



Overtreatment in the see-and-treat approach for high-grade squamous cervical cytology

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ABSTRACT

Objectives: To evaluate overtreatment with the ‘see-and-treat’ approach in patients with high-grade squamous cervical cytology, and identify the clinical factors associated with overtreatment.

Study design: Patients with high-grade squamous intra-epithelial lesion (HSIL) cytology undergoing colposcopy and loop electrosurgical excision procedure (LEEP) in a single visit or the ‘see-and-treat’ approach from January 2005 to December 2019 were reviewed retrospectively. The overtreatment rate and complications following LEEP were explored.

Results: In total, 220 cases were identified. The overtreatment rate was 11.4%, and surgical complications were haemorrhage ($n = 3$, 1.36%) and infection ($n = 9$, 4.09%). On univariable analysis, factors associated with overtreatment were current cytological result and colposcopic impression. On multi-variable analysis, current cytological result of non-HSIL compared with HSIL/cancer, and colposcopic diagnosis of low-grade lesion or normal compared with high-grade lesion or cancer had adjusted odds ratios of 13.81 [95% confidence interval (CI) 1.23–155.20; $p = 0.033$] and 3.58 (95% CI 1.32–9.74; $p = 0.013$), respectively.

Conclusions: The overtreatment rate with the ‘see-and-treat’ approach was 11.4%. Independent factors associated with overtreatment were current cervical cytological result of non-HSIL, and low-grade or normal colposcopic diagnosis.

1. Introduction

Globally, cervical cancer is the fourth most common cancer in women. In 2018, there were 570,000 new cases of cervical cancer worldwide, and 311,000 deaths [1]. The incidence of cervical cancer is decreasing because of the increased early detection rate with the treatment of pre-invasive disease, and human papilloma virus (HPV) vaccination. However, due to health inequities, nearly 90% of the deaths from cervical cancer occur in low- and middle-income countries because access to public health services is limited. In May 2018, the World Health Organization Director-General announced a global call for action to eliminate cervical cancer. In order to eliminate cervical cancer as a public health problem globally, all countries must work towards an incidence rate < 4 per 100,000 women-years [2]. To achieve that goal, high coverage targets for HPV vaccination, screening and treatment of precancerous lesions, and management of cancer must be reached by

2030, and maintained at this high level for decades. Cytology-based screening has been used successfully to achieve these goals when implemented as part of national programmes with high coverage and in settings with resources for patient follow-up, additional diagnostic tests (colposcopy and pathology) and disease management [3].

Generally, women with high-grade squamous cell cervical cytology are managed with a two-step conventional approach when they visit a colposcopy clinic. The first step involves colposcopic examination and biopsy of the suspicious lesion. The second step is informing and advising the patient, and providing management according to pathological reports including additional diagnostic procedures or therapeutic options, such as loop electrosurgical excision procedure (LEEP) [4]. This approach has been reported to have high levels of loss-to-follow-up and to cause high levels of patient anxiety [5].

The ‘see-and-treat’ approach is a single-visit approach for abnormal cervical cytology. Colposcopy and diagnostic and/or therapeutic LEEP

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are performed at the same visit. The advantages of this approach are reduction in cost, reduction in loss to follow-up, and reduction in patient anxiety compared with the conventional two-step approach. However, the 'see-and-treat' approach may lead to overtreatment. Overtreatment is defined as a final cervical pathological report of cervical intra-epithelial neoplasia (CIN) I/low-grade squamous intra-epithelial lesion (LSIL) or normal result from LEEP specimens in high-grade squamous intra-epithelial lesion (HSIL) cervical cytology [6]. The consequences of LEEP are postoperative bleeding and infection. Moreover, a long-term complication is preterm birth, which has been reported to be 1.78 times more common compared with no treatment [7].

In 2015, Ebisch et al. published a meta-analysis which reported an overtreatment rate of 11.6% for the 'see-and-treat' approach for women presenting with HSIL cervical cytology with colposcopic impression indicating a high-grade lesion [8]. Later studies reported overtreatment rates of 3.2–20% [9–14]. A study of factors influencing overtreatment with the 'see-and-treat' approach is still needed. This study aimed to evaluate the overtreatment rate with the 'see-and-treat' approach, and factors associated with overtreatment at a colposcopy clinic.

2. Materials and methods

2.1. Study design

A retrospective study was conducted at the Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Bangkok, Thailand. After approval by the Ethical Committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University (COA. MURA2020/839), cases were recruited from patients attending a colposcopy clinic. Women whose cervical cytology indicated high-grade squamous cytology including atypical squamous cells – cannot exclude HSIL (ASC-H), HSIL or squamous cell carcinoma (SCC), and who underwent colposcopic examination and LEEP at the same visit between 1 January 2005 and 31 December 2019 were included in this study. Women who were pregnant, aged < 25 years, or had medical conditions that required pre-operative preparation (e.g. uncontrolled hypertension, currently on anticoagulants or antiplatelets) were excluded from this study. If there were visible gross lesions, the colposcopically directed biopsies were performed and managed according to the pathological results; thus, these patients were excluded. Furthermore, women with known histopathology, with a history of biopsy or colposcopic examination, were also excluded. All cases were examined or supervised by gynaecologic oncologists.

2.2. Data collection and measurement

Data were extracted from patients' medical records. Patient characteristics and clinical factors such as age, parity, menopausal status, age of first sexual intercourse, number of lifetime sexual partners, method of contraception, presenting symptoms, current cervical cytological examination, and presence or absence of transformation zone in present cervical cytology were collected. Colposcopic findings were collected, including adequacy, type of transformation zone, percentage of lesion extension, and colposcopic impression. The histopathological reports from LEEP were collected. Overtreatment was defined as CIN1 or lesser histological pathology from LEEP specimens [4]. Complications within 2 weeks of procedures, such as haemorrhage and infection, were recorded.

The sample size was estimated using the hypothesis of the infinite population proportion. The error was set at 5%. The reference overtreatment rate was 11.6% [8]. In total, it was calculated that 158 cases were required to reject the null hypothesis with alpha of 0.05 and power of 80%. To allow for data loss of 10%, a sample size of 176 was required.

2.3. Statistical analysis

Patients' clinical characteristics have been presented using frequency and percentage for categorical data, and mean and standard deviation (SD) or median and range for continuous data, as appropriate. To compare the characteristics between patients who were overtreated with patients who were not overtreated, continuous data were determined using Student's *t*-test or the Mann–Whitney *U*-test, as appropriate. Categorical data were compared using Chi-squared test or Fisher's exact test, as appropriate. Co-variables with $p \leq 0.1$ were selected for multi-variable logistic regression analysis. $p < 0.05$ was considered to indicate significance. Results are shown as odds ratios (OR) and 95% confidence intervals (CI). Data were analysed using STATA Version 16 (StataCorp, College Station, TX, USA).

3. Results

From 1 January 2005–31 December 2019, 280 women with high-grade squamous cytology managed with a 'see-and-treat' approach at the study colposcopy clinic were identified. Sixty cases were excluded, as illustrated in Fig. 1, so 220 cases were included in this study. The clinical characteristics are shown in Table 1. The mean age of patients was approximately 38 years. Most patients were premenopausal, asymptomatic and did not use contraception. Cervical cytological profiles indicated HSIL for the majority of patients, with approximately 5% indicating SCC and ASC-H. Colposcopic examination and final histopathological results are shown in Table 2. The colposcopic examination record was missing for one patient. For the other 219 patients, 86.3% of colposcopic impressions were categorized as high-grade lesions or cancer. From 220 women with high-grade squamous cytology undergoing LEEP, the final results were normal for five patients and CIN1/LSIL for 20 patients. Thus, the overtreatment rate was 11.4%. Thirty-one percent of these patients required further management from a positive margin. Bleeding and infection were reported in three and nine patients, respectively.

Current cytological results and colposcopic impression were significantly associated with overtreatment on both univariable and multi-variable analysis (Tables 3 and 4).

4. Discussion

This cohort included 220 women who presented with high-grade squamous cell cytology managed with a 'see-and-treat' approach. In total, 11.4% of women were overtreated. Five and 20 of these 220 patients had final results showing normal and LSIL, respectively. Current cytological results and colposcopic impression were independently associated with overtreatment. ASC-H was 13.81 times more likely to be associated with overtreatment compared with HSIL and SCC cytology (95% CI 1.23–155.20; $p = 0.033$). Patients with normal or low-grade colposcopic impressions were 3.58 times more likely to be overtreated compared with patients with suspected high-grade lesion or cancer (95% CI 1.32–9.7; $p = 0.013$).

As a result, this study focused specifically on the cytological results of 30 patients with normal or low-grade colposcopic impressions; of these, the cervical cytological results showed that three patients had ASC-H, 26 patients had HSIL and one patient had SCC. Of these 30 patients, the HSIL cytology confirmed the previous interpretation of HSIL cytology for seven (23.3%) patients. Unfortunately, the cervical cytology of 15 patients could not be reviewed as the Department of Pathology at the study hospital only preserved cervical cytological material for 5 years. Moreover, eight patients were referred from other hospitals, and the cytological slides were not available.

The American Society of Colposcopy and Cervical Pathology (ASCCP) supported the feasibility of performing a 'see-and-treat' approach as an alternative method in women who were aged > 25 years and non-pregnant with high-grade squamous cytology [15]. In 2016, the

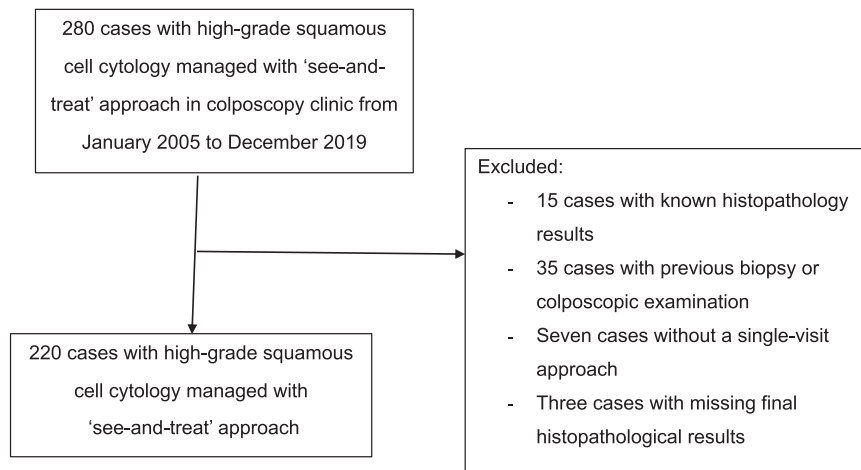


Fig. 1. Study flow diagram of patients managed with the 'see-and-treat' approach.

Table 1

Baseline characteristics.

Characteristics	n (%)
Patient profile	
Age (years); mean±SD	37.37 ± 7.93
Parity; n (%)	
0	68 (30.90)
≥ 1	152 (69.10)
Age at first sexual intercourse (years); mean±SD	22.21 ± 4.62
Number of lifetime sexual partners; median (range)	1 (0–10)
Menopausal status; n (%)	
Premenopausal	212 (96.36)
Menopausal	8 (3.64)
Immunocompromised; n (%)	12 (6.40)
Presenting symptom; n (%)	
Asymptomatic	163 (74.10)
Abnormal bleeding	23 (10.50)
Abnormal discharge	10 (0.40)
Other	21 (9.50)
Contraception; n (%)	
None	92 (52.60)
Oral combined contraceptive pill	31 (17.70)
Tubal ligation	20 (11.40)
LARC	19 (10.90)
Barrier method	13 (7.40)
Cytological profile	
Transformation zone	
Present	82 (79.60)
Absent	21 (20.40)
Current cytology	
ASC-H	4 (1.80)
HSIL	208 (94.60)
SCC	8 (3.60)

ASC-H, atypical squamous cells – cannot exclude HSIL; HSIL, high-grade squamous intra-epithelial lesion; LARC, long-acting reversible contraception; SCC, squamous cell carcinoma.

National Health Service Cervical Screening Programme (NHSCSP) stated that a single-visit treatment approach should be used for high-grade cytology alone, except when an audit has identified that CIN2, CIN3 or cervical glandular intra-epithelial neoplasia is present in at least 90% of excised specimens with mild dyskaryosis cytology [6]. A Dutch population-based study [13] of women with high-grade cytology reported that the overtreatment rate did not differ significantly between the two-step approach and the 'see-and-treat' approach (11.3% vs 14.3%, respectively). This result was comparable with the present study, and supported the 'see-and-treat' approach in women with high-grade cytology. However, the Dutch study had certain limitations, such as lack of colposcopic impression data.

A recent meta-analysis [8] found that women with high-grade

Table 2

Colposcopic findings and final histopathological results from loop electrosurgical excision procedure (LEEP).

	n (%)
Colposcopic examination	
Visualization of the cervix	219 (100)
Type of TZ	
1	155 (70.8)
2	37 (16.9)
3	27 (12.3)
Colposcopic findings	
Normal	10 (4.6)
Low-grade features	20 (9.1)
High-grade features	189 (86.3)
Percentage of the surface area of TZ occupied by lesion	
≥ 50%	127 (58)
< 50%	92 (42)
Colposcopic impression	
Normal/ benign	10 (4.6)
Low grade	20 (9.1)
High grade	184 (84.0)
Cancer	5 (2.3)
Histopathological result of LEEP specimen	
Normal tissue	5 (2.3)
CIN1/LSIL	20 (9.1)
CIN2–3/HSIL	178 (80.9)
Cancer	17 (7.7)

CIN, cervical intra-epithelial neoplasia; LSIL, low-grade squamous intra-epithelial lesion; HSIL, high-grade squamous intra-epithelial lesion; TZ, transformation zone.

cytology and low-grade colposcopic impression were associated with an overtreatment rate of 29.3%. Nonetheless, the overtreatment rate in women with high-grade cervical smear and high-grade colposcopic impression was 11.6%. The overtreatment rate was higher in women with low-grade cervical smear, regardless of colposcopic impression, ranging from 46.4% to 72.9%. Similarly, in 2019, Ciavattini et al. [10] reported overtreatment rates of 22% and 3.2% for low- and high-grade colposcopic impressions, respectively, in women with high-grade cervical cytology. In the present study, when considering normal or low-grade colposcopic impressions in women with high-grade cervical cytology, 30% of women were overtreated. Hence, the two-step approach is recommended in such circumstances to prevent overtreatment.

In terms of cytology, a few studies have considered overtreatment in the 'see-and-treat' approach preceding ASC-H cytology. The overtreatment rate ranged from 24.1% to 51.4% [16,17]. Kietpeerakool et al. compared the 'see-and-treat' approach with the two-step approach for

Table 3
Univariable analysis of factors associated with overtreatment.

	Overtreatment n = 25	Non-overtreatment n = 195	p- value
Age (years), mean±SD	38.32 ± 7.96	37.25 ± 7.94	0.527
Parity, n (%)			
0	9 (36)	59 (60.3)	0.559
≥ 1	16 (64)	136 (69.7)	
Age at first sexual intercourse (years); mean ±SD	22.42	22.19	0.840
Lifetime sexual partners; n (%)			
0–1	13 (52)	114 (58.5)	0.538
≥ 2	12 (48)	81 (41.5)	
Menopausal status; n (%)			
Premenopausal	1 (4)	7 (3.59)	> 0.99
Menopausal	24 (96)	188 (96.41)	
Immunocompromised; n (%)			
Yes	1 (5.6)	11 (6.5)	0.676
No	17 (94.4)	158 (93.5)	
TZ of cytological reports			
Present	9 (75)	73 (80.2)	0.706
Absent	3 (25)	18 (19.8)	
Current cytological results			
ASC-H	3 (12)	1 (0.51)	0.006
HSIL	21 (84)	187 (95.9)	
SCC	1 (4)	7 (3.59)	
Colposcopic findings			
Type of TZ			
1	14 (56)	141 (72.7)	0.210
2	6 (24)	31 (16.0)	
3	5 (20)	22 (11.3)	
Surface area of TZ occupied by lesion			
< 50%	14 (56)	78 (40.21)	0.132
≥ 50%	11 (44)	116 (59.79)	
Colposcopic impression			
Normal/benign	4 (16)	6 (3.09)	0.006
Low grade	5 (20)	15 (7.73)	
High grade	16 (64)	168 (86.6)	
Cancer	0	5 (2.58)	

ASC-H, atypical squamous cells – cannot exclude HSIL; HSIL, high-grade squamous intra-epithelial lesion; SCC, squamous cell carcinoma; TZ, transformation zone.

Table 4
Multi-variate analysis of factors associated with overtreatment.

Factors	Adjusted odds ratio	95% CI	p-value
Current cytological results			
ASC-H	13.81	1.23–155.20	0.033
HSIL and SCC	1		
Colposcopic impression			
Normal/low grade	3.58	1.32–9.74	0.013
High grade/cancer	1		

ASC-H, atypical squamous cells – cannot exclude HSIL; CI, confidence interval; HSIL, high-grade squamous intra-epithelial lesion; SCC, squamous cell carcinoma.

ASC-H cervical cytology [17], and reported an overtreatment rate of 24.1% for the ‘see-and-treat’ approach. When stratified by colposcopic findings, the overtreatment rate was 61.1% for women with low-grade lesions, which was significantly higher than the rate of 7.5% found for women with high-grade lesions. Aue-Aungkul et al. reported the outcomes of the ‘see-and-treat’ approach at the same institute but for a different 4-year period [16]. When focusing on women with ASC-H on cervical cytology, the overtreatment rate was 51.4%. This study did not mention colposcopic findings in ASC-H. Due to the high incidence of cervical cancer in their setting, the incidence of cervical cancer from LEEP specimens was reported to be as high as 11.1–20.8% [16,17]. On

the other hand, 17 (7.7%) patients were diagnosed with cervical cancer in the present cohort, which is fewer than that found by Aue-Aungkul et al. In the present study, four cases of ASC-H cervical cytology were managed with the ‘see-and-treat’ approach, and three of them were overtreated. The final histological reports showed two patients with normal cervical tissue, one patient with CIN1 and one patient with CIN2. According to the ASCCP 2019 risk estimation supporting the consensus guidelines, the risk of immediate CIN3 + in women with ASC-H was 3.4% for those who were HPV negative and 26% for those who were HPV positive [18]. In this circumstance, the management of colposcopy-directed biopsy results of women with CIN1 or no lesions preceded by ASC-H or HSIL can be elected by following up the co-test, reviewing the pathology or performing an excisional procedure. In conjunction with these data, women with ASC-H should be evaluated cautiously with HPV testing. In settings where cervical cancer is less common than in Bangkok (incidence is 7.4 per 100,000 women-years, compared with 14.0 per 100,000 women-years in Chiang Mai), women with ASC-H cervical cytology should be managed with more confidence based on their HPV test results [19]. Considering the high risk of immediate CIN3 + in HPV-positive women with ASC-H, a ‘see-and-treat’ approach would be appropriate. However, in HPV-negative women with ASC-H, a two-step approach should be more relevant, especially in those with fertility concerns.

Despite the risk of overtreatment, the ‘see-and-treat’ approach is uncomplicated, improves compliance, reduces patient anxiety, is inexpensive, and reduces the number of hospital visits [20]. In women with high-risk abnormal cervical smear results such as HSIL, these benefits considerably outweigh the risk of overtreatment, especially in a high-volume, low-resource setting.

The NHSCSP guidelines recommended that, following LEEP, primary haemorrhage requiring haemostasis must be < 5%, and the admission rate for treatment complications must be < 2% [6]. Complication rates following LEEP in this study were low (1.34% haemorrhage, 4.09% infection), and no patients had to be admitted following LEEP.

A strength of this study was the use of colposcopic findings, with colposcopy performed by or under the supervision of experienced gynaecologic oncologists. However, this study also had some limitations. Firstly, the study design was retrospective, which leads to the potential for selection bias. Secondly, the study was conducted in a single institute (a metropolitan teaching hospital), so the results may not be generalizable to other settings. Thirdly, due to limited resources in Thailand, HPV testing has not been performed routinely for most patients in the past 12 years. Hence, it was not possible to include HPV information in this study, especially for women with ASC-H. Finally, due to the study hospital’s policy to preserve cervical cytological material for 5 years, some cytological results could not be reviewed. The quality of care could be improved by utilizing the above information with careful selection of women with high-grade cervical cytology for the ‘see-and-treat’ approach, especially those who wish to preserve their fertility. In women who presented with ASC-H cervical cytology, results of the HPV test should be incorporated into the decision. If HPV testing is unavailable, a two-step approach is appropriate. Moreover, the colposcopic impression should be considered. In normal or low-grade lesions on colposcopy, a two-step approach would still be suitable.

In conclusion, the overtreatment rate using the ‘see-and-treat’ approach in the study setting was 11.4%. Women with cervical cytological results showing ASC-H were overtreated 13.8 times more often than women with HSIL and SCC. Moreover, women with colposcopic impressions showing normal/low-grade lesions were overtreated compared with women with colposcopic impressions showing high-grade lesions.

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Declaration of Competing Interest

None declared.

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