METAL-ON-METAL RESURFACING HIP ARTHROPLASTY VERSUS STANDARD TOTAL HIP ARTHROPLASTY
– a health technology assessment
Summary
What is Health Technology Assessment?

Health Technology Assessment (HTA) 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”
Summary

Introduction

As an introductory remark, the authors would like to draw attention to the fact that after completing the academic work in the report the Danish Orthopaedic Society announced discontinuation of use of metal on metal (MoM) hips, under these HRA. The discontinuation is based on an increased number of reports on and awareness of complications regarding elevated ion measurements, development of pseudo tumours and hip pain. Additional data and experiences were requested before further implementation. It is outside the objective of this report to comment on this statement.

Hip replacement (artificial hip) is used for patients suffering from degenerative hip diseases (mainly osteoarthritis) causing disabling pain and reduced mobility and reduced quality of life and in cases in which non-surgical treatment did not have the desired effect. The present technique, called Total Hip Replacement (THR) is successful in most patients as it provides significant pain relief, improved mobility and improved quality of life. An alternative to THR is Hip Resurfacing Arthroplasty (HRA), used in Denmark since 2004 in a small number of patients (approximately 2%). HRA is presumed to be beneficial to younger patients in particular. As the femoral head and the marrow canal are preserved it is anticipated that future surgery for replacing the artificial hip implant, usually after 10-15 years in 10-15 % of the patients, is possible without extensive loss of bone structure. Due to the large femoral head of the prosthesis, increased mobility as well as lower risk of hip dislocation and improved wear resistance is anticipated. The impact on long-term prognosis in relation to reoperation after 10-15 years is not well documented in Denmark or internationally.

The incentive for this HTA is a recommendation in a commented Warning from the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) with the Danish National Board of Health. In the DACEHTA Warning it is recommended to use HRA in clinical trials only until results of clinical efficiency and improved wear resistance equivalent to THR is collected in randomized studies. Furthermore, there is a need for clarification of patient experiences utility value and the cost-effectiveness of HRA compared to THR.

Purpose

The purpose of this HTA of Hip Resurfacing Arthroplasty prosthesis (HRA) is to evaluate the preconditions and the consequences of introducing the technology in standard procedures at Danish hospitals. HRA is compared to standard Total Hip Replacement (THR) in patients with arthritis in the hip joint based on analysis of technological and patient-related and organisational and financial aspects. The following HTA questions are pursued:

Technology:
- What are the clinical consequences of using HRA rather than THR in relation to pain, mobility, complications and prosthetic survival?
- What are the effects evaluated by the patients of using HRA rather than THR?
- Is there a difference in using HRA and THR in connection to time passed before return to work/daily activities?
Patient:
- How do the patients perceive the result of the surgery and would they possibly recommend it to others?
- How do the patients perceive the information they receive and what would they recommend should possibly be included in future information about the surgery?
- Did the patients have any preference (HRA vs. THR) before the surgery; which procedure did they prefer and why?

Organisation:
- Which are the organisational preconditions for and consequences of introducing and using HRA?

Costs:
- Do research-based studies exist showing HRA to be more cost-effective than THR?
- Based on data from the clinical trial and on supplementary local cost data can HRA be proven to be more cost-effective compared to THR?

Target group
The target group of this HTA report is decision-makers in the Danish healthcare system.

Scope
The focus of this HTA report is resurfacing hip surgery (HRA) as this is a special technology regarding the operation procedure as such. While the HTA is about HRA in general, the primary studies included in the HTA are based on the use of a specific resurfacing hip surgery, Articular Surface Replacement (ASR, Depuy). In autumn 2010, the product ASR was recalled from the market based on reports from the National Joint Registry of England and Wales and from The Australian register showing a reoperation rate of 12-13% within the first five years. It is not possible to rule out that the ASR prosthesis may have influenced the results of the randomised study included in the HTA report. However, use of the specific prosthesis has not had an independent impact on the general conclusions in this HTA report as the report includes a profound review of available literature on as well standard hip surgery as resurfacing hip surgery.

It is not possible to evaluate long-term problems in HRA as the present generation of prosthesis has only been used for approximately ten years.

Method
To clarify the aim of the report and the chosen HTA questions a literature review was performed and studies were conducted by the authors by way of a pilot study and a clinical randomised study along with a questionnaire survey and interviews. Furthermore, organisational and cost consequences were described based on the author’s experiences of introducing the new technology in a Danish orthopaedic surgical ward.
Technology

The surgery predominantly used at present is total hip replacement (THR) in which the femoral neck is partly removed with the femoral head. These parts are replaced by a slightly smaller femoral head in metal or ceramics fixed on a metal stem which is cemented in the femoral bone, or is mechanically fixed into in the femoral canal without cement.

In resurfacing hip arthroplasty (HRA) the worn cartilage on the femoral head and in the hip cup (including a very small part of the surrounding bone) is removed and replaced by a steel cape and cup. HRA is performed in more or less the same way in most countries. The procedure resembles the procedure used for standard THR. However, the surgical cut in the upper tissue is somewhat larger in order to dislocate the hip and it may be necessary to detach the muscle attachment from the femoral bone. As the complete HRA procedure is more complicated to perform the time used for the procedure is expected to be longer than operation time for a standard THR procedure. The post-operative regimes vary between surgeons. In Denmark, it is usually allowed for the patient to apply fully weight-bearing with crutches after surgery. The reported complications include early fracture of the femoral neck, reoperation and concerns about injurious effects of metal particles and development of pseudo tumours and cyst-like tissue.

All in all, it is concluded that both THR and HRA reduces the patient’s pain. However, the results are not immediately comparable due to difference in as well age of the patients as difference in the time of follow-up and because different pain scales are used in the studies. Improved mobility (measured by ROM) is achieved within the first year after the surgery and there seems to be no distinct difference in the two procedures.

The results show good activity scores (UCLA activity score) for HRA patients which are in several cases above the ones of THR. It is, however, difficult to estimate the advantages of HRA unequivocally as the activity scores are influenced by both the patient selection and the instructions in rehabilitation at that time (especially to THR patients) to refrain from certain strenuous sports.

Hip function (measured by Harris Hip Score) is a well-documented outcome. Generally, it takes 1-2 years to achieve a good outcome and there seems to be no difference in outcome between the two procedures.

Regarding self-reported function (measured by WOMAC) the data material is sparse. There is a tendency towards HRA being a little better than THR but the comparison is skewed as the patients in the THR studies are older than the patients in the HRA studies and because the measurement methods are not immediately comparable.

The data material for self-estimated health (measured by EQ-5D) is also sparse. Only one HRA study has been identified in which the EQ-5D is measured to be a little higher in HRA than in THR. In this study as well the patients in HRA were younger and it must be assumed that older citizens have more health related problems than younger ones thus making the frame of reference skewed. Surgery seems to have a distinct effect but it is unlikely that EQ-5D can distinguish between the two procedures.

It is unclear if the procedures have an effect on sickness absence as the matter is poorly documented and as other social aspects other than health may influence sickness absence.
The HRA prosthesis does not appear to have a longer survival rate compared to standard THR. Early reoperation due to fracture of the femoral neck and later reoperation due to pain and loosening of the prosthesis occurs.

The primary studies consisting of the randomised study and the pilot study, show that HRA and THR patients both have an evident and positive effect from the intervention in all goals. There were no significant difference in side-effects between the two procedures and no patients developed pseudo tumours. The expected increase in activity level could not be established and no difference in sickness absence was proved between the two procedures. The results are similar to results reported in literature even if not many studies are looking into the early period after surgery. A few other studies report of patients with a higher activity level but these are younger patients and are most often selected for the surgery.

Patient

This chapter studies data regarding the patient’s experience of and satisfaction with the hip surgery and the information provided ahead of the surgery. As literature on the subject is still sparse the answers to the HTA questions were based on the primary studies. Two focus group interviews were conducted with four women and one man who had HRA surgery, and with five men who had THR surgery, respectively. Three of the informants (all THR) had surgery shortly before the interview took place whereas the others had surgery 12 months before the interview. The subsequent questionnaire survey was answered by 88% and included 84 respondents. Of these 30 were women and 54 were men, 48 respondents had HRA surgery and 36 had THR surgery. There was no significant difference between the two groups regarding gender and age. There was, however, a significant difference in the period of time that had passed since surgery. The respondents in the HRA group had surgery on average 32 months before they answered the questionnaire whereas this period was on average 44 months for respondents in the THR group.

In general, the patients were satisfied with their operation regardless of which type of hip prosthesis they had received and they would recommend the artificial hip to others. According to the interviews the surgery was a good experience and it was marvelous to be relieved of one’s pain. Similarly, the questionnaire survey showed an overall satisfaction with the operation as well as with ten specific parameters for mobility of the hip. In three of these parameters satisfaction was a little lower. This concerned; walking on stairs, walking long distances and participation in sports. There were no differences between the groups of HRA and THR respondents, neither in overall satisfaction nor in specific satisfaction between the respondents who had HRA and THR. But women were significantly less satisfied compared to men regarding ability to walk long distances, regardless of type of prosthesis.

Patients in the THR group stated to a significantly higher degree than the patients in HRA group, to be careful using their artificial hip. It came as a surprise, however, that more than one third of the HRA patients stated that they were careful using their artificial hip as there were no restrictions in using this type of hip prosthesis.

While one third of the patients in the HRA group were concerned regarding how long time the artificial hip would last fewer patients in the THR group had this concern. Regarding possible risks such as diffusion of metal-ions to the bloodstream and dislocation of the prosthesis, the group that had HRA prosthesis were the least concerned. All
in all, the result from as well the interviews as from the questionnaire survey showed great satisfaction with the result of hip surgery regardless of the type of prosthesis received. But it also points out the lack of sufficient information about rehabilitation and support receiving this.

Organisation

Both in general and on the organisational level the HRA procedure does not differ from THR. However, there are some conditions which are important when new technology is introduced, e.g. HRA. Conditions such as; selection of suited patients, training of staff and documentation.

A number of factors are relevant when determining if a patient is suited for HRA. In 2009 recommendations regarding gender, age, hip disease and contraindications were approved by the Danish Orthopaedic Society. The recommendations were that male < 65 years and women < 55 years suffering from primary arthritis were suited for HRA. Later, questions have been raised regarding risk of developing pseudo tumours in women and increased reoperation rate.

Apart from careful selection of suited patients the implementation of HRA demands training of surgeons and nurses and staff in the central sterilisation unit. In literature the training of surgeons is described as covering 20-50 procedures. As the surgical technique in HRA differs substantially from that of THR and is perhaps more difficult to acquire it is recommended that HRA is performed in fewer wards than the standard procedure, according to the Danish national requirements for surgical procedures. Furthermore, it is recommended that the new technology is tested stepwise and implemented through RCT as well as reported to national registers.

Since 2004, 18 wards in Denmark have performed HRA but in 2010 this number was reduced to nine wards. All in all, 172 HRA were implanted in 2010, which is a decrease of 51 operations compared to 2009. The decrease indicates that the surgeons have changed their position on use of the HRA technology.

Costs

The economic analysis was conducted as an evaluation of the existing cost-effectiveness analyses and an assessment of cost-effectiveness in a Danish context.

The literature search revealed that only very little knowledge about the health economic gain of using HRA compared to THR is available. Two studies were found – from U.K and USA, respectively. Both studies were designed as model-based analyses collecting evidence from different sources to describe the long-term effects and costs. The two analyses showed that even with a time frame of 20-30 years HRA introduces increased costs and only a modest extra gain in quality-adjusted life years. Thus, these international studies could not document that HRA was cost-effective compared to THR.

The Danish experiences reported in this study showed that in a one-year analysis perspective only very limited extra gains are present when using HRA compared to THR. No statistical significance was identified in data at one-year follow-up in the health economic health status index EQ-5D. A conservative cost assessment was performed showing the costs of the HRA prosthesis to be slightly lower than for the THR pros-
thesis and, therefore, indicating that HRA in a short-term view was less expensive (approximately 2-3 %) compared to THR. In a wider perspective this may not be the case if costs for elevated complications and reoperations are included.

Overall assessment

New concepts for hip prosthesis is developed and implemented based on problems or limitations in existing prosthesis types. Problems in THR are the recommended restrictions regarding physical activity. These restrictions have, however, changed over the later years and now there are no restrictions in physical use in any of the applied prosthetic hips. Furthermore, there are problems such as the prosthetic survival which is in particular a problem in younger patients who will need at new prosthetic hip due to wear of the prosthesis. The replacement should preferably be as small an operation as possible regarding both bone and operation procedure.

The scope of the HTA was to assess the conditions and consequences of implementing MoM hip replacements such as HRA in standard procedures at Danish hospitals. The HTA is organised as a broad comparison of HRA with standard THR. A number of specific HTA questions were investigated using as well available literature as primary data.

Few randomised studies of HRA are available; they include a small number of patients and a short period of follow-up. Also available are a series of cohort studies with selected patients, therefore, the studies are not suited for broad generalisations. For the group of patients expected to benefit from HRA, being younger active men (less than 65-70 years), no randomised studies are available.

All in all, the new artificial hip HRA did not provide better results compared to standard THR. In a series of parameters such as mobility, activity, patient-assessed effects and costs HRA and THR are estimated to be equal. As well THR as HRA eliminate the pain of the patients. In general, the patients are satisfied with their surgery, regardless of type, and the vast majority would recommend hip surgery to others. Women experience more problems in walking long distances with as well HRA as THR. Patients with HRA are less concerned/careful using their prosthesis. Contrary to this, literature provides evidence that HRA is connected to a slightly higher rate of reoperation in selected patient groups.

The number of reoperation is an important parameter for comparing the two procedures. As the need for reoperation usually occurs after a period of time and at a relatively low rate no clinical trials are designed to clarify differences in reoperation rates. More and more countries have established hip registers in which the hospitals of the country report implantation of new artificial hips and reoperation. These registers can contribute to create an overview of the survival rate of the prosthesis. All in all, the HRA prosthesis does not seem to have a longer survival rate compared to the standard THR prosthesis, it is more the reverse.

Patients having RHA have measurable values of metal ions in their bloodstream. Furthermore, there is a risk of developing pseudo tumours, which is also seen in standard THA. A series of factors for elevated reoperation risk are identified; under this the female gender, small diameter of femoral head and steep hip cup as well as the type of prosthetic implant.
Implementation of new technology makes demands on the organisation in regard to training of staff and setting-up surgical teams and continuous evaluation.

Limited data is available on the health economic gains of using HRA compared to THR. Analysis of differences in resource use has proven that the price of the HRA prosthesis is lower than that of THR but this difference is partially counterbalanced by longer surgery hours and perhaps by an elevated rate of reoperation. As HRA does not yield significantly better treatment results compared to THR and as the costs are not considerably lower it is estimated that there is no significant difference in the cost-effectiveness between HRA and THR.

RHA was introduced as being:
1. bone conserving
2. more wear-resistant
3. reducing risk of joint dislocation (safeguarded by the large femoral head)

compared to standard THA.

All in all, this has not been refuted in the report. However, there is no indication of decrease in the rate of reoperation of RHA and at the same time concerns have been raised about development of reactions in the tissue in the hip (pseudo tumours), incidence of metal-ions and pain. The published studies pointed to possible groups of patients who would benefit from being offered RHA. In particular younger (<65 years) active men as it is well known that these patients have a significant increased risk of reoperation when given a standard THA.

If RHA is to be used in this group of patients in the future it will be essential to establish the early clinical outcome and examine if data exists in current databases in Denmark and internationally supporting implementation of RHA.