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Research Article

# Laparoscopic Radical Hysterectomy is Safe in Management of Early Cervical Cancer Ia2-Ib1: Single Cancer Centre Experience

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## Abstract

**Objective:** The aim of the study was to determine the safety, disease free survival (DFS) and 5-year overall survival (OS) for Laparoscopic Radical Hysterectomy (LRH) in the management of stage Ia2-Ib1 Cervical Carcinoma (2018 FIGO staging).

**Methods:** This is a prospective study over a period of 8 years, including 100 consecutive patients, with cervical cancer FIGO stage Ia2-Ib1 who underwent radical laparoscopic hysterectomy.

**Results:** In our study group undergoing LRH had DFS 98% and OS of 99%. Follow up was a minimum of 5 years, compared to 4.5 years for DFS and 3 years for OS in the LACC trial.

**Conclusions:** This study demonstrates the safety of LRH Querleu Morrow type B1 with SLNB only in the management of high-risk stage IA2 and stage IB1 cervical carcinoma (2018 FIGO staging) with a similar DFS and the same OS as the open arm of the LACC trial, but with a longer follow-up period.

**Keywords:** Laparoscopic radical hysterectomy; Cervical cancer; Sentinel node

### What is already known on this topic?

Recent publications have questioned the safety of LRH in early-stage cervical cancer with respect to DFS and OS. This study reassesses a single center's data, in highly homogenous group of patients with Stage Ia2 and Ib1 cervical Carcinoma, combined with SLNB alone.

### What this study aids

This study demonstrates that LHR with SLNB alone is safe in carefully selected patients with stage IA2 and IB1 tumors (less than 2cm in diameter). When performed by surgeon with long term experience in laparoscopic surgery.

### How this study might affect research, practice, or policy

Since LRH (using the McCartney tube) with SLNB alone did not

negatively affect outcome, further research is needed to confirm safety of this treatment modality in this selected group of patients.

## Introduction

Open radical hysterectomy (ORH) has been the procedure of choice in the management of early cervical cancer for more than a century [1] . Lymph nodal metastasis is the most important prognostic factor and Meigs introduced pelvic lymphadenectomy as a standard addition to RH in the management of early cervical carcinoma [2-5]. In 1992 Nezhat described laparoscopic radical hysterectomy (LRH) with pelvic lymphadenectomy [6]. The LRH approach gained popularity because of the advantages of minimally invasive surgery (MIS) over open surgery: less blood loss, similar intraoperative complications, shorter hospital stay and fewer postoperative complications (within the first 30 days). In addition there is less risk of: thromboembolism, infection, ileus, postoperative pain and there is a better aesthetic result [7-13]. Robotic radical hysterectomy (RRH) is another MIS technique introduced in clinical practice with similar advantages but will not be discussed in this paper [14]. Bilateral pelvic dissection is used to assess nodal status and the complications of this procedure include lymphocyst formation, leg lymphedema and less commonly, vessel and nerve injury [15,16] Sentinel lymph node biopsy (SLNB) can be performed with a similar, if not superior detection rate of involved nodes, but with reduced postoperative side effects [17-23]. The majority of the published data on SLN in cervical carcinoma including recent systematic reviews suggest that this method is accurate in detecting metastasis, with a promising low false negative rate.[20]

In respect to oncological outcome, such as disease free survival (DFS) and overall survival (OS), the majority of published studies did not find a significant difference between open and laparoscopic approaches for early cervical cancer [7,11,24-30]. However, this data was not from randomized controlled trials. In 2018 results from two published studies seriously questioned the concept that LRH has equivalent oncological results to open surgery [31,32].

## Materials and Methods

### Study group

Our study group included 100 consecutive patients diagnosed with early cervical carcinoma measuring less than 2 cm in diameter, in the period January 2009 to January 2017. This cohort of patients included grade 2 or 3 with stage IA2 lymph vascular space invasion (LVSI +) cases and stage IB1 cases according to the FIGO 2018 classification (where IB1 measures <2 cm in diameter) (Table 1). All patients underwent a type B1 radical laparoscopic hysterectomy as described by the Querleu and Morrow classification [22] . The study was conducted at the West Kent Gynecological Oncology center, Maidstone Hospital, Maidstone, Kent, UK. Local Ethics Committee approval was granted in 2004 (ref. 032/02/04) initially for Radical Hysterectomy and Sentinel lymph node dissection (SLND) followed by bilateral pelvic lymph node dissection (BPLND). Patients operated before December 2008 had both SLND and BPLND in order to validate the accuracy of the SLND [18]. In 2009 the interventional procedure panel at our hospital approved the prospective audit of Sentinel Lymph Node Biopsy only (SLNB) including laparoscopic management of cervical carcinoma of stage IA2-IB1 (<2 cm in diameter) as assessed by preoperative Histology and MRI. All patients were given the choice of bilateral pelvic lymph node dissection (BPLND) alone, BPLND with SLND, or SLND only. Sentinel lymph node detection was performed using the double technique, consisting of blue dye and Technetium-99 m as described previously.[18] All patients fulfilling our criteria (tumour <2 cm in diameter and suitable for laparoscopic approach) opted for SLND only in the period between January 2009 and January 2017.

### Surgery

Five patients were stage IA2 grade 2 and 3 with LVSI and 95 patients were stage IB1 <2 cm (FIGO 2018 classification) and all underwent Querleu and Morrow type B1 radical hysterectomy. The decision for laparoscopic radical hysterectomy was based on the preoperative pelvic MRI and staging chest and abdominal CT scan and histology from Large Loop Excision of Transformation Zone (LLETZ). When the SLN was detected unilaterally, a full contralateral pelvic lymphadenectomy was performed [23].

In our publication on SLN biopsy alone in the management of early cervical cancer, we did not detect any positive nodes on the side where the SLN was not detected and a full pelvic lymphadenectomy was performed [23]. In addition, no cases of lymphedema or lymphocyst were noted, our previous study supports the safety of the Sentinel lymph node technique as compared to a full lymph node dissection [23].

A McCartney tube (without an intrauterine manipulator) was used to elevate the uterus and outline the vaginal vault. The use of other type of intra-uterine manipulators may be a factor leading to an increase pelvic recurrence risk (SUCCOR study) [33].

Intraoperative blood loss was less than 400 ml. (Table 4). LRH was associated with a shorter hospital stay and 85% of patients stayed less than 4 days (Table 4). All radical hysterectomies were performed by one surgeon. This removed variations in surgical technique and procedure was highly standardized. Before entering patients in the study, a learning curve was completed involving 30 radical laparoscopic hysterectomies with SLND and bilateral pelvic lymph node dissection (BPLND) between 2007-2009.

The study endpoint was January 2017 in order to have a minimum of 5 years follow up. In our study, we had 10 patients with metastasis in lymph nodes (Table 1), all were detected in the SLN. Two patients had macro metastasis (MaM), 4 micro metastasis (MiM) and 4 isolated tumour cells (ITC) within the SLN. Thirteen had adjuvant treatment: 4 received radiotherapy (RT) only and 9 received chemoradiation. Decisions regarding adjuvant treatment were made by the multidisciplinary team (MDT) of the West Kent Cancer Centre, Maidstone, UK. Each decision was based on risk factors (histological type, grade of tumour, lymph nodal metastasis, tumour margins and LVSI). Isolated tumour cells alone were not an absolute indication for adjuvant treatment, but if ITC were associated with positive LVSI, then this was considered an indication for RT (if the tumour was grade 3 then chemotherapy was also given). All patients with micro and macro metastasis received chemoradiation. Three patients without lymph node metastasis had chemoradiation based on grade 3 histology, LVSI positivity and margins less than 5 mm. We did not have any recurrence or death in the patients who had adjuvant treatment. We had two recurrences in cancers with low-risk features (Table 2). One of those two patients died from the recurrent disease and one is still alive, 7 years after surgery.

Follow up was performed every 6 months post treatment for 3 years and yearly in the last two years, with clinical examination and CT/MRI 6-12 months postoperatively, again after 3 years and once again before discharge after 5 years. Additional CT/MRI scanning was performed if a patient presented with any symptoms suspicious of recurrence.

The disease-free survival (DFS) and overall survival (OS) over 5 years of FU are shown in Table 3.

## Results

One hundred patients underwent a laparoscopic B1 radical hysterectomy with sentinel lymph node only using McCartney tube. Our results are highly standardised as a single surgeon performed all procedures (Querleu Morrow type B1 LRH) with an adequate learning curve and a low conversion rate (2%). The 5 year follow up in this study is longer than the LACC trial (4.5yrs).

Five patients were stage IA2 grade 2 and 3 with LVSI and 95 patients were stage IB1 < 2cm (FIGO 2018 classification), during the period January 2009 to January 2017. Ten patients had lymph nodal metastasis (Table 1). All were found in the SLN, 2 patients with macro metastasis (MaM), 4 micro metastasis (MiM) and 4 isolated tumour cells (ITC). In this study 13 had adjuvant treatment: 4 received radiotherapy (RT) only and 9 received chemoradiation. There were two recurrences in cancers with low-risk features (Table 3).

The main objective of this study was to answer the question as to whether LRH is inferior to open surgery for cervical cancer <2 cm in size (FIGO 2018 stage IA2, Grade 2 and 3 with LVSI and IB1). It was to report on a single centre experience of the surgical management of early-stage cervical cancer with respect to MIS and thereby contribute to the debate. Our publication focuses on results of LRH with SLNB only (Table 1). Since we introduced LRH into our practice in 2007 our criteria for this operation specified inclusion of tumours less than 2cm in diameter and indeed this has been our practice for 11 years; even before FIGO introduced the new definition of stage IB1 in 2018. It has been our practice that tumours equal to or greater than 2cm in diameter require radicality of Querleu Morrow type C LRH and we acknowledge that this operation is not possible in all patients, being dependent on various characteristics (BMI, previous surgery, size of the uterus). We included 100 consecutive cases of FIGO 2018 IA2 grade 2&3 with LVSI or IB1 from 2009 to 2017 and all patients that fitted this criterion had type B1 LRH and SLNB only. The conversion rate was only 2% (one patient for extensive adhesions from previous abdominal surgery and the second due to a large 14cm uterus- and these patients were excluded from the analysis). Data for the study cohort are presented in tables 1-4.

| | |
|---|---|
| Total Number of women(N) | 100 |
| Median age (years) | 40 (range 25-71) |
| Median BMI (Kg/m2) | 26 (range 18-42) |
| FIGO stage | |
| Stage 1A2 (LVSI +, Gr 2 &3) | 5 (5%) |
| Stage 1B1 (< 2cm) | 95 (95%) |
| HISTOLOGY | |
| Squamous cell carcinoma | 59 (59%) |
| Adenocarcinoma | 32 (32%) |
| Adenosquamous carcinoma | 8 (8%) |
| Small cell neuroendocrine carcinoma | 1 (1%) |
| GRADE | |
| Grade 1 tumours | 6 (6%) |
| Grade 2 tumours | 69 (69%) |
| Grade 3 tumours | 25 (25%) |
| Lymphovascular space invasion (LVSI) | 37 (37%) |
| Patients with SLN metastasis | 10 (10%) |
| Isolated tumour cells (ITC) | 4 (4%) |
| Micrometastasis (MiM) | 4 (4%) |
| Macrometastasis (MaM) | 2 (2%) |
| Tumour size (MRI) <20mm | 100 (100%) |
| TYPE OF SURGERY | |
| B1 Querleu & Morrow type laparoscopic radical hysterectomy | 100 (100%) |

**Table 1:** Patient characteristics, FIGO 2018 stages, histology and surgical details.

| | FIGO 2018 | Histological subtype | LN metastasis | (+) SLN (number) | LVSI | Adjuvant therapy | Recurrence (months) | Tx for recurrence | DOD |
|---|---|---|---|---|---|---|---|---|---|
| **1** | 1B1 | Grade 2, squamous | No | (0) | No | No | 41 (ovary) | Surgery, ChT, RT | Alive |
| **2**** | 1B1 | Grade 2. Squamous | No | (0) | No | No | 8 (pelvic) | ChT , RT | Yes |

* LN = Lymph node; SLN = Sentinel lymph node; LVSI = lymphovascular space involvement; Tx= Treatment; DOD = died of disease; RT= Radiotherapy; ChT=Chemotherapy

** Patient No.2 had no indication for adjuvant treatment. Tumour excision margin 16 mm (> 1cm), no LVSI, negative lymph nodes. Recurred 8 months post-surgery with a mass in the pelvis. Started Chemo RT but progressed on treatment. Chemo RT stopped, for palliative treatment, died 17 months post-surgery.

**Table 2**: Details of the recurrences and the patient who died of disease.

| DFS | 3 years DFS | 4.5 years DFS | 5 years DFS |
|---|---|---|---|
| **LSC/robot arm in LACC trial** | 87.1 % | 86.0 % | |
| **Laparotomy arm in LACC trial** | 97.1 % | 96.5 % | |
| **Our own results: WKCC** | 98.0 % | 98.0 % | 98.0% |
| **OS** | **3 years OS** | **4.5 years OS** | **5 years OS** |
| **LSC/ robot arm in LACC trial** | 93.8% | n/a | |
| **Laparotomy arm in LACC trial** | 99.0% | n/a | |
| **Our own results WKCC** | 99.0% | 99.0% | 99.0% |

**Table 3:** Comparison of our DFS and OS survival rate with LACC trial (patient %).

| **Blood loss** | |
|---|---|
| ml | patients |
| < 100 ml | 12 |
| 100-200 ml | 49 |
| 200-400 ml | 39 |
| **Hospital stay** | |
| Days | patients |
| 2-4 | 85 |
| 5-8 | 15 |

**Table 4:** Blood loss and hospital stay (100 patients total).

## Discussion

This is not a randomized study but these were consecutive patients treated at a single Cancer centre by surgeons utilizing the same technique (limited cervical manipulation using a McCartney vaginal tube and no intrauterine manipulator). All patients underwent discussion in a Multi-Disciplinary Team. We are however aware of the limitations of our study in that it is not a randomised trial, which can introduce selection bias. However, the consistency of the surgical technique and the indications and decision-making process being managed by the same multidisciplinary team (MDT) removes many variables associated with multicentre trials. Case selection bias is reduced by including all consecutive patients.

Open radical hysterectomy with pelvic lymphadenectomy was the surgical gold standard until 1992, when laparoscopic radical hysterectomy (LRH) was described [6]. In subsequent years, LRH and later robotic radical hysterectomy (RRH), gained significant popularity in the surgical treatment of early cervical carcinoma. None of the early studies were randomised trials [7,11,27-30]. However, the publication of the Laparoscopic Approach for Cervical Cancer (LACC) was the first randomised controlled, multicentre trial comparing LRH with open radical hysterectomy, published in 2018. This trial raised concerns that LRH had an inferior oncological outcome when compared with the open approach in the management of early cervical carcinoma. Minimally Invasive Surgery (laparoscopic and robotic radical hysterectomy) had a 4.5-year DFS of 86.0% compared with 96.5% for open radical hysterectomy (10.5 % difference between the groups 95% CI: -16.4 to - 4.7; p=0.87 for non-inferiority). The three-year OS rates were 93.8% for the MIS arm and 99.0% for the open approach (HR for death from any cause, 6.00; 95% CI: 1.77 to 20.30) [31].

This publication was the first randomised trial comparing MIS and the traditional open technique and it had a major impact on clinical practice around the world. As a result of this

publication, some societies (ESGO, NCCN, BGCS) changed their recommendations with respect to LRH in the management of early cervical carcinoma. Many institutions and individual surgeons stopped preforming LRH or changed their indication for MIS in early cervical cancer. Although results from the LACC trial had a major contribution to clinical practice in the surgical management of early cervical cancer, there are a number of valid questions left unanswered. Several renowned centres, with significant experiences and with published data of LRH and RRH, did not take part in this trial. Some clinicians raised concern regarding the low level of surgical experience (previous experience of 20 LRH) as the entry criterion to the LACC trial. Some consider this a low number of cases to gain proficiency in this difficult surgical procedure, due to the long learning curve associated with LRH.

In addition, due to the participation of 33 centres, some centres recruited less than 10 patients each which also raises questions regarding the experience of these centres with RLH. Results shown in the open arm were also far superior than ever published previously.

Interestingly recently presented results of the SHAPE trial seems to point that there is no statistically significant difference in oncological outcome for patients Ib1 if they are treated with simple hysterectomy or radical hysterectomy which questions the results of LACC trial.

SLNB alone does not appear to be associated with any higher recurrence rate or mortality in cervical cancer <2 cm. This agrees with our previously published data and other studies on this subject [18,23]. In addition, there were significant benefits with respect to reduced morbidity, especially leg lymphoedema. Ultra-staging of SLNs has increased the detection of metastatic disease in 0 to 19% of patients thought to be node negative on initial routine histology. Micro metastasis appears to have an adverse outcome and should be considered when advising on adjuvant treatment [19]. In view of the benefits of MIS we have continued with the same management protocol as described in this study for early-stage cervical cancer measuring less than 2 cm.

Our results remain consistent and are reviewed on a regular yearly audit analysis. At the pre-surgical consultation, data from both the LACC trial and our own results are discussed with the patient and then informed consent is obtained for the procedure which she chooses. Only one patient during the study period opted for an open procedure when laparoscopic surgery was feasible.

It has been suggested that the increased recurrence rate in the vagina and pelvis in the MIS arms of the LACC and SUCCOR studies may be due to uterine manipulation during laparoscopic surgery. However, in our technique of LRH the McCartney tube is used only for outlining the vagina and removal of the specimen. We did not have any cases of peritoneal carcinomatosis, vaginal recurrence or any of the recurrences attributed to uterine manipulators. From our results we conclude that the McCartney manipulator allows good exposure of the vaginal vault to enable removal of a vaginal cuff without increased risk of recurrence for tumours <2 cm.

## Conclusion

This study of 100 consecutive patients demonstrates the safety of LRH with SLNB only in the management of FIGO 2018 high risk stage IA2 and stage IB1 cervical carcinoma.

Our results support the introduction of SLNB only into clinical practice for this cohort of patients as we have previously published.[23] All patients need informed consent with explanation of results from both the LACC trial as well as the results of the individual centre treating that patient. All results, DFS, OS, and complications, should be prospectively recorded and reported at Clinical Governance meetings and monitored by the Institution. Patients with bulky lymph nodes identified on preoperative imaging or intraoperatively should be excluded from the SLN only procedure and treated as per centre protocol for possible positive lymph nodes. Unilateral SLN detection requires a full contralateral pelvic node dissection. Pathological ultra-staging should be standard procedure in assessment of the SLN.

**Conflict of Interest:** The authors report no conflict of interest.

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