The cost-effectiveness of terazosin and placebo in the treatment of moderate to severe benign prostatic hyperplasia


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
Terazosin in the treatment of moderate to severe benign prostatic hyperplasia.

Type of intervention
Treatment; palliative care.

Economic study type
Cost-effectiveness analysis.

Study population
Patients 55 years of age or older with a clinical diagnosis of BHP based on symptomatology and physical examination, including digital palpation of the prostate. They had a Symptom Index of the American Urology Association (AUA) Symptom Score >

Setting
Academic regional centres and community-based satellite centres. The economic study was carried out in the USA.

Dates to which data relate
The main effectiveness and resource use data were taken from sources dated 1992-93. Resource use was valued using 1992-93 prices.

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 study.

Study sample
A total of 2,084 patients was included in the study. Of these, 1,053 were randomised to terazosin and 1,031 to placebo treatment. It was not stated whether power calculation were used to determine the sample size. Patients were recruited by the clinical investigators from their usual patient population and in some cases advertisements in local newspapers and radio were used. The mean age was 65.7 years.

Study design
This was a double-blind randomised control study involving 141 satellite, community-based centres, and 15 regional centres. The duration of the follow-up was 12 months. Patients were randomised in blocks of 4 at each site. Only 96% of the 2,084 randomised patients were included in the analysis, all being those who had completed the baseline interview and at least one subsequent interview. Some patients were improperly randomised to the study groups (n=50 placebo, n=47 intervention), given the entry criteria stated above.

**Analysis of effectiveness**

The analysis of the clinical study was based on intention to treat. The primary health outcomes used in the analysis were the estimated changes in the disease-specific BPH functional status indicators from baseline and the time to treatment failure, total number of work days lost, total number of usual activity days lost and total number of days confined to bed. The groups were comparable in terms of age, racial distribution, education, employment status, income, insurance coverage, comorbid conditions, AUA Symptom Index scores, AUA Bother Index scores and AUA Quality of Life Index scores. Regional and satellite patients were comparable with respect to baseline characteristics.

**Effectiveness results**

Terazosin-treated patients had significantly greater improvement in symptomatology than patients in the placebo group, (p<=0.001). The mean difference in AUA symptom Scores (95% CI in brackets) was -3.9 (-4.55 to -3.3), -3.2 (-3.7 to -2.7) in the Bother Scores and -1.9 (-2.2 to -1.5) for disease-specific Quality of Life: all in favour of the intervention. The mean work days lost per month were estimated to be 0.40 in the placebo group and 0.44 in the terazosin group for a difference of 0.04 (-0.12 to 0.20), (p=0.61). A total of 89 patients underwent a surgical procedure for BPH during the study. For days of customary activity lost per month, the means were estimated to be 1.02 in the placebo group and 0.91 in the terazosin group for a difference of -0.10 (-0.39 to 0.18), (p=0.48). For bed days per month, the mean was 0.37 in the placebo group and 0.33 in the terazosin group for a difference of -0.04 (-0.18 to 0.11), (p=0.61).

**Measure of benefits used in the economic analysis**

The measure of benefits was improvement in terms of Symptom, Bother and quality of life scores. The benefits were measured as presented in the analysis of results of the clinical study.

**Direct costs**

Some major quantities were analysed and presented separately from the costs. Costs were not discounted as the study covered a time period of one year. The cost elements included were operating health care resource utilisation (outpatient and inpatient, including professional fees and prescription medication use) and adverse events. The quantity/cost boundary adopted was that of the managed care organisation. The date to which the price data refer was 1992-93. Protocol-driven costs (costs of eight office visits required to evaluate patients and to titrate terazosin patients on active drug) were excluded from the base-case analysis.

**Statistical analysis of costs**

Ninety-five percent confidence intervals (95% CI) and two-way repeated measures ANOVA with interaction were used to analyse the cost data.

**Currency**

US dollars ($).

**Sensitivity analysis**

A one-way sensitivity analysis was carried out exploring the effects on the results of the inclusion of copayments, deductibles and coordination of benefits and protocol-driven costs, among other variables.
Estimated benefits used in the economic analysis
All three disease-specific functional status scores improved significantly more in the terazosin group than in the placebo group. The mean difference in improved AUA symptom Scores was -3.9, -3.2 in Bother Scores and -1.9 for disease-specific Quality of Life: all in favour of the intervention.

Cost results
Total payments for health care resources adjusted to reflect 1,000 patients per treatment group were $3,568,263 in the terazosin group and $3,781,803 in the placebo group. The ANOVA analyses yielded a total cost per patient of $3,404 and $2,932 for the placebo and terazosin groups respectively (difference $472, 95% CI: -254 to 1,197), (p=0.19).

Synthesis of costs and benefits
The costs and benefits were not combined since the intervention turned out to be the dominant strategy.

Authors' conclusions
Compared with placebo, terazosin therapy for moderate to severe symptomatic BPH results in approximately equivalent payments for direct medical care, better disease-specific functional status improvement, and comparable change in non-disease-specific functional status measures.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used.

Validity of estimate of measure of benefit
The authors discussed the validity-related problems of the effectiveness study results generated by the patients who withdrew from blinded study drug treatment (n=100 placebo and n=70 in the intervention); the conclusions are unlikely to be affected by such problems. The effects of erroneous randomisation of ineligible patients was not discussed, although such patients were included in the analysis under the intention-to-treat principle.

Validity of estimate of costs
Adequate details of costs were given and major quantities of resource use were analysed separately. Indirect costs were not included in the costing after the statistical analysis showed them not to be different at a statistically significant level.

Other issues
Appropriate comparisons were made with other studies. The study results were considered to be more likely generalisable to other settings than previous studies. The conclusions were found to be robust at one-way sensitivity analyses.

Implications of the study
The study presents evidence on the efficiency of using terazosin for the treatment of moderate to severe benign prostatic hyperplasia.

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