

Statement from the Regional HTA Centre of Region Västra Götaland, Sweden

Robotic surgery for benign gynecologic disease

Question at issue:

Is robotic-assisted laparoscopic surgery better than laparotomy, or laparoscopy, in women having myomectomy for uterus-preserving purpose, excision of deep infiltrating endometriosis or hysterectomy on benign indication, considering serious complications, hospital stay, operating time, bleeding, quality of life, conversion to laparotomy, and ergonomics. Specifically for myomectomy; live birth, pregnancy and uterine rupture during pregnancy are considered.

PICO 1 (Patient, Intervention, Comparison, Outcome)

P = Women

P1: of childbearing age with myoma

P2: with deeply infiltrating endometriosis

P3: to undergo hysterectomy for benign indications

I = Robotic-assisted laparoscopy

C = a) Laparotomy (P1, P3) b) Laparoscopy (P1, P2, P3)

O = Primary: serious complication: visceral damage; hospital stay

Secondary: operating time; blood loss; blood transfusion; conversion to laparotomy; quality of life; ergonomics

For P3 also: Live birth; Pregnancy; Uterine rupture

Summary of the health technology assessment:

Method and target group:

Robotic-assisted laparoscopy for benign gynecological surgery, specifically regarding deeply infiltrating endometriosis, myomectomy, and hysterectomy, in women planned for surgery.

Level of evidence and studied patient benefit

Myomectomy:

The literature search identified five comparative, non-randomized studies, two comparing robot-assisted laparoscopic myomectomy (RALM) with abdominal myomectomy (AM), two studies comparing RALM with laparoscopic myomectomy (LM), and one study comparing all three. Two studies were of moderate quality, and three studies were of low quality. The outcome measures reported in these studies were: complications, hospital stay, operating time, blood loss, blood transfusion, conversion to laparotomy, and pregnancy. None of the studies reported uterine rupture, live birth, or ergonomics.

RALM vs. AM: There is some evidence to support shorter hospital stay, and less bleeding with RALM, but longer operating time. For the outcomes complications and blood transfusion, there were no differences. Altogether, there is low level of evidence to conclude that RALM results in shorter hospital stay, smaller bleeding volume, and longer operating time than AM (GRADE ⊕⊕), and very low level of evidence (GRADE ⊕) for RALM being superior to AM regarding complications and blood transfusion.

RALM vs. LM: There were no differences between the included outcomes. Altogether, there is very low level of evidence (GRADE ⊕) for RALM being superior to LM, regarding all the studied outcomes.

Endometriosis:

One article of low quality was identified, comparing robotic-assisted laparoscopy (RAL) with traditional laparoscopy. The reported outcomes were: complications, operating time, and blood loss. RAL had a significantly longer duration of surgery, but no other differences were seen. Altogether, there is very low level of evidence for RAL being superior to laparoscopy, regarding all the studied outcomes (GRADE ⊕).

Hysterectomy:

The literature search identified eight comparative, non-randomized studies (three of moderate, and five of low quality) comparing RALH with LH. One of the studies also compared RALH with AH. The reported outcomes were: complications, hospital stay, operating time, blood loss, blood transfusion, conversion to laparotomy, and ergonomics.

RALH vs. AH: In one study, RALH was significantly favorable considering hospital stay, blood loss, and blood transfusion. Altogether, there is very low level of evidence (GRADE ⊕) for RALH being superior to AH, regarding all the studied outcomes.

RALH vs. LH: There is some evidence supporting shorter hospital stay with RALH, but longer operating time. Considering the other outcomes, there are small or no differences at all between the methods. Altogether, there is low level of evidence to conclude that RALH results in shorter hospital stay, and longer operating time (GRADE ⊕⊕) than LH, and very low level of evidence (GRADE ⊕) for RALH being superior to LH, regarding complications, blood loss, blood transfusion, conversion to laparotomy and ergonomics.

Ethical aspects

It may be ethically questionable to introduce a method of routine medical care where the scientific evidence for patient benefits is very low. Further research and evaluation of the method is important in order to assess its potential.

Economic aspects

Large investment cost of 21 million SEK + service fees of 1.7 million SEK/year. If 500 surgeries are performed annually, the estimated additional cost of the robot is 17,366 SEK per intervention. Also, the cost of longer operating time needs to be added. The shortened hospital stay, compared with laparotomy, will reduce the cost with approximately 6000 SEK/day.

Summary and conclusion

There is low level of evidence for shortened hospital stay, reduced blood loss, and longer operating time, with robotic-assisted myomectomy, compared to open surgery. There is also low level of evidence for robotic-assisted laparoscopic hysterectomy resulting in shorter hospital stay, and in longer operating time, compared with laparoscopic hysterectomy. For all other comparisons between the robotic-assisted, and open or laparoscopic surgery, the level of evidence is very low.

On behalf of the Regional HTA Centre of Region Västra Götaland, Sweden

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