Prevention of peritonitis with disconnect systems in CAPD: a randomised controlled trial

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
The Y set system and twin bag system (two different dialysis systems) for preventing peritonitis in patients on continuous ambulatory peritoneal dialysis (CAPD) and at high risk for developing peritonitis were investigated.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study sample were patients with end-stage renal disease (ESRD) without any previous replacement therapy who were treated with CAPD and who were of low educational and socio-economic levels, and had high prevalence of malnutrition. Patients with previous abdominal surgery, abdominal hernias, diverticulosis, cancer or AIDS were excluded.

Setting
The economic analysis was carried out in Mexico.

Dates to which data relate
Dates to which data relate were not given.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

Link between effectiveness and cost data
Costing appears to have been performed prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. A total of 154 patients entered the randomisation phase, and 147 began the study. 29 patients were assigned to the conventional group with a mean (SD) age of 39.7 (19) years, 57 patients were assigned to the Y system group with a mean (SD) age of 43.2 (21.3) years, and 61 patients to the twin bag group with a mean (SD) age of 43.6 (21.9) years.
Study design
This was an open, randomised, controlled trial, carried out in 11 centres. The average duration of the follow-up was 11.3 months. Ten patients dropped out of the study because they received a renal allograft. Another 23 died, 8 due to technique failure, and 11 from miscellaneous causes. There were no significant differences in drop out or deaths across the groups. The patients were randomised in the three study groups in a ratio of 1:2:2 to the conventional straight-line spike system, the Y set system or the twin bag system. This randomisation ratio was also maintained within each centre. The allocation of the patients to the groups was carried out centrally with the use of a list of random numbers. The order of allocation was sent to each participant centre in sealed envelopes. Trained nurses had at least three audit visits to each participating centre to certify compliance with the order of allocation. A straight double-cuff Tenckhoff catheter was placed in every patient. The implantation technique was that preferred in each participating centre, but the same technique was used in all the patients within each centre. The patients were seen every two months at scheduled visits, but they were allowed to attend spontaneously at any moment, if dialysis related problems occurred.

Analysis of effectiveness
The principle used in the analysis of effectiveness appears to have been treatment completers only. The primary end points were the peritonitis rate, and the rate of exit site and/or tunnel infection. Peritonitis-free survival to the first and second episodes of peritonitis was also measured. In addition, peritonitis-related hospitalisation was reported. The time of first and second peritonitis-free survival was analysed by Kaplan-Meier curves with the log-rank test. A multiple logistic regression was performed to control for covariates. The incidence of peritonitis was analysed with a Poisson-based regression using the mixed-effects gamma-Poisson model. The groups were comparable in terms of age, gender, and frequency of diabetes mellitus. A high prevalence of malnutrition was found, with no differences across the three groups.

Effectiveness results
There were 55 peritonitis episodes in 20 patients from the conventional group, 57 episodes in 35 patients from the Y system group (p<0.01 versus conventional), and 26 episodes in 18 patients from the twin bag group (p<0.01 versus conventional; p< 0.01 twin bag system versus Y system). Average peritonitis-free intervals were 6.1, 12, and 24.8 months, respectively (p<0.01 for pairwise comparisons). Kaplan-Meier survival analysis of first peritonitis-free intervals showed that the twin bag group had a longer survival than the conventional and Y system groups, (p<0.001). No differences were found between the conventional group and the Y system group. Kaplan-Meier survival analysis of second peritonitis-free intervals showed that the conventional group had a significantly shorter survival than the Y system group (p<0.001), and the Y system group had a significantly shorter survival than the twin bag group, (p<0.025).

There were 58 episodes of exit site tunnel infections, 23 of these being simultaneous with peritonitis episodes, and the causal agent was identified only in a few cases. Thirty-six catheters were replaced: 8 in the conventional group, 14 in the Y system group, and 14 in the twin bag group. These numbers were not significantly different. In six cases tunnel infection was the cause of catheter loss: 3 in the conventional group, 2 in the Y system group, and 1 in the twin bag group. There were no statistical differences among these. The mean (SD) peritonitis-related hospitalisation was 5.3 (2) days/patient/year in the conventional group, 2.7 (1) days/patient/year in the Y system group, and 1.5 (0.9) in the twin bag group, (p<0.01 for pairwise comparisons).

Clinical conclusions
The study results show a considerable advantage of the Y set system and more especially of the twin bag system over the conventional system, for preventing peritonitis in patients on CAPD. The difference in efficacy of the disconnect systems in preventing peritonitis was still evident in spite of the presence of risk factors such as malnutrition, diabetes, and unfavourable socioeconomic conditions.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.
Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Some quantities were reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of dialysis materials, hospitalisation, and antibiotics. The perspective adopted appears to have been that of the hospital. The hospitalisation costs were calculated using the index of "cost per bed per day" developed by the Instituto Mexicano del Seguro Social (IMSS). The commercial price of the dialysis materials was used in the cost analysis. The actual purchasing prices were considered for the antibiotic costs. The price year was not explicitly specified. The cost analysis did not cover the costs of physician or other health care personnel, nor did it include the costs of other treatments not related to peritonitis since these were considered to be common among the study groups.

Indirect Costs
Indirect costs were not considered.

Currency
Mexican pesos. No conversion was made to other widely used currencies.

Sensitivity analysis
Sensitivity analysis was not conducted.

Estimated benefits used in the economic analysis
These were not applicable.

Cost results
The total costs of treatment (pesos/patient/year) were lower for twin bag: Peso 62,159 for the conventional, Peso 70,275 for the Y system, and Peso 54,387 for the twin bag. This was due to its lower peritonitis incidence and associated hospitalisations.

Synthesis of costs and benefits
Costs and benefits were not combined since the use of the twin bag system was the dominant strategy.

Authors' conclusions
Y system and twin bag use was associated with a reduction of 50% and 75% in peritonitis incidence, respectively, in patients on CAPD. The cost of the twin bag was actually lower, because of savings from a decreased usage of antibiotics and fewer hospitalisations.

CRD COMMENTARY - Selection of comparators
A justification was given for the choice of the comparator (the straight-line spike system). It was the conventional dialysis system used in the context in question. You, as a database user should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness results are likely to be internally valid given the randomised nature of the study design. However, power calculations were not performed and no analysis was conducted to investigate the possible differences among the participating centres. Intention to treat analysis does not appear to have been performed. The groups were comparable in terms of age, gender, and frequency of diabetes mellitus. A high prevalence of malnutrition was found, with no differences across the three groups. Adjustments were made for the effects of covariates. The study sample appears to
have been representative of the study population.

**Validity of estimate of measure of benefit**
The authors did not derive a measure of health benefit. The study may therefore be regarded as a cost-consequences analysis.

**Validity of estimate of costs**
Some quantities were reported separately from costs and adequate details of the methods of cost estimation were given. It appears that all relevant direct cost categories were included in the cost analysis. Hospitalisation costs were not based on cost per patient, but on an index of "cost per bed per day", which was deemed to be one of the limitations of the cost analysis. The effects of different procedures on indirect costs were not addressed. Statistical analyses do not appear to have been performed on cost data. The price year was not specified. Cost results may not be generalisable to other settings or countries.

**Other issues**
Sensitivity analyses were not used to account for the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed although appropriate comparisons were made with other studies. The study sample was representative of a high-risk population with low educational and socio-economic levels, and a high prevalence of malnutrition, and this was acknowledged in the authors' comments.

**Implications of the study**
The authors stated that "The reduction in the peritonitis rate itself is sufficient to justify the use of the new systems, but in the longer term it may have enormous importance, because repeated infections may reduce the capacity of peritoneum for dialysis." There is not enough current data to measure the impact of this effect, but the authors consider it highly important given the limited availability of hemodialysis and transplantation in Mexico.

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