A randomized prospective comparison of antibiotic tissue levels in the corpora cavernosa of patients undergoing penile prosthesis implantation using gentamicin plus cefazolin versus an oral fluoroquinolone for prophylaxis

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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
Oral fluoroquinolones (ofloxacin) in penile prosthesis implantation.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Patients undergoing penile prosthesis placement or replacement. The exclusion criteria included the use of any antibiotics within 7 days of surgery or a known hypersensitivity to the medication.

Setting
Hospital, the economic study was carried out in Seattle, USA.

Dates to which data relate
The dates for effectiveness, resource costs data and prices were not clearly reported.

Source of effectiveness data
The evidence and estimates for final outcomes were derived from a single study.

Link between effectiveness and cost data
The costing was not undertaken on the patient sample used in the effectiveness study. Costing data were obtained from a retrospective review of billing records at the study hospital.

Study sample
20 consecutive patients were initially selected from a hospital and randomised (using national insurance numbers) into 2 treatment groups (10 each). No power calculations were stated. Average ages: oral 64.5 years (range: 52-72); intravenous 64.5 years (range: 57-72).

Study design
The study was a randomised controlled trial. Median follow-up was 16 months and no loss to follow-up was stated.
Analysis of effectiveness
The principle used in the analysis was not clearly stated. The primary health outcomes were tissue and serum levels, the number of surgical complications and adverse effects.

Effectiveness results
Wound complications were as follows:
Oral Group = 0, Intravenous Group = 2 (20%).
No implant infections occurred in either group.
Adverse effects were as follows:
Oral Group = 1 (10%), Intravenous Group = 0.
Mean serum/tissue levels (micrograms/ml) were as follows:
Ofloxacin = 2.75 (range: 0.4-4.2)/0.55 (range: 0.4-0.9) - serum to tissue ratio = 5.0,
Gentamicin = 2.6 (range: 1.7-3.8)/0.45 (range: 0-0.5) - serum to tissue ratio = 5.0,
Cefazolin = 24.5 (range: 21.5-76)/4.9 (range: 2.3-6.8) - serum to tissue ratio = 5.77.
The difference in mean serum-to-tissue ratios between ofloxacin and the combination of cefazolin and gentamicin had a p value < 0.03.

Clinical conclusions
There were no implant losses or reoperations, and complications were comparable in the 2 groups. Thus, oral ofloxacin was demonstrated to be as safe and effective as conventional parenteral antibiotics in the prevention of perioperative infection in penile prosthesis surgery.

Measure of benefits used in the economic analysis
Since the effectiveness study showed no difference in clinical benefit between groups, the economic analysis was based on the difference in costs only.

Direct costs
Some quantities were analysed separately from the costs. Operating costs (including unit, materials, labour and hospitalisation costs) and overhead costs were included in the analysis. The source of unit cost data was the billing department of the study hospital (government pricing data). The price year was not clearly reported. Cost of complications or adverse effects were not included in the analysis. Resource use data were based on the description of regimens rather than actual resource use data from a clinical study. The perspective used was that of the hospital.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.
Cost results
The per-patient cost was $23.20 for ofloxacin and $1,476.06 for the cefazolin-gentamicin-cephradine groups. (Estimated US-wide savings using 1994 data, $36,000,000).

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
Oral ofloxacin resulted in significant cost savings when administered on an outpatient basis for penile implant surgery while being as safe and effective as the standard parenteral strategy for penile prosthesis surgery. The authors believed that the study results warranted serious consideration of a change in conventional prophylaxis for penile prosthesis surgery from the routine use of parenteral antibiotics to oral fluoroquinolones.

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

Validity of estimate of measure of benefit
The estimate of measure of benefit is unlikely to be internally valid due to the small study size. It should be noted that the randomization procedure used in the study may not result in truly random allocation.

Validity of estimate of costs
Adequate details of cost estimation were provided, although the costing was not based on actual resource use consumption. Complication costs were not included in the analysis. The price date was not given.

Other issues
Assessment of the generalisability of the results would be difficult in the absence of price year(s), sensitivity analysis, better measures of benefit and power calculations for sample size.

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