EJGO European Journal of Gynaecological Oncology

Learning curve in colposcopic training among gynecologic oncology fellows

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Summary

Objective: To demonstrate the learning curve of colposcopic training among gynecologic oncology fellows at King Chulalongkorn Memorial Hospital. *Materials and Methods:* A retrospective review of colposcopic examinations during June 2014 - April 2017 was performed. The agreement between colposcopic impression (normal vs. low grade lesion vs. high grade lesion) and histopathology (benign *vs*. HPV/CIN1 *vs*. CIN2+) was defined as accuracy. Accuracy rate of attending staffs in the institute during the same period was used as the reference level. Cumulative mean proportion of accuracy rate at each consecutive case was plotted in graph and learning curve was generated. *Result:* Six hundred ninety-one patients were included. Overall accuracy rate of fellows after completion of training was comparable to the attending staffs, which was 68.1% (95% CI 63.4 – 72.4%) versus 68.0% (95% CI 61.9 - 73.6%) Normal colposcopic impression correctly predicted normal histopathology in only 30.3% of cases. Colposcopic impression of low-grade and high-grade lesions correctly predicted low- and high-grade intraepithelial lesions on biopsy in 75.9% and 53.4% of cases, respectively. CIN2+ lesions were misdiagnosed in 2.9% of the patients with normal colposcopic impression and 37.2% of the patients with low-grade lesion. The learning curve showed a plateau after 50 cases at around 70% accuracy rate, which was the similar accuracy rate of attending staffs. *Conclusion:* Colposcopic examination is a procedure that requires comprehensive training. The minimum numbers of 50 colposcopic procedures were required to achieve optimal competency and maintain proficiency.

Key words: Accuracy; Colposcopy; CIN; Learning curve; Training.

Introduction

Cervical cancer remains an important health problem in Thailand and around the world [1, 2]. This preventable disease is the second most common cancer found among Thai women [2]. Colposcopy is a standard procedure recommended by the American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines for women who have abnormal cervical cytology or positive oncogenic HPV testing [3]. The procedure requires comprehensive training and learning curve. Qualified colposcopists must be trained to identify lesions at risk for intraepithelial lesions or cancers and select the appropriated areas for biopsy.The pathologic results from colposcopic directed biopsies will guide further management.

Colposcopic findings and impressions according to colposcopic terminology of the International Federation for Cervical Pathology and Colposcopy (IFCPC) are subjective and based on colposcopist's interpretation [4]. Interobserver variability between colposcopists is quite high [5]. To minimize this subjectivity, specific training with immediate feedback from experienced colposcopists is required. Pathologic review in each patient is another feedback method aiming to achieve standard accuracy of colposcopic diagnosis.

In Thailand, fellowship programs in gynecologic oncology require two years of training. During this period, colposcopic training is one mandatory course. However, there is no systematic evaluation of the learning improvement. Although accuracy of colposcopic impression was reported in many studies, there are limited studies regarding the learning curve of this procedure [6-12]. It is interesting to demonstrate the learning curve of gynecologic oncology fellows, in terms of the accuracy of colposcopic impression. Moreover, it could guide the minimum number of patients required to get a maximal learning experience prior to completion of the fellowship training.

Materials and Methods

This study was approved by the Institutional Review Board, Faculty of Medicine, Chulalongkorn University. Medical records of patients who underwent colposcopy at the Colposcopic Clinic in King Chulalongkorn Memorial Hospital (KCMH) between June 2014 and April 2017 were reviewed.The inclusion criteria were all patients who underwent colposcopic examination, either by attending staffs or fellows during this period. Procedures performed by each fellow were included since the first case through the last case during the two-year period. Exclusion criteria were patients who had no biopsy result and inadequate data such as colposcopic findings and impressions. Baseline characteristics such

Revised manuscript accepted for publication June 11, 2018

Eur. J. Gynaecol. Oncol. - ISSN: 0392-2936
XL, n. 4, 2019
doi: 10.12892/ejgo4770.2019

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as age, parity, menopausal status, contraceptive methods, cervical cytology and human papilloma virus (HPV) DNA testing results were collected. Colposcopic findings such as type of transformation zone (TZ), lesions description, location of lesions, colposcopic impression, pathologic report from colposcopic directed biopsy (CDB), and further treatments such as loop electrosurgical excision procedure (LEEP), cold knife conization (CKC), and hysterectomy were recorded. All fellows were required to complete a basic principal of colposcopy training course organized by Thai Society for Colposcopic and Cervical Pathology (TSCCP) and National Cancer Institute (NCI) before fellowship training. All colposcopic examinations during the first few weeks of the fellowship training had been performed under supervision of the attending staffs. All colposcopic examinations were performed using binocular colposcope and CLL-V1 LED light source. Patients were positioned in lithotomy, vaginal speculum was inserted then TZ type, and lesions were identified. The cervix was soaked with 3-5% acetic acid and waited for 60 seconds, then the lesions were identified. Colposcopic directed biopsy (CDB) at the most severe lesions was done. If there was no abnormal lesion or had TZ type 3, endocervical curettage (ECC) was done. Random biopsy in normal cervix was not routinely performed.

Colposcopic impression was defined according to IFCPC 2011 [4] as follows: 1) normal, 2) low grade lesion – LGL (grade 1 or minor grade): fine mosaic, fine punctation, thin acetowhite epithelium, irregular, and geographic border, 3) high grade lesion – HGL (grade 2 or major grade): sharp border, inner border sign, ridge sign, dense acetowhite epithelium, coarse mosaic, coarse punctuation, rapid appearance of acetowhitening, and cuffed crypt (gland) openings. 4) Suspicious for invasion - atypical vessels, additional signs: fragile vessels, irregular surface, exophytic lesion, necrosis, ulceration (necrotic), and tumor or gross neoplasm

Final histopathologic results were used as gold standard of colposcopic diagnosis. In cases of cyto-pathologic discrepancy, cone biopsy (LEEP or CKC) or hysterectomy was done. The most severe lesions were used as the final histopathologic results. The pathologic result from CDB was used if there was no further surgery or CDB itself was reported as CIN 2 or higher (CIN2+).

There is no standard definition of colposcopic accuracy. Previous studies calculated the accuracy from the agreement of the colposcopic impression with the histologic result within one histologic grade [6, 9]. This definition is still doubtful. Normal colposcopic impression but CIN1 on histologic result or low grade lesion on colposcopic impression but CIN2 on histologic result should be incorrect in practical use. Therefore, the present study proposed other definitions. Three-graded system was categorized in three colposcopic impressions as normal, LGL, and HGL, which is compatible with histopathologic results of benign, CIN1 (HPV infection), and CIN2+, respectively. This definition showed that the colposcopic impression was exactly matched with histopathologic result.

Learning curve was generated. X-axis of the graph was the number of consecutive patients and cumulative number of patients. Y-axis was cumulative mean proportion of accuracy from 0-100% which was calculated from the first case of all included fellows during the study period and the number of consecutive patients on the X-axis. Accuracy rate calculated from attending staffs was used as a standard level of accuracy rate.

There was no established formal sample size formula to consider the agreement in three point scales measured repeatedly as the same rater (normal/LGL/HGL *vs*. benign/CIN1/CIN2+). Sample size was equal to the total number of patients who underwent colposcopy at KCMH between June 2014 and April 2017.

SPSS version 22 was used for statistical analysis. Continuous data were shown in mean or median according to their distribution. Accuracy of colposcopic examination was reported in percentage. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of colposcopic impression of HGL to detect CIN2+ were reported and shown as 95% confidence interval (95% CI).

Results

A total of 1,228 patients underwent colposcopy at KCMH between June 2014 and April 2017. Six hundred ninety-one patients met the inclusion criteria. Demographic data are shown in Table 1. Median age was 38 (range 15-92) years. Three fourths of the participants were pre-menopausal women. More than half (61.9%) did not currently use any types of contraception. Almost of all cervical cytology (98.3%) was collected at the hospital by liquid-based technique, but the rest were collected from the other hospitals. Majority of abnormal cytology was LSIL (41.5%) and ASCUS (27.5%). TZ type 3 was found in 18.5% of patients.

The agreement of colposcopic impression and histopathologic result within one histologic grade (normal colposcopic impression with final histopathology of benign or HPV/CIN1, LGL colposcopic impression with final histopathology of benign or HPV/CIN1 or CIN2, and HGL colposcopic impression with final result of HPV/CIN1 or CIN2+) was 97.5%. When using the present authors' newly proposed definitions in three-graded systems, these accuracy rates were different and are shown in Tables 2. The accuracy rate was 68.0% (10+366+94/691) (95% CI 64.4 - 71.5%). Random biopsy in normal colposcopic impression was done only in 33 patients and pathologic result showed HPV/CIN1 in 57.6% (19/33) and CIN2+ in 12.1% (4/33), thus accuracy of normal colposcopic impression was only 30.3% (10/33). Colposcopic impression of LGL was diagnosed with HPV/CIN1 in 75.9% (366/482), but 12.0% (58/482) of patients had CIN2+. Using LGL as a threshold for biopsy will yield a detection rate of CIN2+ at 98.7% (154/156). For HGL impression, the accuracy for diagnosis of CIN2+ is 53.4% (94/176). Over-diagnosis was 20.2% (58+13+69/691) and under-diagnosis was 11.7% (19+4+58/691). Table 3 shows accuracy rate of colposcopic examination between fellows and attending staffs. Fellows after completion of fellowship training had overall accuracy rate comparable to the attending staffs, which was 68.1% (95% CI 63.4 - 72.4%) versus 68% (95% CI 61.9 - 73.6%).

During the study period, a total number of 432 patients underwent colposcopy performed by fellows. A learning curve combining all fellows is demonstrated in Figure 1. After statistic swing at the early cases, the curve showed acceleration of learning at the beginning, then decreased in its slope and finally reaching a plateau. The curve showed a plateau at around 70% accuracy rate after the 50th case onwards and finished at 67.5% accuracy rate. After the cu-

Table 1. — *Demographic data.*

		n=691	%
Age (years)	< 20	15	2.2
	20-29	114	16.5
	30-39	240	34.7
	40-49	190	27.5
	> 50	132	19.1
Parity	Nulliparous	218	31.5
	Multiparous	422	61.1
	Missing	51	7.4
Menopausal status	Pre-menopause	521	75.4
	Post-menopause	144	20.8
	missing	26	3.8
Contraception	None	428	61.9
	OCP	71	10.3
	DMPA/Implant	51	7.4
	Condom	49	7.1
	IUD	3	0.4
	Tubal resection	65	9.4
	Missing	24	3.5
Cervical Cytology	NILM (+ high risk HPV)	20	2.9
	ASCUS	190	27.5
	LSIL	287	41.5
	ASC-H	55	8.0
	HSIL	105	15.2
	SCCA	11	1.6
	AGC-NOS	19	2.7
	AGC-FN	2	0.3
	Adenocarcinoma	2	0.3
TZ type	TZ1	436	63.1
	TZ2	84	12.2
	TZ3	128	18.5
	S/P hysterectomy	32	4.6
	Missing	11	1.6
HPV DNA testing in NILM/ASCUS (N=210)	Positive type 16	33	15.8
	Positive type 18	11	5.2
	Positive other high risk	68	32.4
	Positive more than one type	18	8.5
	Not done (All were in ASCUS)	80	38.1

OCP – oral contraceptive pills, IUD – intrauterine device, NILM – negative for intraepithelial lesion/malignancy, ASCUS – atypical squamous cell of undetermined significance, LSIL – low grade squamous intraepithelial lesion, ASCH – atypical squamous cell cannot exclude HSIL, HSIL – high grade squamous intraepithelial lesion, AGC-NOS – atypical glandular cell no otherwise specified, AGC-FN – atypical grandular cell favor neoplasia.

Table 2. — *Colposcopic impression compared to final histopathologic results.*

Histopathology				
Colposcopic impression	Normal	HPV/CIN1	CIN2+	Total
Normal	10	19	4	33
LGL (HPV, condyloma)	58	366	58	482
HGL	13	69	94	176
	81	454	156	691

Table 3. — *Accuracy rate of colposcopic examination between fellows and attending staffs*

Colposcopic impression	Level of colposcopists		Total
	Fellows	Attending staffs	
Correct	294	176	470
Incorrect	138	83	221
Accuracy rate (95% CI)	68.1% (63.4-72.4%)	68.0% (61.9-73.6%)	68.0% (64.4-71.5%)

mulative numbers of procedures of 50th, the accuracy rate was stable.

Discussion

The accuracy rate of colposcopic diagnosis was variably reported by many studies [6-12]. Therefore, the accuracy rate between reports is difficult to compare. This study demonstrated that the accuracy rate was 68% when using three-graded system, which was the most strict criteria. This number was higher than previous reports, which showed the rate between 30-40% [7, 9]. Different levels of colposcopic examiners might be the possible explanation,

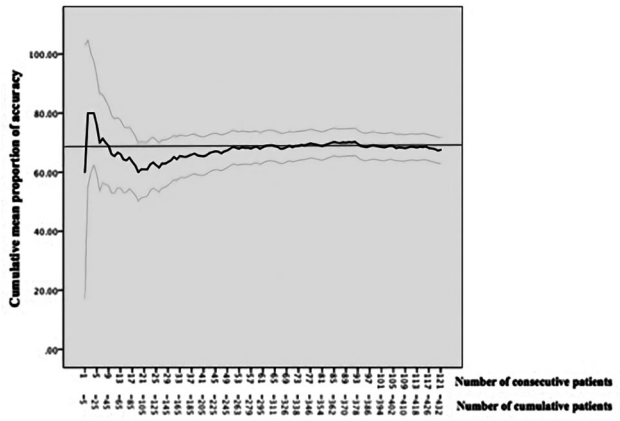

Figure 1. — Learning curve shows cumulative mean proportion of accuracy.

since residents in obstetrics and gynecology were the examiners in those reports. Agreement within one grade between colposcopic impression and histopathology was reported at 77% and 91.7 % from two previous studies [6, 9]. However, CIN2 and CIN3 was classified in similar group in the present study because the management was not different. Thus the accuracy within one grade in this study was as high as 97.5%.

In cases of normal colposcopic impression, 30.3% confirmed normal on final histopathology, 57.6% diagnosed as HPV/CIN1, and interestingly 12.1% diagnosed as CIN2+. If biopsy was omitted in normal colposcopy, 2.6 % of the present patients (4/156) who have high grade cervical lesion will be missed and left untreated. The prevalence of CIN2+ in normal colposcopy from post hoc analysis of ATHENA trial [13] by Huh *et al.* [14] was 1.5% (45/2,839). They also found that 20.1% (81/388) of patients having CIN2+ were diagnosed by random cervical biopsy. However, routinely random cervical biopsy is not a standard guideline for patients with normal colposcopic finding. Moreover, the prevalence of CIN2+ was different between studies. Therefore, caution must be taken in interpreting this data and determining whether random biopsy would be benefit.

Accuracy of LGL and HGL impressions in this study were 75.9% (366/482) and 53.4% (94/176), respectively. Histopathology confirmed CIN2+ was under-diagnosis in 37.1% (58/156) of patients who had LGL impression. Previous studies reported such events at similar rate of 32-39% [8, 9]. Although, the percentage of patients having CIN2+ in LGL impression was high, its clinical significance is minimal because all patients would receive further treatment. Previous literatures reported a detection rate of CIN2+ by using LGL as a cut-off threshold at 87-96.7% [12, 14, 15]. This study showed a comparable detection rate at 98.7% (154/156).

There is limited study on the learning curve of colposcopic training. At early stage of the curve, there was some swing due to the small number of patients. The curve does not start at a low accuracy rate, which represents the high baseline performance of the fellows. It might be explained that every colposcopic examinations during first few weeks were supervised by attending staffs. The curve shows improvement in the accuracy of colposcopic impression and reaches a plateau of nearly 70% of an accuracy rate since the 50th case onward. Overall accuracy of colposcopic impression was 67.5%, which was comparable to the attending staffs (68.0%). Based on the present data, it could be implied that a minimal number of 50 colposcopic examinations were required to achieve optimal colposcopy skills and maintain proficiency. This number could be used as a reference level of competency for fellowship training. Previous studies reported that the minimal numbers to obtain competency should be 25-50 procedures, which is comparable to the present study [16, 17]. The learning curve after the cumulative number of 50 procedures was plateau. The number of 50 procedures should be the passing number to maintain proficiency. The curve could also be used as a reference level of competency for fellows to evaluate themselves at each case to determine whether their performance is on track or below average. Limitation of this study is that this learning curve was based on the fellows from only one institute, which might not represent all fellows. A multicentric trial that combines data from more fellows would improve accuracy of learning curve and could possibly be used for self-assessment, while guiding minimal number of colposcopic training during the gynecologic oncology fellowship period.

In conclusion, colposcopic examination is a procedure that requires comprehensive training. The minimum numbers of 50 colposcopic procedures were required to achieve optimal competency and maintain proficiency.

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