Cost-effectiveness of ursodeoxycholic acid therapy in primary biliary cirrhosis

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
Ursodeoxycholic acid therapy in primary biliary cirrhosis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with PBC.

Setting
The setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness data were collected from studies published between 1991 and 1996. Resource use data were based on profiles derived from expert opinion and 1994 data from the National Institute of Diabetes and Digestive and Kidney Disease. Cost data were collected from 1995 sources. The price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a literature review.

Modelling
A model was used to estimate the cost-effectiveness of PBC. The type of model was not specified.

Outcomes assessed in the review
The review assessed the relative risk of major events and disease scores.

Study designs and other criteria for inclusion in the review
Effectiveness data were collected from a multi-centre, randomised, double-blind, placebo-controlled Mayo trial and a Canadian, randomised, double-blind, placebo-controlled trial.

Sources searched to identify primary studies
Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
At least six primary studies were included.

Methods of combining primary studies
Primary studies were combined using the narrative method. Data on annual incidence rates per 100 person-years were combined and reported as incidence rates and relative risks (RR) with 95% confidence intervals.

Investigation of differences between primary studies
Poisson regression was performed to determine if differences in incidence rates were statistically significant.

Results of the review
The Mayo risk score was similar in both UDCA and placebo patients, although the patients in the Mayo study had a higher Mayo risk score than the Canadian group (5.2 +/- 1.1 versus 4.5 +/- 1.3, p<0.01).

The relative risk of ascites in the placebo group compared with the UDCA group was 1.74, (95% CI: 0.79 - 3.8, p=0.17).

The relative risk of varices was 3.11, (95% CI: 1.57 - 10.65, p=0.0039).

The relative risk of variceal bleed was 1.24, (95% CI: 0.49 - 3.15, p=0.65).

The relative risk of encephalopathy was 2.41, (95% CI: 0.98 - 10.75, p=0.055).

The relative risk of orthotopic liver transplantation was 1.95, (95% CI: 1.14 - 3.68, p=0.017).

The relative risk of death was 1.7, (95% CI: 0.94 - 3.11, p=0.08).

Measure of benefits used in the economic analysis
Life years gained were used as the measure of benefits.

Direct costs
Direct costs were not discounted despite being incurred over a four year period. Quantities and costs were reported separately. Direct costs reflected management costs of major events including costs of medications, and costs of hospitalisation. The quantity/cost boundary adopted was that of the hospital. The estimation of quantities and costs was based on actual data. Costs of medications were based on 1995 average wholesale prices. Costs of hospitalisation were based on Medicare Diagnosis Related Groups reimbursement rates and physician fees obtained from the Medicare Fee Schedule. Costs of UDCA were based on the Drug Topics Red Book and on the cost of drugs from a random survey of 10 pharmacies in the USA. The price year was 1995.
Indirect Costs
Indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were performed to determine threshold values for variables in the model that would result in cost savings. These variables included the incidence of major events, morbidity costs, and the costs of liver transplantation.

Estimated benefits used in the economic analysis
Survival free of liver transplantation at the end of 4 years was 82.8% in the UDCA group and 62.7% in the placebo group, (p=0.03). Survival with liver transplantation was 90.5% in the UDCA group and 83.8% in the placebo group, (p=0.11). The effectiveness of UDCA on gain in life was 0.18 years per patient.

Cost results
Total annual costs per patient were $6,621 in the UDCA group and $7,993 in the placebo group.

Synthesis of costs and benefits
UDCA is the dominant strategy because it not only saves lives, and reduces morbidity, but also saves money. These results were not sensitive to changes in the incidence of major events, morbidity costs, or costs of liver transplantation.

Authors’ conclusions
Compared with the placebo group, patients receiving UDCA had a lower incidence of major complications and lower medical care costs.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used namely no therapy. You, as a user of the database, should decide if these health technologies are relevant to your own setting.

Validity of estimate of measure of benefit
The authors did not state that a systematic review of the literature had been undertaken and more details could have been provided about the review methods and search strategies used. The estimate of benefits was obtained directly from the effectiveness analysis. The authors adopted conservative morbidity estimates and did not include quality adjustments associated with complications.

Validity of estimate of costs
All relevant cost categories were included. Quantities and costs were reported separately. Sensitivity analyses were conducted on costs and on quantities. Charges were used to proxy costs. The price year was reported. No costs were assigned to death. The beneficial economic impact of UDCA was likely to be under-estimated as the authors acknowledged. Costs referred to a 4 year time period, but they do not appear to have been discounted.

Other issues
The authors made appropriate comparisons of their findings with those from other studies, but did not address the issue of generalisability to other settings. The authors did not present their results selectively. The study considered patients
with PBC and this was reflected in the authors' conclusions. The authors noted that the efficacy of UDCA demonstrated in randomised studies may not necessarily translate into effectiveness in the community setting.

**Implications of the study**
The authors recommend UDCA as a safe, effective, and highly cost-effective therapy for patients with PBC that actually reduces the cost of medical care for these patients.

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None stated.

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**Other publications of related interest**


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