Outpatient parenteral antimicrobial therapy (OPAT) for the treatment of osteomyelitis: evaluation of efficacy, tolerance and cost


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 outpatient parenteral antimicrobial therapy (OPAT) in the treatment of osteomyelitis. The antibiotic solutions were prepared by the nurse at the patient's home or delivered to the patient's home in refrigerated coolers. The antibiotics were mixed in 240 mL of normal saline solution or water for injection and were introduced using implanted catheters. The duration of the treatment was related to the stage of the infection.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with osteomyelitis requiring intravenous antibiotic therapy for longer than 4 weeks, and who were able to receive therapy at home. The requirement for parenteral administered antibiotics was defined by the presence of multi-drug-resistant organisms or by allergy to oral antibiotics. The Cierny-Mader classification was used for staging osteomyelitis.

Setting
The setting was outpatient. The economic study was carried out in France.

Dates to which data relate
The effectiveness and resource use data were gathered from November 1997 to May 2000. No price year was reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not performed. The method used to select the sample was not reported. The baseline characteristics of the patients were provided. An overall sample of 39 patients, with a mean age of 44 (+/- 20) years (range: 18 - 86), was included in the analysis. There were 25 men and 14 women. According to the Cierny-Mader classification, there were no patients classified as stage 1, 5 patients were classified as stage 2, 7 as stage
3, and 27 as stage 4. No comparator group (such as patients hospitalised for therapy) was considered in the analysis.

**Study design**
This was a prospective study with a hypothetical control, which was carried out in a single centre (Raymond-Poincare Medical University, Garches, France). The hypothetical control was the implicit assumption that patients treated in hospital could not return to work or school, and that the patients would generally prefer to be at home. A physician specialist in infectious diseases assessed the patients. Laboratory studies were performed weekly during the treatment. The duration of the follow-up was 12 months and 9 patients were lost to follow-up.

**Analysis of effectiveness**
The analysis of effectiveness was limited to those patients who completed the follow-up assessment. The primary health outcome assessed was prolonged cure. This was defined as the lack of symptoms for 12 months after the completion of therapy. The secondary health outcomes were a mean quotient inhibitor (QI) of higher than 10 and adverse effects. The QI equalled the serum antibiotic level divided by the minimal inhibitory concentration to various antibiotics. The indirect benefits resulting from the patient’s ability to be treated outside the hospital, such as the ability to remain at home, to return to work, or to attend school, were also observed.

**Effectiveness results**
The most frequently identified bacterial organism was Staphylococcus aureus, which was present in 44% of the patients.

The most common antimicrobial agent was vancomycin (n=20, 51%), and the second most frequently used was beta-lactams (n=17, 44%).

The mean duration of treatment was 4 (+/- 0.7) months (range: 1.5 - 12).

The mean QI was 22 (+/- 14) and all patients had a QI of greater than 8.

Of the 30 patients evaluable at follow-up, 28 (93%) were considered cured with a mean delay of 24 (+/- 4) months after completing the therapy.

There were few adverse effects during the treatments. One patient experienced a clinical failure, while another sustained a relapse within one month.

All patients cured remained at home during the therapy: 9 patients (23%) returned to work and 10 (25%) attended school.

**Clinical conclusions**
The OPAT proved to be a feasible intervention for patients with osteomyelitis requiring intravenous therapy. The patients were satisfied with home treatment and there was evidence of a return to normal activities, such as going to school or work, which could not have occurred during inpatient treatment.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used. A cost-consequences analysis was therefore carried out.

**Direct costs**
Discounting was not carried out as the costs per patient were incurred over one year. The unit costs and the quantities of resources used were not reported separately. The economic analysis included medication, supplies staff (physiotherapist and nurse), and laboratory tests. The cost/resource boundary adopted was that of the hospital. The resources used and
the costs were estimated using actual data derived from the hospital records. The cost of the treatment that would have been carried out during hospitalisation was assessed as a comparison technology, and the average daily direct variable cost in acute hospital units (infectious disease or orthopaedic unit) was calculated. The quantities of resources were measured from November 1997 to May 2000. No price year was reported.

**Statistical analysis of costs**
No statistical analysis of the costs was carried out.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The daily cost was $129 for OPAT and $710 for the inpatient treatment. The total costs for 39 patients were $360,060 for OPAT and $2,233,945 for inpatient treatment. Thus, the outpatient treatment led to cost-savings of $1,873,885.

**Synthesis of costs and benefits**
Not relevant.

**Authors' conclusions**
Outpatient parenteral antimicrobial therapy (OPAT) may be the best treatment for patients suffering from osteomyelitis and requiring intravenous therapy. The intervention was also associated with substantial cost-savings in comparison with inpatient treatment.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. OPAT was compared with inpatient treatment, as the aim of the study was to assess the benefits and cost-savings of outpatient treatment in comparison with inpatient therapy. However, the comparison was carried out explicitly only for the costs and not for the effectiveness analysis. You should assess whether an inpatient treatment is currently used in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of the effectiveness used a prospective study with a hypothetical control, which was carried out in a single centre. A serious flaw was the lack of real control and implicit assumptions of the comparative effectiveness, which were not acknowledged by the authors.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis and the health outcomes were left disaggregated. The use of a benefit measure reflecting the patients' preferences for the interventions would have been useful.

Validity of estimate of costs
The analysis of the costs was carried out from the perspective of the hospital, and the categories of costs relevant to this perspective were included in the analysis. However, the costs of adverse effects and re-hospitalisation due to therapeutic failures were not included in the analysis. This could have substantially reduced the cost-savings associated with the intervention. The price year was not reported, thus hindering any reflation exercise to other settings. The costs were treated deterministically and sensitivity analyses were not carried out. The cost estimates were specific to the study setting. The unit costs were not reported for all of the cost items included in the analysis. These limitations reduce transparency and generalisability. It would have been interesting if the patient's and caregiver's indirect costs had been included.

Other issues
The authors made few comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out. Thus, the external validity of the analysis was quite low. A sample of patients suffering from osteomyelitis was enrolled in the study, and this was reflected in the conclusions of the analysis.

Implications of the study
The authors recommend the use of outpatient treatment of patients with osteomyelitis. They also recommend that future studies should take into account the costs related with adverse effects and re-hospitalisation. It should be noted that this study was largely uncontrolled and thus the conclusions, particularly in terms of the effectiveness, should be viewed with some caution.

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