Concentrated ascitic fluid reinfusion in cirrhotic patients: a simplified method

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
Filtration and reinfusion of concentrated ascitic fluid using a Cuprophan dialyzer and a roller pump for patients with cirrhosis of the liver.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients with tense, repetitive or refractory ascites caused by liver cirrhosis. There were 8 men and 9 women and they had a mean age of 56.2 years. Seven of the patients had hepatitis C virus infection-induced cirrhosis. The remaining 10 patients had alcohol-induced cirrhosis.

Setting
All procedures were undertaken in a clinical research room in a dialysis unit in Madrid, Spain. The economic evaluation was conducted by clinicians in the same unit.

Dates to which data relate
The study took place over an unstated 12 month period. The dates of both resources used and prices were not reported.

Source of effectiveness data
Evidence for the final outcomes was 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
The sample population included patients with cirrhosis and massive ascites. The cause of the cirrhosis differed, 10 of the patients had alcohol-induced cirrhosis and 7 of the patients had hepatitis C virus-induced infection. No power calculations were used to determine sample size. In total there were 17 patients with no control group. The 17 cirrhosis patients were monitored in terms of clinical and biochemical parameters. Also a group of 10 control patients, who remained in the hospital for reasons other than ascites drainage, was monitored for a 6 day period. The authors did not justify the choice of patient sample. Exclusion criteria included any clinical or bacteriological evidence of ascites infection, fever of unknown origin, presence of encephalopathy (grade I or more), progressive or severe renal failure.
(serum creatinine > 3.5 mg/dL or evidence of daily increment of creatinine of 0.5 mg/dL or more), recent major bleeding and finally, the presence of neoplastic cells or more than 300 leukocytes/mm3 with a predominance of neutrophils.

**Study design**
This was a prospective cohort study. The study was single centred and the patients were followed up for 12 months.

**Analysis of effectiveness**
The analysis of the study was based on intention to treat (but this was not stated). The primary health outcome was successful performance of the drainage/reinfusion procedure and improvement in the subjective symptoms of all the patients.

**Effectiveness results**
Over 12 months, 31 drainage and reinfusion procedures were performed. Although partial clogging of the capillaries occurred in 4 of the sessions, these technical problems were not considered important because the clogging did not preclude completion of the ultrafiltration procedure in 2 of the cases and the other 2 required the use of a new filter. In the intervention group one patient died of sepsis and multiorganic failure. As the authors stated, it is not known whether this patient developed fever as a consequence of ascitic fluid reinfusion procedure-related manipulations, as the patient also had simultaneous intravenous and bladder catheterizations. The same patient had already successfully undergone 3 sessions of drainage/reinfusion. There were no statistically significant changes in clinical and laboratory data that were taken before and after treatment.

**Clinical conclusions**
The findings supported the hypothesis that ascites filtration and reinfusion is a safe, effective and easily performed procedure to treat tense ascites in patients with cirrhosis.

**Modelling**
No modelling was undertaken.

**Measure of benefits used in the economic analysis**
Benefits were evaluated in terms of the success of ascites filtration and reinfusion over the year period covered. No model was used. Health state was measured by physiological response involving hematologic and biochemical tests and changes in the subjective symptoms of patients. Clinicians assessed the health states. Clinical and biomedical parameters were measured early on the day of the procedure and 24 hours later for the patient sample and over a 6 day period for the controls.

**Direct costs**
Costs were not discounted. Costs were reported but not quantities. The costs of the materials used for ascites drainage and reinfusion were given. The cost boundary adopted was not stated explicitly but a health service perspective seems likely. Quantities used were based on actual data, as were costs. No date for price data was given. Although the authors did state the cost of the roller pump and the cost of health professional’s time, they did not include these in the overall cost evaluation, justifying this by saying that these cost components were common to other alternative treatments.

**Statistical analysis of costs**
No statistical analysis was conducted on quantities of resources used or costs.
Indirect Costs
No indirect costs were included.

Currency
Although the study took place in Spain, costs were converted to dollars. As the paper was published in the "American Journal of Kidney Diseases", it seems likely that the currency was US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
In the economic analysis, the benefits of using the Cuprophan filter were considered to be similar to other methods of ascites filtration and reinfusion. No estimated benefit was given.

Cost results
The total intervention cost for the equipment used was reported to be $49.47. In comparison, the cost of the polyamide haemofilter for ascites filtration and concentration was considered to be at least five times more expensive. No discount rate was used.

Synthesis of costs and benefits
The authors reported costs savings of around $266 ($315-$49) per successful ascites drainage and reinfusion using the Cuprophan filter technique.

Authors' conclusions
The authors concluded that the use of a Cuprophan filter was cost-saving.

CRD COMMENTARY - Selection of comparators
The authors compared the Cuprophan filter technique for the ascitic fluid reinfusion with other methods involving ascites drainage. However, the choice for the economic comparison was a polyamide haemofilter.

Validity of estimate of measure of benefit
The benefits were measured in terms of haematologic and biochemical tests as well as the absence of discomfort and major complications. The analysis was not very rigorous and there were no controls for chance, bias and confounding. The trial took place over a 12 month time frame. Given that dialysis for these patients may take place over a much longer time frame, results may not give an accurate representation of effectiveness over an extended time period.

Validity of estimate of costs
Resource quantities were not reported separately from prices. Whilst the authors concluded that the Cuprophan filter technique was cost-saving, the economic evaluation was not very detailed. Whilst a number of different issues are raised, such as time-saving measures and their cost implications, the analysis requires more depth.

Other issues
More detailed economic evaluation is required for any economic results to be drawn from this study. The issue of generalisability was not addressed. Comparisons with other studies were made but the basis for these comparisons is not clear so that it is not possible to draw tight conclusions. More research into this area is required.
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Other publications of related interest

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