Clinical and economic evaluation of the Trellis-8 infusion catheter for deep vein thrombosis

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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.

CRD summary
The objective was to examine the clinical and economic impact of using the Trellis-8 infusion catheter (TIC) in comparison with catheter-directed thrombolysis (CDT) in the treatment of deep vein thrombosis (DVT). The TIC was associated with a better success rate, lower bleeding, and lower costs than traditional CDT. The study had some limitations, both in the clinical and economic analyses, which may have reduced the validity of the authors’ conclusions.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective of this preliminary report was to examine the clinical and economic impact of using the Trellis-8 infusion catheter (TIC) in comparison with catheter-directed thrombolysis (CDT) in the treatment of deep vein thrombosis (DVT).

Interventions
The two strategies were the TIC compared with traditional CDT to provide early and complete clot resolution in acute proximal DVT. The TIC consisted of proximal and distal occlusion balloons, a drug infusion port between the balloons, and a powered oscillation drive unit attached to a sinusoidal wire, which produced oscillations in the catheter.

Location/setting
USA/hospital.

Methods
Analytical approach:
This economic evaluation was based on the comparison between primary data on the TIC and published evidence on CDT. A short time horizon was considered, which was the procedure-related hospital stay. The authors did not explicitly state the perspective.

Effectiveness data:
The effectiveness data came from a retrospective study with a historical control. Specifically, clinical data on the efficacy and safety of TIC were collected through a voluntary, company-sponsored registry which included 147 patients (mean age: 51, standard deviation, SD: 18, 72 men) from 45 sites in the USA and three international sites. The efficacy and safety of CDT were based on a meta-analysis of 14 studies identified through a literature search of the Medline and Embase databases. These data were pooled by means of the random effects method. The primary clinical outcome was the success rate with either therapy, which was defined as the proportion of patients who achieved a combined (Society of Interventional Radiology) grade II and III clot breakdown.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
No summary benefit measure was used. The primary clinical endpoints were the success rate and rate of major haemorrhage.

Cost data:
The health service costs were those of the procedure time in the angiography and interventional suite, monitoring time in a critical care unit, device acquisition, thrombolytic dose, and treatment of bleeding. Some resource use data were derived from the data included in the primary registry for the TIC. Other data came from a published study and a cost study conducted at a university hospital. The price year was not reported and all costs were in US dollars ($).

Analysis of uncertainty:
The issue of uncertainty was not investigated.

Results
The success rate was 93% with the TIC and 79% with CDT (p=0.03). The rate of major haemorrhage was 8.5% with CDT, while no patient in the TIC group experienced immediate post-procedural bleeding (p<0.001). The infusion time was 22 minutes (SD: 11) with TIC and 25.2 hours (SD: 12.2) with CDT (p<0.001).

Although the cost of the device was much higher for the TIC ($2,000) than for CDT ($270), the total costs per patient were $3,697 (range: 3,178 to 4,316) with the TIC and $5,473 (range: 4,764 to 6,263) with CDT (p=0.03). This was due to lower costs associated with the thrombolytic therapy, bleeding, angiography suite and critical care unit monitoring.

Authors' conclusions
The authors concluded that thrombolysis in DVT with the TIC was associated with a better success rate, lower bleeding, and lower costs than traditional CDT. Thus, these preliminary findings supported the need for further evaluation of the TIC for the treatment of DVT.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear and the two strategies were appropriately chosen. The authors provided an extensive description of the TIC strategy.

Effectiveness/benefits:
The study design has some limitations, some of which were pointed out by the authors. First, the two study groups were not evaluated simultaneously and so the methodology may have differed. Second, the retrospective registry was input by individual investigators and no independent analysis of the outcomes was performed. Furthermore, this registry reflected a specific hospital that might not have been representative of other settings. Third, the authors provided only limited details on the inclusion criteria of the published studies on CDT. Moreover, the issues of homogeneity among these studies and their comparability with data from the retrospective registry were not investigated. Finally, no follow-up after hospital discharge was considered, which precluded the evaluation of the long-term efficacy. All these issues might have affected the validity of the comparison of the clinical endpoints.

Costs:
The economic viewpoint of the analysis was not explicitly stated, although the cost categories appear to be relevant to the health care service provider. A breakdown of the costs was provided for most items. The cost of a bleeding episode was reported as a macro-category. The unit costs were reported, but details on the resource use were not given. The price year was not reported.

Analysis and results:
A synthesis of the costs and benefits was not performed and this was, in effect, a cost-consequences analysis. The issue of uncertainty was not addressed. A number of limitations were pointed out and, as the authors noted, the findings should be viewed with caution.

Concluding remarks:
The study had some limitations, both in the clinical and economic analyses, which may have adversely affected the validity of the authors' conclusions.

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