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See-and-treat loop electrosurgical excision procedure for high-grade cervical cytology: Are we overtreating?

Lindsay M. KUROKI, M.D.[1], **Lauren M. BERGERON, M.D.**[1], **Feng GAO, Ph.D., M.P.H.**[2], **Premal H. THAKER, M.D., M.S.**[1], and **L. Stewart MASSAD, M.D.**[1]

[1]Division of Gynecologic Oncology, Department of Obstetrics and Gynecology, Washington University School of Medicine, and Alvin J. Siteman Cancer Center. St. Louis, Missouri, U.S

[2]Division of Public Health Sciences, Department of Surgery, Washington University School of Medicine. St. Louis, Missouri, U.S

Abstract

Objectives—To report the overtreatment rate for see-and-treat versus 3-step conventional strategy (cervical cytology, colposcopic biopsies, then LEEP) for patients with high-grade squamous intraepithelial lesion (HSIL) cytology. Our second aim was to identify risk factors for overtreatment.

Methods—We included 178 women with HSIL cytology from our university-based colposcopy clinic who underwent LEEP between 2007 and 2014. Overtreatment was defined as cervical intraepithelial neoplasia (CIN) 1 or less on LEEP specimen. Differences between treatment groups were compared using Chi-square test, two-sample t-test or Mann-Whitney rank-sum test as appropriate.

Results—CIN2+ was found in 69 (80%) of women in the see-and-treat group and 69 (75%) of the conventional management group (p = 0.093), with overtreatment in 17 (20%) and 23 (25%, p=0.403) respectively. Women who underwent see-and-treat (n=86) were older (mean age 36 vs. 31 years, p=0.007) and a greater proportion completed childbearing (30% vs. 13%, p=0.024). There were no differences in top hat excision; however, a higher proportion of the see-and-treat group had CIN2+ in endocervical samples (54% vs. 27%, p=0.047). Overtreatment, regardless of management strategy, was associated with age at time of LEEP, where older women were more likely to be overtreated (median age 37 vs. 32 years respectively, OR 1.04, 95% CI 1.01–1.08 p=0.011).

Conclusions—A see-and-treat strategy minimizes risk of loss to follow-up with a similar overtreatment rate compared to conventional management. With CIN2+ in some three-fourths of women with HSIL, a see-and-treat should be favored especially when adherence to follow-up is questionable.

CORRESPONDING AUTHOR: Lindsay Kuroki, MD, Department of Obstetrics & Gynecology, 4911 Barnes Jewish Hospital Plaza, Box 8064, St. Louis, MO 63110, Phone: (626) 627-4322, Fax: (314) 362-2893, kurokil@wudosis.wustl.edu.

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Keywords

See-and-treat LEEP; HSIL cytology; overtreatment

Introduction

A fundamental challenge to cervical cancer prevention beyond cost and time is the social disadvantage of women who are at highest risk for cervical cancer. Historically, this vulnerable population has limited access to healthcare and is often non-adherent with multistep approaches for diagnosis and treatment [1]. Typically, women with abnormal cytology follow a 3-step conventional strategy that requires at least 2 follow-up visits after screening; one for colposcopy with biopsies, and at least one other visit for follow-up and/or treatment.

"See-and-treat" loop electrosurgical excision procedure (LEEP) is a management approach that involves the diagnosis and treatment of cervical intraepithelial neoplasia (CIN) in a single visit [1]. It reduces cost [2] and clinic visits, loss to follow-up, and patient anxiety [3]. Although advantageous in certain patient populations, this strategy has potential to result in overtreatment due to limited specificity of atypical and low-grade cervical cytology results. However, some 60% of women with high-grade squamous intraepithelial lesion (HSIL) are diagnosed with CIN2+ at the time of colposcopy [4, 5]. Due to this substantial risk, the American Society for Colposcopy and Cervical Pathology (ASCCP) [6] recommends immediate excision of the transformation zone for non-pregnant women age 25 or older with HSIL, especially when colposcopic examination is inadequate.

Overtreatment of HSIL with see-and-treat LEEP is an important potential drawback when tailoring management according to women's risk of CIN2+. This is especially true given spontaneous regression of some CIN2+, the marginal sensitivity of cervical cytology, and the potential complications of LEEP [7–10]. Previously cited overtreatment rates range from 4 to 18% depending on eligibility criteria and cutoff definitions (e.g. CIN1 or lower versus only negative results on LEEP pathology) [1, 4, 11–14]. However, generalizability is often restricted to low-resource countries that lack cervical cancer screening programs [4, 11, 12, 14, 15]. Studies conducted within the United States (U.S.) are few and outdated, as they were published prior to the 2012/2013 publication of new guidelines for screening and management [1, 4]. Although recommendations for see-and-treat did not change, the underlying risk pool is different. Initiating screening at age 21, allowing longer follow-up intervals with HPV cotesting, and less aggressive management of abnormal cytology for women ages 21 to 24, may have increased CIN2+ risk among women eligible for see-and-treat interventions. Taken altogether, it is important to evaluate differences between management strategies to minimize overtreatment without compromising effectiveness. Therefore, the primary objective of this study was to provide an updated report of overtreatment rates for see-and-treat LEEP versus 3-step conventional strategy (e.g. cervical cytology, colposcopic biopsies, then LEEP) among U.S. women with HSIL cytology. Overtreatment rates were then balanced against our rate of loss to follow-up for our

university-based LEEP clinic. We also aimed to identify correlates of overtreatment among women with HSIL cytology.

Methods

We performed a single institution, retrospective cohort study of women with HSIL cytology who presented to the Colposcopy Clinic at Barnes-Jewish Hospital between January 2007 and December 2014. Our clinic does not have a specific protocol established to recommend see-and-treat LEEP over the 3-step conventional strategy for HSIL cytology. Prior to initiation of our study all procedures were reviewed and approved on March 9, 2015 by Washington University's Human Research Protection Office (Institutional Review Board, IRB Project #201503011). Abstracted data from patient medical records were de-identified, and due to the retrospective nature of this project informed consent was waived.

Women who presented with HSIL cytology and underwent LEEP were included. We distinguished whether women underwent see-and-treat LEEP or 3-step conventional management of HSIL cytology and compared the incidence of CIN1 or less on final LEEP pathology. Long term outcomes between these two management groups are currently being studied and beyond the scope of this manuscript. The 3-step conventional group (control) comprised women with HSIL cytology, but instead underwent colposcopic biopsies showing CIN2+ or had a 2-fold degree difference between cytology and biopsy results. See-and-treat LEEP was offered unless women came with outside colposcopic biopsies showing CIN2+ or logistics including availability of treatment slots or child care or work responsibilities precluded immediate treatment. Patients were included regardless of whether their LEEP was performed in the outpatient setting under local anesthesia or scheduled as an operative procedure under monitored anesthesia care. We excluded women if they underwent see-and-treat LEEP for abnormal cytology other than HSIL, had a positive pregnancy test, or had a history of cervical cancer. All specimens underwent centralized review by subspecialized gynecologic pathologists in the Ackerman Laboratory of Surgical Pathology, Barnes-Jewish Hospital/Washington University School of Medicine.

Patient electronic medical records were reviewed for patient demographics (age, race, insurance status), personal behaviors (smoking status and method of contraception), medical history (HIV status, HPV status) reproductive history (gravidity, age at first intercourse, and number of lifetime sexual partners), time from cytology to LEEP, and colposcopy exam results (satisfactory exam, overall impression, number of biopsies performed, endocervical curettage ECC, and pathology results). We also reported LEEP pathology results and margin status, as well as complications from the procedure.

The distributions of demographic/clinical characteristics were summarized using counts and frequencies (for categorical variables), or means, standard deviations, medians and inter-quartile ranges (for continuous variables). The differences between treatment groups were compared using Chi-square test, two-sample t-test or Mann-Whitney rank-sum test as appropriate. We also assessed whether LEEP overtreatment rate worsened as the time interval between cervical cytology and LEEP increased (regardless of management strategy). To this regard, we categorized the time from HSIL cytology to LEEP into 4 intervals with

roughly equal sample size and compared overtreatment rates using the Cochran-Armitage trend test. The relationship between overtreatment and other demographic/clinical characteristics was assessed using univariate logistic regressions and odds ratios (OR). All analyses were two-sided and an alpha level of 0.05 was used for all statistical tests. Statistical analyses were performed using SAS 9.4 (SAS Institute Inc. 2013. Cary, NC, USA).

Results

We reviewed a total of 178 electronic medical records of women who underwent LEEP between 2007 and 2014. Records on adherence to LEEP appointments were available from January 2013 to August 2015 and revealed a no-show rate of 23%. The demographic and clinical characteristics of patients with HSIL cytology are listed in Table 1. Women who underwent see-and-treat LEEP (n=86) were older (mean age 36±11 vs. 31±10 years, p=0.007) and more likely to have completed childbearing than women in the 3-step conventional group (p=0.024). Otherwise, the two groups were well-balanced and reflective of a population at high risk for CIN2+ disease (Table 1). Specifically, median lifetime number of sexual partners was 6 in both the see-and-treat and 3-step conventional group (p=0.830), and HPV positivity was 55% vs. 51% respectively (p=0.943).

Colposcopy and cervical biopsy results prior to LEEP are listed in Table 2. The colposcopic impression for the see-and-treat group reflects the findings at the time of LEEP, as all excisional procedures were performed under colposcopy. There were no significant differences in number of adequate exams [(including International Federation of Cervical Pathology and Colposcopy transformation zone types 1 and 2); 42 % vs. 56% in see-and-treat vs. 3-step conventional group], and the majority overall had a low-grade colposcopic impression. Most had CIN3 (49%) on cervical biopsy, followed by CIN2 (30%), benign (10%), CIN1 (6%), adenocarcinoma in situ (1%), and microinvasive carcinoma (1%). Endocervical curettage (ECC) results overall showed lower grade disease—58% were benign, 23% CIN3, 8% dysplastic, but unable to be graded, 4% CIN2, 4% CIN1 and 3% were insufficient for diagnosis.

Median time from cervical cytology to LEEP was longer in the 3-step conventional group by 0.7 months compared to the see-and-treat group (3.0 vs. 2.3 months, p=0.01) (Table 3). LEEP outcomes are listed in Table 3. See-and-treat LEEP did not carry a higher risk for overtreatment (CIN1 or less) compared to the 3-step conventional strategy (20% versus 25% respectively, p=0.403). There were no differences in the number of procedures judged to require top hat excision, but nonetheless the top hat endocervical specimens showed a higher proportion of CIN2+ in the see-and-treat group (55% vs. 26%, p=0.047) (Table 3). There were no differences in location of procedure, positive margin status, LEEP specimen size or complications.

We also explored correlates of overtreatment (Table 4) regardless of management strategy. The only factor associated with overtreatment was age at time of LEEP. Older women were more likely to be overtreated than younger women (median age 37 vs. 32 years respectively, OR 1.04, 95% CI 1.01–1.08 p=0.011).

Discussion

See-and-treat LEEP is the preferred management strategy for HSIL cytology where logistically feasible. It requires fewer visits, offers less opportunity for default, and as our data show is associated with an overtreatment rate similar to a 3-step conventional strategy. Our study is the largest published cohort to date evaluating the overtreatment rate of see-and-treat LEEP in the U.S. since implementation of the 2012 ASCCP consensus guidelines. Historically, overtreatment has been cited as a reason for avoiding the efficient use of see-and-treat LEEP. However, we found negligible differences in overtreatment rates between see-and-treat LEEP and 3-step conventional strategy for HSIL cytology. Given the high incidence of CIN2+ at time of LEEP, a see-and-treat management strategy should be favored especially when providing outreach services to indigent women who have limited access to healthcare and adherence to follow-up appointments is questionable, as in our clinic, where patients miss 23% of scheduled LEEP appointments.

Our see-and-treat LEEP overtreatment rate of 20%, although higher than most other studies [1, 4, 11–14], should be taken in context of our study population and no-show rates. Among studies published in the U.S., Numnum et al [1], performed a prospective evaluation of 51 patients with HSIL cytology who underwent see-and-treat LEEP from their university-based colposcopy clinic. They did not include a control group of women who underwent 3-step conventional strategy, but did report a 45% no-show rate. Among 51 LEEP specimens, 35% had CIN2 and 49% CIN3, resulting in an overtreatment rate (CIN1 or less) of 16%. In contrast to our results, they did not find an association between older age at time of colposcopy and HSIL overtreatment. However, their multivariate analysis showed that nulliparous women were 12.4 times more likely than multiparous women to be overtreated. Despite our similar clinical setting of a university-based colposcopy clinic, there are several plausible explanations for our higher rates of overtreatment that are reflected in our patient demographics. Most notably, our study included women who were much older at time of colposcopy (mean age of 36 vs. 26 years old), younger at time of coitarche (mean age of 16 vs 17 years old), and had a higher proportion of inadequate colposcopic exams (52% vs. 15%). Although not reported by Numnum et al [1] our patients had a high HPV-positivity rate, lifetime number of sexual partners and although a minority, included HIV women; all risk factors related to socio-economic barriers that place these women at risk for cervical disease and also make it difficult for them to access care and adhere to recommendations. Centers with lower risk patients may experience increased rates of overtreatment with see-and-treat LEEP, but what is more clinically important is the comparable results between the 2 management strategies within the same risk population. Furthermore, clinicians who care for patients with higher rates of adherence to follow-up may elect a 3-step process, especially for young women who desire future fertility and so would prefer to observe CIN2 and histologic HSIL.

Strengths of our study are highlighted in our methodology, which allow for clinically meaningful comparisons of ASCCP-recommended treatment options for U.S. women with HSIL cytology. Despite lack of a consensual agreement on the definition of overtreatment, we chose our cutoff criteria of CIN1 or less on final LEEP specimen based on ASCCP management algorithms which allow women with HSIL cytology and CIN1 on cervical

biopsy (with adequate colposcopy and negative endocervical sampling) to undergo co-testing at 12 and 24 months as an alternative to a diagnostic excision procedure. We considered broadening our definition of overtreatment to also include p16 negative CIN2, but data on p16 staining is not routinely performed nor is it currently incorporated in the ASCCP recommendations to guide management.

Other study strengths include our evaluation of delays from cervical cytology to LEEP, suggesting the impact of spontaneous regression. Supportive data to validate our spontaneous regression rate of 25% comes from a recently published double-blinded, placebo-controlled trial by Trimble and colleagues evaluating the safety, efficacy and immunogenicity of a therapeutic vaccine for CIN2/3 [17]. In their intention–to-treat analysis, they showed a histopathological regression to CIN1 or less in 30% in their placebo recipients at 3 months after the first injection. The median time from HSIL cytology to LEEP among women in our study was 3.0 and 2.3 months in the 3-step conventional strategy and see-and-treat LEEP respectively. Nonetheless, since there are no guidelines to indicate who should undergo see-and-treat versus 3-step conventional management for HSIL cytology, it is possible that there was a selection bias toward patients with perceived higher risk for CIN2+ or non-adherence to follow-up appointments.

Other limitations of our study that are inherent to our retrospective design are lack of randomization to account for unforeseen potential confounders and limited sample size. One can suspect that if LEEP management strategy is left to provider choice, patients with more concerning visible lesions would be offered a see-and-treat LEEP, if feasible. In this situation the overtreatment rates would be more dependent on the accuracy of the physician’s subjective impression, which has previously been shown by Massad and colleagues [18] to overestimate the severity of disease more often than to underestimate disease (40% vs. 23%). If these assumptions were true, then lack of randomization in our study has potential to overestimate the overtreatment rate of see-and-treat LEEP. However, Tables 1 and 2 demonstrate that both treatment groups were overall well-balanced with regards to sociodemographic and clinical risk factors as well as colposcopic impression. Regarding our sample size, we worked under the volume constraints of our colposcopy clinic and included all patients who met eligibility criteria in order to best estimate our see-and-treat overtreatment rate.

Management of abnormal cervical cytology continues to evolve, especially with the implementation of HPV screening. Future directions should focus on optimizing risk-assessment strategies of CIN3+ to better identify candidates for see-and-treat LEEP and minimize overtreatment rates. We have yet to see the impact of a risk-stratification system based on colposcopic impression, HPV screening, and biomarkers such as p16 and Ki-67 immunohistochemistry to better assess an individual’s risk for CIN3+.

Conclusions

Decision to recommend see-and-treat LEEP versus 3-step conventional strategy for HSIL cytology should be individualized based on the risk for CIN2+, patient adherence to follow-up visits, and balancing overtreatment with the likelihood of spontaneous regression. Based

on our study results, see-and-treat LEEP is a feasible, effective, and safe management strategy for women with HSIL cytology with overtreatment rates that are acceptable compared to 3-step conventional strategy. With longer cervical cancer screening intervals with less aggressive management of abnormal cytology for women ages 21 to 24, we may see a shift toward more severe disease identified after HSIL cytology. From a public health perspective, providing patients with the most efficient and cost-effective management strategy for LEEP has potential to reduce socioeconomic barriers to healthcare and the clinical consequences associated with delayed treatment for HSIL cytology. Future research should evaluate long-term outcomes after see-and-treat LEEP for HSIL cytology, comparing women with CIN1 or less versus CIN2+ on final LEEP specimen. The utility of a see-and-treat strategy for HSIL cytology may be changing as HPV vaccination contributes to a decline in 16/18 infection rates and other less oncogenic high-risk HPV types become more dominant among women with HSIL cytology, increasing the risk of overtreatment.

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List of abbreviations and Acronyms

LEEP	loop electrosurgical excision procedure
CIN	cervical intraepithelial neoplasia
HSIL	high-grade squamous intraepithelial lesion
HPV	human papillomavirus
ASCCP	American Society for Colposcopy and Cervical Pathology
IRB	Institutional Review Board
ECC	endocervical curettage
HIV	human immunodeficiency virus
IQR	interquartile range
LARC	long acting reversible contraception
IUD	intrauterine device

AIS adenocarcinoma in situ

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Table 1

Socio-demographic and clinical characteristics of patients with HSIL cervical cytology

Characteristics	See-and-Treat N=86	3-Step Conventional N=92
Age (mean, years) **	36±11	31±10
Race		
Caucasian	46 (53)	45 (49)
Non-Caucasian	40 (47)	47 (51)
Gravidity (median,IQR)	3 (2–4)	2 (1–4)
Age at first intercourse (years)	16±2	16±3
Lifetime number of sexual partners (median,IQR)	6 (4 – 10)	6 (4 – 10)
High-risk HPV positive	47 (55)	47 (51)
HIV positive	5 (6)	3 (3)
Cigarette smokers	40(47)	41(45)
History of prior LEEP	7 (8)	10 (11)
Method of contraception *		
Pill, Patch, Ring, Condom	10 (13)	19(22)
LARC	22 (28)	33(38)
Permanent sterilization	24 (30)	11(13)
No Method	23 (29)	24(28)

Data are n(%) or mean (SD) unless otherwise specified.

IQR = interquartile range, HPV = human papillomavirus, HIV = human immunodeficiency virus, LARC = long acting reversible contraception (Depo provera, IUD), Permanent sterilization (bilateral tubal ligation or hysteroscopic sterilization)

* For $p < 0.05$,

** for $p < 0.01$.

Table 2

Colposcopy and cervical biopsy results prior to LEEP

Variables	See-and-Treat N=86	3-Step Conventional N=92
Adequate colposcopy		
Yes	28 (42)	51 (56)
No	35 (52)	34 (37)
Unknown	4 (6)	6 (7)
Colposcopic impression		
Benign	12 (19)	9 (10)
Low-grade	25 (40)	46 (51)
High-grade	22 (35)	27 (30)
AIS	1 (2)	3 (3)
Invasive cancer	1 (2)	0 (0)
Unknown	2 (3)	6 (7)
Biopsy performed	--	75 (83)
Number of biopsies per patient (median, IQR)	--	2 (1,2)
Colposcopic biopsy results prior to LEEP		
Insufficient for diagnosis	--	1 (1)
Benign	--	8 (10)
CIN1	--	5 (6)
CIN2	--	23 (30)
CIN3	--	38 (49)
AIS	--	1 (1)
Microinvasive cancer	--	1 (1)
ECC performed	--	71 (78)
Colposcopic ECC results prior to LEEP		
Insufficient for diagnosis	--	2 (3)
Benign	--	41 (58)
CIN1	--	3 (4)
CIN2	--	3 (4)
CIN3	--	16 (23)
Dysplasia cannot grade	--	6 (8)
AIS	--	0 (0)
Microinvasive cancer	--	0 (0)

Data are n(%) or mean (SD) unless otherwise specified.

IQR = interquartile range, ECC = endocervical curettage, CIN = cervical intraepithelial neoplasia, AIS = adenocarcinoma in situ.

† Represents highest grade composite result from either ECC or biopsy.

Table 3

LEEP results

Variables	See-and-Treat N=86	3-Step Conventional N=92
Months from cervical cytology to LEEP * (median, IQR)	2.3 (1.4 – 4.9)	3.0 (2.0 –6.3)
Composite outcome CIN1 or less	17 (20)	23 (25)
Location		
Outpatient clinic	76 (88)	78 (85)
Operating room	10 (12)	14 (15)
Top hat performed	41 (48)	37 (40)
Positive endocervix margin status	11 (26)	8 (20)
Histology		
Composite outcome †		
Benign/CIN1	17 ()	23()
CIN2	14(16)	9(10)
CIN3	54(63)	52(57)
AIS	0(0)	2(2)
Invasive cancer	1(1)	6(7)
Ectocervix		
Benign/CIN1	20 ()	25 ()
CIN2	13 (15)	9 (10)
CIN3	52 (60)	50 (54)
AIS	0 (0)	2 (2)
Microinvasive cancer	1 (1)	5 (4)
Endocervix (Top hat) *		
Unable to grade	1 (2)	1 (3)
Benign/CIN1	18 (43)	28 (72)
CIN2	3 (7)	3 (8)
CIN3	19 (45)	5 (13)
AIS	0 (0)	1 (3)
Microinvasive cancer	1 (2)	1 (3)
Size of specimen		
Ectocervix (mm)		
Length, mean	20 ± 6.3	21 ± 7.2
Width, mean	14.4±5	14 ±4.2
Depth, mean	6.2±2.7	6.4±3.4
Endocervix (top hat, mm)		
Length, mean	15±4.4	16.7±5.8
Width, mean	9.5±2.8	10.7±3.7
Depth, mean	4.9±2	5.1±2.1

Data are n(%) or mean (SD) unless otherwise specified. LEEP = Loop electrosurgical excision procedure, IQR = interquartile range, CIN = cervical intraepithelial neoplasia, AIS = adenocarcinoma in situ.

*For $p < 0.05$.

†Composite outcome = worst histologic grade on LEEP specimen (ectocervix, endocervix, ECC).

Table 4

Factors associated with overtreatment

Variables	CIN1 or less (Overtreatment) N=40	CIN2+ N=138
See-and-treat LEEP	17 (20)	69 (80)
Age (mean, years) *	37±13	32±10
Race		
Caucasian	23 (25)	68 (75)
Non-Caucasian	17 (20)	70 (80)
Gravidity (median, IQR)	4 (2 – 4)	2 (1 – 4)
Age at first intercourse (years)	16.3±2.8	15.7±2.3
Lifetime number of sexual partners (median, IQR)	6 (5 – 10)	6 (4 – 10)
HPV positive	18 (19)	76 (81)
HIV positive	1(13)	7(88)
Cigarette smokers	16(20)	65(80)
History of prior LEEP	2 (12)	15 (88)
Method of contraception		
Pill, Patch, Ring, Condom	3 (10)	26 (90)
LARC	11 (20)	44 (80)
Sterilization	7 (20)	28 (80)
No Method	14 (30)	33 (70)
Time to LEEP from Pap (months)		
<1.5	9 (23)	30 (77)
1.5 – 2.5	8 (18)	37 (82)
2.5 – 5.5	14 (27)	37 (73)
>5.5	9 (21)	34 (79)

Data are n(%) or mean (SD) unless otherwise specified.

% are listed by row.

IQR = interquartile range, HPV = human papillomavirus, HIV = human immunodeficiency virus, LARC = long acting reversible contraception (Depo provera, IUD).

* For $p < 0.05$.