

BYPASS SURGERY PERFORMED WITH OR WITHOUT
THE USE OF HEART-LUNG MACHINE

– a health technology assessment
Summary

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**Bypass surgery performed with or without the use of heart-lung machine
– a health technology assessment; Summary**

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What is HTA?

Health technology assessment contributes to decision making in the health care sector. A HTA collects and assess existing knowledge about a given health technology. A health technology is defined broadly as procedures and methods for prevention, diagnostics, treatment, care and rehabilitation including devices and medicine. An example could be a new method to treat patients. Focus is on healthcare, patient, organisational and economical aspects. New research can be conducted if the number of sufficient studies is limited to elucidate one or more of these aspects.

The HTA results in a report that can contribute to better planning, quality enhancement and prioritizing in the health care sector. The target group is decision-makers in the health political field. The primary users are therefore administrations and politicians and other decision-makers in the health political field. The HTA contributes to decisions within administration as well as political management as to which services should be offered in the health care sector and how they should be organized.

Health technology assessment is defined as:

- HTA is a comprehensive systematic assessment of the prerequisites and consequences of applying a health technology
- HTA is a research-based, application-oriented assessment of relevant existing knowledge about problem areas applying a technology within the field of health and illness.

The project is funded by a HTA-fund that was terminated in 2007. The purpose of the fund was to spread out knowledge and use of HTA locally. The funded HTA-reports are prepared in collaboration with an external interdisciplinary project group. The project group systematically reviews the existing literature, contributes with data collection and produces the chapters and conclusions of the report. The project management is placed at the National Board of Health who is also responsible for the editing of the final report. The report has been submitted to an external reference group and is also externally peer-reviewed.

Find more information about HTA at www.sst.dk/mtv under HTA toolbox:
“Handbook of Methods for Health Technology Assessment”
“Health Technology Assessment – Why? What? When? How?”

Summary

Introduction

Coronary artery stenosis is the most common, serious heart disease in Denmark. Narrowing of the coronary arteries cause decreased blood supply to heart muscle leading to chest pain, loss of heart muscle cells (myocardial infarction), rhythm disturbances and sudden cardiac death.

Coronary artery bypass surgery performed using heart-lung machine (HLM) (Conventional Coronary Artery Bypass Grafting, CCABG) is a well documented treatment of atherosclerosis of the coronary arteries. It provides freedom from heart-related chest pain in many cases, and also improves survival in patients with left coronary main stem stenosis, or with disease in all three coronary arteries.

However, a substantial part of especially the elderly and sick patients experience serious complications after surgery. The overall incidence of death, stroke and heart attack in connection with the operation is approximately 8 % in patients over 70 years.

The development of OPCAB (Off Pump Coronary Artery Bypass, bypass surgery for coronary arteries without the use of HLM)-technology has largely been driven by a concern for potential complications from using HLM. On the other hand, doubts have been expressed as to whether by-pass grafts performed on the “beating heart”, i.e. without the use of HLM, had the same quality and durability as bypasses made on a stopped heart, where visibility and the opportunity to put the stitches accurately, is considered to be better.

Worldwide, as well as in Denmark, the question about the use of HLM in CABG operations is controversial. The best estimates of the proportion of all CABG operations performed without the use of HLM is around 25 % (71). Some reputable, cardiac surgical departments make no CABG without HLM at all, while others almost exclusively use this method. The first years after the advent of new technical devices for the fixation of the heart (1999-2002) saw an explosive increase in the number of CABG operations performed without HLM. In recent years, however, several randomized studies have been published, comparing the outcomes of CABG carried out with and without the use of HLM. Most of these studies are relatively small and cannot by themselves determine which treatment should be preferred. Theoretically, elderly patients with increased risk of complications during surgery, have the greatest benefit by avoiding HLM. This group of patients have been underrepresented in these studies.

There is a need for a study of efficacy, complications, patient effects, costs, learning curve for training of surgeons, etc. by CABG without the use of HLM. Such a study can provide a sound basis for deciding how the most commonly performed cardiac operation in Denmark should be performed.

Purpose

In order to give decision makers evidence of the consequences of an increased or decreased use of HLM in coronary bypass surgery is the purpose of this project:

- To examine the available evidence on the pros and cons of coronary bypass surgery without heart-lung machine in relatively younger patients with relatively low intra-operative risk

- Through a Danish multicenter project to provide evidence of the pros and cons of coronary bypass surgery without heart-lung machine specifically in elderly patients with higher intra-operative risk, including how the costs and benefits are distributed to the Danish healthcare system.

Audience

The target audience is decision makers in health care in general. This includes politicians, civil servants, senior attending physicians and the individual surgeon who takes decision on the surgery, he or she will offer the patient. Also the patients themselves are decision makers as they ultimately determine which operation they either will or will not accept. The HTA report, however, only indirectly addresses patients taking a second purpose of this report is to make existing evidence readily available for the clinicians who inform and advice patients.

Demarcation

The project concerns an assessment of the consequences of performing OPCAB instead of CCABG. We have not assessed other treatments for ischemic heart disease, for example. percutaneous coronary intervention (“balloon treatment”), including “hybrid procedures”, where pre-planned bypass surgery for some coronary arteries and percutaneous coronary intervention on others. In comparison, we have concentrated on comparing CCABG and OPCAB performed with the cutting of the entire sternum and did not include methods in which a smaller incision was made or robotic technology was used to assist the surgeon.

Method

To elucidate the HTA questions in this HTA report, a systematic literature search was performed for each question.

Since the initial literature search almost exclusively resulted in foreign studies involving relatively younger patients that may be operated with a relatively low risk, we also conducted a Danish multicenter study (the DOORS study, Danish On-pump Off-pump Randomization Study), including 900 Danish patients over 70 years

For the patient chapter, surveys were performed before surgery and six months after surgery.

For the organization chapter, questionnaires were filled in by the heads of the participating anaesthetic and thoracic surgery departments. The questions included the use of man-power for the two types of operations and were repeated to clarify any changes of routines as the departments became more familiar with the OPCAB technique.

In addition to the literature search, the economics chapter is based on data collection from the DOORS-study, estimating the costs of the various treatments and the count of use of utensils, work load for different staff groups and hospitalization times, partly on general ward and partly in ICU.

Technology

From the literature search and from the DOORS study, a comparison is made of the effectiveness and safety OPCAB and CCABG operations.

With regard to the efficacy of OPCAB and CCABG, there is no sure evidence that one of the treatments, more so than the other prevents death from any cause, chest pain or need for new re-vascularisation. There is strong evidence from a large, well-executed study of the risk of death from heart-related cause is higher one year after OPCAB than after CCABG, but no evidence of a higher overall mortality rate. There is limited evidence from larger studies that support that OPCAB patients receive fewer bypass grafts than CCABG patients, but this is not the case in studies emanating from surgical groups with extensive experience in OPCAB. Likewise, there is strong evidence that bypass grafts are more likely to close in OPCAB patients, but especially in studies where the surgeons had the most experience.

With regard to the safety of OPCAB and CCABG, there is no evidence of a difference in the risk of death within 30 days after surgery. There is strong evidence of a larger release of biochemical markers of damage to the heart muscle and atrial fibrillation after CCABG, but no evidence of a different risk of clinical myocardial infarctions. There is limited evidence of increased need for inotropic support and intra-aortic balloon pump after CCABG. There is strong evidence of subclinical increased release of markers of kidney damage by CCABG, but not for differences in incidence of clinical renal injury. There is conflicting evidence regarding differences in risk of stroke in relation to the two operation techniques. There is limited evidence for higher levels of neuro-cognitive dysfunction in CCABG patients, particularly patients with three vessel disease at short follow-up. However, there is no evidence that this difference is present later than 3 months after surgery. There is strong evidence for fewer pneumonias and shorter ventilator times in OPCAB patients. There is limited evidence for a difference in the amount of bleeding and need for blood transfusion in the two types of operation, and there is limited evidence of whether the risk of complications in the gastrointestinal tract is reduced by the use of OPCAB in stead of CCABG.

Finally, there is strong evidence from multiple randomized clinical trials for a higher degree of inflammatory response and oxidative stress after CCABG than after OPCAB, but the clinical significance of this finding is uncertain.

Patient

This section addresses the patients' subjective perception of the results of CCABG and OPCAB. Typically, this has been measured using questionnaires of patients' self-reported health-related quality of life after surgery. The answers have been compared with preoperative levels and with the results of a group who had surgery with another surgical technique. A single qualitative study is mentioned, which reports interviews with patients who have tried both types of operation.

There is strong evidence from both previous randomized controlled studies and from DOORS study for a significant improvement in self-reported health related quality of life after surgery compared with before surgery. However, there is little or no evidence of any difference in terms of whether they had undergone CCABG or OPCAB.

Organization

OPCAB and CCABG make different organizational requirements. A specific issue is related to the training of surgeons. If the learning curve for one procedure were significantly longer than the other, it would affect how large departments, measured in the operating volume, would be optimal for the performance of each type of operation.

Overall, there is limited evidence that the introduction of OPCAB technique in wards that are already performing CCABG can be implemented without significant deterioration of complication rate in the transitional period. Learning curve for a surgeon under training shall include in the order of 25-50 operations. This experience could be achieved during a training course similar to what the younger cardio-thoracic surgeons are already undergoing in Denmark and will not require larger surgery volume in each department than it is today.

There is limited evidence that OPCAB operations generally take up operating rooms for a little longer than CCABG operations, while the OPCAB surgery patients generally take up beds in a little less time on both the ICU and wards

Economy

Based on the literature and analysis of data from the DOORS study, we assessed whether OPCAB is cost effective compared with CCABG.

There is strong evidence that OPCAB in the short term is cost effective compared to CCABG. All the included health economic evaluations conducted in continuation of randomized controlled trials (n=6) showed significantly lower costs for OPCAB and similar health benefits. The evaluation of short-term results from DOORS also shows that OPCAB in the short term is cost effective. There is no evidence of whether OPCAB or CCABG is cost effective in the long term (over 1 year).

Overall Assessment

OPCAB and CCABG are both relatively safe procedures that effectively restore blood supply to the heart.

Numerous studies have shown lower incidence of minor complications and fewer biochemical signs of subclinical organ damage in OPCAB operations compared with CCABG operations. No significant differences have been detected in the incidence of serious complications such as stroke, heart attack or death in connection with the two types of operation. Both operations result in a comparable improvement in patients' lives.

There is strong evidence that patients operated with OPCAB method, receive fewer by-pass grafts and that these by-pass grafts are more likely to close, compared with patients operated with CCABG method. This does not, however, result in greater risk of heart attack or death.

In some patient groups, there seems to be an advantage in selecting one type of operation over the other. A study of patients, who had acute surgery and only had a need for grafts to the heart's anterior side, showed that they had a higher chance of surviving the operation if they were operated with OPCAB technique. In all the randomized studies,

some patients, randomized to one technique, had to be converted to the other technique

There is moderate evidence that the introduction of OPCAB technique in wards that are already performing CCABG can be implemented without significant deterioration of the complication rate in the transitional period.

There is strong evidence that OPCAB, in the short term, is more cost effective than CCABG. The evaluation of short-term results from DOORS also shows that OPCAB in the short term is more cost effective. There is no good evidence of whether OPCAB or CCABG is more cost effective in the long term (over 1 year). If this can be shown by longer follow-up studies, from a socioeconomic point of view, it seems to be appropriate if a larger proportion of coronary bypass surgery could be performed with OPCAB technique than what is currently the case.

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