

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

### Robotic assisted laparoscopic surgery for cervical and endometrial cancer

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.

The Head of the Clinical Department of Gynaecology and Reproductive medicine, Inger Bryman has requested the present HTA.

A working group under the chairmanship of Pernilla Dahm-Kähler, senior consultant, Saskia Eklind, senior consultant, and Pär Hellberg, senior consultant, all at Dept of Obstetrics and Gynecology, Sahlgrenska University Hospital, Göteborg, Sweden, produced the HTA report. The participants from the HTA centre were Christina Bergh, MD, PhD, Annika Strandell, MD, PhD, Therese Svanberg, information specialist and Eva Alopaeus, information specialist chair.

Magnus Hakeberg, professor Odontology has critically appraised the report.

#### Question at issue:

Is robotic assisted laparoscopic surgery superior to open surgery or laparoscopic surgery for cervical and endometrial cancer concerning mortality and morbidity?

#### PICO 1

- P = Women with cervical cancer
- I = Robotic-assisted laparoscopic radical hysterectomy with lymph node dissection
- C = Radical hysterectomy with open surgery
- O = Primary outcomes: Mortality/5-year survival, complications, radicality?, number of lymph nodes extirpated  
Secondary outcomes: Length of hospital stay, post-operative bladder function, operative time, blood loss

#### PICO 2

- P = Women with endometrial cancer
- I = Roboticassisted laparoscopic radical or non-radical hysterectomy with lymph node dissection
- C = Hysterectomy with open surgery or laparoscopy
- O = Primary outcomes: Mortality/5-year survival, complications, radicality, number of lymph nodes extirpated, quality of life  
Secondary outcomes: Length of hospital stay, post-operative bladder function? operative time, blood loss

## Summary of the health technology assessment:

Method and patient category: Patients with cervical and endometrial cancer are today managed mainly by open surgery (transabdominal hysterectomy, TAH). Laparoscopic surgery (TLH) has been initiated at certain centra but its development has been limited by technical difficulties and hesitations concerning oncology parameters such as recurrence and survival have arisen. Robotic assisted laparoscopic surgery (TRH) is a new technique in the frontline of gynaecological tumour surgery.

Level of evidence:

**Cervical cancer:** The literature search identified 3 controlled studies and 5 case series. No studies were randomized. No studies report the primary outcomes mortality/5-year survival and quality of life. The primary outcomes which are reported are complications, radicality?? and number of lymph nodes extirpated. The secondary outcomes reported are length of hospital stay, blood loss, operative time and time to recovery to ordinary daily life. The 3 controlled studies, which all have a low level of evidence, show significantly less blood loss with TRH compared with TAH, 2 of the studies show significantly shorter hospital stay, the third study shows no difference. One of the studies shows more extirpated lymph nodes by TRH while 2 studies show no difference. Concerning other outcomes; radicality, operative time, post-operative bladder function, time to recovery to ordinary daily life, no differences were found.

In conclusion, the scientific documentation of TRH to be superior to TAH is insufficient for all studied outcomes.

**Endometrial cancer:** The literature search identified 7 controlled studies and one case series. No studies were randomized. No studies report the primary outcomes mortality/5-year survival, radicality and quality of life. The primary reported outcomes are complications and number of extirpated lymph nodes. The secondary outcomes reported are length of hospital stay, blood loss, operative time and time to recovery to ordinary daily life. 5/7 studies show significantly less complications by TRH compared to TAH and 2/7 studies compared to TLH. 1/7 studies show significantly more lymph nodes extirpated by TRH compared with TAH and 2/7 compared with TLH. 3/3 studies show significantly shorter hospital stay for TRH compared to TAH and 2/7 compared to TLH. 5/7 studies show significantly less blood loss by TRH compared to TAH and 2/5 compared to TLH. 1/1 study shows shorter time to recovery to ordinary daily life for TRH compared to TAH. For the outcome operative time 5/5 studies show longer operative time for TRH compared to TAH and 2/5 compared to TLH. In conclusion, the scientific documentation of TRH to be superior to TAH or TLH is insufficient for all studied outcomes.

Ethical aspects: It is questionable to introduce a method into routine care where the scientific documentation for patient benefit is insufficient.

Economical aspects: Roboict surgery is assessed to create additional costs concerning surgery for cervical cancer of 16.500 SEK per treatment and for endometrial cancer of 26.500 SEK. Simultaneously the procedure is assessed to save 24.000 SEK and 21.900 SEK respectively depending on shorter hospital stay.

**Concluding remarks:** The scientific documentation of a potential beneficial effect by Robotic assisted laparoscopic surgery (TRH) compared with open surgery and laparoscopic surgery (only endometrial cancer) is insufficient concerning all studied outcomes.

On behalf of HTA-centrum Göteborg, Sweden, 2009-02-25

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