Summary of product trials for 10,164 patients: comparing an intravenous stabilizing device to tape
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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 study examined a peripheral intravenous (PIV) catheter-stabilisation device (StartLock).

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 18 months or older who required PIV catheter securement for more than 24 hours.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not reported. The price year was not given.

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

Link between effectiveness and cost data
The costing referred to a hypothetical patient and was not related to the actual consumption observed in the sample of patients included in the effectiveness analysis.

Study sample
Power calculations, if performed, were not reported. However, a very large sample size was used. Eligible patients were identified at the 83 participating hospitals over a 2-week period. During the first week, data were collected on patients who had received tape-secured PIV catheters, while during the second week, data were collected on patients whose PIV catheters were secured with the stabilisation device. It was not stated whether some patients refused to participate or were excluded for any reasons from the study sample. Overall, 10,164 patients requiring 15,004 PIV catheters were included in the study sample. There were 5,832 patients in the tape group and 4,332 in the stabilisation device group. The demographics of the patients were not reported.

Study design

This was a prospective cohort study that was carried out at 83 centres. The length of follow-up was 72 hours or until completion of therapy, whichever came first. Loss to follow-up was not reported. Hospital staff collected the data and submitted them to an external evaluation group for analysis. No blinding was performed.

Analysis of effectiveness

All patients included in the initial study sample appear to have been considered in the analysis of effectiveness. The primary outcome measure was the rate of PIV restarts. Other clinical end points were the rates of phlebitis and of total catheter-related complications. The baseline comparability of the study groups was not discussed.

Effectiveness results

There were 4,123 PIV restarts in the tape group and 717 in the stabilisation device group. Thus, the rate of PIV restarts was 70.7% in the tape group and 16.6% in the stabilisation device group, which corresponds to a reduction of approximately 76% with the stabilisation device. The median difference between the two average restart rates was 0.5542 (confidence interval, CI: 0.5154 to 0.5929; p=0.0001).

The rate of phlebitis was 3.6% in the tape group and 0.7% in the stabilisation device group, which corresponds to a reduction of approximately 80% with the stabilisation device. The relative risk of phlebitis with the tape was 5.0824 times greater than with the stabilisation device (CI: 0.6172 to 7.1411; p<0.001).

The rate of total complications was 47.6% in the tape group and 16.0% in the stabilisation device group, which corresponds to a 67% decrease with the stabilisation device. The relative risk of total complications with the tape was 4.7713 times greater than with the stabilisation device (CI: 4.3832 to 5.1939; p<0.001).

Clinical conclusions

The effectiveness analysis showed that the stabilisation device significantly reduced the need for PIV restarts and catheter-related complications (including phlebitis) in comparison with conventional tape.

Measure of benefits used in the economic analysis

The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

Direct costs

The perspective of the analysis was not explicitly stated, but only hospital costs were included in the study. The items considered were material costs (catheter, extension set with needleless cap, blunt cannula, saline flush, gauze, gloves, and alcohol preparation pad), complications costs (phlebitis and other catheter-related complications) and personnel costs (nurse time). The unit costs were presented separately from the quantities of resources used. The source of the costs was not explicitly reported. Resource consumption referred to a hypothetical patient and was not related to the actual consumption observed in the sample of patients included in the effectiveness analysis. The annual costs referred to a 300-bed hospital with 60,000 annual PIV catheter placements. Discounting was not relevant due to the short timeframe of the analysis. The price year was not reported.

Statistical analysis of costs

The costs were treated deterministically.

Indirect Costs

The indirect costs were not included.

Currency

US dollars ($).

Sensitivity analysis

No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis

See the 'Effectiveness Results' section.

Cost results

The total annual costs of starting a PIV catheter were $264,705.88 in the tape group and $360,000.00 in the stabilisation device group.

The annual costs of unscheduled restarts were $185,294.12 in the tape group and $72,000.00 in the stabilisation device group.

Therefore, the total annual material costs were $450,000.00 in the tape group and $432,000.00 in the stabilisation device group, a difference of $18,000 in favour of the stabilisation device.

Further cost-savings could be realised if the cost analysis took labour costs and complication rates into consideration. Thus, in a hypothetical 300-bed hospital with 60,000 annual PIV catheter placements, the total annual cost reduction with a stabilisation device compared with standard tape would be $277,085 ($18,000 for material costs, $22,320 for complication reduction and $236,765 for nurse time savings).

Synthesis of costs and benefits

A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

Authors' conclusions

The use of a catheter stabilisation device was an effective, safe, and cost-saving alternative to conventional tape in the USA.

CRD COMMENTARY - Selection of comparators

The choice of the comparator was appropriate as it reflected the conventional approach in the author's setting. You should decide whether tape is a valid comparator in your own setting.

Validity of estimate of measure of effectiveness

The effectiveness analysis was based on a prospective observational study. The use of a randomised trial would have been more appropriate since, as the author pointed out, the results of the analysis could have been affected by selection bias. Further, since the two groups were not evaluated concurrently, factors other than the study intervention could have influenced the nurses' behaviour. The fact that blinding was not performed and nurses were aware of the objective of the study could have affected how meticulously the catheters were changed during the intervention period. In addition, data collection did not include the presence of co-morbidities. Thus, it was unclear whether the two groups of patients were comparable at baseline. The evidence came from several centres so the study sample should have been representative of the patient population. No formal justification for the size of the sample was provided, and power calculations were not reported. However, a large sample of patients was included. Details of the follow-up were unclear. These issues tend to limit the internal validity of the analysis, as the author acknowledged.

Validity of estimate of measure of benefit

No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs

The author did not state explicitly which perspective was adopted in the study. The unit costs and a breakdown of the cost items were reported, which enhances the possibility of replicating the analysis in other setting. The source of the costs was not stated. The costs were treated deterministically and the cost estimates were specific to the study setting. The price year was not reported, which will hinder reflation exercises in other time periods. Overall, there was limited information on the cost analysis.

Other issues

The author reported the clinical results from other published studies, which were consistent with the findings from the current economic evaluation. However, no cost-effectiveness analyses were included in the comparison of study findings. The issue of the generalisability of the study results to other settings was not explicitly addressed and the estimates were specific to the study setting, especially on the cost side of the analysis. This could reduce the external validity of the analysis. The study referred to the general population of patients requiring PIV catheter placement and this was reflected in the author's conclusions.

Implications of the study

The study results support the use of a stabilisation device in patients requiring a PIV catheter. The author noted that a prospective, randomised clinical trial should be performed for a better evaluation of the cost-effectiveness of the stabilisation device.

Source of funding

None stated.

Bibliographic details

Schears G J. Summary of product trials for 10,164 patients: comparing an intravenous stabilizing device to tape. Journal of Infusion Nursing 2006; 29(4): 225-231

PubMedID

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Other publications of related interest

Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.

Sheppard K, LeDesma M, Morris N, O'Connor K. A prospective study of intravenous catheter securement techniques in a skilled nursing facility. J Intraven Nurs 1999;22:151-6.

Royer T. Improving short peripheral IV outcomes: a clinical trial of two securement methods. JAMA 2003;8:1-5.

Frey AM, Schears GJ. Why are we stuck on tape and suture? A review of catheter securement devices. J Infus Nurs 2006;29:34-8.

Indexing Status

Subject indexing assigned by NLM

MeSH

Accidents, Occupational /prevention & control; Adhesives /economics /standards; Bandages; Benchmarking /organization & administration; Catheterization, Central Venous /adverse effects /economics /instrumentation /nursing; Catheterization, Peripheral /adverse effects /economics /instrumentation /nursing; Catheters, Indwelling /adverse effects; Clinical Nursing Research; Cost Savings; Equipment Design; Equipment Failure; Humans; Materials Testing; Needlestick Injuries /etiology /prevention & control; Phlebitis /epidemiology /etiology; Prospective Studies; Safety Management; Time and Motion Studies; Workload

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