

Statement from the Regional HTA Centre of the Western Region in Sweden

TREATMENT OF PSEUDOMYXOMA PERITONEI

The Regional Health Technology Assessment Centre (HTA-centrum) of the Western Region in Sweden (Region Västra Götaland, VGR) has the task to make statements on HTA reports carried out in VGR. The statement should summarise the question at issue, level of evidence, efficacy, risks, and economical and ethical aspects of the particular health technology that has been assessed in the report.

Ulf Angerås, Head of Department of Surgery, Östra Hospital, Sahlgrenska University Hospital, Göteborg, Sweden, requested the present HTA.

A working group under the chairmanship of Michael Breimer, MD, professor, Department of Surgery, Sahlgrenska Academy at Göteborg University, Sahlgrenska University Hospital, Göteborg, Sweden produced the HTA report. The other member of the working group was Fredrik Brorson, MD, Department of Surgery, Alingsås Hospital, Alingsås, Sweden.

The participants from the HTA centre were Ola Samuelsson, MD, PhD, Annika Strandell, MD, PhD, Eva-Lotte Daxberg, librarian, and Eva Alopau, chief librarian.

Birgitta Archenholtz, PhD, Sahlgrenska University Hospital, and Joacim Stalfors, MD, PhD, Department of Otolaryngology, Sahlgrenska University Hospital, Göteborg, Sweden, have critically appraised the report.

The project lasted during the time period 2009-04-15 – 2009-12-09.
The literature search covered the time up to September 2009.

Question at issue:

Does complete cytoreduction combined with heated intraoperative intraperitoneal chemotherapy (Sugarbaker procedure) lead to a better survival than usual treatment (chemotherapy i.v. and debulking surgery) in patients with pseudomyxoma peritonei?

PICO:

- P = Patients with pseudomyxoma peritonei
I = Peritonectomy combined with hyperthermic intraperitoneal chemotherapy (CRC+HIPEC; the Sugarbaker procedure)
C = Chemotherapy i.v. and debulking surgery
O = Primary outcome
Mortality, at least one year survival or more
Secondary outcomes
1. Quality of life 2. Time to progress 3. Time to “treatment failure” 4. Progression-free survival 5. Complications 6. Adverse effects 7. Toxicity

Summary of the health technology assessment:

Method and patient category:

Pseudomyxoma peritonei (PMP) is a rare and slowly progressive disease of a tumour arising from the appendix of colon. The tumour cells spread throughout the peritoneal cavity and produces large amounts of mucus. The large quantities of mucinous material produced over several years will eventually obliterate the peritoneal cavity and cause intestinal obstruction with finally fatal outcome. The treatment is surgical reduction of as much tumour mass as possible (debulking surgery). The current method for evaluation is peritonectomy with complete cytoreduction combined with heated intraoperative intraperitoneal chemotherapy, the so-called, Sugarbaker procedure.

Level of evidence:

The systematic literature search identified one British HTA-report from 2004, and case series from 15 highly specialised surgical centres, which have reported long-term survival. The natural course of PMP without any kind of intervention has not been documented.

There has been no randomised or non-randomised controlled trial, or any observational study, which have compared the Sugarbaker procedure with any other kind of intervention or no intervention at all.

The case series are heterogeneous with regard to histopathology of PMP, stage of disease progression, and additional treatment to the Sugarbaker procedure. Centres, which have followed patients for 5 years or longer, report a 5-year survival rate of 52 – 94 %. Those with 10 years follow-up report a 10-year survival rate varying between 36 –85 %.

The level of evidence with regard to survival according to the GRADE system is ⊕000, i.e. insufficient.

Risks

The Sugarbaker procedure is associated with a high rate of complications. The 30-day mortality has been reported to be as high as 7.6 %. Postoperative complications are reported to occur in up to 70 % of all patients, and 30 % are considered as being serious.

Ethical aspects:

Is it acceptable to offer a highly specialised and expensive treatment in selected patients when the level of evidence is insufficient and the risk of complications is substantial?

Economical aspects

The cost per patient can be very high.

Concluding remarks

The scientific documentation of the eventual beneficial effect on survival of peritonectomy combined with hyperthermic intraperitoneal chemotherapy (Sugarbaker procedure) in patients with pseudomyxoma peritonei is insufficient (⊕000).

The procedure is associated with a high rate of serious complications.

On behalf of HTA-centrum Göteborg, Sweden, 2009-12-09

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