A comparative study of radiation dose and screening time between mini C-arm and standard fluoroscopy in elective foot and ankle surgery

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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
This study examined the clinical and economic impact of mini C-arm devices, compared with standard fluoroscopy, during foot and ankle surgery, focusing on radiation exposure as the key endpoint of treatment. The authors concluded that the mini C-arm reduced the radiation dose and saved costs. These conclusions appear to be valid, but some methodological limitations might affect the validity of the results.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the clinical and economic impact of mini C-arm devices, compared with standard fluoroscopy, during foot and ankle surgery, focusing on radiation exposure as a key endpoint of treatment.

Interventions
Standard fluoroscopy was compared against mini C-arm fluoroscopy.

Location/setting
UK/hospital.

Methods
Analytical approach:
The analysis was based on a single study with a short time horizon. The perspective was not clearly stated.

Effectiveness data:
The clinical data were from the prospective review of 127 surgical cases who required intraoperative screening during various elective foot and ankle procedures. There were 72 patients in the standard group, who were screened between June 2006 and September 2007, and 55 patients in the mini C-arm group, who were treated between September 2007 (the date of introduction of the new procedure) and March 2008. The complexity of the surgical procedure was comparable between groups. The length of follow-up was the operation time. The screening time and radiation dose were the key endpoints of the analysis. The radiation dose was measured using dose area product (DAP) meters.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
No summary benefit measure was used. The primary endpoints of the analysis were the screening time and radiation dose.

Cost data:
The costs of standard fluoroscopy included the provision of a radiographer to theatre and the delays to theatre caused by the radiographer being in attendance. The cost of mini C-arm fluoroscopy included the device and surgeon training. These costs and resource quantities were from the institution where the clinical study took place, except for the cost of the theatre, which was from a similar centre. All costs were in UK pounds sterling (£) and the price year was 2009.
Analysis of uncertainty:
Not considered.

Results
The mean DAP was 9.58 centigray (cGy) per cm$^2$ in the standard group and 4.01 cGy per cm$^2$ in the mini C-arm group (p=0.0013). The screening time was 13 seconds in the standard group and 14.5 seconds in the mini C-arm group; this difference was not statistically significant.

The use of mini C-arm in place of standard fluoroscopy, for all 350 annual extremity cases in the authors' centre, was associated with total savings of £9,391 (£5,541 in radiographer delays and £3,840 in radiographer salaries). The cost of the C-arm device was £42,500. At the rate of 350 extremity cases per year the cost of the C-arm device would be offset by the reduction in radiographer costs over five years.

Authors’ conclusions
The authors concluded that the mini C-arm reduced the radiation dose and saved costs compared with conventional fluoroscopy.

CRD commentary
Interventions:
The selection of the comparators was appropriate as the authors compared the usual approach against the proposed strategy. These are likely to be relevant comparators in other settings.

Effectiveness/benefits:
The clinical data came from a prospective study that appropriately compared the two interventions. There was no randomisation, but the two study groups were comparable at baseline. The primary outcome measures were disease specific and might not permit comparisons with the benefits of other health care interventions. The demographic and clinical characteristics of the two groups were reported, but the size of the sample was not justified, making it unclear if it had sufficient power to detect statistically significant differences between groups. The two procedures were performed during two different periods and the authors did not investigate time-related bias in the study outcome; factors other than the interventions might have affected the performance of the two procedures. The authors acknowledged the importance of the learning curve in surgeon's experience.

Costs:
The perspective was not stated, but the study focused on those costs borne by the authors’ centre. The unit costs and resource use were generally reported for the few cost items analysed. The resource use was from the same prospective study that supplied the clinical data. The sources of unit costs were not explicitly reported. The costs were treated deterministically and were not varied in the sensitivity analysis. The price year was reported and no discounting was necessary given the short time horizon of the study.

Analysis and results:
The results were clearly reported, but there were differences between those in the text, those in the abstract, and those in the table. The clinical and economic outcomes were not combined. In effect, a cost-consequences analysis appears to have been carried out. The uncertainty was not investigated and only the significance of the differences in clinical results was tested statistically. The results appear to be specific to the authors’ centre and will not be transferable to other settings. The main limitation of this study was the design of its clinical analysis.

Concluding remarks:
The authors’ conclusions appear to be appropriate, but some methodological limitations might affect the validity of the results.

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