Suture closure of femoral arterial puncture sites after coronary angioplasty followed by same-day discharge

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
Immediate sheath removal with suture closure of the femoral artery followed by early mobilisation and same-day discharge after coronary angioplasty. The Prostar-Plus suture closure device was used which enables immediate sheath removal from the femoral artery and early mobilisation in the presence of systemic anticoagulation. The 8F Prostar-Plus device contains 2 x 3.0 gauge nonabsorbable sutures. If there was an oozing of blood, manual pressure was applied until it resolved. Patients remained on bed rest for 4 hours and were discharged 4 hours after mobilisation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with elective or urgent coronary angioplasty with or without stenting were eligible for the study provided the operator believed same-day discharge would be reasonable. Exclusion criteria included clinical evidence of peripheral arterial disease, a pre-existing femoral haematoma, serum creatinine greater than 150 mmol/L, blood pressure higher than 180/100, or if patients were participating in another research protocol. There were no specific exclusion criteria based on coronary anatomy.

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

Dates to which data relate
The dates for effectiveness and resource use data collection do not appear to have been reported. The price year was 1998.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing was conducted prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. A total of 100 patients were randomly assigned in equal
numbers to either the Prostar-Plus group with a mean (SD) age of 62 (11) years or the c-clamp group with a mean (SD) age of 59 (12) years. 3 operators who had previously been instructed by a physician involved in device development, and had each placed 50 or more similar devices in clinical use before the study performed the suture closure. An experienced clinical nurse applied the c-clamp.

**Study design**
The study took the form of a randomised-controlled trial carried out in a single centre. The duration of the follow-up appears to have been for 72 hours after the procedure. The study had no loss to follow-up. Patients gave consent before angioplasty and were randomly assigned after the procedure, and all patients were receiving 325mg aspirin. All patients completed a questionnaire at 24 hours and were interviewed by telephone 72 hours after angioplasty.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness appears to have been intention to treat. The health outcome measures were time to mobilisation and discharge, number of initial insertion failures, need for vascular surgery; proportion of patients who had ooze of blood or external bleeding, proportion of patients who reported having haematomas (large, medium, or small, categorised according to the largest dimension of induration; less than 5 cm, 5 to 10 cm, greater than 10 cm), and patients’ preference. Patients were assessed for groin complications at 8, 24, and 72 hours. The study groups were found to be comparable in terms of baseline characteristics.

**Effectiveness results**
The effectiveness results were as follows:

Overall, patients who received suture closure were mobilised at 7.1 +/- 5.3 hours and discharged 11.15 +/- 6.22 hours after sheath removal; patients in the c-clamp group were mobilised at 15.49 +/- 3.9 hours and discharged 21.9 +/- 3.8 hours after sheath removal, (p<0.001).

Initial failure of the suture device occurred in 5 patients, with 1 requiring surgery for an entrapped device.

After the procedure, patients with suture closure more frequently had an ooze of blood (55% versus 24%, p<0.001) and a trend to more overt external bleeding (10% versus 2%, p=non significant).

Haematomas were reported by 20% of patients in both groups at 72 hours. All haematomas were small (less than 5 cm) except in 2 (4%) patients with suture closure who had moderate-sized haematomas (5 to 10 cm).

Overall, when assessed by a simple questionnaire, patients preferred the suture closure method of sheath removal.

In this study, failure to insert the suture device in 2 patients was believed to have been caused by unrecognised atherosclerotic disease in the femoral and/or iliac arteries. The device removed surgically was clearly the most important complication. It was returned to the manufacturer; however, neither a device fault nor evidence of operator error was found.

**Clinical conclusions**
Suture closure of 8F arterial puncture sites can facilitate early mobilisation and same-day discharge and is considered acceptable by more patients compared with application of the c-clamp.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only individual clinical outcomes were reported. The economic analysis was conducted on the basis of a cost-minimisation analysis. However clinical outcome equivalence was not demonstrated and, as such, the economic analysis could more appropriately be described as a cost-consequences analysis.
Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. Cost items were reported separately. The cost analysis covered the costs of each treatment strategy (sheath removal/device, overnight stay), and treatment failure (additional device, additional hospitalisation, and vascular surgery (consult and surgical professional fee)). The perspective adopted in the cost analysis was that of the hospital. In-hospital unit costs were obtained from the study hospital’s cost model, including fixed and variable costs based on an economic interpretation of all hospital expenditures into overhead, support centre (admitting/discharge, medical records, etc.), and patient care centre costs. Professional fees were based on a regional fee schedule. The price year was 1998. The preprocedure and other costs were assumed to be similar between the groups.

Indirect Costs
Indirect costs were not considered.

Currency
Canadian dollars (Can$). The exchange rate was Can$1 = US$0.70.

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
See effectiveness results reported above.

Cost results
The average (per-patient) costs by use of the alternative strategies were Can$460.21 for the Prostar-Plus device and $759.16 for the c-clamp, a saving of approximately $300.

Synthesis of costs and benefits
Costs and benefits were not combined since the economic analysis was performed on a cost-consequences basis.

Authors’ conclusions
Suture closure of 8F arterial puncture sites can facilitate early mobilisation and same-day discharge and is considered acceptable by more patients compared with application of the c-clamp. There is potential to realise cost savings with a strategy of same-day discharge.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator; it was the conventional treatment in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results is likely to be high given the randomised nature of the study design, the comparability of the study groups, and the effectiveness analysis being based on intention to treat. However the study had the following limitations: power analysis was not performed to justify the sample size; angiographic assessment of the femoral/iliac arteries and standardising the method of closure of the subcutaneous track might have improved the overall results; every patient ideally would have undergone a vascular ultrasound to determine if subclinical arterial complications were present; because the technique of percutaneous suture closure is novel, results would probably improve with operator experience. The classification of this study by the authors as a cost-minimisation analysis was
Validity of estimate of measure of benefit
The analysis of benefits was based upon therapeutic equivalence of treatment alternatives (although no explicit justification was given for this). The economic analysis therefore included only costs.

Validity of estimate of costs
The validity of the cost analysis was enhanced by the following features: some details of methods of cost estimation were given; the price year, exchange rate, and perspective adopted in the cost analysis were specified; the cost data were based on true costs rather than charges. However, the resource use profile was not fully reported separately from the costs; statistical analyses were not performed on cost data; the effects of alternative treatment strategies on indirect costs were not addressed; and, as the authors acknowledge, the cost results may not be generalisable outside the Canadian context.

Other issues
The authors' conclusions appear to be justified given the uncertainties in the data and the above-mentioned caveats. The issue of generalisability to other settings or countries was not systematically addressed, although appropriate comparisons were made with other studies. The degree to which the study sample was representative of the study population was addressed in the authors comments. It was reported that the study group represented 8% of the total angioplasty population during the course of the study (for a variety of reasons). To some extent there was an under-representation of female patients who made up only 17% of the study group compared with 26% in the general angioplasty population.

Implications of the study
Suture closure of 8F arterial puncture sites is associated with early mobilisation and same-day discharge, resulting in the possibility of realising economic benefits.

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