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# An audit of standards of radical hysterectomy in women with early-stage cervical cancer

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## Summary

*Purpose of investigation:* To audit radical hysterectomy for women with cervical cancer using the European Organization for Research and Treatment of Cancer-Gynecological Cancer Group (EORTC-GCG) guidelines. *Materials and Methods:* The records of 264 women who had undergone radical hysterectomy were reviewed. Quality was determined by assessing adherence to EORTC-GCG indicators. *Results:* The five-year overall survival (OS) and disease-free survival (DFS) of this cohort were 95.0% and 96.9%, respectively. Twenty-one (7.9%) women experienced recurrent diseases. The rate of five-year survival and pelvic recurrence reached the required standard thresholds. Eleven of the quality assessment criteria were not met including one structural indicator, five outcome indicators, and five process indicators. *Conclusion:* The survival and rate of pelvic recurrence achieved the EORTC-GCG required standards. There were 11 unachieved standards that merited further detailed exploration and re-audit.

*Key words:* Radical hysterectomy; Cervical cancer; Audit; Quality assurance.

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## Introduction

Radical hysterectomy with bilateral pelvic lymphadenectomy is the surgical treatment of choice for women with early stage cervical cancer [1]. Although pelvic radiation is equally effective in terms of overall survival (OS) for women with early stage cervical cancer, radical hysterectomy is traditionally offered to young women to preserve ovarian function and minimize the risk of sexual dysfunction [2]. During radical hysterectomy procedures, the entire uterus, cervix, upper vagina, lymphovascular tissues surrounding the cervix and vagina, and pelvic lymph nodes are removed with the aim to simultaneously resect the primary cervical lesion, as well as the potential areas of local metastatic deposits.

Major implications of the advancements in the quality of the surgical procedures result in the improvements of the treatment outcomes and quality of life for cancer patients [3]. Clinical auditing practices are acknowledged as effective tools in evaluating and improving the quality of care provided by a health service [4]. To ensure the completeness of resection of oncologically relevant tissues, while minimizing the risk of significant lasting morbidity, radical hysterectomy procedures and subsequent postoperative care therefore require auditing. Information obtained from clinical auditing will highlight unachieved standards thus providing an opportunity to improve quality of radical hysterectomy.

In 2009, the European Organization for Research and

Treatment of Cancer- Gynecological Cancer Group (EORTC-GCG) proposed the quality indicators for radical hysterectomy and pelvic lymphadenectomy in women with cervical cancer [1]. These guidelines were composed of three domains of quality assurance including structural quality indicators, treatment outcome indicators, and healthcare process indicators [1]. At present, the EORTC-GCG quality assurance for radical hysterectomy has become the internationally accepted standard for evaluating the quality of radical hysterectomy. This study was undertaken to audit radical hysterectomies for women with early stage cervical cancer at Srinagarind Hospital Khon Kaen University, (KKU), Khon Kaen, Thailand by applying the EORTC-GCG quality assurance guidelines.

## Materials and Methods

After approval from the Human Research Ethics Committee, the records of women with cervical cancer International Federation of Gynecology and Obstetrics (FIGO) Stage I-IIa, who underwent radical hysterectomy and pelvic lymphadenectomy as a primary treatment at Srinagarind Hospital, Khon Kaen University, (KKU), between January 2005 and October 2015 were reviewed. Because it was a retrospective study and the data were analyzed anonymously, the need for informed consent was waived by the Ethics Committee. Women who underwent radical hysterectomy for other conditions, such as adjuvant surgery following pelvic radiation or central tumor recurrence were excluded. All radical hysterectomies were performed via laparotomy by the gynecologic oncologists with in-training residents or fellows as assistants.

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Table 1. — *Baseline characteristics of women who met inclusion criteria (264).*

Characteristics	Number (%)
Age (mean $\pm$ SD)	45.47 $\pm$ 8.13
Parity	
Nulliparous	14 (5.3)
Multiparous	248 (93.9)
Unknown	2 (0.8)
FIGO Stages	
IA1	4 (1.5)
IA2	12 (4.5)
IB1	224 (84.8)
IB2	14 (5.3)
IIA1	10 (3.8)
Histologic types	
Squamous cell carcinoma	130 (49.2)
Adenocarcinoma	99 (37.5)
Adenosquamous carcinoma	3 (1.1)
Neuroendocrine	8 (3.0)
Unknown	24 (9.1)

SD, standard deviation; FIGO, International Federation of Gynecology and Obstetrics.

Abstracted data included patient characteristics, operative notes, intraoperative and postoperative complications, detailed pathological tissue reports, and recurrence/OS data.

In the KKU institute, adjuvant concurrent weekly cisplatin (40 mg/m<sup>2</sup>) concomitant with pelvic radiation or whole pelvic radiation alone were given if the pathological report revealed at least one of the following high risk factors: lymph node metastasis, parametrial metastasis, or involved surgical margins. In addition, whole pelvic radiation was offered if there were two intermediate risk factors including deep cervical stromal invasion, large tumor size, and presence of lymphovascular space invasion.

Patients were followed every three to four months in the first two years after completion of treatment and every six months thereafter. A pelvic examination was performed at every visit. Further investigations were carried out when indicated. OS was defined as a period of time between the month of operation and that of death of any cause. Disease-free survival (DFS) was defined as survival until the appearance of a new lesion of disease.

The quality of radical hysterectomy for early stage cervical cancer was determined by assessing adherence to each EORTC-GCG quality indicator. The results are provided as the number (percentage) of patients, mean [standard deviation (SD)], and median [interquartile range (IQR)] as appropriate. Statistical analyses were carried out using SPSS version 17.

## Results

The medical records of 264 women who underwent radical hysterectomy and pelvic lymphadenectomy for cervical cancer FIGO Stage I-IIa were reviewed. There were four gynecologic oncologists in the Hospital during the study period. Table 1 displays the baseline characteristics of the patients. Mean age was 45.5 (range, 26-67) years. Mean operative time was 213.1 (SD, 50.9) minutes. Median blood loss during operations was 400 (IQR, 200 and 600) ml.

Fifty-six (29.2%) patients received adjuvant treatments after radical hysterectomy including pelvic radiation (47), concurrent chemoradiation (7), and systemic chemotherapy (2).

At a median follow-up of 95 months, 21 (7.9%) women had experienced recurrent diseases including locoregional recurrence (6, 2.2%), distant recurrence (8, 3.0%), and combined locoregional and distant recurrences (7, 2.7%). The five-year DFS was 96.9% and OS 95.0%.

Table 2 shows the audit results of radical hysterectomy using the EORTC-GCG quality assurance indicators. Eleven of the quality assessment criteria were not met: number of radical hysterectomies by surgeon per year (6.6) did not achieve the requirement of 10; the incidences of urinary tract injury (1.5%), bowel obstruction (1.5%), symptomatic lymphocyst (2.3%), and ureteric stenosis (1.9%) were slightly higher than the standard requirement of less than 1% for each complication; percentage of radical hysterectomy specimens with tumor-positive resection margins (6.4%) was higher than the 5% minimum required. For six indicators for healthcare process assessment, only the percentage of patients receiving adequate administration of perioperative antibiotics (100%) achieved the minimum requirements of 95%. The remaining five quality assurance indicators including adequate operation information, percentage of adequate number of excised pelvic lymph nodes, percentage of complete pelvic lymphadenectomies, percentage of radical hysterectomies without peritoneal closure and retroperitoneal drainage, and percentage of patients starting on a normal diet on the first day after operation did not achieve the standard requirements.

## Discussion

In the present study, the authors evaluated the quality indicators for radical hysterectomy in women with early-stage cervical cancer using the recent EORTC-GCG guidelines. Several unachieved standards were observed which highlighted the issues of radical hysterectomy that require detailed exploration.

Previous studies consistently demonstrated the strong relation between high volume hospitals/providers and better oncological outcomes after cancer surgery [5-8]. For example, in centralization initiatives undertaken by the Dutch Society of Obstetrics and Gynecology, cytoreductive surgery for advanced ovarian cancer is recommended to be carried out by specialized gynecologic oncologists in institutions in which a minimum of 20 cytoreductive surgeries take place annually. After national implementation, rate of optimal cytoreduction among women with advanced ovarian cancer has increased greatly resulting in more favorable survival outcomes [6]. In the present study, the average annual cases of radical hysterectomies by a surgeon in the KKU institute were 6.6 which did not achieve the 10 minimum required. The average annual case-load per institu-

Table 2. — Audit of the quality indicators for radical hysterectomy in women with early stage cervical cancer using EORTC-GCG 2009 guidelines.

Quality indicators	Audit results	Accepted standard	Conclusion
Structure			
Number of radical hysterectomies per surgeon per year	6.6	10	Failed
Number of radical hysterectomies by institution per year	26.4	20	Achieved
Outcome			
Five-year survival (%)	95.0	80	Achieved
Percentage of cervical cancer patients suffering pelvic recurrence after radical hysterectomies	4.9	15	Achieved
Percentage of patients having short-term complications			
Postoperative mortality	0	1	Achieved
Postoperative hemorrhage	0.4	1	Achieved
Urinary tract injury	1.5	1	Failed
Bowel obstruction	1.5	1	Failed
Deep venous thrombosis	0.8	1	Achieved
Percentage of patients having long-term complications			
Symptomatic lymphocyst	2.3	1	Failed
Ureteral stenosis	1.9	1	Failed
Incisional hernia	0.8	1	Achieved
Fistula requiring surgery	0.8	1	Achieved
Percentage of radical hysterectomy specimens with tumor-positive resection margins	6.4	5	Failed
Process			
Percentage of surgery reports that contained information on mode of access, radicality of the different steps of the operation, and completeness of lymphadenectomy	19.6	95	Failed
Percentage of pelvic lymphadenectomy specimens that contained >11 examined lymph nodes	88	90	Failed
Percentage of pelvic lymphadenectomy specimens that contained at least one examined lymph node in each common iliac, external, and internal iliac and obturator area	0	95	Failed
Percentage of radical hysterectomies without peritoneal closure and retroperitoneal drainage	26.1	95	Failed
Percentage of patients undergoing radical hysterectomy who received adequate administration of perioperative antibiotics	100	95	Achieved
Percentage of patients starting normal diet on day1 after a radical hysterectomy	0	90	Failed

EORTC-GCG, European Organization for Research and Treatment of Cancer- Gynecological Cancer Group.

tion of, however, approximately 26 which was above the EORTC-GCG minimum standards of 20 cases. The low number of radical hysterectomies per surgeon per annum in the KKU institute seems to have had no impact on the main oncological outcomes since the rates of five-year OS and locoregional recurrences achieved the required standards.

Perioperative complications following radical hysterectomy are relatively uncommon. A previous study which was conducted in Thailand to evaluate the outcomes of 1,253 patients who underwent abdominal radical hysterectomy for cervical cancer noted that the common complications following radical hysterectomy included severe lymphedema (7.4%), persistent bladder dysfunction (5.1%), symptomatic lymphocyst (2.5%), urinary tract injury (1.3%), bowel obstruction (0.3%), and bowel injury (0.1%) [9]. In a retrospective cohort study conducted among 1,495 women undergoing abdominal radical hys-

terectomy for cervical cancer during 2001-2010, the rate of ureteric injury was 1.5% [10]. The rate of vesicovaginal and ureterovaginal fistula after radical hysterectomy for cervical cancer was approximately 1.2% of women undergoing abdominal radical hysterectomy for cervical cancer performed in the English National Health Service between 2000 and 2008[11].

In the present study, rates of postoperative mortality, severe postoperative hemorrhage, deep vein thrombosis, incisional hernia, and fistulas requiring surgical correction achieved the requirements recommended by the guidelines of less than 1% for each complication. Although rates of urinary tract injury (1.5%), bowel obstruction (1.5%), symptomatic lymphocyst (2.3%), and ureteric stenosis (1.9%) were just slightly higher than the accepted standards, these perioperative complications can pose serious consequences. Detailed evaluations of the affected cases and effective interventions to prevent the complications follow-

ings radical hysterectomy are thus worthy of consideration.

Of six process indicators, only one indicator which was the rate of prophylactic antibiotics (100%) achieved the 95% minimum standard. The quality of operative reports was suboptimal. Although the rate of pelvic lymphadenectomy specimens containing more than 11 examined nodes was slightly below the required standard (88% vs. 90%), no pelvic lymph node specimens in the present study contained the common iliac node which was due to local management policy. The benefit of routine resection of common iliac lymph node is unclear in the KKU institute, therefore the common iliac lymphadenectomy will be carried out only when pelvic lymph node metastasis is highly suspected.

It has become evident that the use of peritoneal closure and retroperitoneal drainage has no significant benefit in prevention of perioperative morbidities and lymphocyst formation [1, 12]. In addition, early postoperative feeding after gynecologic surgery for malignant conditions is safe and feasible [13]. Reasons underlying the high rate of peritoneal closure and retroperitoneal drainage use and low rate of starting normal diet on the first day post-surgery in the present study therefore need to be determined.

Because of the retrospective nature of this study, data were retrieved from medical records, thus the possibility of incomplete data recording cannot be excluded. This stimulates the institute to create a data recording template to use during future audits. Despite this limitation, this is the first study conducted in a developing country in an area with a high incidence of cervical cancer, to audit the quality of radical hysterectomy using the internationally-accepted standard guidelines.

In conclusion, the five-year survival and rate of locoregional recurrence among women undergoing radical hysterectomy for early-stage cervical cancer in the present study reached the standard thresholds. There were 11 unachieved standards that require further exploration.

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