Cost-effectiveness of duloxetine: the Stress Urinary Incontinence Treatment (SUIT) study
Mihaylova B, Pitman R, Tincello D, van der Vaart H, Tunn R, Timlin L, Quail D, Johns A, Sculpher M

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.

CRD summary
The objective was to assess the cost-effectiveness of duloxetine compared with conservative therapy for women with stress urinary incontinence. The authors concluded that, although there were limitations due to the use of observational data, duloxetine therapy seemed to be cost-effective. The methods were good, and they and the results were reported sufficiently. The authors' conclusions appear to be appropriate, given the limitations of the data.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective was to assess the cost-effectiveness of duloxetine, compared with conservative therapy, in women with stress urinary incontinence.

Interventions
The four options were duloxetine alone, duloxetine with conservative therapy, conservative therapy alone, and no treatment. The conservative therapy included treatments, such as lifestyle interventions or pelvic floor muscle training.

Location/setting
UK/primary care.

Methods
Analytical approach:
The economic analysis was conducted alongside the Stress Urinary Incontinence Treatment (SUIT) study (van der Vaart, et al. 2010, see 'Other Publications of Related Interest' below for bibliographic details). The time horizon was one year. The authors reported that the perspective was that of the health care system, including the costs of protective materials paid by the patients. The analysis included women who were not undergoing any treatment for stress urinary incontinence at baseline, and who were undergoing one of the four options at three months.

Effectiveness data:
The effectiveness data were from the SUIT study. This was a prospective, observational, naturalistic, multicentre, multicountry (UK, Ireland, Germany, and Sweden) study. Multivariate regression and three methods of propensity score matching were used to account for any selection bias. A total of 1,510 patients were analysed, with 394 (26%) receiving duloxetine alone; 212 (14%) receiving duloxetine plus conservative therapy; 623 (41%) receiving conservative therapy alone; and 281 (19%) receiving no treatment. These patients were followed-up for one year. The main clinical effectiveness estimate was the number of leaks avoided per week. A multivariate multiple-imputation framework was developed to impute the missing baseline and outcome data.

Monetary benefit and utility valuations:
The utilities were derived directly from the trial population, using the European Quality of life (EQ-5D) questionnaire at baseline and at each follow-up visit (three months, six months, and one year). These were weighted using a set of valuations from the general UK population.

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs).
Cost data:
The direct costs included visits to health care professionals, diagnostic procedures, pharmacological treatments, conservative treatment, and protective materials, for stress urinary incontinence. The resource use for these categories was collected in the study using case-record forms. The SUIT study was multinational, but the resources were valued using UK unit costs and these were reported in an appendix. All costs were updated to 2007 prices, using the Hospital and Community Health Services (HCHS) pay and price index. Multivariate regression and propensity score matching were used to account for any selection bias. All costs were reported in UK pounds sterling (£).

Analysis of uncertainty:
No sensitivity analyses were conducted, but the incremental cost-effectiveness ratios (ICERs) were presented for each of the three propensity score methods.

Results
There were no statistically significant differences in costs between any of the interventions. There were no significant differences in the QALYs gained between conservative therapy and no treatment; and between duloxetine and duloxetine plus conservative therapy. With duloxetine, the QALYs gained were 0.027 compared with no treatment, and 0.031 compared with conservative therapy. With duloxetine plus conservative therapy, they were 0.025 compared with no treatment, and 0.030 compared with conservative therapy.

The incremental cost per QALY gained varied depending on the propensity score matching method, as did the probability that this ratio was below the cost-effectiveness threshold of £20,000.

There was a low probability that conservative therapy was cost-effective compared with no treatment, ranging from 0.28 to 0.35, with ICERs from £2,970 to £6,379. There was a high probability that duloxetine treatment was cost-effective compared with no treatment, ranging from 0.86 to 1.00 and that it was cost-effective compared with conservative therapy, ranging from 0.91 to 1.00. The probability that duloxetine treatment was cost-effective compared with duloxetine plus conservative therapy ranged from 0.54 to 0.59.

The probability that duloxetine treatment plus conservative therapy was cost-effective compared with no treatment ranged from 0.74 to 0.92, and compared with conservative therapy it ranged from 0.68 to 0.99.

Authors’ conclusions
The authors concluded that, although there were limitations due to the use of observational data, duloxetine therapy for stress urinary incontinence seemed to be cost-effective.

CRD commentary
Interventions:
The interventions were reported clearly.

Effectiveness/benefits:
The effectiveness data were from a prospective observational cohort study. As the authors acknowledged, this study design is prone to selection bias, but they appear to have adequately controlled for this, using multivariate regression and propensity score matching. Any differences in baseline characteristics that were not measured could not be controlled for in this way, while randomisation could avoid these differences. QALYs were an appropriate benefit measure given the impact of incontinence on quality of life.

Costs:
All the relevant major cost categories and costs, for the health care and patient perspective, appear to have been analysed. The methods used to derive the resource use and the sources for the unit costs were reported. The details of the unit costs, their sources, and the resource use were provided in an appendix. The costs were from the UK and the resource use and outcome data were from all four countries, but the multivariate regression found no statistically significant interactions between country of residence and treatment cohort for the QALYs and costs. The price year, currency, and time horizon were reported. The costs were not discounted as the time horizon was one year.
Analysis and results:
The costs and benefits were synthesised, using an incremental cost-utility ratio, but only the incremental QALYs were reported and no absolute values. Adequate statistical analyses were undertaken, and the potential impact of missing data on the results was tested using multiple imputation methods. Both the methods and the results were reported sufficiently. The main limitation was that effectiveness data were from a cohort study rather than a randomised controlled trial, but appropriate statistical techniques were used to control for any selection bias.

Concluding remarks:
The methods were good, and they and the results were reported sufficiently. Given the limitations of the design of the source study, as acknowledged by the authors, their conclusions appear to be appropriate.

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