

Research Article

Long-term Impact on Quality of Life and Lymphedema in Early-Stage Endometrial Cancer Survivors Based on Lymph Node Staging Technique

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Abstract

Objective: assess the impact on overall health perception (oHP) and health-related quality of life (HRQoL) in patients surgically treated for early-stage endometrial cancer (EC) based on the lymph node staging technique used: pelvic sentinel lymph node (SLN) biopsy versus complete pelvic lymphadenectomy (CL).

Methods: This prospective observational cohort study included 97 patients who underwent surgical treatment for early-stage EC. Patients were divided into two groups: 50 who underwent both SLN biopsy and CL (CL group), and 47 patients who underwent only SLN (SLN group). HRQoL was assessed using the EQ-5D-26 3L questionnaire. oHP was measured on a scale from 0 to 100, while symptomatic lymphedema was evaluated using the Self-report Lower-Extremity Lymphedema Questionnaire (LELQ). Scores were compared between both groups.

Results: The SLN group showed significantly better oHP and HRQoL scores compared to the CL group. Specifically, the median oHP score was 85 in the SLN group versus 70 in the CL group ($p=0.001$). The HRQoL score was 5 in the SLN group versus 7 in the CL group ($p=0.001$). Symptomatic lymphedema was observed in 7.0% of patients in the SLN group compared to 34.4% in the CL group ($p=0.002$). Additionally, 3.1% of patients in the CL group developed lymphocele, whereas no cases were reported in the SLN group.

Conclusions: The SLN procedure was associated with better oHP and HRQoL, as well as a lower incidence of symptomatic lymphedema and lymphocele, compared to the CL procedure. There were no significant differences in intra- and postoperative complications between the two groups.

Keywords: Quality of life; Endometrial cancer; Lymphedema; Sentinel Lymph node; Cancer survivors

Abbreviations

EC: Endometrial Cancer; oHP: Overall Health Perception; HRQoL: Health-related Quality of Life; SLN: Sentinel Lymph Node; CL: Complete Pelvic Lymphadenectomy; WHO: World Health Organization; QoL: Quality of Life; MRI: Magnetic Resonance Imaging.

Introduction

The World Health Organization (WHO) defines health as a state of complete physical, mental, and social well-being. Based on this definition, quality of life (QoL) is considered an integral component of health status among cancer survivors. Endometrial cancer (EC) is the most common malignancy of the female genital tract in high-income countries, with a 132% increase in incidence over the past 30 years [1]. Fortunately, patients diagnosed at stage I have an overall survival rate greater than 90%, making EC one of the cancers with the highest number of long-term survivors, following breast cancer [2]. Although the majority of cases are diagnosed in women over 55 years old, it is

important to note that approximately 14% of cases occur in younger women, under the age of 40, at the time of diagnosis [3]. Cancer survivors often experience lasting side effects from treatment, which may significantly impact their psychological well-being by constantly reminding them of their cancer history. Given that life expectancy for women in Europe ranges from 81 and 85 years [3] the impact of treatment on their QoL could last for many years. This, in turn, may influence their psychological well-being and, as a result, impact their overall health status as defined by the WHO.

Performing a lymphadenectomy in EC patients primarily aims to stage the disease, with no demonstrated impact on survival [4,5]. For this reason, sentinel lymph node (SLN) biopsy has been introduced in leading clinical guidelines over the past decade as a staging technique for early-stage EC [6,7]. We aimed to evaluate the impact of lymph node staging techniques on patients' quality of life. Several studies have demonstrated that SLN biopsy is associated with lower morbidity and reduced rates of lymphedema [8]. However, there is currently no

evidence to suggest that SLN biopsy has better outcomes in terms of impact on QoL than complete pelvic lymphadenectomy (CL). The hypothesis is that SLN biopsy has a less pronounced negative impact on the postoperative QoL for women with an early-stage EC, compared to CL.

Therefore, the main objective of this prospective study is to assess the QoL of patients with early-stage EC based on the lymph node staging technique (SLN vs. SLN plus CL).

Materials and Methods

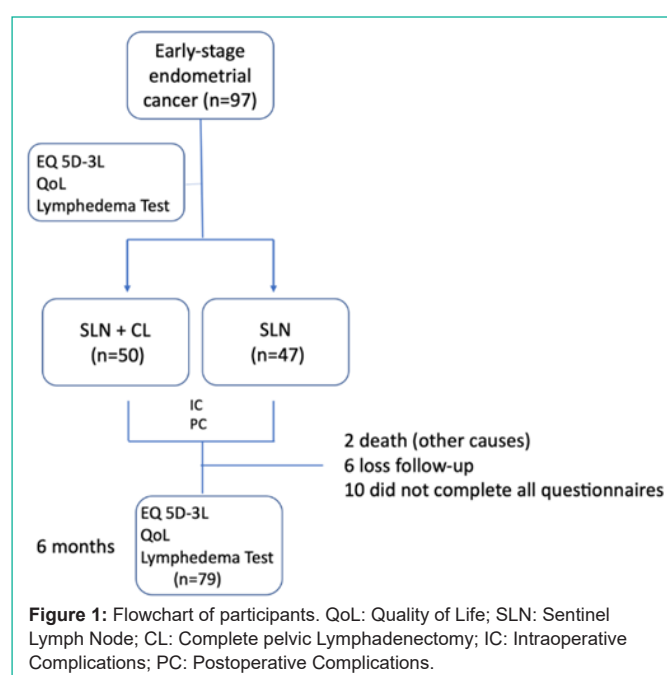
Study Design

This was a prospective, longitudinal, single-center study involving two cohorts of patients with early-stage endometrial cancer (EC), treated surgically at a tertiary-level hospital using a minimally invasive approach (laparoscopy/robot-assisted surgery).

The patients included at the beginning of the study were part of the period during which we validated the sentinel lymph node (SLN) technique. We performed SLN biopsies and a backup pelvic lymphadenectomy. Our group's findings are detailed in an article published in *Cancers* in 2022 [9].

Participant

A total of 97 patients diagnosed preoperative with early-stage EC, who underwent primary surgical treatment between January 2019 and November 2022, were included and divided into two groups based on the type of nodal assessment performed during the primary surgical treatment: **CL Group** (SLN plus CL): 50 patients included during the validation period of the SLN technique in our center and those at high histological risk in which clinical guidelines recommend performing CL after SLN [6]; **SLN group** (SLN only): 47 patients, comprising those with preoperative EIN histology who were diagnosed postoperatively for EC, and those included after validation of the SLN technique (Flow chart in Figure 1).



In cases where intraoperative SLN analysis indicated nodal involvement, pelvic and para-aortic lymphadenectomy (from the aortic bifurcation to the left renal vein) was performed. Clinical and demographic characteristics of the study population are presented in Table 2.

Surgical Approach

All women underwent minimally invasive surgery (MIS). We performed the laparoscopic approach (KarlStorz Endoscope, Tuttlingen, Germany) from January 2019 to March 2020. From March 2020 our center introduced robotic surgery (da Vinci® Surgical System Version Xi, Intuitive Surgical Inc., Sunnyvale, CA, USA). Therefore, from the beginning of 106 2020, all patients underwent robotic surgery.

Patient-Report Outcome

Two surveys were administered before surgery and at the 6-month follow-up. Patients completed the following questionnaires: a) HRQoL: Assessed using the EQ-5D-3L questionnaire (scores range from 5 to 15, with higher scores indicating a greater negative impact on patients' QoL [10]; b) Overall Health Perception (oHP): evaluated on a scale from 0 to 100, with higher scores indicating better health perception. At the 6-month follow-up, patients also completed the Self-Report Lower-Extremity Lymphedema Questionnaire (LELQ), developed by Yost et al., which measures lymphedema-related symptoms (10). Scores range from 0 to 52, with a score of ≥ 5 indicating positive lymphedema [11].

The EQ-5D-3L questionnaire covers five health dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[10]. To compare the impact on QoL and oHP between groups, the scores from both questionnaires reported by each patient were analysed.

Lymphedema cases and intra- and postoperative complications were recorded for each group. For lymphocele diagnosis, a thoracoabdominal CT scan was performed at 6 months. Inclusion and exclusion criteria are described in Table 1. Preoperative assessment included transvaginal ultrasound and magnetic resonance imaging (MRI) to assess myometrial invasion. In high-risk patients, a thoracoabdominal CT was performed.

All patients signed a specific consent form. The present study was approved by the local Ethics Committee of Balearic Islands, Spain (CEI-IB. Ref. IB 4103/20 PI). Patients' data were collected prospectively during the study by the investigation team (A.T., A.S., A.R. and L.F.).

Table 1: Inclusion and exclusion criteria.

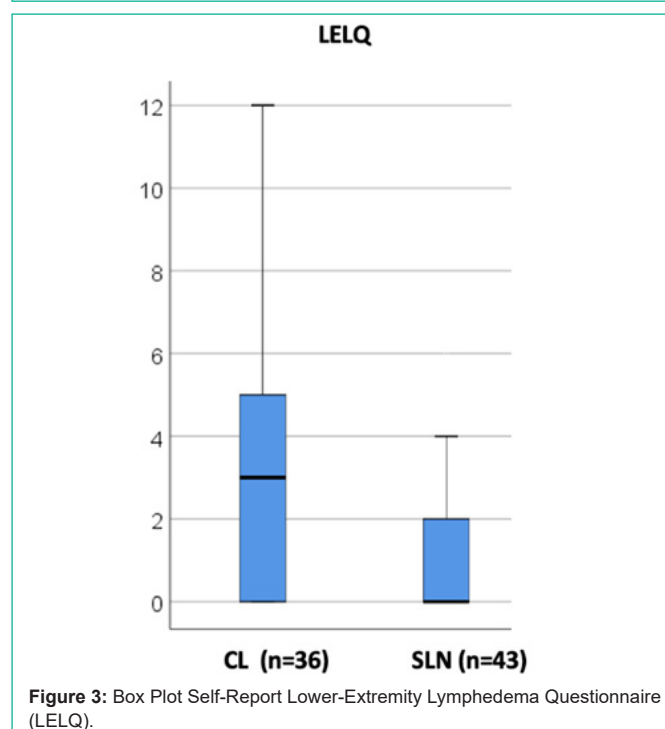
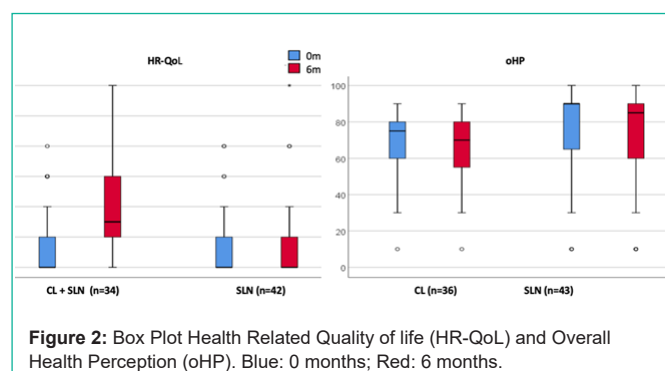
Inclusion Criteria:
<ul style="list-style-type: none"> • Histological diagnosis of endometrial adenocarcinoma. • Diagnosis of early-stage disease (FIGO stage I-II) confirmed by imaging studies. • Absence of extrauterine disease.
Exclusion Criteria:
<ul style="list-style-type: none"> • Contraindication for surgical treatment. • Contraindication for ICG and/or Tc99m injection. • Patients with a history of pelvic or abdominal radiotherapy. • Patients experience recurrence during the study period. • Patients who die during the study, either due to the disease or other medical conditions.

ICG: Indocyanine Green; Tc99m: Technetium-99m.

Table 2: Clinical and Demographic Characteristics of the Study Population (n = 97).

		Total	SLN + CL (%)	SLN	P
		N=97(%)	(n=50)	(n=47)	
Age		62.0 (56.0-71.0)	64.5 (56.0-74.0)	61.0 (56.0 – 70.0)	0.392
BMI		30.0 (25.0-37.0)	30.0 (25.0-36.0)	30.0 (25.0-37.0)	0.54
Surgical approach	BMI <30	44 (45.4%)	24 (48%)	20 (42.6%)	0.59
	BMI ≥/ > 30	53 (54.6%)	26 (52%)	27 (57.4%)	
	Laparoscopic	32 (33%)	26 (52%)	6 (12.8%)	
Histological type	Robotics	65 (67.0%)	24 (48.0%)	41 (87.2%)	0.000
	Endometrioid	71 (73.2%)	35 (70%)	36 (76.6%)	
	Serous	13 (13.4%)	10 (20%)	3 (6.4%)	
	Clear cell	2 (2.1%)	1 (2%)	1 (2.1%)	
	Carcinosarcoma	6 (6.2%)	4 (8.0%)	2 (4.3%)	
	Others	5 (5.2%)	0 (0.0%)	5 (10.6%)	
ESGO/ESTRO/ESP Risk group	Low	37 (38.1%)	16 (32.0%)	21 (44.7%)	NA
	Intermediate	29 (29.9%)	10 (20%)	19 (40.4%)	
	High-intermediate	31 (31.3%)	24 (48%)	7 (14.9%)	
Adjuvant Therapy	No	37 (38.9%)	14 (28%)	24 (51.1%)	0.018
	Yes	60 (61.8%)	36 (72%)	23 (48.9%)	
Para-aortic lymphadenectomy	No	57 (58.8%)	19 (38%)	38 (80.9%)	0.000
	Yes	40 (41.2%)	31 (62%)	9 (19.1%)	

BMI: Body Mass Index; ESGO/ESTRO/ESP: European Society of Gynaecological Oncology/European Society for Radiotherapy and Oncology; European Society of Pathology; CL: Complete Lymphadenectomy; SLN: Sentinel Lymph Node biopsy.



Data Analysis

A descriptive analysis of all variables was performed to define the characteristics of the study group, using frequencies and percentages for qualitative variables and median and interquartile range for numerical variables. Comparisons between the two groups were made using the Mann-Whitney U test for quantitative variables and the Chi-square test or Fisher's exact test for categorical variables. To analyze the possible association of complications with other variables, multivariate regression methods were applied to eliminate potential confounding factors. A p-value of < 0.05 was considered indicative of significance. Data analysis was conducted by the Methodological and Statistical Support Platform of the Health Research Institute of the Balearic Islands. The statistical software used for data analysis was IBM-SPSS v.26 (SPSS Inc., Chicago, IL, USA).

Results

A total of 97 patients were included, with 50 (51,5%) undergoing CL and 47 (48,5%) undergoing pelvic SLN biopsy (Flowchart, Figure 1). At six months, 79 patients (43 (54,4%) in the SLN group and 36 (45,6%) in the CL group) completed all three questionnaires. Both groups were homogeneous in terms of age, BMI, histological type, and risk level. Clinical and demographic features are presented in Table 1.

Intra-Operative and Post-Operative Complications (Table 3)

All intraoperative complications (3.1%) were recorded in the CL group (three complications). However, there were no statistically significant differences between the two groups regarding intraoperative ($p = 0.243$) or postoperative complications ($p = 0.833$). Among the postoperative complications (eleven patients; 11.3%), six (12%) were in the CL group and five (10.6%) in the SLN group. Notably, there were four cases (two in each group) of decreased sensitivity in the inner thigh area and reduced adduction, indicative of obturator nerve neuropathy. All obturator nerve injuries were thermal; none were due to partial or total nerve section. Three cases resolved with rehabilitation, with patients being asymptomatic at six months, while

Table 3: Intra and post-operative complications.

Complications	Total	SLN + CL, n (%)	SLN, n (%)	p
Intraop. Complications	3 (3.1%)	3 (6.0%)	0 (0%)	0.243
Bladder injury	1	1	0	
Intestinal injury	1	1	0	
Anesthetic complication	1	1	0	
Post-op. Complications	11 (11.3%)	6 (12.0%)	5 (10.6%)	0.833
Surgical wound infection	4	2	2	
Over-infected lymphocele	2	2	0	
Obturator nerve neuropathy	4	2	2	
Fever	1	0	1	

Intraop: Intraoperative; Post-op: Postoperative. CL: Complete Pelvic Lymphadenectomy; SLN: Sentinel Lymph Node Biopsy.

one case (in the SLN group) had mild symptoms persisting at six months post-surgery.

Results of the HR-QoL Questionnaire and oHP (Figure 2)

According to HR-QoL assessment (Questionnaire EQ-5D-3L), the SLN group had significantly better results, which included less impact on morbidity, self-care, daily activities and pain (HR-QoL 5 vs 7, $p=0.001$), Table 4. A total of 61.1% of patients in the CL group reported a deterioration in their perception of HR-QoL at six months post-surgery, compared to 37.2 % in the SLN group (Fig.2) Regarding the oHP, the CL group had significantly worse oHP at six months post-surgery compared to the SLN group (85 vs 70, $p=0.001$), Table 4. Additionally, when comparing the oHP between 0-6 months in both groups, the differences were also statistically significant (median of -7.5 in the CL group vs median of 0 in the SLN group, $p=0.011$). A multiple regression analysis, considering potential confounding factors such as the addition of para-aortic lymphadenectomy, robotic surgery, and adjuvant treatment, showed that the SLN group had a lower risk of worsening oHP at six months post-surgery (OR 0.208, 95% CI 0.063-0.688, $p=0.010$).

Results of Self-report Lower-Extremity Lymphedema Questionnaire (LELQ) (Figure 3)

A positive LELQ score (greater than five) was observed in 34.4% of patients in the CL group and 7.0% of patients in the SLN group ($p=0.002$). In the multiple regression analysis, considering the same confounding factors as those used for HR-QoL and oHP, the SLN group showed a lower risk of lymphedema compared to the CL group (OR 0.096 [0.020-0.459], $p=0.003$).

Table 4: EQ-5D-3L-Health-Related Quality of Life Questionnaire, oHP and LELQ scores according to nodal staging.

EQ-5D-3L	Total	SLN + CL, n (%)	SLN, n (%)	p
N	79	36 (45.6%)	43 (51.4%)	
Median at 6 months	6.0 (5.0-7.0)	7.0 (6.0-8.0)	5.0 (5.0-6.0)	0.001
Diff (0-6 months)	0.0 (0.0-1.0)	1.0 (0.0-2.0)	0.0 (-1.0)	0.012
EQ-5D-3L worsening	38/79 (48.1%)	22/36 (61.1%)	16/43 (37.2%)	0.044
oHP				
Median at 6 months	80 (60-85)	70 (60-80)	85 (60-90)	0.001
Diff (0-6 months)	0 (-10-0)	-7.5 (-10-0)	0.0 (-10-0)	0.011
oHP worsening	38/79 (48.1%)	25/36 (69.4%)	13/43 (30.2%)	0.001
LELQ median				
Median at 6 months	1 (0-4)	3 (0-5)	0 (0-2)	0.006
Score >5	16/79 (20.2%)	13/36 (36.1%)	3/43 (7.0%)	0.002

Diff: Difference between 0 and 6 months. oHP: overall Health Perception; LELQ: Self-report lower-Extremity Lymphedema Questionnaire.

During the first six months post-surgery, five patients (5.2%) developed lymphedema and three patients (3.1%) developed lymphocele, all of whom were in the CL group.

Impact of Body Mass Index (BMI)

Most lymphedemas (80%) and lymphoceles (66.7%) were diagnosed in patients with a BMI <30, with no differences in lymphedema screening (symptoms). In our series, obesity (BMI >30) was associated with a worsening of HRQoL (62.9% vs 37.1%) and oHP (57.9% vs 42.1%), but these differences were not statistically significant ($p>0.05$).

Impact of Para-Aortic Lymphadenectomy

In the CL group, more para-aortic lymphadenectomies were performed (62%) compared to the SLN group (19.1%) ($p=0.000$). However, in the multiple regression analysis, the addition of a para-aortic lymphadenectomy to any staging technique was not associated with a higher risk of lymphedema (OR 1.750 [0.559-5.481], $p=0.337$) or a worsening of HRQoL (OR 1.024 [0.402-2.609], $p=0.960$) or oHP (OR 1.744 [0.697-4.364], $p=0.235$).

Impact of Adjuvant Treatment

In the CL group, 73.5% received adjuvant treatment after surgery (brachytherapy and/or external radiotherapy with or without chemotherapy). In the SLN group, 50.0% received complementary treatment ($p=0.018$). Among the patients who scored positive (>5) on the LELQ, 80% (12/15) had received adjuvant treatment, compared to only 20% (3/15) of the patients who did not receive complementary treatment. However, the differences were not significant ($p=0.093$), likely due to the small sample size.

Discussion

Despite the growing evidence of SLN mapping in EC, many studies have shown a lower incidence of lymphedema, but few prospective studies analyze the impact on quality of life (QoL). One of the main prospective studies comparing the incidence of lymphedema in women with EC undergoing SLN biopsy versus CL was published in 2018 by Geppert et al [12]. SLN alone resulted in a lower incidence of leg lymphedema than CL (1.3% vs 18.1%, $p=0.0003$). This study did not assess the impact on QoL of having lymphedema, and all patients in the CL group also underwent para-aortic lymphadenectomy in addition to CL. In our series, patients who underwent para-aortic lymphadenectomy did not show statistically significant differences in LELQ, HR-QoL, or oHP.

The hypothesis that CL negatively affects the overall perception of QoL in patients is still lacking substantial evidence. In the prospective study by Wedin M et al. [13] the health-related quality of life (HRQoL) and lymphedema-specific QoL at twelve months were compared in patients treated for early-stage EC who underwent CL versus those who did not undergo any lymph node excision. Unlike our study, patients who underwent lymphadenectomy did not seem to experience an adverse effect on generic HRQoL. The presence of lower limb lymphedema negatively affected the lymphedema-specific HRQoL, mainly in physical and functional domains, but had no impact on generic HRQoL. In 2023, the first prospective study evaluating lymphedema and QoL comparing SLN mapping (74.3% of

patients) and SLN with the addition of lymphadenectomy (25.7% of patients) in EC was published [14]. They noted, similar to our study, a higher rate of lymphedema after lymphadenectomy but no difference was found in overall QoL between both groups. Our study is also prospective and we found statistically significant differences favoring higher oHP and less impact on HRQoL in the SLN group compared to the CL group. Additionally, in our study, the sample sizes of both groups are more similar (48.5% vs 51.5% CL group) than in other studies.

In our series, the diagnosis of lymphedema (10% in the CL group vs 0% in the SLN group) is lower than reported in the literature. However, it is important to note that in our study, lymphedema was only explored if the lymphedema test scored more than five, as our aim was to assess the impact on the patient's QoL rather than visual lymphedema rates. These lymphedema rates are significantly lower in the SLN group (0% compared to 10% in the CL group, 5 patients; $p=0.057$) and remain much lower than in other studies (e.g., study number Law et al. [10] and Goncalves et al. [14]. The overall rate of lymphocele at six months was 3.1% (3 patients), all of whom were in the group that underwent systematic lymphadenectomy. Therefore, the lymphocele rate in the CL group is 6% (three patients) compared to none (0%) in the SLN group. Although the differences are not statistically significant ($p=0.243$), it is noteworthy that two patients diagnosed with lymphocele required laparoscopic or radioguided drainage (Clavien-Dindo grade III complication).

García-Pineda et al. ($n=90$) did not find statistically significant differences in overall QoL when comparing their CL group (67.8%) with the SLN group (32.2%). However, the SLN group had significantly less impact on patients' functional and symptom scores than the lymphadenectomy group [15]. In addition, SLN group presented a significantly less post-treatment pain.

Other risk factors, such as obesity and age, can influence QoL scales. The study by Karatasli et al. investigated the impact of BMI on the QoL of patients with endometrial cancer and concluded that the group with morbid obesity had poorer physical functioning than the group without morbid obesity ($p < 0.011$) [16]. In our series, patients with a BMI >30 showed a worsening of HR-QoL (62.9% vs 37.1%; $p=0.308$) and worse oHP (57.9% vs 42.1%; $p=0.872$). The majority of lymphedemas (80%) and lymphoceles (66.7%) were diagnosed in patients with a BMI <30 , but there were no differences in the LELQ, which reflects lymphedema symptoms.

Pelvic radiation has been suggested as an important risk factor for lymphedema although other authors did not find post-operative radiation to be a predictive factor for lymphedema. In our series, after multivariate analysis, 80% (twelve patients) of those with an LELQ score >5 (symptomatic lymphedema) had received complementary treatment (brachytherapy/external radiotherapy with or without chemotherapy), whereas only 20% of patients who had not received complementary treatment scored positive on the LELQ. These differences were not statistically significant ($p=0.093$), likely due to the small number of cases in both groups.

We must consider that there are multiple external factors unrelated to the oncological disease that could negatively influence overall QoL, especially in patients over 60 years of age. These factors include the

onset of new conditions such as osteoarthritis, cardiovascular diseases, fractures, or other causes that were not accounted for in these studies.

Strengths and Weaknesses

The sample size of our study may be considered small, as it is a unicentric investigation. Consequently, strong conclusions cannot be drawn, and this issue warrants further exploration. Our study is one of the few prospective comparative studies to evaluate the impact on QoL according to lymph node staging technique in patients undergoing surgical treatment for early-stage EC. Unlike other studies ([14,15], the sample sizes of both groups in our study are very similar, which strengthens the results. The series by Dinoi et al [17] present a fairly large and balanced sample size between both groups (101 patients in CL group and 120 in SLN group), although the study is retrospective. Additionally, we accounted for the potential bias of receiving complementary treatment after surgery. However, we used a very generic HR-QoL scale and did not consider, unlike other studies, the impact on the sexual domain. Further, we did not account for confounding factors such as the onset of new conditions unrelated to EC during the follow-up period.

Conclusions

Our study demonstrates that pelvic sentinel lymph node (SLN) biopsy in early-stage endometrial cancer patients results in better overall health perception (oHP) and health-related quality of life (HRQoL) compared to complete lymphadenectomy (CL). The SLN group exhibited significantly lower rates of symptomatic lymphedema and lymphocele. No significant differences were observed in intra- and postoperative complications between the SLN and CL groups. These findings support the use of SLN biopsy as a preferable staging technique to minimize morbidity and enhance quality of life in endometrial cancer survivors.

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