A single center randomized trial assessing use of a vascular hemostasis device vs conventional manual compression following PTCA: what are the potential resource savings


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
A collagen vascular hemostasis device versus manual compression.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing PTCA.

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

Dates to which data relate
Effectiveness and resource data were collected in the period May to December 1993. No prices were used.

Source of effectiveness data
Single study.

Link between effectiveness and cost data
The same sample of the effectiveness analysis was used in costing.

Study sample
No power calculations were reported. 460 patients underwent PTCA between May and December 1993 in the study hospital and were considered for inclusion. 273 patients were excluded pre-procedure and 86 were excluded peri-procedurally, leaving 101 patients (22%) enrolled in the trial. 50 patients were randomised to manual compression and 51 to vascular hemostasis.

Study design
It was a single centre randomised controlled trial with computer-generated randomisation. Follow-up was by telephone 48 to 72 hours later and follow-up at the clinic was 28 to 35 days after sheath removal.
Analysis of effectiveness
The analysis was based on intention to treat (after exclusion). The outcomes studied were time to hemostasis, ambulation time, pain intensity/distress score and complications. The comparability of groups in terms of demographic and clinical features was addressed.

Effectiveness results
The time to hemostasis was shorter with VHD than manual compression: median 5 minutes for VHD against median 27 minutes for manual compression (p<0.001).

The ambulation time with VHD was a median of 8.5 hours and in the control group was 24 hours (p<0.001). There were no major complications and the minor complications experienced were not significant.

Pain intensity/distress score. For the VHD group, 22 out of 51 patients rated intensity of pain greater than 5 (moderate pain) on the visual analogue scale against 19 out of 49 of the control patients. Distress, defined as "suffering or anxiety" associated with the sheath removal and hemostasis procedure, was ranked at the 5th level or higher by 14 (27.5%) of the VHD group as compared to 7 (14.3%) of manual compression patients, (p=0.029). At 48-72 hours, 28% of the VHD patients reported mild swelling in the area as compared to 6% in the control group (p=0.40). At follow-up clinic 28-35 days post-procedure, 11 patients in the VHD group had mild swelling against 2 patients in the manual group (p=0.015).

Measure of benefits used in the economic analysis
The outcomes were time to hemostasis, ambulation time, pain intensity/distress score and complications.

Direct costs
Only quantities were reported. Nursing time and length of hospital stay were the resources measured.

Currency
Not applicable.

Sensitivity analysis
No sensitivity analysis was carried out.

Estimated benefits used in the economic analysis
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Cost results
The nursing time per patient differed significantly between the groups. Total GRASP (nursing time measurement) score for VHD was 10.7 vs 14.1 in the control group (p<0.001). The length of hospital stay was significantly shortened in the VHD group. The total number of days spent in hospital by the VHD group was 61 days vs 87 days in the control group: a difference of 26 bed days.

Synthesis of costs and benefits
The vascular hemostasis device was the dominant strategy.

Authors' conclusions
The use of a VHD reduced resource use and may lead to significant reductions in cost in the general coronary angioplasty population.

CRD Commentary
The data on resource use was good but no prices were reported. A lot of the patients were excluded before the trial and the reasons for exclusion were not clearly stated. The sample size was much lower than those enrolled.

Source of funding
Datascope Corp., Montvale, NJ, producers of the VasoSeal VHD.

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