Health technology assessment of screening for abdominal aortic aneurysm

– SUMMARY –

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Summary

The objective of this health technology assessment of screening for abdominal aortic aneurysm (AAA) is to assess the consequences of introducing an AAA screening programme, in the Central Denmark Region.

Initially, the report comprises a description of the clinical, epidemiological, aetiological, prognostic and treatment- & screening-related issues of the condition. Furthermore, it offers an assessment of the evidence value of existing Danish and international studies in the field. Subsequently, the report includes an ethical assessment and a systematic review and assessment of the patient-related consequences associated with the introduction of a screening programme. Furthermore, the organisational scope is discussed. Finally, a systematic review and assessment of the Danish and international economic literature is included along with a health-economic analysis of the economic consequences of the introduction of a screening programme.

An increase in AAA occurrence and consequently in the mortality caused by AAA rupture in conjunction with the ability to diagnose the condition and perform prophylactic surgery has stimulated the implementation of scientific studies as well as the debate concerning the introduction of an AAA screening programme.

Technology and evidence assessment

The objective of the technology chapter and the study evidence assessment is to provide an introduction to AAA with regards to clinical issues, epidemiology, mortality, aetiology, life-style and screening, as well as an assessment of the effect of the screening studies. The following highlights from the two chapters deserve mention:

- The typical AAA patient is a male above 65 years of age whom is a current or former smoker. The patient frequently also has other cardiovascular conditions or chronic obstructive pulmonary disease. The mean age of patients dying from AAA rupture is currently 76 years.

- The review of Danish and international literature shows that AAA screening of males aged 65-75 years can reduce AAA mortality considerably. Currently, no medical treatment options are available with the exception of surgery. Known measures against cardiovascular risk factors, including smoking cessation, may presumably limit AAA growth and therefore reduce rupture risk.

- The screening method is ultrasound scans which are quick, safe and reliable. The aorta is visible in 98-99% of the scanned patients – sensitivity has been calculated to 98% and specificity to 99%.

Patient perspective assessment

Any consequences for the participants in screening may, among others, be assessed using the Quality of Life concept. The objective of this chapter is to assess if the participants’ quality of life is affected by participation in screening for AAA.

The optimal design for measurement of changes in quality of life among the screening participants is to compare the participants with a control group which do not take part in screening. Such a comparison should be performed in the time period in which the course of screening takes places. Such a study design has not been found among the reviewed studies concerning quality of life, therefore:
Overall, it is not possible to determine with certainty if the participants’ quality of life is affected by screening compared to a control group which did not participate in screening.

The conclusions below are based on studies in which the participants’ quality of life primarily was assessed by comparing the participant’s quality of life before and after screening or by comparing the relevant patients with other groups of patients also participating in screening. The following should be emphasised:

- There has not been identified documentation neither for, nor against the implementation of screening for AAA.
- Screening participation does not seem to have any substantial effect on the quality of life
- The participants who are diagnosed with AAA probably have a poor quality of life before screening participation.

Most changes in quality of life, is registered within the relatively large group of participants who are diagnosed with a minor AAA. However, the changes in quality of life are still limited. The available treatment option for this group of patients comprises participation in a process which includes regular follow-up scans. Depending on the size and growth rate of the aneurism, the patients will participate in the monitoring process until the aneurysm requires surgery or until the patient dies of other causes.

- In connection with the implementation of AAA screening extra attention and support may be needed for the participants offered regular monitoring.

Assessment of the ethical perspective

According to the Danish National Board of Health’s criteria for assessment of screening programmes, any ethical consequences must be assessed. This is done by assessing the ethically relevant properties of a technology and subsequently the ethical issues of such properties. Finally, an ethical assessment is performed.

- According to the ethical assessment, it is obvious – all things being equal – that the health care system should introduce the screening programme, because of the essential life-saving effect of the programme.

Such a presumption is underpinned in the ethical part of the assessment by the assumption that the health care system is based on the obligation to do good. The negative consequences are assessed ethically. It should be emphasised that:

- The negative consequences concerning the screening for AAA should not neglect the right to make an informed decision.

It is a crucial precondition that the offer comprise clear information concerning possible findings and any consequences of such findings (surgery, (life-long) monitoring, etc.), allowing each potential participant to make an informed decision concerning his or her participation.

- The conclusion with regards to ethics is that the principle of autonomy and self-determination serves as an argument for the introduction of AAA screening.

It should be noted that a relevant ethical issue is raised as sufficient economic resources are a prerequisite for the introduction of a screening programme. This aspect of the issue is associated with the principle of a fair distribution. This ethical issue is therefore interconnected with the economic analysis.
Organisational perspective
The objective of the organisational perspective is to account for the elements which a screening should comprise and to identify how AAA screening is organised in the studies and finally to design models for the organisation of an AAA screening programme in the Central Denmark Region. The following should be emphasised:

- Screening is a programme rather than simply a test.
- The overall management of the screening programme, including the division of responsibilities, must be clear-cut and the screening programme should be thoroughly and comprehensively described. Optimal quality control may be underpinned by establishing a steering group for the screening programme with responsibility for the operation as well as for any research and development tasks associated with the programme.
- The primary clinical focus is on the effect of the actual screening test, as reflected in the health science studies. The studies’ lack of focus on overall management tasks means that study results – with regard to clinical effect as well as the financial analyses based on the studies – are primarily consequences of the screening test, rather than of the entire screening programme.
- The review of the studies generally demonstrates a limited account for the organisation of the screening studies. Identification and invitation of the participants is described, but the remaining tasks of the patient-related screening process are only mentioned briefly.
- On a possible implementation of a screening programme for AAA, two approaches can be considered: a general practice model and a hospital-based model. In the two models there are several settings in which the screening test can take place, and simultaneous satisfy the criteria for centralisation of the screening technology and a high percentage of participation.

Economics
In the Danish National Board of Health’s criteria for screening programme assessment, the need to have sufficient funding before a programme is initiated is stressed as a relevant ethical issue.

Furthermore, attention is drawn to the prioritisation of health care resources – an element which is linked to the principle of fair distribution of societal resources. In order to assess the screening programme in relation to the principle of fair distribution of societal resources, an economic analysis is needed.

The economical analysis is divided into two parts: chapter 7 and chapter 8. In chapter 7, a review of previously published health-economic analyses is completed. These analyses are reviewed in terms of relevance, quality and generalisability.

The review in chapter 7 demonstrated:

- that all articles, except one (the MASS-study), conclude that screening is cost-effective (i.e. screening is "good value for money")
- that the MASS-study, nonetheless, is the best foreign study of cost-effectiveness on medium-long terms. ICER is estimated at £ 36,000 (DKK 360,000) per QALY. If a threshold value is estimated at £ 20,000-30,000 (DKK 200,000-300,000) per QALY, the results of the analysis must then determine that screening is not cost-effective.
Summary

- that this and a previous review state uncertainties about the quality of previous health-economic studies. This entails that adequate documentation to assess whether implementation of AAA screening in Denmark will be cost-effective does not exist.

Consequently, a new Danish model for assessment of cost-effectiveness of the implementation of a screening programme for AAA is completed.

The new health economic model is completed in order to calculate the expected health benefits and costs derived from the introduction of an AAA screening for all males aged 65 years in the Central Denmark Region. The model demonstrated the following:

- The result calculated was DKK 409,194/QALY (DKK 307,145-621,068), which must be interpreted to mean that the introduction of AAA screening is not cost-efficient provided a threshold value of cost-efficiency of approx. DKK 300,000 per QALY is adopted.

- The result is not sensitive to changes in model assumptions provided a threshold value of cost-efficiency of approx. DKK 300,000 per QALY is adopted.

For further illustration of the consequences of introducing a continued screening programme a model simulation was made (chapter 8).