European Journal of Surgical Oncology 44 (2018) 754–759

Contents lists available at ScienceDirect

European Journal of Surgical Oncology

journal homepage: www.ejso.com

Robotic versus laparoscopic radical hysterectomy in early cervical cancer: A case matched control study

Valerio Gallotta [a, *], Carmine Conte [a], Alex Federico [a], Giuseppe Vizzielli [a], Salvatore Gueli Alletti [a], Lucia Tortorella [a], Luigi Pedone Anchora [a], Francesco Cosentino [a], Vito Chiantera [b], Anna Fagotti [a], Marco D'Indinosante [a], Silvia Pelligra [a], Giovanni Scambia [c], Gabriella Ferrandina [d]

[a] Division of Gynecologic Oncology, Fondazione "Policlinico Universitario A. Gemelli", Catholic University of the Sacred Heart, Rome, Italy
[b] Division of Gynecologic Oncology, University of Palermo, Palermo, Italy
[c] Department of Women's and Children's Health, Catholic University of the Sacred Heart, Rome, Italy
[d] Department of Medicine and Health Sciences, University of Molise, Campobasso, Italy

ARTICLE INFO

Article history:
Accepted 16 January 2018
Available online 13 February 2018

Keywords:
Early stage cervical cancer
Laparoscopy
Robotic surgery

ABSTRACT

Background: This study aims at evaluating the feasibility, surgical outcome and oncological results observed after robotic radical hysterectomy (RH) compared to laparoscopy for patients with early stage cervical cancer (ECC) patients.

Methods: Between January 2010 and October 2016, 210 patients underwent RH for treatment of ECC: 70 underwent robotic approach (Cases), and 140 underwent laparoscopic approach (Controls).

Results: There was no statistically significant difference between the two approaches with regard to clinical patient characteristics and in terms of extent of RH and rate of pelvic and aortic lymphadenectomy. Operative time was significantly longer in the robotic versus laparoscopic group (median = 243 min, range 90–612 versus median = 210 min, range 80–660; p value = 0.008). Conversion to laparotomy was necessary in 4 patients (1.9%) in the whole series.

No difference was found in terms of intraoperative and postoperative complications between the two groups. Overall, during the observation period, 34 (16.2%) patients experienced any grade postoperative complications, and 21 (10.0%) had >G2 complications.

The 3-yr DFS was 88.0% versus 84.0% in robotic and laparoscopic group, respectively (p value = 0.866). Central and/or lateral pelvic disease represented the most common site of relapse. The 3-yr OS was 90.8% in patients underwent robotic RH versus 94.0% in patients underwent laparoscopic RH (p value = 0.924).

Conclusions: The present study shows the equivalence of robotic and laparoscopic approaches to radical surgery of ECC patients, in terms of perioperative and postoperative outcomes with equivalent survival figures, and thus the choice of approach can be tailored to the choice of patient and surgeon.

Introduction

Cervical cancer is the second most common gynecologic malignancy, and represents the leading cause of cancer related deaths in women from low- and middle income countries [1]. Radical hysterectomy (RH) is the standard surgical procedure for treatment of early stage cervical cancer (ECC) patients, resulting in 5-year survival rates of 75–90% [2,3].

Minimally invasive approach to RH has been increasingly performed over the last two decades, and has now been established as the preferred surgical modality for treating ECC patients [4–7].

The shift of surgical approach from open to minimally invasive procedures for this neoplasia is based on the demonstration of equivalent survival figures and better surgical outcome compared to the open approach: in particular, several studies in this clinical setting showed the feasibility and safety of laparoscopic and robotic radical hysterectomy which carry out some advantages, such as less postoperative pain, lower incidence of postoperative complications, faster recovery, etc compared to open approach [5,8–11].

* Corresponding author. Dept. Obstetrics and Gynecologic, Catholic University, L.go A. Gemelli, 8, 00168, Rome, Italy.
E-mail address: gallottav@gmail.com (V. Gallotta).

https://doi.org/10.1016/j.ejso.2018.01.092
0748-7983/

As far as the comparison between robotic and laparoscopic approach is concerned, the recent meta-analysis by Shazly et al. [11] has concluded that laparoscopy and robotic RH are equivalent in terms of perioperative outcomes; however, it has to be acknowledged that heterogeneity was elevated for all analyses of peri- and postoperative outcomes with the exception of intra-operative morbidity, thus making the pooled estimates less reliable. This weakness could be ascribed to the different methods employed to assess the outcomes as well as to small sample size of some series [11].

In this context, we were prompted at comparing surgical outcomes, including also intra-operative morbidity as well as early and late complications in a large series of ECC patients triaged to robotic RH (RRH), and laparoscopic RH (LRH). Exploratory analysis of survival outcome has been also carried out.

Materials and methods

Study groups

This is a case-control study comparing surgical and clinical outcomes of 210 ECC patients submitted to RRH (*Cases)* versus LRH *(Controls*), between January 2010 and October 2016, at the Catholic University of Rome, Italy.

All patients gave a written informed consent for their data to be collected and analyzed for scientific purpose. The Institutional Review Board approved the study.

We planned to select for this analysis patients with histologic diagnosis of cervical cancer (any histotype) and FIGO stage IA2-IB2 at gynecologic examination under anesthesia according to FIGO staging rules, and maximum tumor size of 5 cm. In order to reduce as much as possible the heterogeneity related to surgeons' skillfulness, only the data of patients operated by surgeons (V. G., G. S., F. C., V. C.) with a long experience in laparoscopic and robotic gynecologic oncologic procedures were collected. To avoid imbalance between the 2 groups *Cases* were matched with *Controls* using the propensity score with a 1:2 ratio.

The following data were collected: preoperative radiological work out, clinical and pathological features, extent of radical hysterectomy defined according to Querleu and Morrow classification [12], perioperative details (operative time, estimated blood loss-EBL-), intra- and postoperative early (i.e. any adverse event occurring within 30 days from surgery) and late complications (i.e. any adverse event occurring after 30 days from surgery) classified according to Memorial Sloan Kettering Cancer Center (MSKCC) surgical grading system [13], and duration of hospital stay calculated since the first day after surgery.

Details about procedures employed in robotic and laparoscopic surgery have been extensively described elsewhere [14–17]. Data relative to eventual adjuvant radiotherapy in high risk patients were also collected. Occurrence of recurrent disease as well as pattern and treatment of disease were extracted, and update of follow up was carried out.

Statistical analysis

Differences of surgical outcome between *Cases* and *Controls* were analyzed using the Fisher's test or $\chi 2$ test for categorical data, and with the Wilcoxon rank sum non parametric test in case of continuous values, as appropriate. Differences were considered statistically significant at p value <0.05. Disease-free survival (DFS) was calculated from the date of surgery to the date of relapse or the date of the last follow-up; overall survival (OS) was calculated from the date of diagnosis to the date of death or the date of the last follow-up. Medians and life tables were computed using the product limit estimate by Kaplan–Meier method [18], and the log-rank test was used to assess the statistical significance [19].

All statistical analyses were carried out by SPSS statistical software program, version 17.0 (SPSS Inc.,Chicago, IL, USA).

Results

Patient features are shown in Table 1: in the whole series, median age of patients at surgery was 47 years, and median BMI was 24.1 kg/m^2; there was no difference in the distribution of these parameters between the 2 groups. Rate of previous abdominal surgery and previous cervical conization did not differ between *Cases* and *Controls*.

Most patients were clinically staged as Stage IB1 disease (77.6% of the whole series); pelvic lymph node status at imaging was negative in 92.4% of all patients. There was no difference between *Cases* and *Controls* in terms of extent of RH and rate of pelvic and aortic lymphadenectomy.

As shown in Table 2, 25 patients in the whole series (11.9%) were found to harbour stage II tumors; however, there was no difference in the distribution of pathologically assessed extension of disease between the 2 groups. In addition, no difference has been found in the distribution of other pathological features with the exception of number of aortic lymph nodes removed, which was significantly higher in patients undergoing robotic than laparoscopic surgery

Table 1
Patient characteristics.

Characteristics	Whole series N. (%)	*Cases* RRH N. (%)	*Controls* LRH N. (%)	p value
All cases	210	70	140	–
Age, years				
median (range)	47 (25–80)	46 (28–73)	47 (25–80)	0.575[a]
Body Mass Index (BMI), kg/m^2				
median (range)	24.1 (17–48)	24.6 (18–48)	23.5 (17–34.9)	0.118[a]
BMI, kg/m^2				
<30	172 (81.9)	54 (77.1)	118 (84.3)	
≥30	37 (18.1)	16 (22.9)	22 (15.7)	0.254[b]
Previous abdominal surgery				
Yes	64 (30.5)	21 (30.0)	43 (30.7)	
No	146 (69.5)	49 (70.0)	97 (69.3)	0.874[b]
Previous cone biopsy				
Yes	76 (36.2)	24 (34.3)	52 (38.8)	
No	134 (63.8)	46 (65.7)	88 (62.8)	0.546[b]
Clinical FIGO Stage				
IA2	36 (17.1)	12 (17.1)	24 (17.1)	
IB1	163 (77.6)	50 (71.4)	113 (80.8)	
IB2	11 (5.2)	8 (11.5)	3 (2.1)	0.980[b,d]
Clinical tumor size (mm)				
Median (range)	18 (5–50)	20 (4–50)	17 (5–50)	0.531[a]
<20	102 (48.6)	28 (40.0)	74 (52.8)	
≥20 < 40	84 (40.0)	33 (47.1)	51 (36.4)	
≥40 < 50	24 (11.4)	9 (12.9)	15 (10.7)	0.203[c]
Pelvic LN status at imaging				
Negative	194 (92.4)	63 (90.0)	131 (93.6)	
Positive	16 (7.6)	7 (10.0)	9 (6.4)	0.411[b]
Aortic LN status at imaging				
Negative	210 (100)	70 (100)	140 (100)	–
Type of radical hysterectomy				
B1	42 (20)	11 (15.7)	31 (22.1)	
B2	54 (25.7)	14 (20.0)	40 (28.6)	
C1	114 (54.3)	45 (64.3)	69 (49.3)	0.217[c]
Lymphadenectomy				
Pelvic	205 (97.6)	68 (97.1)	137 (97.8)	0.999[b]
Aortic	25 (11.9)	9 (12.9)	16 (11.9)	0.826[b]

[a] Calculated by Mann-Whitney test.
[b] Calculated by Fisher's exact test for proportion.
[c] Calculated by $\chi 2$ test BMI= Body Mass Index. LN = lymph nodes.
[d] Calculated subgrouping Stage IA2 versus IB1-IB2.

Table 2
Pathological characteristics.

Characteristics	Whole series N. (%)	*Cases* RRH N. (%)	*Controls* LRH N. (%)	p value[a]
All cases	210	70	140	–
Pathological FIGO Stage				
IA2	40 (19.0)	12 (17.1)	28 (20.0)	
IB1	131 (62.4)	40 (57.1)	91 (65)	
IB2	14 (6.7)	8 (11.4)	6 (4.3)	
IIA/IIB	25 (11.9)	10 (14.3)	15 (10.7)	0.5[c]
Tumor histology				
Squamous	142 (67.6)	43 (61.4)	99 (70.7)	
Adenocarcinoma	56 (26.7)	22 (31.4)	34 (24.3)	
Adenosquamous	4 (1.9)	3 (4.3)	1 (0.7)	
Other (neuroendocrine, clear cell)	8 (3.8)	2 (2.9)	6 (4.3)	0.211[d]
Grading				
G1	7 (3.3)	2 (2.9)	5 (3.6)	
G2	138 (65.7)	43 (61.4)	95 (67.8)	
G3	65 (31.0)	25 (35.7)	40 (28.6)	0.342[e]
LVSI				
Present	77 (36.7)	24 (34.3)	53 (37.8)	
Absent	133 (63.3)	46 (65.7)	87 (62.2)	0.867
Depth of cervical stromal invasion				
≤50%	119 (56.7)	36 (51.4)	83 (59.3)	0.303
>50%	91 (43.3)	34 (48.6)	57 (40.7)	
Involved resection margins				
Yes	8 (3.8)	4 (5.7)	4 (3.0)	
No	202 (96.2)	66 (94.3)	136 (97.0)	0.450
N. LNs removed				
Median (range)				
Pelvic	23 (2–64)	24 (3–58)	21 (2–64)	0.157[b]
Aortic	13 (3–36)	17 (6–36)	9 (3–36)	**0.010**[b]
Metastatic LNs				
Pelvic	29 (13.8)	11 (15.7)	18 (12.8)	0.396
Aortic	0	0	0	–

Bold represents the significative statistical differences.
[a] Calculated by Fisher's exact test for proportion.
[b] Calculated by Mann-Whitney test; LVSI = Lymphovascular space invasion.
[c] Calculated subgrouping stage IA2-IB2 versus stage IIA/IIB.
[d] Calculated subgrouping squamous versus other histotypes.
[e] Calculated subgrouping G1-G2 grade versus G3.

(median = 17 LNs, range 6–36 versus median = 9 LNs, range 3–36,respectively; p value = 0.010).

As far as the end-points are concerned, peri- and post-operative details are shown in Table 3: operative time was significantly longer in the robotic versus laparoscopic group (median = 243 min, range 90–612 versus median = 210 min, range 80–660; p value = 0.008).

Table 3
Peri- and post-operative details.

Characteristics	Whole series N = 210	*Cases* RRH N = 70	*Controls* LRH N = 140	p value[a]
Operative time, min median (range)	227 (80–660)	243 (90–612)	210 (80–660)	**0.008**
EBL, ml median (range)	100 (20–600)	100 (50–600)	100 (20–400)	0.786
Intraoperative blood transfusion	0	0	0	–
Conversion to laparotomy	4	3	1	0.118[b]
Hospital stay, days median (range)	3 (1–24)	3 (2–14)	3 (1–24)	0.990

EBL = estimated blood loss.
Bold represents the significative statistical differences.
[a] Calculated by Mann-Whitney test.
[b] calculated by Fisher's exact test for proportion.

However, a significant difference was registered for operative time between the first 20 patients and the subsequent 50 ones operated with the robotic approach (median = 315, range 170–480, versus median = 210 min, range 90–612, respectively; p value = 0.001). On the other hand, there was no difference between *Cases* and *Controls* in terms of EBL, and length of hospital stay (Table 3).

Conversion to laparotomy was necessary in 4 patients (1.9%) in the whole series; of them, 3 were in the RRH group and required conversion due to injury of parametrial vein (N = 1), presence of bulky pelvic lymph nodes (N = 1), and massive visceral adhesions (N = 1). On the other hand, only 1 patient in the laparoscopic group needed conversion due to bladder injury (N = 1) during the parametrectomy step.

Intraoperative complications occurred in 5 cases: of them, 2 were documented during robotic surgery and included injury of the ureter (N = 1), and of parametrial vein (N = 1), which were both successfully managed intraoperatively. In the laparoscopic group there were 3 intraoperative complications including bladder injury (N = 2), and external iliac artery injury (N = 1).

Overall, during the observation period, 34 patients experienced any grade postoperative complications, and 21 of them (10.0% of the whole series) had ≥G3 complications. Moreover, 24 experienced only early morbidity, 8 patients suffered from late complications, while 2 patients experienced both early and late morbidity. There was no statistically significant difference in the distribution of patients experiencing postoperative complications between *Cases* and Controls (Table 4).

Type and grade of early complications in the 2 groups is shown in Table 5: of 16 early complications registered in the robotic group, 8 (50.0%) were ≥G3; the most frequent pattern of morbidity was represented by hematological or vascular complications (37.5%), followed by infection-related morbidity (31.2%). Of 20 early complications occurring in laparoscopic group, 5 (25.0%) were ≥G3; also in the this group the most frequent complications were hematological/vascular (30.0%), and infection-related (25.0%).

As shown in Table 6, there were 4 late complications in the robotic versus 6 complications in the laparoscopic group: ≥G3 morbidity was found in 3 patients underwent RRH and in 4 patients underwent LRH.

Survival outcome

Based on definitive histology, 101 high risk patients were triaged to adjuvant radiotherapy; there was no difference in the distribution of patients in the 2 groups (data not shown).

As of May 2017, median follow up was 24 months in the robotic group and 36 months in the laparoscopic group. At time of analysis, relapse of disease was observed in 6 out of 70 cases (8.6%) underwent RRH, and in 16 out of 140 patients underwent LRH (11.4%), respectively (p value = 0.636). As summarized in Table S1, by analising the pattern of relapse, most of recurrences were central and/or lateral pelvic site: in RRH group there were 4 out of 6 recurrences (66.7%) versus 9 out of 16 recurrences in the LRH group (56.2%). However, the parameters of recurrence were not

Table 4
Distribution of patients with complications.

Characteristics	Whole series N. (%)	*Cases* RRH N. (%)	*Controls* LRH N. (%)	p value[a]
Patients without complications	176 (83.8)	54 (30.7)	122 (69.3)	
Patients with complications	34 (16.2)	16 (47.0)	18 (52.9)	0.075

[a] Calculated by Fisher's exact test for proportion.

Table 5
Type of early postoperative complications according to organ system and grade.

Organ System	RRH		LRH	
	N. (%)	Type	N. (%)	Type
All	16		20	
Hematologic or Vascular system	**6 (37.5)**		**6 (30.0)**	
Grade 1	2	Pelvic Haematoma (N = 2)	1	Pelvic Haematoma (N = 1)
Grade 2	2	Anemia (N = 2)	3	Anemia (N = 1) Chylous ascites (N = 1) Lymphocele (N = 1)
Grade 3	2	Chylous ascites (N = 1) Haemoperitoneum requiring embolization (N = 1)	2	Lymphocele requiring surgery (N = 1) Haemoperitoneum requiring surgery (N = 1)
Infection	**5 (31.2)**		**5 (25.0)**	
Grade 1	–		2	Fever (N = 2)
Grade 2	4	Sepsis (N = 2) Fever (N = 1) Pelvic abscess (N = 1)	3	Fever (N = 2) Pelvic Abscess (N = 1)
Grade 3	1	Pelvic abscess (N = 1)	–	
Urinary	**1 (6.25)**		**4 (20.0)**	
Grade 2	–		1	Urinary infection (N = 1)
Grade 3	1	Uretero-vaginal fistula (N = 1)	3	Vesico-vaginal fistula requiring surgery (N = 2) Hydronephrosis (N = 1)
GI	**1 (6.25)**		**2 (10.0)**	
Grade 2	–		2	Paralytic ileus (N = 2)
Grade 3	1	Incisional Hernia (N = 1)	–	
Nervous system	–		**2 (10.0)**	
Grade 1	–		1	Neuropathy Motor of iliopsoas (N = 1)
Grade 2	–		1	Neuropathy Motor (N = 1)
Other	**3 (18.7)**		**1 (5.0)**	
Grade 2	–		1	Lower back pain (N = 1)
Grade 3	3	Vaginal cuff dehiscence (N = 3)	–	

Bold represents the number and rate of complications of the single organ system and not of the grade's subgroups.

Table 6
Type of late postoperative complications according to organ system and grade.

Organ System	*Cases* RRH		*Controls* LRH	
	N. (%)		N. (%)	
All	4		6	
Hematologic or Vascular system	1 (25.0)		–	
Grade 3	1	Lymphocele requiring drainage (N = 1)	–	
Infection	**2 (50.0)**		**1 (16.6)**	
Grade 2	1	Pelvic abscess (N = 1)	1	Sepsis (N = 1)
Grade 3	1	Pelvic abscess (N = 1)	–	
Gastrointestinal	–		**2 (33.3)**	
Grade 3	–		2	Incisional Hernia (N = 2)
Urinary	**1 (25.0)**		**2 (33.3)**	
Grade 3	1	Hydronephrosis (N = 1)	1	Uretero-vaginal fistula requiring nephrostomy (N = 1)
Grade 4	–		1	Ureteral stenosis requiring surgery (N = 1)
Other	–		**1 (16.6)**	
Grade 3	–		1	Vaginal cuff dehiscence (N = 1)

Bold represents the number and rate of complications of the single organ system and not of the grade's subgroups.

associated with the surgical approach and not strictly related to pathological features of primary tumor characteristics (grade of differentiation, tumor size, depth of stroma infiltration, invasion of the lymphovascular spaces, lymph nodes metastasis).

The 3-yr DFS was 88.0% in patients undergoing RRH versus 84.0% in patients undergoing LRH (p value = 0.866) (Figure S1).

Death of disease was registered in 7 patients (2 in RRH and 5 in LRH group): 3-yr OS was 90.8% in patients undergoing RRH versus 94.0% in patients undergoing LRH (p value = 0.924) (data not shown).

Discussion

To the best of our knowledge, the present study is one of the largest series comparing perioperative and postoperative outcomes

in patients triaged to robotic versus laparoscopic radical surgery in ECC patients.

Overall, our data confirm the available lines of evidence supporting the equivalence of robotic and laparoscopic approaches to radical surgery of ECC patients, in terms of perioperative and postoperative outcomes: in particular, no difference has been found in EBL, and length of hospital stay, as also summarized in the meta-analysis by Shazly et al. [11]. On the other hand, our study documented a statistically significant longer operative time in patients undergoing robotic surgery compared to laparoscopic group; even though similar results have been already reported by other authors [20–22], we think that the most reasonable explanations of our findings are represented by prolongation of surgery due the more extensive aortic lymphadenectomy, as testified by the higher number aortic lymph nodes removed. Despite that, also the impact of the learning curve of the novel approach should not be underestimated: indeed, in our experience, operative time of robotic surgery decreased over time.

With respect to post operative morbidity rate, 34 (16.2%) patients experienced post-operative complications in the whole series, a figure which well matches with some previous results [6,11,20–27] with no significant differences between the 2 groups.

It has, however, to be acknowledged that discrepancies with other studies are really difficult to be explained given the heterogeneity of enrolled patients, differences among systems of evaluation and scoring of morbidity, as well as and duration of time frame of postoperative morbidity monitoring [11].

Besides, differences among surgical techniques as well as preoperative and postoperative care protocols may differ across centers; for instance, a wider adoption of sentinel LN procedure as well as the application of principles of pelvic neuroanatomy could support a less aggressive approach to lymphadenectomy, thus minimizing/preventing the risk of either lymphovascular complications and/or damages of sympathetic and parasympathetic nervous system strictly correlated to postoperative bladder morbidity. In this context, it has to be highlighted that several studies confirm that minimally invasive surgery improves performance of the nerve sparing technique, and consequently reduces the risk of autonomic nerve injury [14,15,27].

Despite the evaluation of survival outcome was considered the subject of an exploratory analysis due to the relatively short follow up, we reported equivalent survival figures between the 2 groups in terms of DFS, thus confirming the available literature findings [5–8].

Admittedly, potential limitations of this study are represented by the retrospective design and the relatively short follow up due to the time elapsed since the adoption of robotic surgery for the management of this neoplasia in our Institution. Conversely, the strength of the study is the relatively large and homogeneous series; furthermore all patients were managed in a single high volume gynecological cancer center, operated only by surgeons with a long experience in laparoscopic and robotic gynecologic oncologic procedures.

In conclusion, RRH appeared to be equivalent to LRH in terms of short-term surgical outcomes and complications. It is important to emphasize how the choice of approach can be tailored to the patients' features and choice, as well as to surgeons' preference. Thus, the decision to choose one option over the other may be guided by availability of tools, surgical expertise and, in particular, by total costs of the whole procedure [8,10,11].

We believe that improvement of technology, such as the new platform of Da Vinci Robot, as well as new generation of the three-dimensional high definition laparoscopic vision system, and further articulated instruments may allow a wider expansion of laparoscopic and robotic approaches for surgical treatment of ECC.

Well-designed prospective clinical trials are required to evaluate the long-term survival outcomes of robotic surgery in cervical cancer.

Conflict of interest statement

The authors declare that they have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.ejso.2018.01.092.

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