Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER466
Topic:	Robot-assisted benign gynaecological surgery
Summary of findings:	Some non-cancerous gynaecological conditions may require surgical treatment. These procedures may be performed as a robot-assisted surgery by inserting a robotic surgical probe into a small laparoscopic or 'keyhole' incision. Conventional approaches include surgery through a large incision in the abdomen or as a laparoscopic surgery without robot assistance. One guidance position on the use of robot-assisted surgery for benign gynaecological conditions was identified. The American College of Obstetricians and Gynecologists states robot-assisted surgery seems to be comparable to laparoscopy and have improved outcomes compared with open surgery. They recommend selecting robot-assisted cases based on the likelihood of improved outcomes compared with other approaches. A health technology assessment (HTA) by Ireland's Health Information and Quality Authority assessing robot-assisted surgery was identified. Robot-assisted hysterectomy was found to be superior to open surgery for peri-operative outcomes and outcomes were similar or slightly improved compared to laparoscopy. Evidence for other benign gynaecological robot-assisted surgeries suggested non-inferiority to conventional approaches. A cost-minimisation analysis for robot-assisted hysterectomy found an incremental procedure cost of €3,019 per case. All the included evidence was judged to be of low quality or certainty. Five systematic reviews were identified; they include a range of trial designs and there was significant overlap in the included studies. The reviews suggest robot-assisted procedures have comparable operative outcomes to conventional approaches but are associated with longer operative times and higher costs. All evidence sources were judged to be of low certainty and there was a low number of RCTs reported. The evidence synthesis in two of the reviews was also of poor quality. The current state of evidence of clinical effectiveness for robot-assisted benign gynaecological surgery is of low certainty but suggests non-inferiority to conventional surgical approaches.

Introduction and aims

Surgery may be required to treat non-cancerous gynaecological conditions, such as endometriosis, removal of uterine fibroids and pelvic organ prolapse, amongst others. Traditionally these procedures were performed as an open or abdominal surgery, through a large incision in the abdomen. Laparoscopic or 'keyhole' surgeries were then developed, which use much smaller incisions through which surgical instruments are inserted. More recently, robot-assisted surgery has been developed, which offers an alternative laparoscopic approach.

Robot-assisted surgery has been used in gynaecology since the 1990's and was approved for use in gynaecology in the USA by the Food and Drug Administration in 2005. Between 1 April 2006 and 31 March 2018, 4,384 elective gynaecological surgeries were carried out with robotic assistance by NHS England (El-Hamamsy et al. 2022).

Robot-assisted surgery is a laparoscopic procedure that the surgeon operates from a separate remote console and can provide improved dexterity, 3D vision, improved ergonomics, autonomy of camera control and a shorter learning curve than conventional laparoscopy. Benign gynaecological procedures that robot-assisted surgery may be used for include hysterectomy, myomectomy, sacrocolpopexy (repair of vaginal prolapse), tubal re-anastomosis (joining of the fallopian tubes), and treatment of endometriosis.

Health Technology Wales (HTW) researchers searched for evidence on the clinical and cost effectiveness of robot-assisted benign gynaecological surgery.

Evidence overview

Guidance and Standards

One set of guidance for robot-assisted benign gynaecological surgery and one health technology assessment (HTA) for various robot-assisted surgeries, including benign gynaecological, were identified.

The American College of Obstetricians and Gynecologists (ACOG) recommend that "robot-assisted cases should be selected based on the likelihood of improved outcomes compared with other surgical approaches due to the complexity of the case or patient factors, with appropriate consideration to costs" (ACOG 2020). The authors state that further comparative studies are needed to assess the longer-term outcomes and patient safety as most current evidence is of low quality or certainty.

An HTA by Ireland's Health Information and Quality Authority (HIQA) assessed the clinical and cost effectiveness of robot-assisted surgery for benign gynaecological conditions and for hysterectomy (HIQA 2012). Limited, low-quality evidence was found for myomectomy, tubal re-anastomosis and sacrocolpopexy. It was found that robot-assisted myomectomy was associated with longer operative times than laparoscopy or open surgery, shorter hospital stays than open surgery, similar or shorter hospital stays than laparoscopy and lower estimated blood loss than open surgery. Robot-assisted tubal re-anastomosis was associated with longer operative times and shorter hospital stays than open re-anastomosis but potentially worse outcomes for pregnancy rates and abnormal pregnancies. Robot-assisted sacrocolpopexy was associated with significantly longer operative time, shorter hospital stays and lower estimated blood loss than open surgery, based on one non-randomised cohort study. Complication rates for sacrocolpopexy were not analysed due to the poor quality of the evidence. HIQA summarised that there was limited, low-quality evidence to support

the role of robot-assisted myomectomy, tubal re-anastomosis and sacrocolpopexy and evidence suggested that these were comparable, but not superior, to laparoscopic or open approaches.

Due to higher quantities of evidence, a meta-analysis was able to be performed for robot-assisted hysterectomy, however the evidence was still deemed to be of low quality (HIQA 2012). HIQA state that robot-assisted hysterectomy is superior to open surgery for peri-operative outcomes. Robot-assisted hysterectomy was associated with longer operative time, shorter hospital stays, lower estimated blood loss and lower risk of transfusion or complications than open hysterectomy. These differences were reduced in comparisons to laparoscopy, though still often statistically significant, whilst operating times were not significantly different.

Through a cost-minimisation analysis, they also found that incremental procedure costs for robot-assisted hysterectomy over a combination of laparoscopic and open hysterectomy was €3,019, 95% confidence interval (CI) €2,582 to €3,733. The budget impact analysis ranged from €0.49 million a year in year one to €1.15 million a year in year five.

Secondary Evidence

HTW researchers identified five systematic reviews of robot-assisted benign gynaecological surgery: two systematic reviews of randomised controlled trials (RCTs) (Aarts et al. 2015, Lawrie et al. 2019), two systematic reviews of RCTs and quasi-randomised controlled trials (qRCTs) (Albright et al. 2016, Jerbaka et al. 2022), and one systematic review of RCTs and large retrospective trials (Capozzi et al. 2022). Two of these reviews were for hysterectomy only, whilst the remaining three covered various surgeries for benign gynaecological conditions.

The review by Aarts et al. (2015) included two studies comparing robot-assisted hysterectomy to conventional laparoscopic hysterectomy, these two studies were included in all five systematic reviews identified. Albright et al. (2016) included an additional two studies, one of which was included in all later reviews and one which was excluded from all except Jerbaka et al. (2022) due to its quasi-randomised design. The three most recent systematic reviews (Lawrie et al. 2019, Capozzi et al. 2022, Jerbaka et al. 2022) had different inclusion criteria and did not contain all the same RCTs, though there was significant overlap in the included studies. Due to the above, only the findings of the three most recent systematic reviews will be reported.

Hysterectomy

Lawrie et al. (2019) included five RCTs (n = 486) comparing robot-assisted hysterectomy to conventional laparoscopy for benign conditions and included meta-analyses. Capozzi et al. (2022) included four RCTs and one retrospective cohort analysis comparing robot-assisted hysterectomy to laparoscopic, abdominal, or vaginal hysterectomy (n = 265,100). Jerbaka et al. (2022) included 31 RCTs and qRCTs comparing the robot-assisted procedure to laparoscopy; numbers of participants were not reported.

Robot-assisted hysterectomy was found to have similar rates of intra-operative and post-operative complications compared to laparoscopy. No statistically significant difference was found for intra-operative and post-operative complication rates by Lawrie et al. (2019); risk ratio 0.76 (95% CI 0.38 to 1.53). Estimated blood loss or the need for transfusion is claimed to be slightly lower for robot-

assisted hysterectomy by Jerbaka et al. (2022); Lawrie et al. (2019) found no statistically significant difference for these outcomes.

The duration of surgery was generally longer with robotic surgery; however, Capozzi et al. (2022) state that, when performed by experienced surgeons, robot-assisted surgery times were non-inferior to laparoscopy. Jerbaka et al. (2022) claim that the increased surgery times are mostly due to time needed for equipment set up. There was no statistically significant difference in the rate of conversion to another surgical approach (Lawrie et al. 2019, Jerbaka et al. 2022). Jerbaka et al. (2022) reported no difference in length of hospital stay for the two procedures, however Lawrie et al. (2019) found robot-assisted surgery led to slightly shorter hospital stays. This result was statistically significant with a mean difference of -0.30 days (95% CI -0.53 to -0.07); however, this was based on very low certainty evidence.

Myomectomy

Capozzi et al. (2022) included eight retrospective studies comparing robot-assisted myomectomy to either laparoscopic or open surgery (n = 1,721). No RCTs were identified.

Robot-assisted myomectomy is stated to be "as effective and safe" as laparoscopy. The review refers to peri-operative and post-operative outcomes, but it is not certain if this includes complications and there was variability in whether robot-assisted surgery performed better, the same, or worse for these outcomes. Operating times were longer for robotic surgery compared to both laparoscopy and open surgery. Robot-assisted myomectomy was also found to lead to shorter lengths of stay in hospital.

Treatment for endometriosis

All three reviews found one RCT for robot-assisted surgical treatment for endometriosis compared to laparoscopy (n = 73); this was the only study included for this intervention in the review by Lawrie et al. (2019). Capozzi et al. (2022) also included four retrospective studies, which brought the total number of participants to 1,527. Jerbaka et al. (2022) identified a further five trials that can be assumed to be qRCTs due to the three reviews' varying inclusion criteria but the authors did not report on outcomes for endometriosis treatment separately.

Capozzi et al. (2022) found that complication rates were comparable between robotic surgery and laparoscopy for endometriosis. The RCT found that robot-assisted surgery was non-inferior to laparoscopic surgery for most measured outcomes. Only quality of life at 6-weeks' follow-up was statistically significantly different with robotic surgery (mean difference -2.3, 95% CI -3.79 to -0.81). However, quality of life was not statistically significantly different at 6-months' follow-up (mean difference 1.3, 95% CI -0.58 to 3.18) (Lawrie et al. 2019).

Sacrocolpopexy

Lawrie et al. (2019) reviewed three RCTs comparing robot-assisted sacrocolpopexy to laparoscopic (n = 186). Capozzi et al. (2022) included three RCTs, two of which were the same as Lawrie et al. (2019) and one that appears to be more recent results of the other included trial, and one

retrospective study (n = 1,380). Jerbaka et al. (2022) included ten trials for robot-assisted sacrocolpopexy versus laparoscopy.

The three reviews found that intra-operative and post-operative complication rates were similar for the two procedures. However, low certainty evidence suggests post-operative pain may be worse after robot-assisted sacrocolpopexy (Lawrie et al. 2019, Capozzi et al. 2022).

Robot-assisted surgery may be associated with longer operation times, whilst lengths of hospital stay were found to be similar between the two procedures. Conversion to another surgical approach was similar for the two techniques, but this is based on one RCT with very low numbers (Lawrie et al. 2019). Quality of life may also be similar post-operatively but this is also based on only one RCT.

The overall conclusions of the three reviews were that robot-assisted surgery for benign gynaecological conditions is non-inferior to laparoscopic or open surgical approaches in terms of surgical and post-operative outcomes but is associated with longer operating times and higher costs. However, Lawrie et al. (2019) only concluded this for hysterectomy and sacrocolpopexy due to lack of evidence for the other procedures.

Economic Evidence

The cost-minimisation analysis developed by HIQA, reported above, found an incremental cost for robot-assisted hysterectomy of €3,019 per case (HIQA 2012). No other economic analyses were identified, though cost has been reported in individual studies and was reported in the systematic reviews as being higher for robot-assisted surgery.

An RCT from the USA comparing robot-assisted sacrocolpopexy to laparoscopy found that initial hospital costs were much higher for robotic surgery (US$19,616 versus US$11,573, $p < 0.001$) and costs remained significantly higher over six weeks (Anger et al. 2014). An RCT set in Sweden found that robot-assisted hysterectomy was significantly more expensive than laparoscopic or vaginal hysterectomy with a mean increased cost per patient of US$1,607 when including basic costs of the robot (Lönnerfors et al. 2015). Both studies state that the cost of robot-assisted surgery is similar to laparoscopy when the robot is considered a pre-existing investment and the purchase price is excluded.

A retrospective cohort study comparing robot-assisted and laparoscopic hysterectomy in a US setting found that direct costs were similar between the two procedures (Ghomi et al. 2022). They state that the profitability of robot-assisted surgery increases significantly when more than 45 procedures are performed annually.

Areas of uncertainty

There was quite significant overlap in the studies included in the systematic reviews and, therefore, the outcomes of the reviews should not be compounded. Additionally, most of the evidence sources were deemed to be of low or very low certainty, or high risk of bias. They also included very small numbers of RCTs, with no RCTs identified for myomectomy. The inclusion of retrospective studies by Capozzi et al. (2022) had a big effect on the number of participants, with most coming from these

studies. For example, of the 265,100 participants included for hysterectomy, 264,758 came from one retrospective cohort study.

The level of evidence synthesis by Capozzi et al. (2022) and Jerbaka et al. (2022) was poor. They did not include any meta-analyses and, for many outcomes, they quoted specific studies individually rather than a pooling of results. It was also not clear which studies Jerbaka et al. (2022) included for each analysis; results for the different procedures were not clearly reported separately and no details of the included studies were given.

There appears to be a lack of longer-term outcomes reported in the literature and there is also a lack of evidence regarding patient satisfaction.

Only one cost-minimisation analysis was identified, which is over ten years old and was not modelled in a UK setting. All other data reported on costs are also not from a UK setting and so the applicability to NHS Wales is uncertain.

Literature search results

Health technology assessments and guidance
ACOG. (2020). Robot-assisted surgery for noncancerous gynecologic conditions: ACOG committee opinion, Number 810. Obstetrics & Gynecology. 136(3). doi: https://doi.org/10.1097/AOG.0000000000004048 HIQA. (2012). Health technology assessment of robot-assisted surgery in selected surgical procedures. Health technology assessment. Health Information and Quality Authority. Available at: https://www.hiqa.ie/sites/default/files/2017-01/HTA-robot-assisted-surgery.pdf [Accessed 25 April 2023].
Evidence reviews and economic evaluations
Aarts JWM, Nieboer TE, Johnson N, et al. (2015). Surgical approach to hysterectomy for benign gynaecological disease. The Cochrane database of systematic reviews. (8): CD003677. doi: https://doi.org/10.1002/14651858.cd003677.pub5 Albright BB, Witte T, Tofte AN, et al. (2016). Robotic versus laparoscopic hysterectomy for benign disease: a systematic review and meta-analysis of randomized trials. Journal of Minimally Invasive Gynecology. 23(1): 18-27. doi: https://doi.org/10.1016/j.jmig.2015.08.003 Anger JT, Mueller ER, Tarnay C, et al. (2014). Robotic compared with laparoscopic sacrocolpopexy: a randomized controlled trial. Obstetrics & Gynecology. 123(1): 5-12. doi: https://doi.org/10.1097/aog.0000000000000006 Capozzi VA, Scarpelli E, Armano G, et al. (2022). Update of robotic surgery in benign gynecological pathology: systematic review. Medicina. 58(4). doi: https://doi.org/10.3390/medicina58040552 Ghomi A, Nolan W, Sanderson DJ, et al. (2022). Robotic hysterectomy compared with laparoscopic hysterectomy: is it still more costly to perform? Journal of Robotic Surgery. 16(3): 537-41. doi: https://doi.org/10.1007/s11701-021-01273-w Jerbaka M, Laganà AS, Petousis S, et al. (2022). Outcomes of robotic and laparoscopic surgery for benign gynaecological disease: a systematic review. Journal of Obstetrics and Gynaecology. 42(6): 1635-41. doi: https://doi.org/10.1080/01443615.2022.2070732 Lawrie TA, Liu H, Lu D, et al. (2019). Robot-assisted surgery in gynaecology. Cochrane Database of Systematic Reviews. (4). doi: https://doi.org/10.1002%2F14651858.CD011422.pub2 Lönnerfors C, Reynisson P, Persson J. (2015). A randomized trial comparing vaginal and laparoscopic hysterectomy vs robot-assisted hysterectomy. Journal of Minimally Invasive Gynecology. 22(1): 78-86. doi: https://doi.org/10.1016/j.jmig.2014.07.010
Individual studies
HTW researchers searched for primary evidence from 2021 onwards after the search date of the latest systematic review. No relevant evidence was identified.
Ongoing research
No relevant evidence identified.
Background information
El-Hamamsy D, Geary RS, Gurol-Urganci I, et al. (2022). Uptake and outcomes of robotic gynaecological surgery in England (2006–2018): an account of Hospital Episodes Statistics (HES). Journal of Robotic Surgery. 16(1): 81-8. doi: https://doi.org/10.1007/s11701-021-01197-5

Date of search:	April 2023
Concepts used:	Robot-assisted surgery, robotic surgery, gyn(a)ecology, benign

Proposed research question and evidence selection criteria (if selected)

Proposed research question	What is the clinical and cost effectiveness of robot-assisted surgery for benign gynaecological conditions compared to standard care?

	Included	Excluded
Population	People in whom gynaecological surgery is indicated for a benign condition	Malignant conditions/cancer
Intervention	Robot-assisted gynaecological surgery	
Comparison/ comparators	Laparoscopic surgery Open surgery	
Outcomes	Duration of surgery Duration of hospital stay Rate of complications/adverse events (intraoperative or postoperative) Rate of conversion to open/laparoscopic surgery from robot-assisted surgery Estimated blood loss Quality of life Patient satisfaction	
Study design	RCTs, observational studies, economic analyses	

Categorisation:	Obstetrics and gynaecology