A randomized controlled trial of piroxicam in the management of acute ankle sprain in Australian regular army recruits: the Kapooka ankle sprain study

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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
The use of piroxicam (from the oxicam group of non-steroidal anti-inflammatory drugs (NSAIDs)) in the management of acute ankle sprain. Piroxicam is a highly potent inhibitor of prostaglandin synthesis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Australian Regular Army recruits. Subjects with previous major soft tissue injuries or ankle or foot fractures in the affected ankle, history of chronic instability in the affected ankle, history of adverse reaction to NSAIDs, proven peptic ulcers or gastrointestinal bleeding and current drug intake other than that outlined in the drug protocols were excluded from the study.

Setting
Community and hospital. The economic study was carried out at recruit training facilities in Kapooka, New South Wales, Australia.

Dates to which data relate
Effectiveness and resource use data were collected between 19 June 1988 and 19 May 1990. The price year was not clearly reported.

Source of effectiveness data
Effectiveness data were derived from a single study.

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

Study sample
400 potential subjects were identified during the study period, of whom 34 were excluded from the trial because of ankle or foot fractures. Two subjects did not wish to be involved. None of the remaining 364 subjects (aged between 18 and 35 years, 85% men) were lost to follow-up. Extensive power calculations related to the sample size were performed.
Study design
Randomised, double-blinded, controlled trial from a single centre. The duration of follow-up was 6 months after injury. The randomisation schedule was constructed based on three sets of random numbers generated by the Systat 5.1 statistical data management programme. Patients were stratified according to injury grade (minimal pain and swelling - Grade 1, moderate pain and swelling - Grade 2, and severe pain and swelling - Grade 3). Of the 364 subjects, 184 were allocated to the piroxicam group and 180 to the placebo group.

Analysis of effectiveness
The analysis was based on treatment completers only (after patients with grade 3 injuries had been excluded from the study due to the small numbers involved (n=9)). The main health outcomes used in the analysis were: number of training days lost, degree of pain experienced, speed of resuming training and exercise, and exercise endurance on resumption of activity. Side effects were also considered. Romberg's test (performed on athletes in order to assess their capacity to resume training) and visual analog pain scores were used. Groups were comparable in terms of age distribution, sex and severity grade.

Effectiveness results
The mean number of training days lost was 2.74 from the piroxicam group and 8.57 from the placebo groups (p < 0.001). Compared with the placebo group, subjects treated with piroxicam had less pain, were able to resume training more rapidly and were found to have increased exercise endurance on resumption of activity. Nausea was the only side effect reported significantly more often in the treatment group than in the placebo group (6.8% versus 0.3%, p<0.005). Subjects treated with piroxicam also showed some evidence of local abnormalities such as instability and reduced range of movement.

Measure of benefits used in the economic analysis
The measure of benefits was the number of days of training saved.

Direct costs
Some quantities of resource use were analysed separately from the costs, although this was not clearly reported. It is not clear what elements were included in the cost. A mean cost of treatment and a total cost of treatment were calculated. Ice, compression, elevation and rehabilitation therapies were considered, as well as medication. The resource use data were based on actual data from the clinical study. The price year was not clearly stated.

Statistical analysis of costs
Student t-tests and ANOVA tests were used.

Currency
Australian dollars (Aus$) (a conversion to US$ was also performed).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
570 training days were saved by the intervention.

Cost results
The mean cost of treatment was Aus$159.23 (US$ 122.21) for piroxicam patients and Aus$321.46 (US$246.72) for placebo group patients (p<0.05).

**Synthesis of costs and benefits**
Although the authors reported average cost-effectiveness results for each group, costs and benefits did not need to be combined since the intervention (piroxicam) turned out to be the dominant strategy. The piroxicam group's average cost-effectiveness was reported to be Aus$2.14 (US$1.64) per training day saved; for the placebo group, this was Aus$4.70 (US$3.60).

**Authors' conclusions**
The piroxicam group had a favourable outcome in the long term, both in terms of morbidity and cost. However, the authors sounded a note of caution regarding the instability and lower range of motion recorded in the piroxicam patients.

**CRD COMMENTARY - Selection of comparators**
The reason for the choice of comparator (placebo) was clear. You, as a user of this database, should consider if this applies to your own setting.

**Validity of estimate of measure of benefit**
Data do not appear to have been used selectively to prove a particular point and the choice of health outcomes was justified. Additionally, power calculations were conducted based on prior evidence. Double-blinded and stratified randomisation supports the validity of the results. On the other hand, the exclusion from the analysis of patients with grade 3 injuries (n=9) appears to be a weakness in the analysis.

**Validity of estimate of costs**
Few details of cost estimation were given. Good comparisons were made with studies dealing with the same topic.

**Other issues**
Whilst the conclusions were justified, given the uncertainties in the data, cost results may not be generalisable to other settings/countries.

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