The Efficacy of Neoadjuvant Paclitaxel-Carboplatin Chemotherapy Followed by Radical Hysterectomy Compared to Radical Hysterectomy alone in Bulky Stage IB2-IIA Cervical Cancer

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Objective: *To compare the efficacy of neoadjuvant paclitaxel-carboplatin chemotherapy followed by radical hysterectomy with radical hysterectomy alone in patients with bulky cervical cancer stage IB2-IIA.*
Material and Method: *From January 2000 through December 2009, 80 patients with bulky cervical cancer stage IB2-IIA that received neoadjuvant paclitaxel-carboplatin chemotherapy (n = 40) or immediate primary surgery (n = 40) were reviewed. The efficacy of neoadjuvant chemotherapy on the basis of feasibility in operation and pathological prognostic factors and the percentage of patients who needed postoperative adjuvant concurrent chemoradiation therapy were compared.*
Results: *There were no significant differences between group in age, tumor size, FIGO staging, histologic type and grading at the time of diagnosis. All patients in neoadjuvant chemotherapy group successfully underwent radical hysterectomy. The pathological findings included tumor size, deep cervical invasion, parametrial involvement, positive surgical margin and lymphovascular space invasion were statistically significant decrease in neoadjuvant chemotherapy group. Nevertheless, the pelvic nodal metastasis was not different between both groups. Adjuvant concurrent chemoradiation therapy had a statistically significant decrease in the neoadjuvant chemotherapy group.*
Conclusion: *Neoadjuvant chemotherapy significant by improves the feasibility in operation and the pathological prognostic factors, and decreases the percentage of patients who needed postoperative adjuvant concurrent chemoradiation therapy.*

Keywords: *Bulky cervical cancer stage IB2-IIA, Neoadjuvant chemotherapy, Radical hysterectomy, Rajavithi Hospital*

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Cervical cancer is the most common gynecological malignancy in the developing countries. For early-stage cervical cancer, radical surgery is accepted as the standard treatment. However, there is still no agreement on the best approach for bulky cervical cancer[1]. Therapeutic modality targeted to bulky early stage cervical cancer included radical hysterectomy with lymphadenectomy, radiotherapy or concurrent radiotherapy and neoadjuvant chemotherapy. Surgery may preserve ovarian function and vaginal length compared with radiotherapy. The survival rate of patients with early-stage cervical cancer was about 80-90% in non-bulky tumors, but decreasing to 50-60% in bulky tumors[1,2]. Bulky cervical cancers had a higher incidence of central recurrence, pelvic and para-aortic lymph node metastasis and distant metastasis. Therefore, a new therapeutic modality targeted to bulky early stage cervical cancer should be developed. The most common failure pattern following radical surgery for cervical carcinoma is pelvic relapse. The pathologic prognostic factors for the recurrence of cervical cancer were proposed by Delgado et al[3], in which these factors were separated in intermediate and high risk groups.

Neoadjuvant chemotherapy (NAC) prior to surgery has been applied as a therapeutic strategy for bulky and locally advanced cervical cancer[4,5]. Several studies suggested that the NAC was effective in the reduction of tumor size, control of micrometastasis, improving operability and the surgical downstaging of

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patients[5-7]. The response rate of neoadjuvant chemotherapy in bulky and locally advanced cervical cancer is as high as 73.1-95.0%[8-16]. Therefore, the objective of the present study was to evaluate the efficacy of neoadjuvant chemotherapy by comparing the efficacy of neoadjuvant paclitaxel-carboplatin chemotherapy followed by radical hysterectomy with radical hysterectomy alone in patients with bulky stage IB2 to IIA cervical cancer on the basis of feasibility in operation, pathologic prognostic factors and the percentage of patients who needed adjuvant concurrent radiation after treated.

Material and Method

The present study design was retrospective cohort. Complied with the Institutional Research Ethics Committee approval, 80 patients with bulky cervical cancer FIGO stage IB2-IIA treated at Gynecologic Oncology Unit, Department of Obstetrics and Gynecology, Rajavithi Hospital were retrospectively reviewed from January 1, 2000 through December 31, 2009. The patients' data included age, medical illness, performance status, clinical staging of cervical cancer, and histological type and grading were reviewed. All patients received standard pretreatment evaluation, which consisted of physical and pelvic examination, chest x-ray, cystoscopy and intravenous pyelogram. The pelvic examinations were performed under anesthesia by two gynecologic oncologists and one radiologist. The tumor diameters were assessed by pelvic examination. Bulky tumor was defined as a visible cervical tumor with the longest diameter more than 4 cm. The clinical staging by FIGO 1994 staging system was consensus by two gynecologic oncologists and one radiologist. Eligibility criteria were newly diagnosed primary bulky cervical cancer stage IB2-IIA, histologically confirmed squamous cell carcinoma or adecarcinoma, neither concurrent nor previous malignant disease, no previous treatment, no complicating medical disease and performance status of 1 or less.

The patients were recruited for controlled subjects matching 1:1 for the following variable:FIGO staging, tumor size, age. The sample size was calculated by the compared mean formula based on the sample size in the previous studied[16]. Forty patients were treated with paclitaxel and carboplatin as neoadjuvant chemotherapy (NAC) and 40 patients underwent immediate primary surgery (PS) by radical hysterectomy alone.

In the NAC group there was no guideline for practice among Rajavithi Hospital Rajavithi Hospital. The physicians individually made the decision regarding the type of treatment according to age of the patient. Reproductive-age groups were considered to the NAC group.

The NAC consisted of 1-3 cycles of intravenous paclitaxel 175 mg/m^2 drip for 3 hours and carboplatin AUC 5, every 3-4 week intervals. Consideration to the number of chemotherapeutic cycles and surgery according to the personal decision of the physician based on the tumor response. Patients were required to meet all of the following laboratory criteria:hemoglobin level $\geq$ 10 g/dL, WBC count $\geq$ 3,000/mm^3 or absolute neutrophil count $\geq$ 1,500/mm^3, platelet count $\geq$ 100,000/mm^3, serum transaminase (AST, ALT) levels $\leq$ 40 U/L, total serum bilirubin level $\leq$ 1.5 mg/dL, serum creatinine level $\leq$ 1.5 mg/dL and blood urea nitrogen level $\leq$ 20 mg/dL.

All patients in the NAC group underwent radical hysterectomy and systematic pelvic lymphadenectomy, three to 4 weeks after the completion of NAC.

Patients in the PS group underwent immediate radical hysterectomy and systematic pelvic lymphadenectomy (RHPL). All surgery was performed by a gynecologic oncologist with fellow or resident assistants. Dissection of the pelvic lymph nodes consisted of removal of all fatty lymph-node bearing tissue that were anterior, lateral and posterior to the common, external and internal iliac vessels and anterior to the obturator nerve. Operative morbidities included operating time, estimated blood loss, blood transfusion, intraoperative and post-operative complications were assessed.

In the NAC group, the new tumor response according to the Response Evaluation Criteria In Solid Tumors (RECIST) published in February 2000[21] were analysed. Assessed by pelvic examination before each chemotherapy cycle and surgery and the final clinical response was determined upon pelvic examination immediately before surgery. Complete response (CR) was defined as the complete disappearance of the tumor in the cervix, partial response (PR) as a more than 30% decrease of longest diameter (LD), progressive disease (PD) as a more than 20% increase of longest diameter, and stable disease (SD) as a decrease or increase less than PR or SD. Overall response rate (RR) were defined as the sum of CR and PR.

The complications following chemotherapy were analyzed and revised according to the WHO Toxicity Criteria version 3.0[22].

Pathological prognostic factors included tumor size, lymphovascular space invasion, deep cervical invasion, nodal metastasis, parametrial involvement and surgical margin were assessed. Postoperative concurrent chemoradiation or radiotherapy alone was administered to high and intermediated risk groups. The operative morbidities, pathological findings and postoperative adjuvant therapy were compared both groups.

Statistical analyses were carried out using SPSS version 17.0 software. Comparison of categorical variables was calculated by use of the two-sided Chi-square test. Whereas, the continuous variables were compared by the student t-test and Mann-Whitney U test. Statistical significance was defined as $p < 0.05$.

Results

In the present study, 40 patients were received NAC followed by radical hysterectomy and 40 underwent radical hysterectomy alone. The characteristics of the patients are summarized in Table 1. Both groups were similar in age, tumor size, FIGO staging, histological type and grading at the time of diagnosis. There are no medical illness and Eastern Cooperative Oncology Group (ECOG) scores were 0-1 in all patients.

There were 3 (7.5%), 22 (55.0%) and 15 (37.5%) patients received 1, 2 and 3 cycles of paclitaxel and carboplatin, respectively. One patient (2.5%) and 36 patients (90.0%) received 3-week and 4-week intervals of paclitaxel and carboplatin, respectively. There were no delayed or dose reduction during chemotherapy.

Treatment-related toxicities in the NAC group are listed in Table 2. Alopecia was the most common adverse event in 35 patients (87.5%), whose most common grading was 1-2. There were no life-threatening complications following chemotherapy. All patients were successfully underwent radical hysterectomy and complete pelvic nodal dissection. Tumor responses of the NAC group are summarized in Table 3. None of the patients showed progressive disease.

All patients successfully underwent abdominal radical hysterectomy and complete pelvic nodal dissection. The operative and pathological data were compared in both groups and shown in Table 4. There were similar operating time and intra-operative complication rate both groups and significant by higher blood loss and intra-operative transfusion in the NAC group (800 ml vs. 600 ml, $p = 0.019$ and 40.0% vs. 17.5%, $p = 0.026$, respectively). Post-operative bladder dysfunctions were higher in the NAC group (25.0% vs. 5.0%, $p = 0.012$) as shown in Table 5. Median time of bladder dysfunction were 21 and 31.5 days for NAC and PS group, respectively ($p = 0.509$). However, all patients with bladder dysfunction were recovered to normal function later.

The statistically significant reduction of tumor size, deep cervical invasion, lymphovascular space invasion, parametrial involvement and positive surgical margin was detected in the NAC group as shown in Table 4. However, there was no significant difference in pelvic lymph node metastasis in both groups. Post-operative adjuvant concurrent chemoradiation therapy was administered to 11/40 (27.5%) of the NAC group and 23/40 (57.5%) of the PS group ($p = 0.007$) as shown in Table 5. Nodal metastasis was the most common indication for post-operative concurrent chemoradiation therapy both groups.

Discussion

From the previous studies, the NAC had shown a high response rate, 53-94%, with complete pathological response rates of 10.0%-13.8%[7,17-19]. Complete response of 20.0% (8/40), along with significant reduction of tumor size in the NAC group compared to radical hysterectomy alone were identified in the present study. These findings suggested that NAC might be improved feasibility in operation of patients with bulky cervical cancer by reduction of tumor size, but the operative morbidities such as postoperative bladder dysfunction, blood loss and intraoperative blood transfusion were significantly increase in the NAC group. Tumor necrosis induced by chemotherapy may result in dense fibrosis and adhesions, which makes surgical planes difficult to be maintained[20] leading to more intra-operative blood loss and post-operative complication in the NAC group. However, there was no life threatening complications following chemotherapy.

Several reports suggested that the NAC had an effect on pathological prognostic factors in patients with bulky stage IB-IIB cervical cancer than those were treated with radical hysterectomy alone[6,16]. The pathological prognostic factors for recurrence of cervical cancer were proposed by Delgado et al[3]. Metastatic disease in the pelvic lymph nodes is a poor prognostic sign. Pelvic nodal metastasis may be associated with lesion size, deep stromal invasion and lymphovascular space invasion[3]. Sardij et al[6] reported that the NAC with cisplatin, vincristine and bleomycin regimen decreased the pathological prognostic factors including lymphovascular space invasion, parametrial

Table 1. Patient Characteristics

Characteristics	Neoadjuvant chemotherapy (n = 40)	Primary surgery (n = 40)	p-value
Mean Age (years) ± (SD)	42.98 (± 6.67)	43.13 (± 9.67)	0.941
Initial tumor size, cm			
Median (range)	5.00 (4.5-6)	5.00 (4.5-6.5)	0.367
Clinical staging			0.803
Stage IB2	27 (67.5%)	28 (70.0%)	
Stage IIA	13 (32.5%)	12 (30.0%)	
Histology			0.263
Squamous	34 (85.0%)	30 (75.0%)	
Adenocarcinoma	6 (15.0%)	10 (25.0%)	
Grading			0.147
Grade 1	12 (30.0%)	20 (50.0%)	
Grade 2	23 (57.5%)	18 (45.0%)	
Grade 3	5 (12.5%)	2 (5.0%)	

Table 2. Treatment-related Toxicity in the Neoadjuvant Chemotherapy Group

Toxicity	Number of patients (%)		
	Grade 0	Grade 1-2	Grade 3-4
Hematologic			
Anemia	33(82.5%)	7 (17.5%)	-
Leukopenia	39(97.5%)	1 (2.5%)	-
NeutropeniaNeurotoxicity	39(97.5%)	1 (2.5%)	-
Peripheral neuropathy	8 (20.0%)	32 (80.0%)	-
Alopecia	5 (12.5%)	34 (85.0%)	1 (2.5%)

Table 3. Tumor Response of the Neoadjuvant Chemotherapy Group

Tumor response	Number of patients (%)
Complete response	8 (20.0%)
Partial response	29 (72.5%)
Overall response	37 (92.5%)
Stable disease	3 (7.5%)

invasion and lymph node involvement in unresected bulky stage IB patients. Cho YH et al[16] reported that the NAC with paclitaxel and carboplatin had an efficacy on reduction of the pathological prognostic factors except lymph node metastases, lymphovascular space invasion and parametrial involvement. In the present study, neoadjuvant paclitaxel-carboplatin chemotherapy was statistically significant decrease in tumor size, lymphovascular space invasion, deep cervical invasion, parametrial involvement and positive surgical margin when compared to radical hysterectomy alone. Nevertheless, the pelvic nodal metastases did not differ between both groups. Less efficacy of neoadjuvant chemotherapy in metastatic disease of the pelvic lymph nodes was observed in the present study, similar to previous report by Cho YH et al[16]. Dosage of this chemotherapeutic regimen may insufficient in the reduced lymph node metastasis, on the other hand this neoadjuvant chemotherapy might be ineffective in the management of high risk patients such as tumor size more than 4 cm, deep cervical invasion with lymph node metastasis. However, dose intensity, chemotherapeutic regimens and prospective design should be further studied in a larger number of patients with bulky cervical cancer.

Lower proportion of patients in the NAC

Table 4. Surgical and Pathological Outcomes

	Neoadjuvant chemotherapy (n = 40)	Primary surgery (n = 40)	p-value
Operating time, min			
Median (min-max)	245.00 (150-365)	210.00 (160-400)	0.056
Estimate blood loss, ml			
Median (min-max)	800.00 (300-3500)	600.00 (300-1700)	0.019*
Intra-operative transfusion	16 (40.0%)	7 (17.5%)	0.026*
Intra-operative complications			0.310
Injury of ureter	1 (2.5%)	0 (0.0%)	
Injury of great vessel	0 (0.0%)	0 (0.0%)	
Median node count (min-max)	17.00 (9-41)	20.00 (3-39)	0.094
Pathological findings			
Median tumor size, cm (range)	2.10 (0-4.5)	5.00 (4.5-6.5)	0.000*
Lymph node metastasis	9.00 (22.5%)	14.00 (35.0%)	0.220
Median number of lymph node metastasis (range)	1.00 (0-2)	1.50 (1-7)	0.041*
Parametrial involvement	3 (7.5%)	13 (32.5%)	0.010*
Positive surgical margin	0 (0.0%)	4 (10.0%)	0.040*
Lymphovascular space invasion	7 (17.5%)	17 (42.5%)	0.020*
Deep cervical invasion	8 (20.0%)	19 (47.5%)	0.009*

* Significance at level $p < 0.05$

Table 5. Post-operative Outcomes

	Neoadjuvant chemotherapy (n = 40)	Primarysurgery (n = 40)	p-value
Post-operative bladder dysfunction (%)	10 (25.0%)	2 (5.0%)	0.012*
Median time of bladder dysfunction, days (range)	21.00 (14-49)	31.50 (21-42)	0.509
Post-operative adjuvant concurrent chemoradiation therapy (%)	11 (27.5%)	23 (57.5%)	0.007*
Nodal metastasis only	8 (72.7%)	9 (39.1%)	
Parametrial metastasis only	2 (20.0%)	6 (26.1%)	
Surgical margin involvement only	0 (0.0%)	1 (4.3%)	
Node and parametrial metastasis	1 (10%)	4 (17.4%)	
Parametrial metastasis and surgical margin involvement	0 (0.0%)	2 (8.7%)	
Node and parametrial metastasis and surgical margin involvement	0 (0.0%)	1 (4.3%)	

* Significance at level $p < 0.05$

group required post-operative adjuvant concurrent chemoradiation therapy (25.0% vs. 57.5%, p = 0.003). These findings suggest that the NAC significant decrease in the percentage of bulky cervical cancer patients who needed postoperative adjuvant concurrent chemoradiation. So neoadjuvant chemotherapy may provide conservation of ovarian and sexual functions and should be consistent in younger patients with bulky cervical cancer to affording better quality of life.

The limitations of the present study were retrospective design, and the small number of patients. Also, disease free survival and overall survival was not evaluated in the present study. Therefore, the

efficacy of neoadjuvant chemotherapy to survival outcome should be further studied.

Potential conflicts of interest

None.

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ประสิทธิภาพของการให้ยาเคมีบำบัดโดย paclitaxel และ carboplatin ก่อนการผ่าตัดร่วมกับการผ่าตัดเทียบกับการผ่าตัดมดลูกแบบถอนรากถอนโคนเพียงอย่างเดียวในผู้ป่วยมะเร็งปากมดลูกระยะ IB2-IIA

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วัตถุประสงค์ *: เพื่อเปรียบเทียบประสิทธิภาพของการให้ยาเคมีบำบัดก่อนการผ่าตัดด้วย paclitaxel และ carboplatin ร่วมกับการผ่าตัด กับการผ่าตัดแบบถอนรากถอนโคนเพียงอย่างเดียวในผู้ป่วยมะเร็งปากมดลูกระยะ IB2-IIA*

วัสดุและวิธีการ *: ตั้งแต่ มกราคม พ.ศ. 2543 ถึง ธันวาคม พ.ศ. 2552 ผู้ป่วยมะเร็งปากมดลูกระยะ IB2-IIA จำนวน 80 ราย ได้รับการศึกษาย้อนหลัง แบ่งผู้ป่วยออกเป็นสองกลุ่มคือ กลุ่มที่ได้รับยาเคมีบำบัดก่อนการผ่าตัดร่วมกับการผ่าตัด 40 ราย และกลุ่มที่ได้รับการผ่าตัดเพียงอย่างเดียว 40 ราย เปรียบเทียบประสิทธิภาพของการให้ยาเคมีบำบัดโดยพิจารณาจากการเพิ่มโอกาสของความเป็นไปได้ในการผ่าตัดลักษณะทางพยาธิวิทยาที่มีผลต่อพยากรณ์โรคและจำนวนผู้ป่วยที่จำเป็นต้องได้รับการรักษาโดยรังสีรักษาหลังการผ่าตัด ในผู้ป่วยทั้งสองกลุ่ม*

ผลการศึกษา *: ลักษณะของประชากรทั้งสองกลุ่มได้แก่ อายุ ขนาดรอยโรคบริเวณปากมดลูก ระยะของโรค ลักษณะทางพยาธิวิทยา ไม่มีความแตกต่างกันอย่างมีนัยสำคัญ ผู้ป่วยในกลุ่มที่ให้ยาเคมีบำบัดสามารถทำผ่าตัดมดลูกแบบถอนราก ถอนโคนได้ประสบผลสำเร็จทุกราย ในกลุ่มที่ได้รับยาเคมีบำบัดพบว่าช่วยลดลักษณะทางพยาธิวิทยาได้แก่ tumor size, deep cervical invasion, parametrial involvement, positive surgical margin and lymphovascular space invasion ได้อย่างมีนัยสำคัญ ยกเว้นการกระจายไปบริเวณต่อมน้ำเหลืองบริเวณช่องเชิงกราน และพบว่าในกลุ่มที่ได้รับยาเคมีบำบัดก่อนการผ่าตัด ช่วยลดการได้รับรังสีรักษาร่วมกับเคมีบำบัดหลังผ่าตัดได้อย่างมีนัยสำคัญ*

สรุป *: การให้ยาเคมีบำบัดก่อนการผ่าตัดเพิ่มโอกาสในการผ่าตัด ลด pathologic prognostic factors และจำนวนผู้ป่วยที่ต้องได้รับรังสีรักษาหลังการผ่าตัด*