direct costs
The authors did not report the perspective from which the costing was carried out. They reported that fixed costs and additional costs, including chest X-ray, thrombolytic therapy and t-PA infusion, were included in the analysis. The fixed costs comprised the costs of ports, initial access infusion, post-access infusion, nursing access time and infusion room time. Implantation costs, costs of catheter infection, and venous thrombosis were not included in the analysis as they were the same in both groups. The unit costs and the quantities were analysed separately. Discounting was not carried
out as the costs were incurred during less than 2 years. The resource use data were obtained from the patients and nursing records. The source of the unit costs was not given. The dates and price year were not reported. The total costs and average cost per patient were reported.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was reported.

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

**Cost results**
The total cost was $35,035 for the PASV group and $38,867 for the control group.

The average cost per patient was $947 for the PASV group and $1,080 for the control group. This resulted in a net saving of $133 per unit in the valved group when compared with the nonvalved group.

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
The valved subcutaneous port (PASV) system resulted in less infusion room and nurse-access time, and fewer instances where chest radiography, physician consultations and tissue plasminogen activator (t-PA) infusions were required. It also gave rise to net savings of $132 per unit in comparison with the nonvalved port.

**CRD COMMENTARY - Selection of comparators**
The authors explicitly justified the choice of the comparator, the nonvalved port. You should judge whether this comparator is relevant in your setting.

**Validity of estimate of measure of effectiveness**
The analysis was based on a prospective randomised clinical trial, which was appropriate given the study question. An appropriate statistical analysis was conducted to compare the groups at baseline, and the study sample appears to have been representative of the study population. However, the study presented several drawbacks, some of which the authors acknowledged. First, the method of randomisation was not reported. Second, the assessment was not blinded. Third, the lack of power calculations and the subsequent small sample size meant that it was unclear whether the study sample was sufficiently large to detect significant differences in the complication rates. These drawbacks limit the internal validity of the study.
**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefits. The analysis was therefore categorised as a cost-consequences study.

**Validity of estimate of costs**
Although the perspective adopted was unclear, it appears that cost categories relevant to the hospital perspective have been included. The authors reported that some costs were omitted from the analysis because they were not easily quantifiable. These costs were associated with additional office visits, delay in patient treatment and premixed solutions not being used. Therefore, the authors may have underestimated the true cost-savings. The costs were reported separately from the quantities, which will help the generalisability of the results to other settings. The resource use quantities were taken from a single study, while the unit costs were taken from the authors' setting. No statistical or sensitivity analyses of the quantities or prices were carried out, and this limits the interpretation of the results. No price year was reported, which will prevent any possible inflation exercises. Discounting was unnecessary, as all the costs were incurred during a short time, and hence was not performed.

**Other issues**
The authors compared their clinical results with those from other studies, finding different results in terms of complications. However, they did not compare their economic results with other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors were aware of the limitations of their study.

The reader should be aware of the potential conflicts of interest by the financial support of Boston Scientific, the manufacturer of the valved subcutaneous port system.

**Implications of the study**
The authors did not make any specific recommendations for changes in policy or practice and/or the need for further research. The authors emphasised that the PASV port has become the port of choice at their institution.

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