Closed fractures of the tibial shaft: a meta-analysis of three methods of treatment

Authors' objectives
To evaluate the clinical outcomes of the treatment of closed fractures of the tibial shaft with immobilisation in a cast, open reduction with internal fixation, or fixation with an intramedullary rod.

Searching
MEDLINE was searched from January 1966 to August 1993 for studies on fractures of the tibial shaft. Citation lists of eligible reports from earlier publications were also examined. Only published reports written in English were eligible for inclusion.

Study selection
Study designs of evaluations included in the review
The authors reviewed 2 randomised controlled trials (RCTs), 3 non-randomised, comparative studies and 14 uncontrolled case series. Studies were eligible for inclusion if they had a minimum of 20 patients; there was a clear description of an isolated, closed fracture of the tibial shaft, treated within 21 days after the injury; one of the three treatments of interest had been used; and at least one of the outcomes of interest was described.

Specific interventions included in the review
The specific interventions were: immobilisation in a cast or brace; open reduction with internal fixation, with screws alone or with screws and a plate; or fixation with an intramedullary rod, including open nailing.

Participants included in the review
The participants were adults with closed fractures of the tibial shaft; children were excluded.

Outcomes assessed in the review
Twelve outcomes were assessed in the 'cohort' phase of the review:

- time to union (in weeks);
- mortality;
- superficial infection, defined by the use of such terms as cellulitis, soft-tissue infection, local infection or skin necrosis;
- deep infection, defined by the use of terms such as fistula, infected non-union, osteomyelitis, osteitis, deep abscess, and sequestration;
- late reoperation or an operative procedure after treatment with a cast;
- union by 20 weeks;
- delayed union, defined as union 24 to 36 weeks after the injury;
- nonunion, defined as incomplete healing more than 36 weeks after injury;
- slow union, defined as union between 20 and 36 weeks after injury;
- amputation;
- refracture; and
duration of hospitalisation (in days).

Only the first six outcomes were used in the comparative phase of the review.

How were decisions on the relevance of primary studies made?
Two authors reviewed each citation for inclusion. If there was any disagreement then the complete report was obtained and reviewed by the two reviewers. Any further disagreement was resolved by three orthopaedic surgeons. The reviewers were blinded to the names of the institutions, authors and journals.

Assessment of study quality
The authors used a quality score (0 to 15 points) to evaluate the follow-up measures and the research design for each study. This comprised four specific questions on follow-up measures (blind outcomes rating; attrition rate; subjective outcomes; active or passive follow-up) and one rating of study design (randomisation and control). The authors do not state how the papers were assessed for quality, or how many of the authors performed the quality assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
In the first phase, each cohort was assigned to one of three groups on the basis of the treatment. The median of the published rates of a given outcome after each treatment was determined, and then the medians across groups were compared using the Kruskal-Wallis test (a ranked non-parametric analogue to analysis of variance) to calculate p-values.

In the comparative phase, the authors used a random-effects model to calculate the individual confidence intervals (CIs) and p-values for the odds ratios (ORs) and risk differences. The individual ORs and risk differences were not combined.

How were differences between studies investigated?
The authors did not investigate heterogeneity between the studies.

Results of the review
Nineteen reports met the inclusion criteria, of which 5 were controlled trials. There were two phases of analysis. In the first phase, the authors treated each group of patients (whether from a case-series or from one arm of a comparative study) as a single eligible cohort. Twenty-seven independent groups were extracted from the 19 eligible reports for this analysis: 16 groups (2,005 patients) had been treated with a cast or brace, 8 groups (474 patients) had been treated with open reduction and internal fixation, and 3 groups (407 patients) had been treated with an intramedullary rod. The second comparative phase used 5 studies and divided them into the three methods of treatment groups. Only two of the methods of treatment (cast and open reduction with internal fixation) had sufficient data for a comparative analysis.

The quality scores for the included studies ranged from 3 to 11 points (median 6 points; mean 6.4 points). Linear regression analysis indicated that these scores improved with time, by about 0.11 points per year (p=0.005).

In the comparative analysis, treatment with a cast was associated with a lower rate of superficial infection (OR 0.20, 95% CI: 0.08, 0.50) with a risk difference of -5.81% (p=0.02).

Treatment with a cast was also associated with a trend towards a lower rate of deep infection (OR 0.50, 95% CI: 0.13, 2.03) with a risk difference of -0.99% (p=0.36), which was not statistically significant.

For union by 20 weeks, treatment with open reduction with internal fixation was superior to treatment with a cast (OR 0.21, 95% CI: 0.06, 0.68), with a risk difference of -18.07% (p=0.008).
There was no significant difference between open reduction with internal fixation and treatment with a cast for mortality rates, \((p=0.82\)), reoperation or an operative procedure after treatment with a cast \((p=0.45\)), and nonunion \((p=0.47\)).

In the case-series cohort analysis, the outcomes were grouped according to time to union, failure of treatment, and complications.

In the time to union group (time to union in weeks, union by 20 weeks, delayed union, nonunion and slow union), the median time to union was 20.0 weeks after fixation with an intramedullary rod, 14.7 weeks after immobilisation in a cast, and 13.0 weeks after open reduction and internal fixation, but this was not statistically significant \((p=0.06\)).

In the failure of treatment group (late reoperation, operative procedure after treatment with a cast, and refracture), the median rate of an operative procedure after primary treatment with a cast was 4%. The median rate for reoperation after primary open reduction and internal fixation was 0.8%. The median rate of refracture after treatment with a cast was 2.3%. The median rate of refracture after open reduction and internal fixation was 0.8%.

In the complications group (mortality, superficial infection, deep infection and amputation), rates were higher for those treated operatively. The rate of superficial infection ranged from 0 to 4% after closed treatment, and from 0 to 22% after open reduction and internal fixation \((p=0.05\)). A similar but non significant trend was seen for deep infection.

The authors stated that the median death rate was 0%; however, this is not to say that no deaths occurred. The maximum reported death rate was 6% for patients treated with a cast.

The rate of amputation was 4% after treatment with a cast (1 study), and 1% after open reduction and internal fixation (1 study).

**Authors' conclusions**

The results of the present review suggest that the data from the published literature are inadequate for decision-making with regard to the treatment of closed fractures of the tibia. However, there appears to be a trend in favour of open reduction and internal fixation.

**CRD commentary**

The authors conducted a good review of the literature and summarised their results in several tables and graphs. The review may have missed relevant studies, since the analysis was limited to English language studies and the details of the search strategy were not reported.

The inclusion criteria for the individual trials were well stated and the authors conducted a good quality review of the included studies. However, information on who performed the quality review and extracted the data was not provided, e.g. how many reviewers were involved and whether there was independent assessment.

The authors reviewed the literature in two design phases, grouping the higher-quality studies in a comparative analysis, separate from the lower-quality case-series data. While this approach addressed the differences between the included studies, the wide heterogeneity between the participants and the study designs included was very apparent; the results of combining these studies should, therefore, be viewed with caution. The authors' conclusions, that there appears to be a trend in favour of open reduction and internal fixation, follow from the results of the review. However, these must also be viewed with extreme caution because of the quality of the included studies and the methods used to combine them.

**Implications of the review for practice and research**

**Practice:** The authors do not state any implications for practice.

**Research:** The authors state that multicentre, large randomised controlled trials with unselected patients drawn from community practice are necessary to improve clinical decision-making. These should focus on improved patient data and adhere to the range of outcome measures detailed in this review. The authors also give suggestions for sample sizes,
based on power calculations for such studies.

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