A comparison of once-daily and 8-hour gentamicin dosing in the treatment of postpartum endometritis


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
Using gentamicin once-daily doses in patients with postpartum endometritis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Postpartum women with endometritis diagnosed on clinical finding of fever (either two oral temperatures greater than 38°C over a 4-hour period, or one temperature of 39°C or more) and the presence of uterine tenderness, in the absence of any other source of infection. Additional entry criteria were as follows: initial serum creatinine concentration of more than 1.4mg/dL, no history of renal insufficiency and no allergy to either of the drugs studied.

Setting
Hospital. The economic study was carried out in Chicago, Illinois, USA.

Dates to which data relate
The effectiveness and resource use data were collected between February 1991 and March 1993. The prices used were those prevailing in 1991-92.

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

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

Study sample
Power calculations were reported: the final sample size was sufficient to detect a difference of 11 hours of fever and 21 hours in length of stay, with a power of 0.8 and significance value of 0.05. A total of 142 patients was originally included in the study. After exclusion of 15 patients (10.5%) due to violation of the study protocol, the remaining 127 patients formed the final study sample. 62 patients with an average (SD) age of 27.7 (6.5) years were randomly included in the intervention group, and 65 patients, with an average (SD) age of 26.6 (7.1) years, were included in the control group.
Study design
This was a randomised controlled trial (double-blinded) carried out in a single centre. The duration of follow-up was until hospital discharge (i.e. a mean of 77.8 hours for the intervention group and 89.9 hours for the comparator group, once the fever had disappeared). Sealed opaque envelopes were used to assign patients between strategies and the randomization was performed by means of a computer-generated random number table. No loss to follow up was reported for the main analysis (only 106 patients had complete data for the pharmacokinetic analysis).

Analysis of effectiveness
The principle (intention to treat or treatment completers only) used in the analysis of effectiveness was not explicitly specified. The primary health outcome used was response rate. This was defined as the length of time the patient remained with fever (temperature above 37.4°C) after initiation of therapy. The post-treatment serum creatinine level and clinical ototoxicity and nephrotoxicity were among other clinical outcomes addressed in the study. The groups were shown to be comparable (no statistically significant differences found) in terms of age, weight, parity (primiparous or multiparous), private patients, race, labour characteristics and bacteremia at the start of therapy.

Effectiveness results
The mean duration of fever for patients in the intervention group was 20.8 (SD 14.8) hours, whereas for patients in the comparator group it was 23.7 (22.1) hours, (p>0.05). The post-treatment serum creatinine level (mg/dL) was 0.84 (SD, 0.19) in the single daily dose group versus 0.79 (0.21) in the 8-h dosing group. (NS). It was reported that no cases of clinical ototoxicity or nephrotoxicity were observed in either group.

Clinical conclusions
The intervention resulted in 'consistently high' peak serum levels of gentamicin and is as effective as the comparator in patients with postpartum endometritis.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic study, and only separate clinical outcomes were reported.

Direct costs
Costs were not required to be discounted due to the short time frame of the study. The quantities were reported separately. The only costs measured were pharmacy costs, (including the costs of drug, infusion bag, pharmacy technician, and pharmacists' time) while nursing time was also calculated as well as length of hospital stay. The cost boundary adopted was the hospital. The estimation of costs and quantities of resource use was based on actual data. The quantities were measured between February 1991 and March 1993. The source of unit costs for drugs was the institution's pharmacy acquisition costs for 1991-1992. The estimation of length of stay was obtained from patients with no readmission after discharge, whereas the estimation of nursing time was partly based on 'published standards'.

Statistical analysis of costs
Mean and standard deviations (SD) were reported. Unpaired Student’s t test was used to compare the groups in terms of costs and resources used.

Indirect Costs
Not considered.

Currency
US dollars ($).
Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean pharmacy costs were estimated to be $16.12 (SD, 5.68) for the intervention and $41.75 (SD 17.41), for the comparator, (p<0.001). The nurse time was 13.62 (SD 2.56) minutes for the intervention, and 28.06 (SD 8.77) minutes for the comparator, (p<0.001).

Synthesis of costs and benefits
Not performed.

Authors' conclusions
In patients with postpartum endometritis, once-daily gentamicin dosing provides consistently high peak serum levels of gentamicin, requires less nurse tasking time, costs less, and is as effective as the 8-hour dosing regimen.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear.

Validity of estimate of measure of benefit
The estimate of measure of effectiveness is likely to be internally valid given the randomised design adopted in the study. Since the study did not identify a summary benefit measure in the economic analysis, it may be regarded as a cost-consequences study.

Validity of estimate of costs
The resource quantities were reported separately from the prices and adequate details of methods used in the cost estimation were reported.

Other issues
The generalisability of the study results to other settings or countries was not discussed. However, comparisons with other studies were made in respect of the clinical study results. The results were not presented selectively.

Source of funding
Supported in part by an Amoco Foundation Award for Women's Health given through the Northwestern Memorial Foundation and by grants GM-47819 and GM-07842 from the National Institute of General Medical Sciences.

Bibliographic details

PubMedID
8649712

Original Paper URL

Indexing Status
Subject indexing assigned by NLM

MeSH
Adult; Anti-Bacterial Agents /administration & dosage /pharmacokinetics; Clindamycin /administration & dosage; Costs and Cost Analysis; Double-Blind Method; Drug Administration Schedule; Endometritis /drug therapy; Female; Gentamicins /administration & dosage /economics /pharmacokinetics; Humans; Puerperal Infection /drug therapy

AccessionNumber
21996000660

Date bibliographic record published
31/05/2000

Date abstract record published
31/05/2000