



Topic Exploration Report ¹

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).
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Topic exploration report number	TER423
Topic	Advanced electrosurgical bipolar vessel sealing systems during hysterectomy
Summary of findings	<p>Hysterectomy is a commonly performed major surgical procedure. Current standard techniques to control bleeding during hysterectomy include mechanical suture or clamping, electric coagulation, ultrasonic activated scalpel and standard electrosurgical bipolar vessel sealing (EBVS). Advanced EBVS using higher currents and lower voltage energy and tissue sensing technology have been developed to improve tissue sealing.</p> <p>We identified one health technology assessment, one network meta-analysis, two systematic reviews and meta-analyses and nine individual studies studying advanced EBVS. Most included studies were randomised controlled trials (RCTs). Main outcomes were blood loss, operating time, complications, and length of hospital stay. Studies were heterogenous in terms of type of hysterectomy and the comparators used.</p> <p>Compared to suturing, there was evidence that use of advanced EBVS reduced blood loss in both vaginal and open hysterectomy. For open hysterectomy there was evidence that operating time and pain were reduced. Evidence for differences in operating time was more mixed during vaginal hysterectomy although length of hospital stay may reduce. When compared with standard EBVS in laparoscopic hysterectomy there was some evidence for reductions in blood loss and operating time, although these may not be clinically significant. Four RCTs compared different advanced EBVS systems in laparoscopic hysterectomy and found all systems to be equally clinically effective with no differences in outcomes. There was no difference in complications reported in any study. We did not identify any full economic analyses.</p> <p>There is a need for studies that examine the impact of use of advanced EBVS on hospital stay and patient outcomes, particularly in minimally invasive techniques and that consider cost-effectiveness.</p>

¹ [Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg](#)
[Translation of published technical HTW documents from English into Welsh](#)

Introduction and aims

Hysterectomy is a commonly performed major surgical procedure: approximately 40,000 women have a hysterectomy each year in the UK. During a hysterectomy, current standard techniques to control bleeding are suture, standard monopolar electrosurgery or standard electrosurgical bipolar vessel sealing (EBVS). Monopolar electrosurgery and standard EBVS use low energy electric current to seal blood vessels of up to 2mm in diameter. In standard EBVS electrodes are positioned at the ends of the instrument, which means the current does not pass through the patient's body, resulting in improved coagulation over monopolar electrosurgery. Both sutures and standard electrosurgery are associated with overnight or prolonged hospital stay.

Advanced EBVS systems have been developed that use higher currents and lower voltage energy, allowing tissue cooling during use. This is combined with system-specific mechanical forceps that apply high pressure evenly. Systems measure tissue impedance to monitor the effect of the current on the tissues to ensure a seal is achieved before automatically turning off the current. The systems seal vessels directly by fusing elastin and collagen. Different systems use different designs for forceps and different tissue impedance values which gives rise to variations in performance. Advanced EBVS can seal arteries and veins and large tissue bundles of up to 7mm in diameter.

It is proposed that use of advanced EBVS in hysterectomy reduces operating time and length of hospital stay and reduces post-operative pain, adverse events, side effects and complications. The LigaSure Vessel Sealing System (Medtronic) was identified as a specific example of the technology by the Topic Proposer. HTW also identified the Plasma Kinetic Gyrus (PK Gyrus, ACMI, Minnesota, USA), BiClamp (Erbe Elektromedizin GmbH), ENSEAL G2 (Ethicon Endo-surgery, US) and Marseal IQ 5mm (KLS Martin). The Topic Proposer has estimated that, in Wales, 70% of hysterectomies employ advanced EBVS, 25% use other advanced energy types and 5% use conventional sutures or monopolar electrosurgery.

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of advanced EBVS during laparoscopic, vaginal, or open hysterectomy conducted for any reason.

Evidence overview

Health Technology Assessment

An evidence review published by the NHS Purchasing and Supply Agency in 2007 was provided by the Topic Proposer. The review examined the clinical and cost-effectiveness of advanced EBVS during vaginal hysterectomy for benign conditions compared to traditional suturing. Six studies were identified, three of which were randomised controlled trials (RCTs). The other three were a non-randomised comparative study, an observational study with a historic comparator and a study described as 'mixed'. The review concluded that use of advanced EBVS allowed surgeons to undertake vaginal hysterectomy for more complex cases than traditional suturing did and resulted in reduced operating time and less pain for patients. There was evidence that length of hospital stay reduced by one day, although this observation was reported to be dependent on surgeon and patient expectations.

Secondary evidence

We identified two relevant systematic reviews and meta-analyses and one network meta-analysis. Pergialiotis et al., (2014) conducted a systematic review and meta-analysis comparing use of advanced EBVS vs traditional suture during vaginal hysterectomy. Searches were conducted between 1966 and 2013. Eight randomised trials were included, involving 772 women. Pooled interoperative mean difference (MD) blood loss was lower for advanced EBVS compared with suture (MD: -49.5 [95% CI: -67.6, -31.4]). There was no difference reported for operating time, intraoperative, major, or minor postoperative complications. The authors comment that the included studies were heterogenous which made firm conclusions difficult.

Zorzato et al., (2023) conducted a systematic review and meta-analysis comparing use of advanced EBVS vs standard EBVS in total laparoscopic hysterectomy. The search period was from January 1989 to November 2021. The review included two randomised controlled trials and two retrospective studies involving 314 women. Pooled estimated total intraoperative blood loss and operating time were lower for ABVS compared with conventional bipolar sealing devices (-39mL [95% CI: -65.8, -12.6, p=0.004] and - 8min [95% CI: -16.7, -0.8, p =0 .033]). There were no differences for hospital stay or overall surgical complication rate. The authors comment that the evidence was uncertain and observed differences in blood loss and operative time appear to be clinically unimportant.

Guo et al., (2016) conducted a network meta-analysis comparing all methods for haemostasis during open, laparoscopic or vaginal hysterectomy. Included methods were LigaSure, standard EBVS, conventional suture and three drug-related methods. Searches were conducted up until June 2016. A total of 20 studies were identified, of which nine were comparisons involving LigaSure either with standard EBVS or with suture. Direct meta-analysis showed that, compared with suture, LigaSure reduced blood loss (Standard MD: -1.42 [95% CI: -2.39, -0.44, p=0.004]), although this analysis included studies in both vaginal and open hysterectomy. Network meta-analysis found that LigaSure was the best method for controlling bleeding in open hysterectomy. No difference in blood loss for laparoscopic hysterectomy was found between LigaSure and standard EBVS.

Primary studies

We identified nine additional relevant RCTs published since 2016 that were therefore not included in the network meta-analysis.

Dubey et al., (2023) conducted a parallel arm RCT comparing advanced EBVS with suturing in open hysterectomy. The study included 30 patients in each arm. Use of EBVS compared to suturing reduced mean operating time (27 (8.9) vs 34 (8.6) minutes, p=0.005) and mean intra-operative blood loss (111 (53) mL vs 320 (194) mL, p=0.001). Pain scores in the first three post-operative days were reduced for patients in the EBVS arm.

Shady et al., (2021) also conducted an RCT comparing advanced EBVS (n=45) with suturing (n=45) in open hysterectomy in overweight and obese women. Again, use of EBVS compared to suturing reduced mean operating time (62 (16) vs 96 (10) minutes, p=0.0001) and lower blood loss (340 (57) vs 579 (71) mL, p=0.0001). There was no difference between the groups for requirement for blood transfusion or surgical complications.

Wang et al., (2018) conducted an RCT comparing advanced EBVS with 'conventional technology' in 96 women with cervical cancer referred for open hysterectomy. The study reported that duration of surgery, intraoperative blood loss, length of hospital stay, pain scores in the first three post-operative days and post-operative complication were all improved for the advanced EBVS group (p<0.05).

Batra et al., (2022) conducted an RCT involving 120 patients referred for laparoscopic hysterectomy for any benign indication. Patients were randomised to receive advanced EBVS or standard EBVS. Mean total operating time was lower for advanced vs standard EBVS (136 vs 143 minutes, p=0.002). There was no difference between the groups for mean blood loss or length of hospital stay.

Taskin et al., (2018) randomised 68 women with early-stage endometrial cancer also referred for laparoscopic hysterectomy to receive advanced EBVS or standard EBVS. Mean operation time was lower for advanced vs standard EBVS (134 (30) vs 164 (28) minutes, p<0.001). There was no difference between the groups for mean blood loss or length of hospital stay.

Four RCTs compared different advanced EBVS systems with each other in laparoscopic hysterectomy for benign indications.

Wong et al., (2020) compared LigaSure with Gyrus PKS in 67 women. Reported time to haemostasis was 14.2% less (p=0.03) when using LigaSure, but this was not considered clinically significant by the study authors. There were no differences reported between the arms for intra-operative blood loss, complications, conversion to open surgery or length of hospital stay. Aykan Yuksel et al., (2019) compared LigaSure with ENSEAL One in 132 women. No differences were reported in total operating time, blood loss or perioperative complications. Shiber et al., (2018) compared LigaSure with ENSEAL G2 in 140 women. No differences were reported for operative time, blood loss or complication rates. Hasanov et al., (2018) compared LigaSure 5mm with Marseal IQ 5mm in 74

women. There were no differences reported between devices for operating time or blood loss. All three studies reported that all the devices used provided effective vessel sealing.

Cost-effectiveness

The 2007 evidence review conducted by the NHS Purchasing and Supply Agency conducted a cost analysis. The observed reduction in hospital stay was reported as leading to a potential reduction in costs, although this was dependent on the price of the advanced EBVS system and consumables used. We did not identify any further studies that considered cost-effectiveness, although Dubey et al., (2023) reported that the instrument cost per hysterectomy was around \$64.

Areas of uncertainty

- Potential cost-savings may arise due to a reduction in hospital stay, in part arising from a reduction in blood loss, but it is uncertain as to exactly how use of advanced EBVS impacts on hospital stay.
- There are uncertainties as to the impact of advanced EBVS on patient reported outcomes, particularly in laparoscopic and vaginal hysterectomy when compared with standard EBVS.
- How many EBVS systems are available in the UK or have UK regulatory approval.

Literature search results

Health technology assessments and guidance

Peirce SC, Crawford DC. (2007). Evidence review: Electrosurgical vessel sealing in vaginal hysterectomy. Clinical Engineering Device Assessment and Reporting. Available at: www.cedar.wales.nhs.uk

Evidence reviews and economic evaluations

Guo T, Ren L, Wang Q, et al. (2016). A network meta-analysis of updated haemostatic strategies for hysterectomy. International journal of surgery (London, England). 35: 187-95. doi: <https://dx.doi.org/10.1016/j.ijso.2016.10.002>

Pergialiotis V, Vlachos D, Rodolakis A, et al. (2014). Electrosurgical bipolar vessel sealing for vaginal hysterectomies. Archives of gynecology and obstetrics. 290(2): 215-22. doi: <https://dx.doi.org/10.1007/s00404-014-3238-0>

Zorzato PC, Ferrari FA, Garzon S, et al. (2023). Advanced bipolar vessel sealing devices vs conventional bipolar energy in minimally invasive hysterectomy: a systematic review and meta-analysis. Arch Gynecol Obstet. Epub ahead of print. doi: <https://dx.doi.org/10.1007/s00404-023-07270-8>

Individual studies

Aykan Yuksel B, Karadag B, Mulayim B. (2019). Comparison of the efficacy and safety of two advanced vessel sealing technologies in total laparoscopic hysterectomy. J Obstet Gynaecol Res. 45(11): 2220-7. doi: 10.1111/jog.14096

Batra S, Bhardwaj P, Dagar M. (2022). Comparative Analysis of Peri-Operative Outcomes Following Total Laparoscopic Hysterectomy with Conventional Bipolar-Electrosurgery versus High-Pressure Pulsed LigaSure Use. Gynecology and minimally invasive therapy. 11(2): 105-9. doi: https://dx.doi.org/10.4103/GMIT.GMIT_69_20

Dubey P, Dube M, Kanhere A, et al. (2023). Electrothermal Vessel Sealing Versus Conventional Suturing in Abdominal Hysterectomy: A Randomised Trial. Cureus. 15(1): e34123. doi: <https://dx.doi.org/10.7759/cureus.34123>

Hasanov M, Denschlag D, Seemann E, et al. (2018). Bipolar vessel-sealing devices in laparoscopic hysterectomies: a multicenter randomized controlled clinical trial. Archives of gynecology and obstetrics. 409-14. doi: 10.1007/s00404-017-4599-y

Shady NW, Farouk HA, Sallam HF. (2021). Perioperative Outcomes of LigaSure Versus Standard Ligature Technique Among Overweight and Obese Women Undergoing Abdominal Hysterectomy: A Randomized Clinical Trial. Journal of Gynecologic Surgery. 37(4): 345-51. doi: 10.1089/gyn.2020.0158

Shiber L-DJ, Ginn DN, Jan A, et al. (2018). Comparison of Industry-Leading Energy Devices for Use in Gynecologic Laparoscopy: Articulating ENSEAL versus LigaSure Energy Devices. Journal of minimally invasive gynecology. 25(3): 467-73.e1. doi: <https://dx.doi.org/10.1016/j.jmig.2017.10.006>

Taşkın S, Şükür YE, Altın D, et al. (2018). Bipolar Energy Instruments in Laparoscopic Uterine Cancer Surgery: A Randomized Study. J Laparoendosc Adv Surg Tech A. 28(6): 645-9. doi: 10.1089/lap.2017.0639

Wang K, Wu H, Li D, et al. (2017). Clinical efficacy of ligasure vessel sealing system combined with total abdominal hysterectomy in treatment of cervical carcinoma. International Journal of Clinical and Experimental Medicine. 10: 5429-34.

Wong C, Goh A, Merkur H. (2020). Comparison of surgical outcomes using Gyrus PKS™ vs LigaSure™ in total laparoscopic hysterectomy: A randomised controlled trial. Australian and New Zealand Journal of Obstetrics and Gynaecology. 60(5): 790-6. doi: <https://doi.org/10.1111/ajo.13217>

Ongoing research

No ongoing or recently completed trials were identified.

Date of search	November 2023
Concepts used	Hysterectomy, electrothermal vessel sealing, electrosurgery, electrocoagulation, haemostasis/hemos(Shady et al. 2021, Shiber et al. 2018, Taşkın et al. 2018, Wang et al. 2017, Wong et al. 2020)tasis, ligation, LigaSure Vessel Sealing System

Proposed research question and evidence selection criteria (if selected)

Proposed Research question	What is the clinical and cost-effectiveness for advanced EBVS compared with standard care in hysterectomy?
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	Inclusion criteria	Exclusion criteria
Population	Open, laparoscopic, or vaginal hysterectomy for any indication	
Intervention	Advanced EBVS	
Comparison/ Comparators	Conventional sutures Monopolar electrosurgery Standard EBVS Other advanced EBVS systems Other advanced energy systems	
Outcome measures	Blood loss; operation time; complications; length of hospital stay; patient reported outcomes (pain, quality of life especially); costs	

Proposed speciality	Obstetrics and gynaecology
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