

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

Intraoperative Magnetic Resonance Imaging in Neurosurgery

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.

Associate professor Hans Silander, MD, PhD, and the Head of the Department of Neurosurgery, Sahlgrenska University (SU/S), Göteborg, Sweden, requested the present HTA.

A working group under the chairmanship of associate professor Bertil Rydenhag, senior consultant at the Department of Neurosurgery, SU/S, produced the HTA report. The other members of the working group were Hans Silander, senior consultant and head of the Department of Neurosurgery, Mats Johansson Högfeldt, senior consultant, Department of Neurosurgery, SU/S, Lars Jönsson, senior consultant, Department of Neuroradiology, SU/S, Thomas Skoglund, senior consultant, Department of Neurosurgery, SU/S and Göran Starck, associate professor Göran Starck, Dept. of Medical Physics and Biomedical Engineering, SU/S.

The participants from the HTA centre were Lennart Jivegård, MD, PhD, Ola Samuelsson MD, PhD, Therese Svanberg, librarian and information specialist, and Eva Alopaues, head of the library.

Thomas Lindén, M.D, PhD, and Karin Manhem, MD, PhD, have critically appraised the report.

Question at issue:

Does intraoperative MRI lead to better outcome in patients with intracerebral or pituitary tumours, and does it increase the neurosurgical precision?

PICO 1

- P = Patients with brain tumour (intracerebral or pituitary tumour) subjected to neurosurgery
- I = Intraoperative MRI
- C = No intraoperative MRI
- O = 1) Survival 2) Frequency of reoperations 3) Quality of life 4) Symptom relief 5) Degree of resection
6) Risks/Complications

PICO 2A

- P = Patients operated for intracerebral tumours
- I = Intraoperative MRI
- C = Postoperative MRI within 72 hours
- O = Concordance between the methods as evaluated by residual tumour volume (sensitivity/specificity)

PICO 2B

- P = Patients operated for pituitary tumours
- I = Intraoperative MRI
- C = Postoperative MRI within 6 months
- O = Concordance between the methods as evaluated by residual tumour volume (sensitivity/specificity)

Summary of the health technology assessment:

Method and patient category:

Most patients with glioma or pituitary adenoma undergo neurosurgery with the aim to remove as much tumour tissue as possible. The complex structure of the brain and the difficulties to exactly identify and visualize the exact borders of a tumour and the location of very important brain areas prompts further development of imaging of high accuracy during neurosurgical procedures. Intraoperative MRI (ioMRI) represents a technique with the potential to facilitate for the surgeon to remove as much tumour tissue as possible.

Level of evidence:

The systematic literature search identified one Canadian HTA-report from 2004. Articles published after 2004 included one study of moderate scientific quality that compared the use of low-to-mid field strength (0.2 T - 1.0 T) ioMRI with high-field strength (≥ 1.5 T) postoperative MRI with regard to survival, and one study of low scientific quality that compared the two with regard to the extent of surgical tumour resection. The former study did not show any difference in survival, and the latter reported a significantly greater extent of tumour tissue removal. The level of evidence with regard to these outcomes according to the GRADE system is $\oplus\text{OOO}$, i.e. insufficient.

Four studies were identified that evaluated the diagnostic performance of low-to-mid field ioMRI with high field MRI performed postoperatively. The diagnostic performance to detect residual tumour mass in patients with intracerebral tumours was evaluated in two studies, and to detect residual tumour mass in patients operated for pituitary tumours was evaluated in two studies. The sensitivity for intraoperative tumour detection in the studies of moderate scientific qualities varied between 82 - 100 %, and the specificity between 91 - 100 %. The level of evidence with regard to diagnostic performance is limited.

No study that compared the efficacy of ioMRI with postoperative MRI with regard to frequency of reoperations, quality of life or relief of symptoms was identified.

Risks

The use of ioMR was not associated with any risks for the patients.

Ethical aspects:

Is it ethically acceptable to perform neurosurgical procedures without the use of the ioMRI technique when there is some, albeit limited, scientific documentation that the extent of tumour removal is inferior without ioMRI. Surgery without ioMRI would then result in unnecessary repeated neurosurgical procedures, and may possibly result in less favourable overall outcome for patients who require neurosurgery for intracerebral or pituitary tumours.

Economical aspects

Data are incomplete and sparse. Rough estimations indicate that the cost of each procedure will increase by 19%. However, the need for reoperations will most probably decrease but it is not possible to estimate how much this will reduce overall cost. Therefore, presently the total change of cost is difficult to define.

Concluding remarks

The scientific documentation of the eventual beneficial effects of intraoperative MR on survival is insufficient (⊕000).

The scientific documentation of the potential beneficial effects of intraoperative MR with regard to surgical precision, i.e. the extent of tumour tissue removal, is insufficient (⊕000).

The scientific documentation of intraoperative MR as a diagnostic tool during neurosurgery is limited.

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

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