Submitted: 17 May, 2022 Accepted: 27 June, 2022 Published: 15 December, 2022 DOI:10.22514/ejgo.2022.055

ORIGINAL RESEARCH

European Journal of Gynaecological Oncology

Vaginal hysterectomy using the ERBE BiClamp® bipolar vessel sealing system as a surgical approach for endometrial cancer—single surgeon experience from a district general hospital

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Abstract

Uterine cancer is the most common gynaecological malignancy with increasing incidence due to rising ageing, increasing obesity within the population and falling rates of hysterectomy for benign disease. European and British guidelines advocate a minimally invasive surgery (MIS) even in patients with high-risk endometrial cancer (EC). The standard surgical procedure is total hysterectomy with bilateral salpingo-oophorectomy. Our study examines vaginal hysterectomy (VH) performed using the ERBE BiClamp® bipolar vessel sealing system as a surgical approach for EC following studies demonstrating its safety in VH for benign disease. Retrospective review of a single surgeons practice of patients booked for VH as the surgical treatment of EC (2011–2019). Patients' electronic records and paper charts were reviewed. Primary outcome was oncological safety and secondary outcomes were intra-operative blood loss, complications encountered, and length of hospital stay (LOS). The comparison group where previously studied patients undergoing BiClamp® VH by the same surgeon for benign/pre-malignant conditions. A total of 127 patients were included (median age 64 years, median BMI 32 kg/m^2). Mean Hb drop was 9.3 g/L. 50.4% of patients were discharged on the 1st post-operative day and 82.7% by day 2. A total of 35 patients received adjuvant treatment. There were 2 cases of vault recurrence and 2 patients died from disease progression. Overall, 5 year survival was 92.9% with the majority of deaths dues to cardiac causes or a separate malignancy. The rate of disease progression was 3.1%. This study suggests that BiClamp® VH is an oncologically safe procedure and could be considered as an alternative MIS approach in the cohort of patients who are not suitable for laparoscopic or robot-assisted staging surgery. The technique affords a short operative time, minimal bloods loss, short LOS with acceptable surgical outcomes and similar oncologic outcomes to other surgical approaches.

Keywords

Endometrial cancer; Vaginal hysterectomy; BiClamp®

1. Introduction

Uterine cancer is the most common gynaecological malignancy. The incidence in the UK has risen 59% since the early 1990's with rising ageing and increasing obesity within the population and the falling rates of hysterectomy for benign disease [1, 2]. There are now around 9700 new cases in the UK every year [3]. The annual incidence in Northern Ireland is 265 new cases every year [4]. The incidence of endometrial cancer increases with age and is highest in females aged 75–79 in the UK [3]. Multiple co-morbid conditions, specifically those related to the metabolic syndrome are more prevalent in patients with endometrial cancer than in the general population [5].

Guidance from the European Society of Gynaecological Oncology and the British Gynaecological Cancer Society advocates a minimally invasive surgical approach, including patients with high-risk endometrial cancer [6, 7]. The standard surgery is a total hysterectomy and bilateral salpingo-oophorectomy without vaginal cuff resection [7]. The Laparoscopic Approach to Cancer of the Endometrium (LACE) trial was a randomised trial comparing total laparoscopic hysterectomy with total abdominal hysterotomy for stage 1 endometrial cancer and the results demonstrated oncological safety with equivalent disease free survival in both cohorts [8]. A Cochrane review concluded that for early stage primary endometroid adenocarcinoma of the endometrium, laparoscopy is associated with similar overall survival and disease free

survival and associated with reduced post-operative morbidity and hospital stay when compared with laparotomy [9].

Several authors have described standard vaginal hysterectomy (VH) as a reasonable alternative to other surgical methods for the treatment of endometrial cancer, especially in patients with Class II/III obesity, elderly, medically compromised, or otherwise poor surgical candidate [10–15]. When compared with robot-assisted hysterectomy, VH has similar surgical and oncologic outcomes but a shorter operating time and is a less costly procedure [16].

With regards to the surgical approach for hysterectomy in the management of benign gynaecological disease, a Cochrane review concluded that VH was the superior procedure. It was associated with a more rapid return to normal activities, had the earliest discharge from hospital, and the shortest operation time [17]. The American College of Obstetricians and Gynaecologists, in keeping with the Cochrane consultation, recommends VH as the approach of choice for benign disease whenever feasible [18] as evidence demonstrated that it is associated with better outcomes when compared with other approaches to hysterectomy. Although in an EC setting they advocate a full surgical staging, (ideally via a laparoscopic or robot-assisted approach), there is an acknowledgment that VH may be an alternative for early stage endometroid endometrial cancer in selected patients who carry a high risk of surgical morbidity [19]. A study reviewing the route of hysterectomy in endometrial cancer cases in England revealed that only 1.7% of patients had a VH [20].

The safety of the ERBE Medical BiClamp® Bipolar Vessel Sealing System (BVSS, ERBE Elektromedizin GmbH, Tübingen, Germany) in performing a VH for benign gynaecological disease has been demonstrated in several studies. The patients experienced less intra-operative blood loss, had reduced post-operative analgesic requirements, and their post-operative length of stay was shorter than patients undergoing traditional VH [21–28].

We investigated the use of the ERBE BiClamp® BVSS in VH for the surgical management of endometrial cancer.

2. Materials and methods

2.1 Inclusion criteria

The setting was a district general hospital in Northern Ireland. This hospital is a satellite cancer unit undertaking procedures for early stage gynaecological cancers. All patients were discussed at the regional gynaecological oncology Multi-Disciplinary Team (MDT) meeting-with review of the histopathology from their endometrial biopsy and the cross sectional Magnetic Resonance (MR) imaging to establish their pre-operative Fédération Internationale de Gynécologie et d'Obstétrique (FIGO) staging. The decision tree is demonstrated below (Fig. 1).

We conducted a retrospective case review of all patients who were booked for a VH as the surgical management of endometrial cancer over a nine-year period (January 2011–December 2019). The patients were operated on by a single surgeon who had experience of using the ERBE BiClamp® BVSS since 2006. The patients were identified from the surgeon's theatre log.

The BVSS is a haemostatic control device that can seal vessels up to 7mm in diameter by denaturing collagen and elastin within the vessel wall and in the surrounding connective tissue [24, 28].

We reviewed the patients' electronic care records and paper charts were requested when further information was required. The study group was compared with previously analysed and published cohort who underwent BiClamp® BVSS VH for benign/pre-malignant disease [29].

2.2 Details of the surgical device and technique

The surgeon follows the technique previously described [29]. Vaginal bilateral salpingo-oophrectomy (BSO) is also possible following removal of the uterus. The infundibulopelvic ligament is identified and clamped. It is secured with an Endoloop® ligature before being divided and the tube and ovary removed vaginally.

2.3 Outcome measured

Data collected included patient demographics, pre-operative staging and type of procedure including additional vaginal, laparoscopic, or open BSO.

2.3.1 Primary outcome

Evaluation of oncological safety by reviewing changes to post-operative staging, adjuvant treatment requirement and overall survival and rate of disease progression.

2.3.2 Secondary outcomes

Secondary outcomes measured included:

- Peri-operative blood loss, determined by haemoglobin drop between pre-operative and post-operative values.
- Complication rate: intraoperative, short term and long-term complications.
- Length of post-operative stay: in post-operative days.

The perioperative outcomes (bloods loss, complication rate and length of post-operative stay were compared with the patients who had a BiClamp® VH for benign indications.

2.4 Statistical information

Median and mean values were recorded for the outcomes measured. Interquartile ranges and 95% confidence intervals were calculated. Overall survival was calculated from the date of surgery to date of death by any cause.

3. Results

A total of 132 patients were planned for BiClamp® VH over a nine year period (January 2011 to December 2019). The comparison group included 135 patients planned for BiClamp® VH over an almost eight year period (September 2006–May 2014). Both group are shown in Fig. 2.

The median age of the patients was 64 years (Range 41–90 years). The pre-operative Body Mass Index (BMI) was

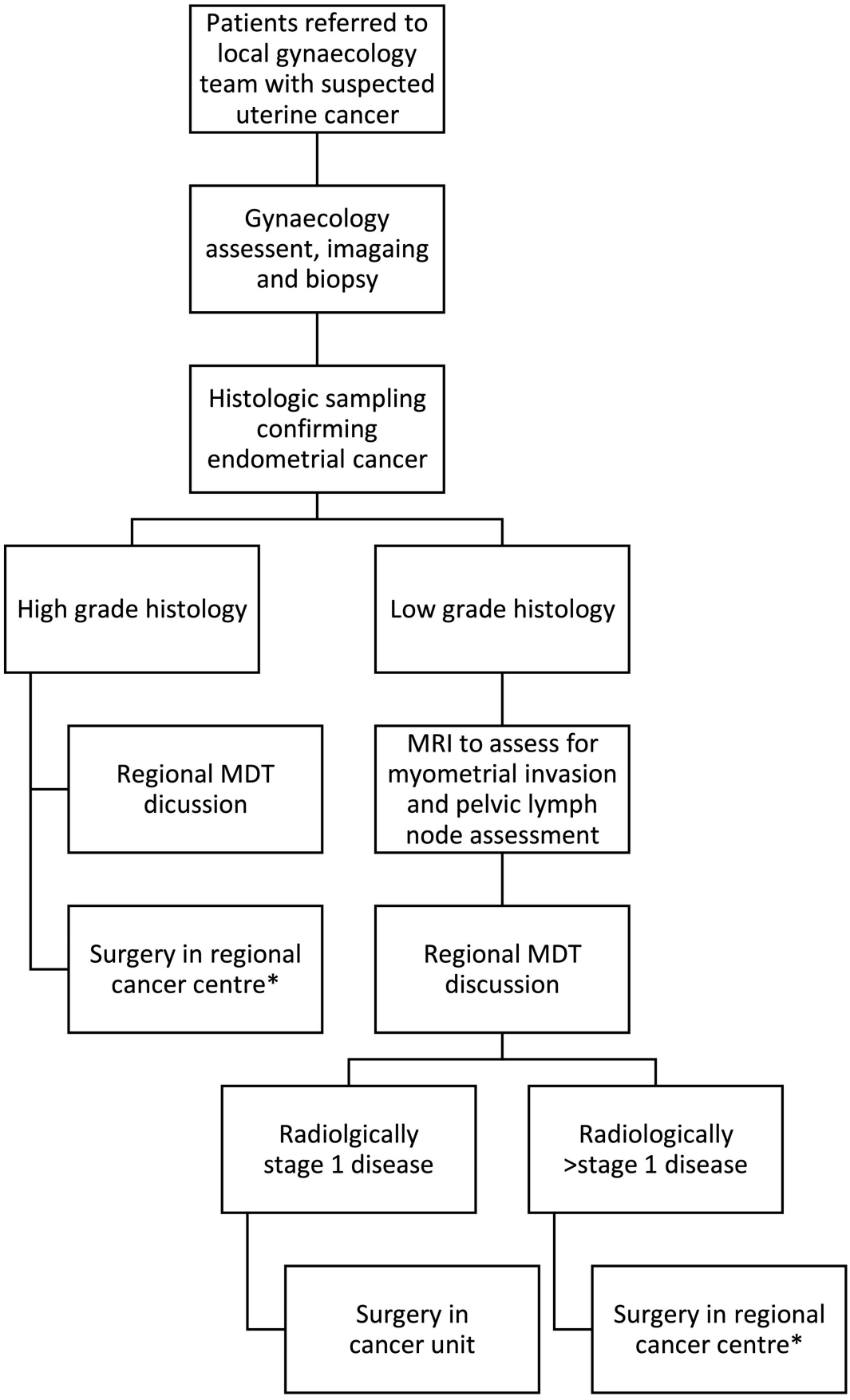

FIGURE 1. Decision tree detailing regional guidance on patient selection for location of surgery for EC. *Patients with a significant perioperative risk and deemed unsuitable for full staging surgery may be offered a simple hysterectomy in their local cancer unit. MDT: Multidisciplinary Team, MRI: Magnetic Resonance Imaging

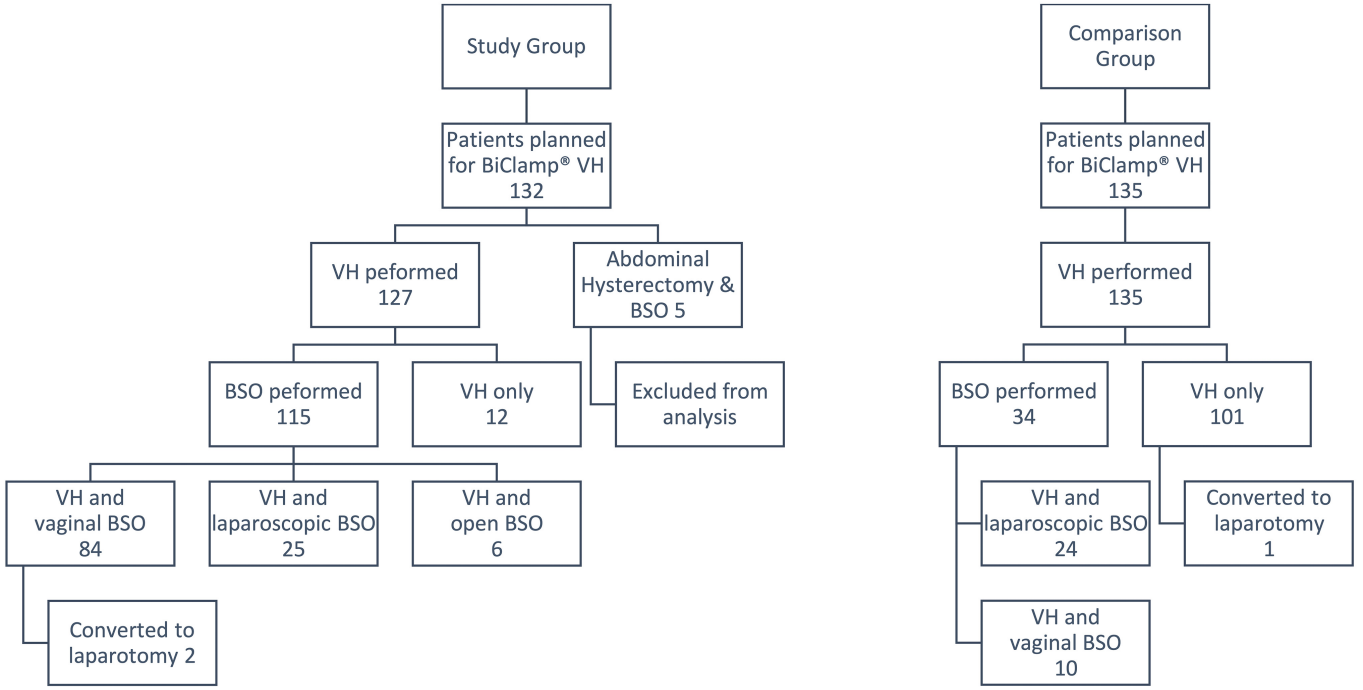

FIGURE 2. Formation of the study and comparison cohorts. VH: vaginal hysterectomy; BSO: bilateral salpingo-oophrectomy.

recorded for 93.7% of patients, median 32 kg/m^2 (Interquartile Range (IQR) 8.85, Mean 33.19 +/− 7.42, 95% Confidence Interval (CI) 31.85–34.52), with 21.8% of patients with Class II obesity and 16% with Class III. Demographics of the study and comparison groups are shown in Table 1. There was a high level of medical co-morbidities amongst the cohort. These are summarised in the Table 2. A total of fifty patients had two or more medical co-morbidities documented.

Pre-operative FIGO staging was available for 92.9% of patients (118 patients). The majority of the patients (116) were classified as stage 1 based on review of their MRI scan, (Stage 1A- 91 patients, Stage 1B- 25 patients). Two patients were radiologically staged as Stage 2 and deemed not suitable for extensive surgery. The first patient was aged 81 years old with a BMI of 38 had carcinosarcoma on endometrial biopsy with a past medical history of type 2 respiratory failure, osteoarthritis, congestive cardiac failure, and chronic obstructive pulmonary disease. The second was 68 years old with a history of deep vein thrombosis and breast cancer.

Indications for surgical intervention in the comparison group were for the following benign/pre-malignant conditions: Menorrhagia, persistent cervical intraepithelial neoplasia, pelvic pain/endometriosis uterine prolapse, endometrial hyperplasia or risk reducing surgery for a genetic pre-disposition to gynaecological malignancy [29].

3.1 Peri-operative blood loss

Post-operative Hb was checked in 87 patients (68.5%). This was not felt to be warranted in the other patients due to the minimal blood loss. The mean drop in Hb from the pre-operative level with 95% confidence intervals are shown for both the study and comparison groups in the graph below (Fig. 3).

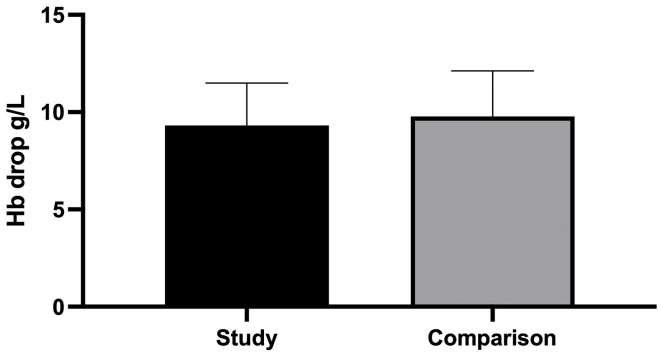

FIGURE 3. Mean intra-operative blood loss with 95% Confidence intervals.

3.2 Length of post-operative hospital stay

50.4% of patients were discharged on the first post-operative day and 82.7% of all patients were discharged by the second post-operative day. The median length of stay was 1 (IQR 1. Mean 1.98 +/− 2.20, 95% CI 1.56–2.36). In the comparison group 40.7% of patients were discharged on the first post-operative day and 68.6% by the second. Their median length of stay was 1 post-operative day.

3.3 Operating time

The operating time was recorded in 46 cases without an open component to the operation in the study group and is shown in Table 3.

3.4 Conversion to open procedure

A total of five patients were converted to total abdominal hysterectomy due to difficult access or bleeding. Of the remaining

TABLE 1. Demographics of the study and comparison cohorts.

	Study Group	Comparison group
Number of patients	127	135
Median age in years (range)	64 (41–90)	47 (24–83)
Median Body Mass Index (BMI) kg/m^2 (% available)	32 (93.7%)	27 (42.0%)
Class I Obesity	29.4%	12.3%
Class II Obesity	21.8%	3.5%
Class III Obesity	16.0%	17.3%
Two or more medical co-morbidities (% available)	50 patients (89.0%)	17 patients (54.8%)

TABLE 2. Medical co-morbidities of the study cohort.

	No. of patients		No. of patients
Hypertension	48	Asthma/Chronic obstructive pulmonary disease	9
Type 2 Diabetes	17	Hypothyroidism	15
Ischaemic Heart Disease	8	Breast Cancer	6
Atrial Fibrillation	7	Rheumatoid Arthritis	4
Congestive Cardiac Failure	5	Osteoarthritis	18
Stage 3 Chronic Kidney Disease	13	Epilepsy	2
Previous Venous thromboembolism	4	Dementia	2
Cerebral vascular accident/Transient ischaemic attack	2	Bowel cancer	2
Peripheral vascular disease	2	Obstructive sleep apnoea	1

TABLE 3. Operating time for the various surgical approaches.

	Study Group		Comparison Group	
Procedure	Median operating time (Range) in minutes	Number of cases	Median Operating Time (Range) in minutes	Number of cases
VH and BSO	50 (27–114)	31	59 (39–73)	10
VH only	45 (24–103)	7	40 (23–100)	99
VH and lap BSO	83 (50–100)	9	70 (50–100)	23

VH: vaginal hysterectomy; BSO: bilateral salpingo-oophrectomy.

TABLE 4. Post-operative surgical staging and histology results.

	Endometrioid adenocarcinoma			Serous carcinoma
	Grade 1	Grade 2	Grade 3	
Stage 1A	60*	30#	1	2
Stage 1B	10	9	1	
Stage 2	4	6		
Stage 2	3	1		

**One patient had an incidental finding of a STIC lesion.*
#one patient had a small synchronous ovarian primary endometroid adenocarcinoma.

analysed cohort, eight patients required an open component to their surgical procedure (6.29%): 6 of whom required an open procedure to complete the BSO following VH (4.72%), and two patients (1.57%) required laparotomy following VH and salpingo-oophorectomy—one patient for bleeding and the other to identify the remaining tube/ovary (surgically absent at laparotomy). In the comparison group, one case was converted to laparotomy for bleeding from the upper aspect of the fallopian tube following VH.

3.5 Short term complications

Of the patients who had vaginal +/− laparoscopic surgery only, short term complications were observed in 9 patients (7.6%). Three patients experienced urinary retention requiring catheter reinsertion for a further 24 hours. One patient was treated for a lower respiratory tract infection (LRTI). Two patients required a return to theatre: one for bleeding on Day 1 and one for a jejunal perforation. A patient was transferred to the urology team for ureteric stenting due to concerns of a potential ureteric injury on the background of an acute kidney injury. Two patients were readmitted in the first 14 days: one with urosepsis and one with non-specific abdominal pain.

In the patients who had open surgery following VH, 4 patients experienced short term complications. One patient had a vault haematoma and three had wound infections (of which one required a return to theatre for debridement).

In the comparison group, short term complications were observed in 17 patients (12.6%) with 7 patients treated for urinary tract infections and 4 patients experiencing urinary retention. One patient was noted to have burn in the gluteal region, 4 patients developed a vault haematoma (one required evacuation in theatre) and one patient returned to theatre on day 1 due to post-operative haemorrhage. There was concern regarding ureteric injury in one patient who was transferred to the central urology service on the second post-operative day.

3.6 Long term complications

Very few long-term complications were recorded in the EC cohort. Two patients were admitted between 2–3 weeks post-operative with a vault haematoma. The remaining long term issues were of a urogynaecological nature. Six patients were reviewed for urinary incontinence, one for overactive bladder syndrome, two for pelvic organ prolapse and one for bladder pain.

In the comparison group, five patients were reviewed for pelvic pain, one patients for vault prolapse, one patient was investigated for stress urinary incontinence and one patient diagnosed with a pelvic inclusion cyst.

3.7 Post-operative staging

All patients were discussed at the regional Cancer Centre MDT meeting following surgery and histopathological specimens are centrally reviewed. Results are shown in Table 4. Eight patients were up-staged from stage 1 to stage 2 following surgery, three patients from stage 1 to stage 3 and one per-menopausal patient was documented as stage 3 (pre-operative staging not available. Two patients were down-staged from stage 2 to stage 1B (one was a carcinosarcoma). There was an incidental finding of an occult serous tubal intraepithelial carcinoma (STIC) lesion in one patient and another patient had a small synchronous primary ovarian endometroid adenocarcinoma (FIGO 1A). Both cases underwent completion staging surgery at the regional Cancer Centre.

3.8 Adjuvant treatment

A total of 35 patients received adjuvant treatment for deep myometrial invasion or unfavourable histology. 13 patients had vaginal vault brachytherapy (22 Gy in 3 or 4 fractions), 16 patients had vaginal vault brachytherapy and external beam pelvic radiotherapy (vault brachy 8 Gy in 2 fractions and external beam 45 Gy in 25 fractions) and four patients had systemic chemotherapy combined with vaginal vault brachytherapy and external beam pelvic radiotherapy for high grade or Stage 3 disease. Of the four patients receiving systemic therapy, two patients were upstaged from stage 1 preoperatively to stage 3 on final histological review and the other two had high grade disease on final histology (low grade on initial biopsy).

3.9 Survival

Vault recurrence was documented in two patients (both Stage 1A Grade 2) and one patient had distant disease documented 2 years later (Stage 2). There has been 11 deaths within the cohort, two of which were due to advanced endometrial cancer; (one six months post-surgery Stage 1B Grade 2) and the other seventeen months post-surgery (Stage 1B Grade 3). The other causes of death included 6 patients who died from other cancers (breast, lung, bowel, T cell leukaemia), and three who died from cardiac causes (congestive cardiac failure, ischaemic heart disease).

4. Discussion

This retrospective case cohort study demonstrates that BiClamp® VH in carefully selected EC patients is oncologically safe. To our knowledge, this is the only study evaluating BiClamp® VH as the surgical approach for the management of endometrial cancer.

The median age (64 years) and BMI 32 kg/m^2 were higher than the previous studies reviewing this technique for the management of benign gynaecological disease [24, 25, 27]. Both age and BMI were higher in the study than in the comparison group (47 years, BMI 27 kg/m^2). The association between elevated BMI and EC risk is well recognized-although mechanisms that may underly are not fully characterised but likely include higher oestrogen levels in postmenopausal women, hyperinsulinaemia and a chronic inflammatory state [30].

The survival data within this study cohort demonstrated a disease specific survival of 99.2% at 1 year and 93.9% at 5 years with overall survival of 99.2% and a 5 year survival of 92.9%—with many of the deaths due to cardiac causes or a separate malignancy. The overall progression rate was 3.1% within the study period. This is an improved overall survival rate and a lower progression rate, when compared with the nationally reported survival statistics and lower progression rate than that quoted in systematic reviews [31]. This suggests

that BiClamp® VH is an oncologically safe approach for selected cases of EC.

There was minimal intra-operative blood loss with a mean haemoglobin reduction of 9.3 g/L on pre-operative levels. The explanation previously postulated for the minimal blood loss with this procedure may be the avoidance of retrograde bleeding and the more efficient sealing of smaller vessels, a step that can be technically difficult during a traditional VH [24].

The conversion to open procedure rate was low (6.3%) following vaginal hysterectomy. This was principally to enable completion of the salpingo-oophorectomy in difficult cases. This was higher than the comparison group who had benign indications for their surgery therefore significantly less patients had a salpingo-oophorectomy performed. The comparison population also had a lower median BMI and as a consequence the surgery was potentially less challenging. Of the study group, 73% of the patients having a bilateral salpingo-oophorectomy had it performed vaginally and only two patients required open surgery demonstrating the safety of this surgical approach.

In comparison with studies evaluating traditional VH for the management of endometrial cancer, our cohort had a much shorter post-operative length of stay, (mean 1.9 post-operative days) and 82.7% of patients discharged by day 2 post-op [14, 32, 33]. This was actually better than the comparison group undergoing vaginal hysterectomy for benign/pre-malignant conditions who had a lower median age and less documented co-morbidities.

All patients had a pre-operative assessment of pelvic lymph nodes by MR imaging and reviewed at the regional Cancer Centre MDM. Risk stratification was undertaken at the MDM following the regional guidance. Those in this study cohort who were felt not to have radiological evidence of lymph node metastases, were deemed suitable for primary surgical treatment in a Cancer Unit. Patients at higher risk of nodal metastasis had their care centralised to the Cancer Centre. We do appreciate that the patients did not have histological lymph node assessment, either by ultrastaging of sentinel lymph nodes or through systematic pelvic and para-aortic lymphadenectomy, and we may understage a small percentage of these patients. The small number of patients deemed not fit for complex oncological surgery would also not have been suitable candidates for adjuvant chemotherapy and, consequently, nodal assessment was not necessary and the benefit would not have outweighed the surgical risk.

5. Conclusions

This study, to our knowledge is the only published work reviewing the ERBE BiClamp® BVSS to perform VH (+BSO) for the management of endometrial cancer. It suggests that it is an oncologically safe procedure and could be considered as an alternative approach in the cohort of patients who are not suitable for a laparoscopic or robot-assisted staging surgery due to medical co-morbidities. It is also an option for patients with low grade, early stage endometrial cancer where histological lymph node assessment is not required as discussed above. The short and long term complications in this study group were less than those observed in the comparison group undergoing BiClamp® BVSS VH for benign/pre-malignant conditions. This procedure can be performed under spinal anaesthesia which is useful in patients who are a significant general anaesthetic risk. The technique affords a short operative time, minimal intra-operative bloods loss, short length of hospital stay and acceptable surgical outcomes.

AUTHOR CONTRIBUTIONS

NH and JPB—designed the research study, NH, JPB, GVB, LH and DC—performed the research, NH and JPB—analysed the data and wrote the manuscript. GJD, DQ, NH and JPB—participated in the surgery and GJD—was the supervising consultant and lead surgeon or surgeon directly supervising trainees. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

As this project was solely an audit of intra- and post-operative outcomes for the purpose of service evaluation and improvement. The audit and governance department deemed it unnecessary to seek ethical formal approval.

ACKNOWLEDGMENT

Not applicable

FUNDING

This research received no external funding.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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How to cite this article: Niamh Haughey, James P. Beirne, Gillian V. Blayney, Lynsey Hinds, Declan Quinn, Donald Chandranath, et al. Vaginal hysterectomy using the ERBE BiClamp® bipolar vessel sealing system as a surgical approach for endometrial cancer—single surgeon experience from a district general hospital. European Journal of Gynaecological Oncology. 2022; 43(6): 26-33. doi: 10.22514/ejgo.2022.055.