Femoral shaft fracture treatment in patients age 6 to 16 years

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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.

Health technology
Methods for the treatment of femoral shaft fractures. The treatment methods were traction followed by spica casting, external fixation, flexible intramedullary (IM) rods, compression plating and reamed IM nailing.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients between the ages of 6 and 16 seen with a femur fracture. All patients who had underlying neuromuscular problems, who had undergone previous surgery on the affected femur, or who had any bone pathology were excluded.

Setting
Hospital. The economic analysis was carried out in Georgia, USA.

Dates to which data relate
Effectiveness and resource use data corresponded to patients treated in the study hospital during the period between January 1988 and January 1995. The price year was 1995.

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 retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. Originally, a total of 93 femur fractures in 89 patients were reviewed. One patient died of multiple injuries and 7 were lost to follow-up. The study sample consisted of 85 fractures in 81 patients with clinical follow-up of 6 months or more.

The distribution of the patients to the various study methods was as follows:

25 patients, early spica group;
10 patients, traction followed by spica casting;
22 patients, external fixation;
11 patients, flexible intramedullary (IM) rods;
4 patients, compression plating;
13 patients, reamed IM nailing.

**Study design**
This was a retrospective cohort study, carried out in a single centre. The mean duration of follow-up was 19 months (range: 6 - 88 months). 7 patients were lost to follow-up. Hospital records, clinic records, and all radiographs of the patients were reviewed. Those patients who were treated with traction followed by spica casting were either from the early years of this review or had special circumstances making this the treatment of choice. The choice of treatment was made by the attending pediatric orthopedic surgeon and was varied based on the judgement of each surgeon. It was the policy of all surgeons treating patients included in this study to treat femur fractures by early spica casting whenever possible. However, the level of trauma, fracture pattern, patient age, patient weight, or associated injuries were indications for the use of other treatment methods.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was treatment completers only. The clinical outcome measure was the time until full weight bearing. This was considered to be the best measure of healing as time to healing was deemed to be difficult to measure accurately. The clinical outcome was recorded in the charts of all patients. The complication rates and the amount of callus formation were also reported. Regarding the comparability of the patient groups, it was noted that there was a tendency for the younger patients, who also tended to weigh less, to be treated with early spica casting, whereas adolescents were treated with reamed IM fixation. Those patients treated with external fixation and flexible IM nails tended to be older and heavier than those treated with casting. However, the overlap in the two groups was considerable, reflecting factors other than height and weight.

**Effectiveness results**
The average (range) time to full weight bearing (weeks) was as follows:

- 10 (range: 6 - 20), early spica group;
- 12 (range: 8 - 16), traction followed by spica casting;
- 22, external fixation;
- 11, flexible IM rods;
- 4, compression plating;
- 13, reamed IM nailing.

The average major complication rates were as follows:

- 0.12, early spica group;
- 0.3, traction followed by spica casting;
- 0.96, external fixation;
- 0.09, flexible IM rods;
0. compression plating;
0.15, reamed IM nailing.

Callus formation at time at which full weight bearing was permitted was as follows:

2.43, early spica group;
2.1, traction followed by spica casting;
1.64, external fixation;
2.73, flexible IM rods;
1.25, compression plating;
2.62, reamed IM nailing.

Clinical conclusions
This report demonstrated that fracture of the femoral shaft in children from 6 to 16 years of age can usually be treated without permanent sequelae. This report also suggested that different treatments are more appropriate in certain circumstances.

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.

Direct costs
Costs were not discounted, which should be considered in the light of the average follow-up period of 19 months (range: 6 - 88 months). Quantities (operating time and days in hospital) were reported separately from the costs. The cost breakdown was not reported separately. The cost analysis covered the costs associated with the treatment of an isolated femur fracture: hospital costs, including radiology and anaesthesiology; physician costs, including orthopedist, radiologist, and anaesthesiologist; and outpatient radiology. Cost analysis also included metal removal, plus complications. The perspective adopted in the cost analysis was not explicitly specified. The charge data were used as a proxy for true costs. The source of hospital charges was the study institution. The market-basket conversion factors were used to calculate the increase in price of the same item over the course of the study. The price year was 1995.

Indirect Costs
Indirect costs were not included.

Currency
US dollars ($)

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.
Cost results
Early spica casting gave excellent results with low complications and low costs. The average charge for isolated fracture treatment was $5,264 and the average charge for the patient who failed the initial early spica was $15,304 per patient. All surgical treatment cost approximately the same: 3 times the cost of early spica and equivalent to traction followed by spica casting (with an average charge for isolated fracture treatment of $15,980).

Synthesis of costs and benefits
Costs and benefits were not combined.

Authors' conclusions
Indications from this report are that early spica casting is the best method when feasible. Flexible IM rods result in earlier healing with fewer complications than external fixation and are best in simple transverse and short oblique fractures. External fixation is best for long spiral and comminuted fractures, and reamed IM rodding should be reserved for those at or near skeletal maturity.

CRD COMMENTARY - Selection of comparators
The strategy of early spica casting, as the treatment of choice whenever possible, was explicitly regarded as the comparator. 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 can not be guaranteed given the retrospective nature of the study design, the lack of power calculations to justify the sample size, the non-comparability of the study groups and fact that the effectiveness analysis was based on treatment completers only rather than on intention to treat. Furthermore, experience is likely to have played some role in determining the effectiveness outcomes. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
No summary benefit measure was identified in the economic study, and as a result, the study used a cost-consequences design.

Validity of estimate of costs
Some details of the methods of cost estimation were given, the price year was specified and adjustment was made for inflation. However, the following characteristics may have undermined the validity of the cost results. The cost analysis was performed on a retrospective basis, comprehensive resource use/unit cost profiles were not provided, the perspective adopted in the cost analysis was not specified, charge data were used instead of true costs and some cost items may have required discounting. In addition, the effects of alternative procedures on indirect costs were not addressed, statistical analyses were not performed on resource use and cost data, and no sensitivity analysis was performed to assess the robustness of the cost results.

Other issues
In view of the inherent limitations the study design, and the lack of both sensitivity analysis and statistical analysis of costs, the study results should be treated with some degree of caution. The issue of generalisability to other settings or countries was not addressed. Appropriate comparisons were made with other studies and it was noted that the unusually high complication rate in the group receiving external fixation may have been directly or indirectly related to the delayed union in this group of patients. This makes the delay in union a key factor in the use of the external fixator.
Implications of the study
Further research is required to examine and refine the best method for treating each fracture in its specific circumstances.

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