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## GYNAECOLOGY

# The Utility of Routine Endocervical Curettage at the Time of Colposcopy for Low-grade Cytologic Abnormalities to Improve Diagnosis of High-grade Diseases

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### ABSTRACT

**Objective:** To determine the use of endocervical curettage(ECC) at the time of colposcopy for low-grade cytologic abnormalities to improve the diagnosis of high-grade diseases.

**Materials and methods:** A prospective diagnostic study was conducted. We included women with low-grade cytologic abnormalities: low-grade squamous intraepithelial lesion (LSIL) who had undergone colposcopy at Chonburi Hospital between January 2014 to March 2015. Data collected were age, menopausal status, HIV status, parity, contraception, colposcopic findings and pathological report of biopsy and ECC.

**Main outcome measure:** Primary outcome was the increasing rate of ECC in colposcopy for LSIL to detect high-grade lesion.

**Result:** Eighty-seven women met criteria. Nine cases (10.3%) were ECC positive for high-grade lesion. Of these nine cases, seven cases were only ECC positive, resulting in 8.04% increased detection with ECC independently of biopsy, with a sensitivity of 20.0%, specificity of 91.91%, positive predictive value of 22.22% and negative predictive value of 89.74%. Therefore, twelve to thirteen ECCs needed to be performed to detect one case of high-grade diseases. Among post-menopausal women or women older than 40 years old, the sensitivity of ECC improved, with a sensitivity of 100% and 85% respectively.

**Conclusion:** The increased detection rate of ECC to detect high-grade lesions in women who had low-grade cytological abnormalities in our study was 8.04%. Routine ECC at the time of colposcopy for LSIL in young women is debatable. However, the sensitivity of ECC was found to be increased in women aged over 40 and post-menopausal women. Therefore, ECC may be useful in older and post-menopausal women.

**Keywords:** Endocervical curettage, Low-grade squamous intraepithelial lesion, LSIL, Colposcopy, ECC

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## Introduction

According to the International Agency for Research on Cancer (IARC) report in 2008, in Thailand, almost ten thousand women were diagnosed with cervical cancer and 5,216 women died from this cancer[1]. Cervical cancer is a preventable cancer of which the primary lesion develops from a pre-invasive state named cervical intraepithelial neoplasia (CIN) and then progresses to invasive cervical carcinoma. Pap smear was an effective screening test for cervical cancer.

According to a large randomized multicenter trial, the atypical squamous cell of undetermined significance- low-grade squamous intraepithelial lesions (ASCUS-LSIL) Triage Study (ALTS), which involved more than 5,000 patients, CIN 2 or CIN 3 was identified in 12% to 16% of women with either LSIL or ASC-US (low-grade intraepithelial lesion: LGILs) who had a positive test for high-risk HPVDNA[2-4].

A study by Chaivirattana S5 showed that the prevalence of histological high-grade lesions from conventional Pap smear reported as LSIL in Chonburi Hospital was 16.52%.

LGILs are the majority group of abnormal Pap smears requiringfurther careful evaluation[6].

According to the American Society for Colposcopy and Cervical Pathology (ASCCP) 2013, endocervical sampling is recommended in women with low-grade cytologic abnormalities under two conditions: unsatisfactory colposcopy, and nonpregnant women with no lesion. However, endocervical curettage (ECC) is now acceptable when the colposcopy is satisfactory and a lesion is present[7-9].

The utility of ECC has been debated in the literature over the past 40 years. A recent study by Irvin et al[9], reported low diagnostic utility of ECC. The results of ECC changed the management of 13 patients (4.3%) out of 304 patients who were evaluated for abnormal cytology. Of these, no case had carcinoma that would have been missed if ECC had not been performed. Pretorius et al10 recently studied 364 women with satisfactory colposcopy and CIN2+ final pathologic result. They found that 20 cases (5.5%) out of 364 cases of CIN 2+ were diagnosed by ECC results. They concluded that ECC should be performed even when the colposcopic examination is satisfactory. In summary, current literature regarding the utility of ECC is still controversial.

The purpose of our study is to determine the use of routine endocervical curettage (ECC) at the time of colposcopy in women with low-grade cytologic abnormalities to improve the diagnosis of high-grade diseases.

## Materials and Methods

This study was approved by The Ethics Committee for Human Research of Chonburi Hospital. The prospective diagnostic study was conducted. The study group consisted of patients with low-grade cytologic abnormalities: LSIL who had undergone colposcopy at outpatient service of department of Obstetrics and Gynecology at Chonburi Hospital between January 1, 2014, and March 31, 2015.

Eligible cases were women who had LSIL cytology and underwent colposcopically directed biopsy (CDB) and ECC at the time of colposcopic examination regardless of whether the findings were satisfactory or unsatisfactory.

Patients were excluded from the study if they were pregnant, if they had inadequate tissue from ECC for pathological diagnosis or did not have visible lesion for CDB. The sample size was calculated by an acceptable error of 5% ($\alpha$=0.05) with the prevalence of high-grade lesion on ECC in LSIL of 4.2% from prior study6. We obtained a sample size of 80 subjects after addition of 10% of calculated subjects.

The colposcopic examinations were performed by qualified gynecologic oncologists or gynecologists with colposcopic training experience. Conventional and liquid-base Pap smear methods were used in the study. Pathological results were evaluated and interpreted by pathologists at Chonburi Hospital according to Bethesda system 2001[11].

Primary outcome was the detection rate of ECC for high-grade lesions. Secondary outcomes were the sensitivity, specificity, positive predictive value and

negative predictive value of ECC, compared with biopsy.

***Statistical analysis***

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS 18.0, SPSS Inc.,USA). Descriptive continuous data such as age was presented in mean with standard deviation due to the normal distribution of the data. Categorical data such as age group, HIV status, menopausal status, smoking status, type of contraception, colposcopic findings and parity was presented in percentage of proportion. The sensitivity, specificity, positive predictive value and negative predictive value of ECC were calculated and presented with 95% confidence interval (95% CI), compared with biopsy.

## Results

Ninety-seven patients were initially included in the study. Two patients were excluded because they were pregnant. Eight additional patients were excluded because they did not undergo ECC or biopsy. The remaining 87 patients who had undergone colposcopy and ECC were included in the analysis. (Fig. 1).

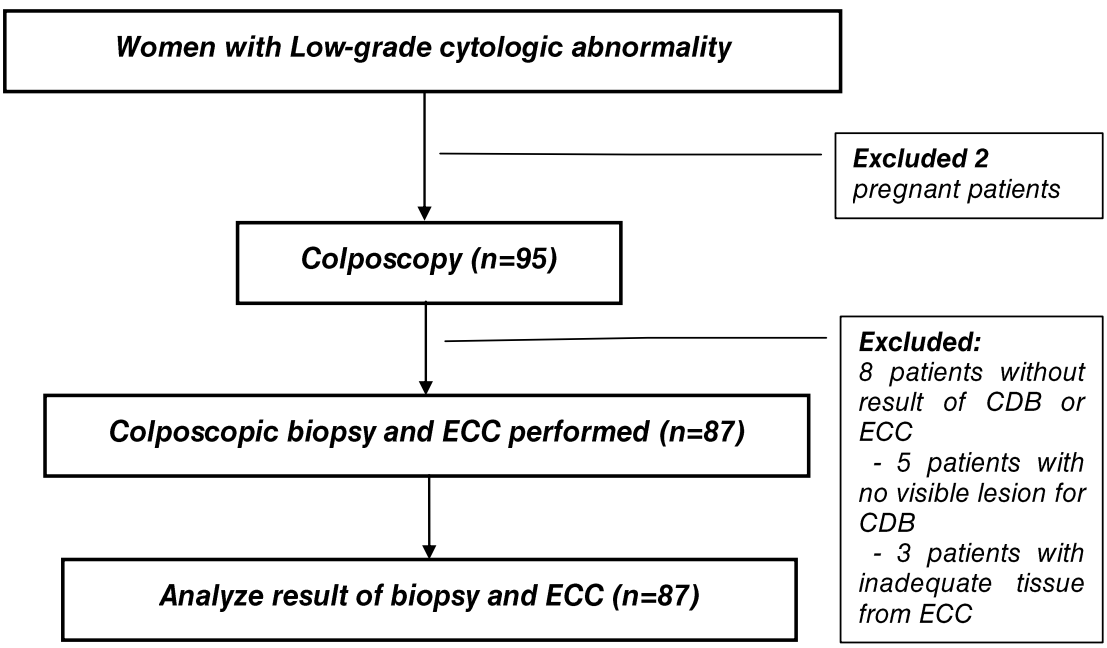


**Fig. 1.** The inclusion/exclusion flow diagram.

Patients in the study group ranged in age from 16 to 73 years and had a mean age of 36.9 years; 87.4% of the patients were pre-menopausal, 17.2% were anti-HIV-positive, and 21.8% were smoking. The characteristics of women in this study were presented in Table 1.

Eighty seven women met criteria and were included in the analysis. Nine cases (10.3%) were ECC positive for high-grade dysplasia: CIN 2+. Of these 9 cases, 7 cases were exclusively positive for CIN 2+ by ECC, without a positive biopsy result. Therefore, ECC resulted in 8.04% increase in detection rate, independently of biopsy result. The sensitivity of ECC was 20.0% (95% CI2.52% to 55.61%); specificity was 91.91% (95% CI 82.16% to 96.27%); PPV was 22.22% (95% CI 2.81% to 60.01%); NPV was 89.74% (95% CI 80.79% to 95.47%). Therefore, 12 to 13 ECCs needed to be performed to detect 1 case of high-grade dysplasia. (Table 2.)

**Table 1.** Demographic data and clinical findings of women at colposcopy. (N=87)

| Characteristics | Total N = 87<br>N (%) |
|---|---|
| Mean Age (±SD) year | 36.91* (±11.52) |
| AGE (y) | |
| < 40 | 51 (58.6%) |
| ≥ 40 | 36 (41.4%) |
| Anti HIV status | |
| Negative | 72 (82.8) |
| Positive | 15 (17.2) |
| Menopause status | |
| Pre-menopause | 76 (87.4) |
| Post-menopause | 11 (12.6) |
| Parity | |
| Nulliparity | 22 (25.3) |
| Multiparity | 65 (74.7) |
| Smoking | 19 (21.8) |
| Non smoking | 68 (78.1) |
| Contraception | |
| OCP | 18 (20.7) |
| DMPA | 13 (14.9) |
| Condom | 10 (11.5) |
| TR | 17 (19.5) |
| No | 29 (33.3) |
| Colposcope | |
| Satisfactory | 77 (88.5) |
| Unsatisfactory | 8 (9.2) |
| Method of Pap Smear | |
| Conventional | 71 (81.6) |
| Liquid base | 16 (18.3) |

* normal distribution of data SD = standard deviation

A stratified analysis by age showed that the sensitivity of ECC was higher in women older than 40 years old, compared with those younger than 40 years old. Of all women under 40 years old in this study, no one was ECC positive for high-grade dysplasia. By contrast, among women aged 40 years and older, the sensitivity of ECC in the detection of CIN 2+ was 67% (95%CI 9.43% to 99.16%); specificity was 85% (95%CI 68.10% to 94.89%); PPV was 29% (95%CI 3.67% to 70.96%); NPV was 97% (95%CI 82.24% to 99.91%). Therefore, 7 to 8 ECCs needed to be performed to detect 1 case of high-grade dysplasia. (Table 2.)

In addition, subgroup analyses were done according to menopausal status, anti-HIV status, colposcopic findings, and parity.

The sensitivity of ECC was increased in post-menopausal group, compared with pre-menopausal group. In post-menopausal women, the sensitivity was 100% (95%CI 5.46% to 100%); specificity was 70% (95%CI 35.36% to 91.90%); PPV was 25% (95%CI

1.31% to 78.05%); NPV was of 100% (95%CI56.09% to 100%). Therefore, 3 to 4 ECCs needed to be performed to detect 1 case of high-grade dysplasia. By contrast, in pre-menopausal women, the sensitivity was 11.1% (95%CI 0.05% to 49.32%); specificity was 94.0% (95%CI 84.65% to 98.07%); PPV was 20% (95%CI 1.05% to 70.12%); NPV was 88.7% (95%CI 78.46% to 94.66%).Therefore, 19 ECCs needed to be performed to detect 1 case of high-grade dysplasia. (Table 2.)

In anti-HIV negative group, the sensitivity of ECC was 13% (95%CI 0.32% to 52.65%); specificity was 92% (95%CI 82.70% to 97.41%); PPV was 17% (95%CI 0.42% to 64.12%); NPV was 89% (95%CI 79.36% to 95.63%). Therefore, 14 to 15 ECCs needed to be performed to detect 1 case of high-grade dysplasia. In anti-HIV positive group, the sensitivity was 50% (95%CI 1.26% to 98.74%); specificity was 85% (95%CI 54.55% to 98.08%); PPV was 33% (95%CI 0.84% to 90.57%); NPV was 92% (95%CI61.52% to 99.79%). Therefore, 7 to 8 ECCs needed to be performed to detect 1 case of high-grade dysplasia. (Table 2.)

In satisfactory colposcopy group, the sensitivity of ECC was 22% (95%CI 2.81% to 60.01%); specificity was 93% (95%CI 83.67% to 97.57%); PPV was 29% (95%CI 3.67% to 70.96%); NPV was 90% (95%CI 80.48% to 95.88%). Therefore, 15 to 16 ECCs needed to be performed to detect 1 case of high-grade dysplasia. Among those with unsatisfactory colposcopy, no case was ECC positive for high-grade dysplasia. (Table 2.)

Lastly, when stratified by parity, no one in the nulliparous group was ECC positive for high-grade dysplasia. In multiparous group, the sensitivity was 20% (95%CI 1.05%-70.12%); specificity was 88% (95%CI 76.2% to 94.79%); PPV was 13% (95%CI 0.66% to 53.32%); NPV was 93% (95%CI 82.17% to 97.73%). Therefore, 9 to 10 ECCs needed to be performed to detect 1 case of high-grade dysplasia. (Table 2.)

**Table 2.** Sensitivity, specificity, PPV and NPV of Endocervical Curettage for Cervical Intraepithelial Neoplasia 2+ Diagnosed in summary..

| | **Sensitivity (95%CI)** | **Specificity (95%CI)** | **PPV (95%CI)** | **NPV (95%CI)** | **No. of ECC *** |
|---|---|---|---|---|---|
| **Total** | 20% (2.52%-55.61%) | 91% (82.16%-96.27%) | 22% (2.81%-60.01%) | 89% (80.79%-95.47%) | 12-13 |
| Age group | 67% | 85% | 29% | 97% | 7-8 |
| Age >40 | (9.43% 99.16%) | (68.10%-94.89%) | (3.67%-70.96%) | (82.24%-99.91%) | |
| Age <40 | **No case was positive for ECC** | | | | |
| **Menopausal status** | | | | | |
| Post-menopause | 100% (5.46%-100%) | 70% (35.36%-91.90%) | 25% (1.31%-78.05%) | 100% (56.09%-100%) | 3-4 |
| Pre-menopause | 11% (0.05%-49.32%) | 94% (84.65%-98.07%) | 20% (1.05%-70.12%) | 88.7% (78.46%-94.66%) | 19 |
| **HIV status** | | | | | |
| HIV negative | 13% (0.32%-52.65%) | 92% (82.70%-97.41%) | 17% (0.42%-64.12%) | 89% (79.36%-95.63%) | 14-15 |
| HIV positive | 50% (1.26%-98.74%) | 85% (54.55%-98.08%) | 33% (0.84%-90.57%) | 92% (61.52%-99.79%) | 7-8 |

**Table 2.** Sensitivity, specificity, PPV and NPV of Endocervical Curettage for Cervical Intraepithelial Neoplasia 2+ Diagnosed in summary. (Cont.)

| | Sensitivity (95%CI) | Specificity (95%CI) | PPV (95%CI) | NPV (95%CI) | No. of ECC * |
|---|---|---|---|---|---|
| **Colposcopic findings** | | | | | |
| Satisfactory | 22% (2.81%-60.01%) | 93% (83.67%-97.57%) | 29% (3.67%-70.96%) | 90% (80.48%-95.88%) | 15-16 |
| Unsatisfactory | **No case was positive for ECC** | | | | |
| **Parity** | | | | | |
| Nulliparity | **No case was positive for ECC** | | | | |
| Multiparity | 20% (1.05%-70.12%) | 88% (76.2%-94.79%) | 13% (0.66%-53.32%) | 93% (82.17%-97.73%) | 9-10 |

*Number of ECC that needed to be performed to detect 1 additional case of high-grade lesion
ECC : endocervical curettage

## Discussion

Current evidence supporting routine ECC for all non pregnant women with low-grade abnormalities on their Pap smears is controversy.3

Currently, according to the American Society for Colposcopy and Cervical Pathology (ASCCP), ECC is preferred in women with low-grade cytologic abnormalities when the colposcopic examination is unsatisfactory and for non pregnant women when no lesion is identified. However, ECC is also acceptable when the colposcopy is satisfactory and alesion is present.7,12

According to Pretorius et al10 who evaluated the relative importance of colposcopically directed biopsy, random biopsy, and ECC in the diagnosis of CIN 2 or worse in more than 3000 women with both low-grade or high-grade Pap smears with satisfactory colposcopy, it was found that 15% of women with low-grade abnormal Pap smears had high-grade dysplasia found on their ECC results, independently of colposcopic biopsy results.

On the other hand, no case of high-grade dysplasia from ECC in 159 women with low-grade cytologic abnormalities and adequate colposcopic examinations was identified in a study of Williams et al13. In addition, El-Dabh et al14 showed a false positive rate of 82% for ECC in the diagnosis of high-grade lesions, compared with cone biopsy. There is an absence in the literature regarding evidence-based guidelines or consensus for ECC to be performed at the time of colposcopy in women who are less than 35 years of age with Low grade squamous intraepithelial lesion or high risk HPV15

Our studyshowed8.04% (7 cases) increased detection rate of high-grade lesions from ECC in all women who had low-grade cytologic abnormalities. Of these 7 cases, 5 cases (71.43%) were older than 40 years old, and 3 cases (42.5%) were in post-menopausal group. Twelve to thirteen ECCs needed to be performed at the time of colposcopy to diagnose one additional case of high-grade dysplasia that would not have been identified on ectocervical biopsy. The detection rate of ECC for high-grade lesionsin our study was lower when compared to prior study10 due to limitation of sample size. (10.3% vs.15%)

In subgroup analysis, ECC showed minimal diagnostic utility in women under 40 years old; on the other hand, the sensitivity of ECC was found to be increased among women aged 40 years and over. Seven to eight ECCs needed to be performed at the time of colposcopy to diagnose1 additional case. Thus, ECC may be useful in older women with low-grade abnormalities. Moreover, the sensitivity of ECC was found to be higher in post-menopausal women, compared with pre-menopausal women. Three to four ECCs needed to be performed

at the time of colposcopy to diagnose 1 additional case. The increased sensitivity of ECC in older and post-menopausal women was most likely explainable by the inversion of transformation zone of the cervix due to the effect of hypoestrogenic stage or true lesion at endocervical canal.16

On the other hand, our study showed no difference in the sensitivity of ECC when stratified by parity, colposcopic status and anti-HIV status. These findings might be affected by the limitation from small sample size.

Although the advantage of routine ECC for all non pregnant women with low-grade cytology is that it could possibly reduce the rate of high-grade lesions being missed, routine ECC is not a general practice because it is an uncomfortable procedure. This procedure has been rated as a 5.8 on a visual analog scale of pain scores from 0 to 10 in Church L et al study.17 In another study, median pain scores on a 10-point scale for ECC and biopsy were 3.50 and 3.00 respectively.9 However, this advantage should be weighed against the disadvantage of routine ECC.

At Chonburi Hospital, clinic and pathology costs for an ECC in addition to colposcopy is 300 Baht per case. From our study, we would need to pay extra cost of 3,600 to 3,900 Baht in order to detect 1 additional case of high-grade diseases. Whether this is worth it is the question that still requires an answer. Further study involving cost-effectiveness analysis should be considered.

The result in our study may be affected by limitation due to small sample size, as mentioned above. This study may also contain a selection bias due to the exclusion of cases with no visible lesion. In addition, the conventional gold-standard test, which is definite histopathological tissue from Loop Electrosurgical Excision Procedure (LEEP) or cone biopsy, was unfortunately not performed in all cases due to its invasiveness in nature. In this study, we evaluated the utility of ECC by using CDB as a gold-standard test instead of LEEP or cone biopsy per to ASCCP guideline7.Women whose ECC or biopsy results were positive for CIN2+ subsequently underwent LEEP for a definite diagnosis and appropriate treatment at the end of the study. Spectrum bias and verification bias were not found in this study. Finally, we recommend that future studies be conducted to evaluate and compare different methods in search of a more valuable and suitable test for the identification of lesions in the endocervical canal.

## Conclusion

The increased detection rate of ECC for high-grade lesions in women who had low-grade cytological abnormalitiesin our study was 8.04%. Routine ECC at the time of colposcopy for LSIL in young women is debatable. The sensitivity of ECC was found to be higher in women aged over 40 years or post-menopausal. Therefore, ECC may be useful in older and post-menopausal women.

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## *ประโยชน์ของการเก็บตัวอย่างเยื่อบุปากมดลูกด้านใน ในผู้ป่วยทุกรายที่รับการส่องกล้องตัดปากมดลูก สำหรับความผิดปกติทางเซลล์วิทยาของเยื่อบุสเควมัสของปากมดลูกระดับต่ำ เพื่อช่วยในการวินิจัยรอยโรคระดับสูง*

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***วัตถุประสงค์****: เพื่อศึกษาประโยชน์ของการเก็บตัวอย่างเยื่อบุปากมดลูกด้านใน (ECC) สำหรับผู้ป่วยทุกรายที่รับการส่องกล้องตัดปากมดลูก สำหรับความผิดปกติทางเซลล์วิทยาของเยื่อบุสเควมัสของปากมดลูกระดับต่ำ (LSIL) เพื่อช่วยในการวินิจฉัยรอยโรคระดับสูง*

***วัสดุและวิธีการ****: ศึกษาเชิงวินิฉัยในสตรีที่เข้ารับการส่องกล้องตัดปากมดลูกสำหรับความผิดปกติ LSIL ณ โรงพยาบาลชลบุรี ตั้งแต่มกราคม 2557 ถึง มีนาคม 2558 โดยบันทึกข้อมูลอายุ, สภาวะประจำเดือน, สภาวะ HIV, จำนวนการคลอดบุตร, การคุมกำเนิด, ผลการส่องกล้องตัดปากมดลูก, และผลชิ้นเนื้อจากการส่องกล้องตัดปากมดลูก และการทำ ECC เพื่อหาอัตรการเพิ่มขึ้นของรอยโรคระดับสูงในผู้ป่วย LSILจากการทำ ECC*

***ผลการศึกษา****: หญิง 87 ราย เข้าร่วมการวิจัยมี 9 ราย (10.3%) ที่พบรอยโรคระดับสูงจากการทำ ECC และในจำนวนนี้มี 7 รายที่มีพบรอยโรคระดับสูงจากการทำ ECC อย่างเดียว โดยไม่พบร่วมกับผลการส่องกล้องตัดชิ้นเนื้อ โดยสรุปการทำ ECC ทำให้วินิจฉัยรอยโรคระดับสูงเพิ่มขึ้นได้ 8.04% โดยมีค่าความไว 20.00% ความจำเพาะ 91.91% ค่าพยากรณ์บวก 22.22% ค่าพยากรณ์ลบ 89.74% โดยทุกการทำ ECC ของผู้ป่วย 12-13 คน จะช่วยเพิ่มการวินิจฉัยรอยโรคระดับสูงได้เพิ่มมากขึ้น 1 คน และในกลุ่มสตรีวัยหมดประจำเดือนหรือสตรีที่มีอายุมากกว่า 40 ปี พบว่ามีค่าความไวของการทำ ECC เพิ่มขึ้นเป็น 100.00% และ 85.00% ตามลำดับ*

***สรุป****: อัตราการวินิจฉัยรอยโรคระดับสูงเพิ่มขึ้น 8.04% จากการทำ ECC ในผู้ป่วย LSIL การทำ ECC สำหรับผู้ป่วยทุกรายสำหรับการส่องกล้องตัดปากมดลูกสำหรับความผิดปกติ LSIL ยังคงไม่มีข้อสรุปที่แน่ชัด แต่ในสตรีวัยหมดประจำเดือน หรือสตรีอายุมากกว่า 40 ปี การทำ ECC มีค่าความไวที่เพิ่มขึ้น ดังนั้นการทำECC อาจมีประโยชน์ในกลุ่มสตรีวัยหมดประจำเดือนหรือสตรีสูงอายุ*