Comparison of costs and safety of a suture-mediated closure device with conventional manual compression after coronary artery interventions


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 percutaneous suturing device that allows the surgical closure of the femoral artery after coronary artery interventions. In particular, the suture-medicated closure (SMC) device was designed to close femoral artery access sites from 6 to 10 Fr in size immediately following an elective percutaneous coronary intervention (PCI), irrespective of anticoagulation levels. The patients were permitted to ambulate 4 hours after this procedure, subject to the absence of bleeding at the femoral access site.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients undergoing elective PCIs using a 6 or 7 Fr femoral access.

Setting
The setting was secondary care. The economic study appears to have been undertaken in Switzerland.

Dates to which data relate
The date of the trial was not reported. Consequently, the dates relating to the efficacy and resource use data were also not reported. The price year for some costs was 2000. The exchange rates used to convert other costs related to October 2000 and December 2001.

Source of effectiveness data
The effectiveness data came from a single study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not reported. The sample was selected on the basis of patients undergoing elective PCI using a 6 or 7 Fr femoral access. There were 193 participants overall, 96 in the intervention group and 97 in the control group. There was no information on whether any patients refused to participate or were excluded from the study.
Study design
This was a single-centre, prospective randomised study. The patients were followed up during their hospital stay. In addition, measures of different types of pain were collected over a 3-month period. There was no reported loss to follow-up.

Analysis of effectiveness
The type of analysis employed (intention to treat or treatment completers only) was not stated. The primary health outcomes were time to achieve haemostasis, time between PCI and ambulation, and decrease in haemoglobin. Patient discomfort was measured on the basis of pain due to SMC, sheath removal and compression, back pain, urinal problems and groin pain. A visual analogue scale graded 0 (best) to 10 (worst) was used to measure these types of pain.

There were no significant demographic differences between the two groups. However, there were some statistical differences between the SMC and MC groups. Patients in the former group (SMC) had slightly lower haemoglobin levels before PCI and a higher percentage of larger sheaths were used.

Effectiveness results
Of the SMC group, 85% of patients were successfully ambulated on the day of the PCI.

The following results are reported as the mean value plus or minus (+/-) the standard deviation (in brackets).

The time to achieve haemostasis was 7.1 (+/- 3.4) minutes in the SMC group and 22.9 (+/- 14.0) minutes in the MC group, (p<0.001).

The time between PCI and ambulation was 6.8 (+/- 5.0) hours in the SMC group and 18.4 (+/- 2.1) hours in the MC group, (p<0.001).

The decrease in haemoglobin was 0.63 (+/- 0.98) g/dL in the SMC group and 0.56 (+/- 0.94) g/dL in the MC group, (p=0.61).

The patients' rating of pain due to SMC, sheath removal or compression was 1.7 (+/- 2.2) in the SMC group and 2.9 (+/- 2.7) in the MC group, (p<0.001).

The patients' scoring of back pain was 2.8 (+/- 2.7) in the SMC group and 4.5 (+/- 2.9) in the MC group, (p<0.001).

The patients' rating of urinal problems was 1.2 (+/- 1.8) in the SMC group and 1.8 (+/- 2.4) in the MC group, (p=0.05).

The patients' ranking of groin pain was 3.0 (+/- 2.0) in the SMC group and 2.0 (+/- 2.2) in the MC group, (p<0.001).

Clinical conclusions
Patients in the SMC group were ambulated before those in the MC group. The discomfort recorded by patients in the treatment group was statistically significantly lower than that recorded by those in the control group. The incidence of minor complications was similar in both groups.

Measure of benefits used in the economic analysis
No summary health benefit was used. A cost-consequences analysis was therefore performed.

Direct costs
Discounting was not relevant since the costs were incurred in less than one year. The quantities and the costs were not reported separately. The cost analysis was restricted to those costs arising during the post-PCI treatment period. The costs of the SMC device, infrastructure and personnel costs were included in the analysis. The costs of the
catheterisation room, hospitalisation and personnel were derived from an analysis conducted by the accounting department of the University Hospital Zurich.

**Statistical analysis of costs**
The paper stated that Student's t-test, Mann-Whitney U-test and Fisher's exact test were used. However, it did not specify which, if any, of these tests were used when comparing the costs.

**Indirect Costs**
No indirect costs were included in the analysis.

**Currency**
The costs were reported in two currencies, Euros (Euro) and US dollars ($). The conversion rates were Euro1 = 1.477 Swiss francs (Sfr) (October 2000) and 1.477 Sfr=$0.878 (December 2001).

**Sensitivity analysis**
No sensitivity analysis was undertaken.

**Estimated benefits used in the economic analysis**
No summary measure of benefit was used. See the 'Effectiveness Results' section.

**Cost results**
The following results are reported as the mean value +/- the standard deviation (in brackets).

The total post PCI costs were reduced in the SMC group by 13% (+/- 3%). The costs were Euro469 (+/- 145) in the SMC group versus Euro539 (+/- 57) in the MC group, (p<0.001).

Savings in ward costs due to earlier discharge offset the additional cost of the Perclose device (Euro225). The savings were Euro178 (+/- 132) in the SMC group versus Euro481 (+/- 55) in the MC group, (p<0.001).

Personnel costs were also reduced. The reductions for a cardiologist were Euro21 (+/- 8) in the SMC group versus Euro50 (+/- 21) in the MC group, (p<0.001). The reductions for a nurse were Euro5 (+/- 2) in the SMC group versus Euro8 (+/- 5) in the MC group, (p<0.001).

**Synthesis of costs and benefits**
Not relevant as a cost-consequences analysis was carried out.

**Authors' conclusions**
Despite the additional costs of the device, suture-mediated closure (SMC) reduced the total costs significantly, mainly due to earlier discharge. The device was timesaving for the interventional cardiologist and nursing staff. The authors also found that the inconvenience for the patients was reduced, and that the majority of the patients with experience of both methods expressed a preference for SMC in the event of future interventions.

**CRD COMMENTARY - Selection of comparators**
No explicit justification was given for the comparator used. However, it would appear to have represented current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.
Validity of estimate of measure of effectiveness
The analysis of effectiveness used a prospective randomised study, which appears to have been appropriate for the study question. The study sample was representative of the study population. The patients’ demographic characteristics were shown to have been comparable at baseline.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The analysis of costs was restricted to those costs arising during the post-PCI treatment period. The analysis was undertaken from the perspective of the institution. It appears that all of the relevant direct costs have been included in the analysis. However, the authors did not include the costs of additional drugs incurred as a result of patient discomfort (e.g. sleeping pills, painkillers, and local anaesthetics). They argued that these costs were small and were common to both groups. It was unclear whether the costs of treating minor complications were included in the analysis but, since the incidence of minor complications was similar in both groups, the omission of these costs may not affect the difference in costs between the two groups. No sensitivity analyses were conducted. The price year stated was 2000, although the exchange rates for dollars were calculated using the exchange rates for December 2001. The authors performed appropriate currency conversions. Discounting was unnecessary since all of the costs were incurred in less than one year. The costs and the quantities were not reported separately.

Other issues
There were no comparisons with similar studies, as it was the authors' belief that the current study was the first that had compared these two treatments. However, the authors did examine other studies that assessed other techniques for haemostasis after PCI. Due to the nature of the intervention, the patients were aware of the intervention to which they were assigned and this may have biased the results, especially if the patients had prior experience of the intervention. The authors acknowledged that there were other limitations of the study. For instance, to investigate the safety and efficacy of the device, SMC patients were not discharged from hospital, even though immediate discharge had been shown by other studies to be safe. Further, the authors recognised that the generalisability of the results may be restricted since this study was based on treatment patterns and costs prevailing in Switzerland. Consequently, the authors applied costs from other countries to test the robustness of their results. The results continued to show cost-savings for SMC.

Implications of the study
The authors stated that SMC devices may be used routinely in patients having femoral access for elective PCI.

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None stated.

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