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Full length article

Evaluation of the French medical practices in endometrial cancer management by using quality indicators

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ABSTRACT

Study objective: To evaluate the French quality of care of endometrial cancer using published relevant quality indicators and researche explanatory factors influencing its management.

Study design: We used databases from the "Echantillon Généraliste de Bénéficiaires", sample of the French population, to identify cases operated on between 2005–2014. Quality indicators evaluated were: three years survival rate, time between surgery and adjuvant treatment, use of IRMT and 3DCRT for radiotherapy, rate of minimally invasive surgery. Multilevel analysis was performed to identify explanatory factors.

Results: 405 women were included. 323 had a follow-up of more three years, and 250 were alive at three years (77.0%). 70 (17.3%) underwent minimally invasive surgery. 73 women of the 153 who received adjuvant treatment (47.8%) started it within 60 days after surgery. Among the 60 patients who received adjuvant radiotherapy, 50 (83.3%) underwent the IRMT or 3DCRT technique. In multilevel analysis, diabetes (OR = 1.24: 95% CI [1.08; 1.41]), and age under 65 (OR = 1.15: 95% CI [1.01; 1.35]) were associated with an increase of the three years survival rate.

Lymphadenectomy (OR = 1.12: 95% CI [1.03; 1.22]), and management in an university institution (OR = 1.13: 95% CI [1.01; 1.25]) were associated with adequate technique for the adjuvant radiotherapy. Laparoscopic surgery increased after 2010 (OR = 1.18: 95% CI [1,10; 1,25]).

Conclusion: Improvements should be made to increase the rate of laparoscopy and reduce the delay before adjuvant treatment for the management of endometrial cancer in France, specifically in non-university centers.

Introduction

In developed countries, endometrial cancer (EC) is the most common gynecological pelvic cancer. The estimated incidence in Europe was 88 000 in 2012 [1].

The quality of EC management has been evaluated only in a few studies [2,3]. Wright et al. suggested that surgeons and hospital activity volume have both (surgeon activity, and hospital oncological activity) a little effect on perioperative morbidity and mortality [4,5]. Moreover, it has been shown that EC with higher risk of extra-uterine disease, who may require lymphadenectomy, should be referred to a gynecological oncologist. Since care provided by gynecologic oncologists has been associated with better survival in high-risk EC [6].

Quality criteria should enable to assess and analyze the practice of healthcare professionals, through the comparison of expected practices (recommendations) to an individual analysis with their own practice and the practices of colleagues.

The Belgian Cancer Registry used the RANK method (combination of consensus, review of the literature and panel of experts) to propose 36 Quality Indicators (QIs) for the EC management [7]. These QIs concerned all the processes of care in different steps of management (with treatment decision, surgery, adjuvant treatment and outcomes), and included three dimensions of quality of care (timeliness, effectiveness, and safety).

A multicenter study has evaluated these QIs in 13 French University institutions and has identified five relevant QIs by their measurability (at least 80% of patients were affected by the indicator) and their improvability (difference between the theoretical target and the observed rate was below 5%) [8]. These

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fives QIs were included in three dimensions of quality of care (outcome, safety and perioperative management).

The "Echantillon Généraliste de Bénéficiaires" (EGB) is a national representative sample of 1/97th of the French population set up and managed by the national French health insurance.

We aimed to evaluate the quality of care of EC in France using relevant QIs and EGB database and to search explanatory factors influencing quality of care. The QIs evaluated were integrated into three dimensions of quality of care suggested by The Belgian Cancer Registry (surgical treatment, adjuvant treatment and outcomes) [7].

Materials and methods

Study population

The EGB databases from January 2005 to December 2014 were used to identify cases of EC treated in France. We extracted socio-demographic characteristics such as age, health insurance regime including Universal Healthcare Coverage, date of death and comorbidities (diseases completely covered by the national insurance, diabetes or high blood pressure) and data concerning EC management such as type of institution, oncological activity, adjuvant treatment, and time between surgery and adjuvant treatment.

We only included women who were operated on for EC (patients diagnosed with EC and who did not undergo surgery were not included) because their identification was more specific and reliable considering available information in the EGB database.

We included patients operated on for EC, between January 2005 and December 2014, and used the surgery date to the diagnosis date.

We excluded the patients with a diagnosis of primary EC unclear [discordance between cancer diagnosis declaration and diagnosis associated with hysterectomy (mainly ovarian cancer)].

Quality indicators

Among QIs suggested by the Belgian Cancer Registry [7] and by the French multicenter study [8], we were able to evaluate the five following QIs in three relevant dimensions of quality of care:

QI 1: Proportion of patients who are alive 3 years after their diagnosis.

QI 2: Proportion of patients receiving adjuvant treatment, within a maximum waiting time of 60 days (between date of surgery and date of 1st session of radiotherapy or chemotherapy).

QI 3: Proportion of patients who received adjuvant external radiotherapy with IMRT (Intensity Modulated Radiotherapy) or 3DCRT (three-dimensional conformal radiotherapy) techniques.

QI 4: Proportion of patients with clinical stage I cancer who underwent minimally invasive surgery (MIS) laparoscopy or robot-assisted.

QI 5: Proportion of patients operated who died within the 30 days after surgery.

Two QIs covered the dimension of quality of care about adjuvant treatment (QI 2, 3), one about surgical management (QI 4), and two covered the outcomes (QI 1, 5).

Statistical analysis

The main objective of the study was to describe the adherence to the QIs for patients in our population. Data on baseline clinical characteristics are described in Table 1. All continuous variables are presented with confidence intervals (95% CI), all categorical data are presented as proportion with % (N, %).

To search explanatory factors, we used a random intercept multilevel regression univariate and multivariate to estimate the parameters considering the non-independence between patients of the same institution and the identification of a contextual effect in individual analysis. The two levels were individual and institutional level:

- Individual level: age, comorbidities (diabetes, high blood pressure), surgical characteristics (route of hysterectomy, lymphadenectomy) and adjuvant treatment (radiotherapy, chemotherapy, radio-chemo and brachytherapy).
- Institutional level: public, university or private status and oncological activity (by the number of breast cancer cases, and endometrial cancer hysterectomy operations per year). The median surgical activities in institutions in terms of hysterectomies for EC was 200 during 10 years from 2005 to 2014, and 1200 cases during 10 years for breast cancer. To define the high volume centers, we used 20 endometrial cancer hysterectomy operations per years to define the EC activity, and 120 cases of breast cancer to the breast oncological activity. In multilevel analysis, we used the high volume activity to identify explanatory factors of our QIs. University institution were defined by an institution which combines the services of a hospital with the education of medical students and with medical research.

We included in the multivariate analysis the variables with a significance level less than 0.20 in univariate analysis.

The statistical software used for the study were SAS guide for extracting data from the interface of the EGB and R for statistical analysis (http: //lib.stat.cmu.edu/R/CRAN).

Table 1
Characteristics of the 405 patients.

N = 405	mean [95%CI] – n (%)
Age (years, 95%CI)	66.6 [65.5; 67.7]
Follow up (months, 95%CI)	55.7 [52.2; 59.2]
Public	191 (47.2%)
Private	179 (44.2%)
NA	35 (8.6%)
Adjuvant treatment	153 (37.8%)
Adjuvant external radiotherapy	60/153 (39.2%)
Adjuvant chemotherapy	16/153 (10.5%)
Adjuvant associated treatment (radio-chemo and brachytherapy)	77/153 (50.3%)
Universal Healthcare Coverage	31 (7.6%)
Diabetes	68 (16.8%)
Hysterectomy route	
-Laparotomy	335 (82,7%)
-Laparoscopy	70 (17.3%)
Lymph nodes resection associated	215 (53.1%)

CI: Confidence Interval.

Results

Patients characteristics

Between 2005 and 2014, 547 cases of EC were identified among the EGB. 116 women (21.2%) did not have surgical treatment and 26 (4.8%) had another diagnosis associated with hysterectomy for EC (Fig. 1). We included 405 women operated on for EC.

Patient characteristics are shown in Table 1. The mean age of patients was 66.6 years old [95% CI: 65.5; 67.7], with a mean follow-up on 55.7 months [95% CI: 52.2; 59.2]. The rate of EC managed in public institution was comparable to the rate of EC in private, 47.2% and 44,2% respectively, with 8.6% of missing data.

Adherence to QIs in EC management

Results concerning completion of the studied QIs are shown on Table 2. Every QI evaluated was defined with a clear denominator and numerator.

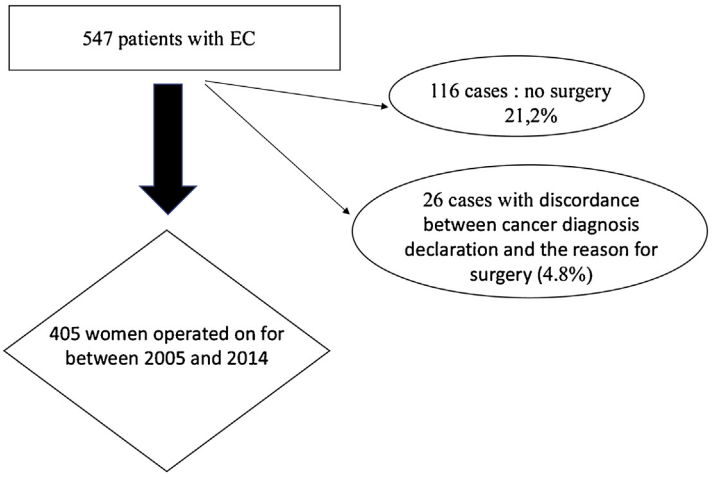

Fig. 1. Flow Chart.

Table 2
Proportion of completed QI in the EGB.

QI	Denominator	Numerator	Adherence to QIs
QI 1	Proportion of patients	Who are alive 3 years after their diagnosis(3-year overall survival)	250 / 323 **(77.0%)**
QI 2	Proportion of operated patients receiving adjuvant anticancer treatment	within a maximum waiting time of 60 days. (between date of surgery and date of 1 st session of radiotherapy or chemotherapy)	73 /153 **(47.8%)**
QI 3	Proportion of patients who received external radiotherapy as adjuvant treatment	for whom the technique was IMRT or 3DCRT	50 /60 **(83.3%)**
QI 4	Proportion of patients with clinical stage I cancer	who were operated by MIS	70 / 405 **(17.3%)**
QI 5	Proportion of patients operated	who died within the 30 days after the operation (30-days mortality rate)	2/ 405 **(0.5 %)**

Data are expressed as n (%).

Among our 405 women 323 had a follow-up of more three years, and 250 were alive three years after diagnosis of EC (250/323 = 77.0%).

153 patients received adjuvant treatment. Among them, 73 (47.8%) started adjuvant treatment within 60 days after surgery.

Among the 60 patients who received external adjuvant radiation, 50 (83.3%), received IMRT or 3DCRT radiotherapy.

Among the 405 women operated on for EC, 70 (17.3%) underwent MIS.

Two patients (0.5%) died within the 30 days after surgery.

Analysis of determinant factors

Results of univariate and multivariate multilevel analysis for each QI are shown in Tables 3–6. Since only 2 patients among the 405 died within one month (QI number 5), we did not perform multilevel analysis for this QI.

In multivariate multilevel analysis, diabetes (OR = 1.24: 95% CI [1.08; 1.41]), and age under 65 (OR = 1.15 : 95% CI [1.01 ; 1.35]) were associated with a higher three years survival probability.

No variable in multivariate multilevel analysis was associated with the completion of QI n°2 (time between surgery and adjuvant treatment).

Lymphadenectomy and management in an university institution were significantly associated with the completion of QI n°3 (respectively OR = 1.12: 95% CI [1.03; 1.22] and OR = 1.12: 95% CI [1.03; 1.22]) in multivariate multilevel analysis. At the contrary, laparotomy (OR = 0.88: 95% CI [0.77; 0.88]) was significantly associated with the non respect of QI n° 3, about technique of radiotherapy.

In multivariate multilevel analysis, EC treatment after 2010 was significantly associated with respect of QI n°5 (OR = 1.18: 95% CI [1.10; 1.25]).

In multivariate analysis, the high volume center was no significant for any QIs evaluated.

Comment

Using a representative sample of the French national population, we assessed the quality of EC management over the last decade in France with relevant QIs. For two of the five QIs evaluated, management cannot be considered satisfactory. First, the adjuvant treatment delay was less than 60 days for less than half of patients with adjuvant radiotherapy. Secondly, the MIS rate was below 20%. To evaluate the practices in medical management, the use of QI is new and innovate and the comparative data in another country were relatively poor. To our knowledge, this study is the first French national project which used relevant QIs to evaluate medical practice in EC management.

In order to identify QI to the specific care of patients with gynecological carcinoma, a US project used a list of 12 quality measures to gynecologic oncology management and these measures were ranked by the gynecologic oncology program [9]. This project identified important quality measures for EC such as the cancer survival or MIS rate. This study had shown a large variability in the completion of these quality measures. This US project could not obtain guidelines about the quality measures to be used in the Prospective Payment System-Exempt Cancer Hospitals [9].

In the present study, the three years survival rate was 77%, which is in accordance with the previous studies [10]. Diabetes and

Table 3
Univariate and Multivariate Multilevel Analysis: QI 1.

QI 1: Patients alive 3 years after their diagnosis						
	UNIVARIATE			MULTIVARIATE		
	INDIVIDUAL FACTORS					
	OR	CI	p	OR	CI	p
Disease 100% covered by the national insurance	1.02	[0.88–1.15]	0.734	–	–	–
Age > 65 years	**0.85**	[0.72–0.98]	**0.016**	**0.87**	[0.74–0.99]	**0.033**
Diabetes	**1.27**	[1.10–1.44]	**0.004**	**1.24**	[1.08–1.41]	**0.009**
Comorbidities	0.96	[0.83–1.09]	0.589	–	–	–
CMU	0.92	[0.68–1.17]	0.550	–	–	–
Surgical approach laparotomy	1.00	[0.81–1.18]	0.995	–	–	–
Lymphadenectomy	**1.14**	[1.01–1.27]	**0.042**	1.11	[0.98–1.24]	0.101
Adjuvant therapy	1.03	[0.89–1.16]	0.669	–	–	–
Operated on before 2010	1.05	[0.91–1.19]	0.425	–	–	–
	INSTITUTIONNAL FACTORS					
Public non-university	1	–	–	1	–	–
University Institution	0.89	[0.69–1.10]	0.315	–	–	–
Private Institution	0.97	[0.83–1.11]	0.691	–	–	–
Oncology activity for EC	0.99	[0.97–1.01]	0.649	–	–	–
Oncology activity for breast cancer	0.99	[0.99–1.00]	0.635	–	–	–

CI: Confidence Interval.

Table 4
Univariate and Multivariate Multilevel Analysis: QI 2.

QI 2: Adjuvant treatment within 60 days after surgery						
	UNIVARIATE			MULTIVARIATE		
	INDIVIDUAL FACTORS					
	OR	CI	p	OR	CI	p
Disease 100% covered by the national insurance	0.99	[0.74–1.24]	0.983	–	–	–
Age > 65 years	1.06	[0.82–1.29]	0.625	–	–	–
Diabetes	1.13	[0.85–1.42]	0.367	–	–	–
Comorbidities	1.21	[0.98–1.44]	0.102	1.19	[0.95–1.42]	0.140
CMU	0.67	[0.22–1.12]	0.087	0.70	[0.25–1.14]	0.119
Surgical approach laparotomy	1.13	[0.84–1.41]	0.399	–	–	–
Lymphadenectomy	0.84	[0.58–1.10]	0.216	–	–	–
Adjuvant therapy	1.06	[0.36–1.77]	0.856	–	–	–
Operated on before 2010	1.02	[0.78–1.25]	0.846	–	–	–
	INSTITUTIONNAL FACTORS					
Public non-university	1	–	–	1	–	–
University Institution	1.05	[0.74–1.36]	0.732	–	–	–
Private Institution	0.89	[0.62–1.16]	0.417	–	–	–
Oncology activity for EC	1.01	[0.97–1.05]	0.378	–	–	–
Oncology activity for breast cancer	1.00	[0.99–1.00]	0.404	–	–	–

CI : Confidence Interval.

lymphadenectomy were associated with a higher survival rate. It can be explained by the fact that lymphadenectomy was performed in patients having less comorbidity. Diabetes is a predisposing factor for histological type 1 EC which is associated with a higher survival rate and diabetic patients possibly had type 1 EC more frequently. In accordance with a previous results [11], the present study confirms a decrease of three years survival rate in patients over 65 years. Indeed, women older than 65 years have more comorbidity such as high blood pressure, diabetes, vascular disease, and metabolic disease.

In this study, adjuvant treatment delay was less than 60 days for less than half of the patients with adjuvant radiotherapy. Few studies have evaluated the impact of time between surgery and adjuvant treatment on outcomes and survival of women with EC. The impact on disease free survival has been suggested by Cattaneo and al. [12]. In this study, less than 9 weeks between surgery and the beginning of adjuvant radiotherapy was a significant predictive factor for a higher five years disease-free survival. In an Italian study [13] included 127 patients operated on for EC, all relapses occurred in patients who received radiotherapy after more than 9 weeks. Ahmad et al. [14], reported a decrease of disease-specific survival and a significantly worse local control when radiotherapy started more than 6 weeks after hysterectomy. But to our knowledge, there is no national project who tried to identify explanatory factors individual or institutional to this delay.

The present study shows that there is a good completion of the use of IMRT or 3DCRT technique for radiotherapy with a rate of 83.3%. At individual level, lymphadenectomy was significantly associated with the completion of this QI. At institutional level, management in an university institution was also significantly associated with the completion of this QI. IMRT is a technique for the radiation in pelvic area after pelvic cancer, recommended for adjuvant treatment in EC [15]. A study had shown the interest of IMRT technique in EC adjuvant treatment with a decrease of

Table 5
Univariate and Multivariate Multilevel Analysis: QI 3.

QI 3: Technique IMRT or 3DCRT for external radiotherapy as adjuvant treatment						
	UNIVARIATE			MULTIVARIATE		
	INDIVIDUAL FACTORS					
	OR	CI	p	OR	CI	p
Disease 100% covered by the national insurance	1.03	[0.94–1.12]	0.476	–	–	–
Age > 65 years	0.97	[0.88–1.07]	0.629	–	–	–
Diabetes	1.08	[0.96–1.20]	0.164	1.04	[0.94–1.14]	0.390
Comorbidities	0.97	[0.88–1.06]	0.590	–	–	–
CMU	0.93	[0.76–1.11]	0.479	–	–	–
Surgical approach laparotomy	**0.84**	[0.72–0.96]	**0.006**	**0.88**	[0.77–0.98]	**0.018**
Lymphadenectomy	**1.12**	[1.03–1.22]	**0.008**	1.04	[0.96–1.12]	0.292
Adjuvant therapy	1.40	[1.31–1.48]		1.34	[1.25–1.42]	
Operated on before 2010	0.95	[0.85–1.04]	0.305	–	–	–
	INSTITUTIONNAL FACTORS					
Public non-university	1	–	–	1	–	–
University Institution	**1.22**	[1.08–1.36]	**0.004**	**1.13**	[1.01–1.25]	**0.046**
Private Institution	**0.90**	[0.81–1.00]	**0.041**	0.93	[0.84–1.01]	0.102
Oncology activity for EC	1.00	[0.99–1.02]	0.417	–	–	–
Oncology activity for breast cancer	1.00	[0.99–1.00]	?	–	–	–

CI: Confidence Interval.

Table 6
Univariate and Multivariate Multilevel Analysis: QI 4.

QI 4: Surgery with minimally invasive surgery (laparoscopy or robot) for clinical stage I cancer						
	UNIVARIATE			MULTIVARIATE		
	INDIVIDUAL FACTORS					
	OR	CI	p	OR	CI	p
Disease 100% covered by the national insurance	0.98	[0.87–1.08]	0.726	–	–	–
Age > 65 years	0.99	[0.89–1.10]	0.936	–	–	–
Diabetes	1.06	[0.92–1.20]	0.358	–	–	–
Comorbidities	1.01	[0.90–1.11]	0.814	–	–	–
CMU	0.96	[0.76–1.15]	0.695	–	–	–
Lymphadenectomy	1.06	[0.95–1.16]	0.262	–	–	–
Adjuvant therapy	1.05	[0.94–1.16]	0.346	–	–	–
Operated on before 2010	**0.85**	[0.75–0.96]	**0.003**	**0.85**	[0.75–0.96]	**0.003**
Operated on after 2010	**1.18**	[1.10–1.25]	**0.003**	**1.18**	[1.10–1.25]	**0.003**
	INSTITUTIONNAL FACTORS					
Public non-university	1	–	–	1	–	–
University Institution	1.15	[0.98–1.32]	0.090	1.14	[0.97–1.30]	0.112
Private Institution	1.04	[0.93–1.16]	0.405	1.04	[0.93–1.15]	0.411
Oncology activity for EC	0.99	[0.98–1.01]	0.846	–	–	–
Oncology activity for breast cancer	0.99	[0.99–1.00]	0.905	–	–	–

CI: Confidence Interval.

gastrointestinal toxicity and a better tolerance, compared to the standard radiotherapy [16], for all patients even in women older or with comorbidity [17]. University institutions have regulation to respect recommended national guidelines; oncologists or gynecologists have to participate to medical learning, and to use as much often as possible the recommended therapeutic strategy.

Since 2002 the French guidelines [18] and since 2010 the European Society for Medical Oncology (ESMO) [19] recommended a MIS, laparoscopy or robot-assisted laparoscopy for EC surgical treatment, especially for stage I FIGO. Furthermore, since 2014, the American College of Surgeons' Commission on Cancer approved the use of MIS as a quality measure for the treatment of stage I-III EC [20]. Laparotomy and laparoscopy were compared in many randomized controlled trials [21] without significant difference in carcinologic outcomes while MIS is associated with shorter length of hospitalization, decreased of blood loss, and lower incidence of post-operative complications. Similar findings were made in high risk EC [22], and in women over 65 years with comorbidities [23]. Because the EGB database does not provide information on the disease stage and grade the MIS rate represents an average rate for all EC stages. We could not produce a specific MIS rate for EC stage I using the EGB database. However, we should keep in mind that the majority of patients operated on for EC present with clinical early stage disease and should undergo MIS.

A Dutch study has evaluated surgical approach in a cohort of women with a surgical treatment for EC between 2010 and 2014 [24]. The proportion of laparoscopy of 19% was comparable with our result. Only the histological type and the stage of EC were identified as significant influencing factors to choose the surgical approach. A recent study [25] included 1621 patients with a surgical treatment for EC all stage combined, in 2014, and reported a laparoscopic rate of 20.9% only. In this study, uterine size >12 cm and stage III or IV were the only influencing factors.

Another US study has shown that women are less likely to undergo laparoscopic hysterectomy for EC if they underwent surgery in a hospital with a low EC activity. In the high-volume

centers (more than 30 cases annually), MIS was only influenced by disease factors such as size of the tumor, or stage at diagnosis [26]. Two US studies have evaluated the use of MIS for hysterectomy compared with open hysterectomy, on retrospective cohorts of 9 799 women by using the National Inpatient Sample database [26] and on 32 560 women with non-metastatic EC [27]. Laparoscopic surgery increased from 22.0–50.8% from 2007 to 2011. Laparoscopy was more frequent for patients with a private insurance or for white patients, and more frequent in high-volume cancer institution, or university center. In the present study, the only factor influencing the rate of laparoscopy was the management after 2010. This result suggests that the last guidelines from 2010 [19] have an impact on EC management, and on adherences with recommendations.

The management cannot be considered satisfactory for two of the QIs evaluated, and after identifying explanatory factors, we could try to propose areas for improvement.

First, the adjuvant treatment delay was less than 60 days for less than half of patients with adjuvant radiotherapy. This delay could be improved by the development of a medical management network with surgeons, oncologist, radiotherapists, and with a large information about the benefit on overall and disease-specific survival when this delay is reduced.

Secondly, the MIS rate was below 20%. This rate could be improved with an increase of medical teaching for minimally invasive surgery (first in laparoscopy and after in robotically assisted laparoscopy) for the oncologist surgeons. Indeed, robotic surgery requires specific and long trainings and is expensive for the medical centers. For women with EC, few studies suggested that with robotically assisted surgery the estimated blood less were significantly lower than in laparoscopy, while the number of complications was significantly higher than in laparoscopy. A meta-analysis showed no significant differences between robotically assisted surgery and laparoscopy about the operating time, and the length of hospital stays [28].

A recent study suggests no significant survival difference between robotic minimally invasive surgery and laparoscopic minimally invasive surgery in women with early-stage (FIGO I and II) endometrial cancer [29].

However, further studies are required to evaluate difference about overall survival or quality of post-operative life between laparoscopy and robot-assisted laparoscopy for women with EC.

The present study has several limits, such as the small number of patients, which could decrease its statistical power.

However, the QIs evaluated were relevant because they were included in three dimensions of quality of care, and concerned adjuvant treatment, surgical management and outcomes.

Furthermore, EGB database is a relevant representative sample of French population this sample is exploitable to study EC management in French practices. Indeed, characteristics of our patients are matching with the characteristics of women with EC (age at diagnosis, the diabetes rate . . .). Similarly, the survival rate at three years is 77% including all stages and is comparable to the already known data.

Conclusion

To conclude, the present study has evaluated French practices in the management of EC. They are unequally respected. The adherence was good for the use of adequate technique of adjuvant radiotherapy, and in our population the three years survival rate was in accordance with previous studies.

Despite of improvements are necessary for two QIs: the delay between surgery and adjuvant radiotherapy, and the laparoscopic rate for EC surgical treatment, specifically in the non-university center.

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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