Diagnosis of ligament rupture of the ankle joint: physical examination, arthrography, stress radiography and sonography compared in 160 patients after inversion trauma

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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
Strategies for the diagnosis of ligament rupture, consisting of combinations of physical examination, arthrography, sonography and stress radiography.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
Patients attending an Emergency Department within 2 days of acute inversion injury of the ankle. Only patients without previous ankle injury or without fractures were included in the study.

Setting
Hospital. The economic study was carried out in Amsterdam, The Netherlands.

Dates to which data relate
The effectiveness and resource use data were collected between March 1988 and January 1990. The price year used in the final analysis was 1990.

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

Link between effectiveness and cost data
The costing was undertaken 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. A total of 160 patients between 18 and 40 years of age was included in the analysis. These patients had a physical examination immediately after admission, followed by arthrography 5 days later, and a new physical examination, followed by a stress radiography and a sonography. Patients underwent surgery based on a positive physical examination at day 5 and/or a positive arthrogram. Examinations were carried out by an experienced orthopaedic surgeon and independently, by one of four inexperienced interns.
Study design
Prospective case series. The study was carried in a single centre. The duration of the follow-up was at least 6 months. No loss to follow up was reported. One out of four "inexperienced but well-instructed interns" assessed the patient health status without knowing the result of the experienced orthopaedic surgeon's examination.

Analysis of effectiveness
The principle used in the analysis of effectiveness was intention to treat. The primary outcome used was the accuracy of diagnostic procedures, which was presented in terms of sensitivity and specificity values for each strategy. The probabilities were derived from the clinical study. The diagnosis of presence of lateral ligament rupture was based on formation of hematoma, location of pain on palpation and the result of the anterior drawer test. Stress radiography was performed using the Sheuba device. It yielded a positive result when talar tilt exceeded 10 degrees or the talar tilt left-right difference was greater than 5 degrees, and/or when an anterior drawer of more than 4mm was noted or there was a left-right difference of more than 2mm. The confirmation of diagnosis was based on the results of surgery, for those operated on, whereas, for those who did not undergo an operation, final diagnosis was determined from the clinical diagnosis at follow-up. The decision analysis model yielded the final overall estimates of specificity and sensitivity for each diagnostic strategy.

Effectiveness results
There were 25 cases of negative arthrogram, 6 positive delayed examinations and a negative arthrogram, 12 negative delayed examinations and a positive arthrogram, and 117 positive delayed examinations and a positive arthrogram. The sensitivity and specificity estimates, for each diagnostic strategy, were calculated as follows: Strategy 1, 71% and 33%; Strategy 2, 82% and 33%; Strategy 3, 79% and 33%; Strategy 4, 81% and 33%; Strategy 5, 96% and 71%; Strategy 6, 68% and 71%; Strategy 7, 92% and 64%; Strategy 8, 96% and 84%; Strategy 9, 99% and 75%; Strategy 10, 100% and 72%; Strategy 11, 89% and 70%; Strategy 12, 94% and 63%; Strategy 13, 97% and 61%.

Clinical conclusions
The authors found a great improvement in sensitivity and specificity when the physical examination was delayed until 5 days after trauma. One explanation of this improvement is that pain at palpation is better localised to the site of ligamentous injury.

Modelling
A decision analytic framework was used to calculate the sensitivity and specificity of each strategy.

Measure of benefits used in the economic analysis
The primary outcome used was the accuracy of diagnostic procedures, which was presented in terms of sensitivity and specificity values for each strategy. The confirmation of diagnosis was based on the results of surgery (all three lateral ankle ligaments, as well as the anterior tibiofibular ligament, were inspected), for those operated on, whereas, for those who did not undergo operation, final diagnosis was determined from the clinical diagnosis at follow-up. The decision analysis model yielded the final overall estimates of specificity and sensitivity for each diagnostic strategy.

Direct costs
Discounting of costs was not required due to the short time frame of the study. The quantities of resource use were not reported. Cost items were not reported separately. The cost analysis consisted of those costs associated with administering the diagnostic test. Therefore, the costs included were operating and capital costs. The cost boundary adopted was that of the hospital. The estimation of costs was based on actual data, which was obtained from interviews with "co-workers who dealt with the primary process". The costs associated with morbidity (suffering, disability) were not included in the analysis.
Statistical analysis of costs
Mean values reported.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
Multiple sensitivity analysis was conducted on the variables of the model. A sensitivity analysis consisted of a comparison of results for two scenarios: One, where inconclusive judgements were considered as negative, and another, in which those judgements were considered as positive.

Estimated benefits used in the economic analysis
The sensitivity and specificity estimates for each diagnostic strategy, were reported above.

Cost results
The costs of each strategy were reported as follows: Strategy 1, $23; Strategy 2, $36; Strategy 3, $30; Strategy 4, $34; Strategy 5, $141; Strategy 6, $78; Strategy 7, $111; Strategy 8, $44; Strategy 9, $56; Strategy 10, $55; Strategy 11, $40; Strategy 12, $49; Strategy 13, $52.

Synthesis of costs and benefits
The results were not combined (the authors considered three dominant strategies: Strategy 1, Strategy 8 and Strategy 11). The sensitivity analysis resulted in no alteration of the ranking of the procedures for variation along "plausible ranges" of parameter values, while the scenario with inconclusive judgements considered as positive, yielded inferior results (in terms of cost-effectiveness) to those obtained when those judgements were considered as negative.

Authors' conclusions
The strategy consisting of delayed physical examination at day 5 after injury (Strategy 8) led to the highest overall sensitivity (96%) and specificity (84%) for the detection of a ligament rupture. All other strategies supplied little additional information at a considerable cost.

CRD COMMENTARY - Selection of comparators
No specific health technology was regarded as the comparator.

Validity of estimate of measure of benefit
The estimate of measure of benefit is likely to be internally valid given the use of a prospective design.

Validity of estimate of costs
The resource quantities were not reported separately from the prices and insufficient detail was provided with regard to the methods of cost estimation.

Other issues
Given the uncertainties in the data, the authors' conclusions were justified in terms of the sensitivity analysis and by a modification of the assumption of conditional independence of diagnostic procedures (reported as having potentially negligible effects on the results). Some comparisons of the clinical results were made with other studies (supporting the
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