Clinical effectiveness and costs of the Sugarbaker procedure for the treatment of pseudomyxoma peritonei

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CRD summary
This review assessed the effectiveness of the Sugarbaker procedure for the treatment of pseudomyxoma peritonei. The authors concluded that the evidence was of poor quality, but that there was some evidence of benefit with the procedure. This was a well-conducted review and the authors' conclusions are likely to be reliable, though better quality studies are required.

Authors' objectives
To assess the clinical and cost-effectiveness of the Sugarbaker procedure for pseudomyxoma peritonei (PMP).

Searching
Twelve electronic databases including MEDLINE, EMBASE and the Cochrane Controlled Trials Register were searched to April 2004 for studies reported in English; the search terms were reported. In addition, the reference lists of relevant papers were checked and experts were contacted.

Study selection
Study designs of evaluations included in the review
The highest level of evidence available was sought. Only case series were identified.

Specific interventions included in the review
Studies of traditional surgery involving debulking resection of all gross disease, cytoreductive surgery combined with chemotherapy or cytoreductive surgery combined with heated adjuvant intraperitoneal chemotherapy (IPEC), known as Sugarbaker procedure, were eligible for inclusion. All of the included studies were of cytoreductive surgery. In one of the included studies cytoreduction was combined with IPEC (mitomycin C (MMC) and 5-fluorouracil (5-FU)), in two with hyperthermic IPEC (MMC), in one with IPEC and intravenous chemotherapy, and in one with IPEC early after surgery (MMC and 5-FU) plus three cycles of adjuvant systemic MMC and IPEC with 5-FU.

Participants included in the review
Studies of people diagnosed as having PMP were eligible for inclusion. The PMP diagnosis had to be characterised by histologically benign tumours with indolent course originating in the appendix. Studies of patients with peritoneal carcinomatosis and hybrid variants were excluded. Some patients in the included studies did not meet the inclusion criteria for the review based on histological or cytological diagnosis, and these patients were not included in the synthesis.

Outcomes assessed in the review
Studies reporting survival, recurrence or quality of life as primary outcomes, and complications as secondary outcomes, with a minimum length of follow-up of 2 years, were eligible for inclusion. The included studies varied in the outcomes reported, though they all reported survival. Where reported, the mean length of follow-up ranged from 62 to 104 months.

How were decisions on the relevance of primary studies made?
One reviewer assessed studies for relevance and a second reviewer checked the assessment. Any disagreements were resolved through discussion.

Assessment of study quality
The studies were quality assessed using criteria from CRD Report 4. Consideration was given to whether: a representative sample was used; explicit inclusion criteria were used; individuals entered the study at a similar point in their disease progression; follow-up was long enough for events to occur; objective criteria were used to assess outcomes or whether blinding was used; and whether there was a sufficient description of any subseries and the distribution of prognostic factors. One reviewer quality assessed the studies and a second reviewer checked the assessment. Any disagreements were resolved through discussion.

Data extraction
One reviewer extracted the data and a second reviewer checked the extraction. Any disagreements were resolved through discussion.

Methods of synthesis

How were the studies combined?
The studies were combined in a narrative and in tabular format.

How were differences between studies investigated?
Differences between the studies were discussed and reported in tabular format. To investigate the potential impact of clinical experience, studies led by the clinician who developed the technique were compared with the other studies.

Results of the review
Five retrospective case series of 390 participants were included.

The retrospective case series were generally of a poor quality. Most of the quality criteria were either not met or it was unclear whether they were met.

Two-year survival with the Sugarbaker procedure was 91% (1 study), 3-year survival ranged from 81 to 90% (3 studies), 5-year survival ranged from 75 to 86% (3 studies), and 10-year survival ranged from 60 to 68% (2 studies). At the end of follow-up, between 41 and 70% of patients had no evidence of disease (3 studies). Death due to disease was reported as 2% (median length of follow-up 12 months) to 31% (mean length of follow-up 96 months). Commonly reported complications were anastomotic leaks, fistula formation, wound infection, small bowel perforations or obstructions, and pancreatitis. The authors stated that when compared with an estimated 5- and 10-year survival of 50% and 18%, respectively, with PMP, there appeared to be some benefit with the Sugarbaker procedure.

Cost information
Economic evaluations were sought but none were identified. A Monte-Carlo simulation model was used to estimate the marginal cost of providing the Sugarbaker technique rather than standard treatment for PMP. One poor-quality U.S.-based study, together with UK unit price data and expert opinion, was used to populate the model. The cost for one patient over a maximum of 5 years was estimated to be £9,700 (standard deviation 1,300).

Authors’ conclusions
Evidence of the effectiveness of the Sugarbaker procedure was limited in quantity and quality, but suggested that there may be some benefit for patients. The economic costs were only an example of the likely costs of the procedure, given the lack of information about the current alternative.

CRD commentary
This review addressed a clear research question using defined inclusion criteria. Appropriate sources were searched for published and unpublished studies. Only English language studies were included, therefore some relevant studies might have been missed. The review methodology was well described and included measures to avoid the introduction of bias. The quality of the included studies was assessed and their limitations discussed. Relevant details of the individual studies were provided and the use of a narrative synthesis was appropriate. The authors’ conclusions are appropriate.
Implications of the review for practice and research
Practice: The authors stated that several practical barriers to implementation would need to be considered if additional specialist centres were established in the UK. These included training of staff, the skills-mix required and maintaining skills levels.

Research: The authors stated that research to compare the effectiveness of the Sugarbaker procedure with standard debulking using different adjuvant treatments, as well as research assessing the effectiveness of treatments for patients with residual disease following maximal efforts at cytoreduction, is required. High-quality prospective cohort studies with economic evaluations were recommended.

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