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Utility of Conization with Frozen Section for Intraoperative Triage Prior to Definitive Hysterectomy

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Abstract

Objective—To review our experience with conization with intraoperative frozen section analysis and to compare results from our tertiary cancer center with those from 2 community hospitals.

Methods—The records of all women who underwent conization with intraoperative frozen section analysis from January 1, 1997, through April 30, 2011, at The University of Texas MD Anderson Cancer Center and 2 community hospitals—The Woman's Hospital of Texas and St. Luke's Episcopal Hospital—were reviewed. Findings on pathologic analysis of frozen sections, permanent loop electrosurgical excisional procedure/conization specimens, and hysterectomy specimens were compared for each patient, and results from the cancer center were compared to those from the community hospitals.

Results—One hundred fifty-three patients met the inclusion criteria. Rates of accuracy of conization with frozen section analysis in predicting definitive pathologic findings were as follows: cervix with no residual disease after prior extirpative procedure 96.5% (95% CI 86.9–100%); cervical squamous carcinoma in situ, 95.4% (95% CI 84.5–100%); cervical adenocarcinoma in situ, 98.7% (95% CI 92.7–100%); microinvasive carcinoma, 97.4% (95% CI 90.1–100%); and invasive carcinoma $\geq$ 3 mm, 100%. Most importantly, conization with frozen section analysis was 100% accurate for triaging patients to simple or radical hysterectomy. Finally, this approach performed equally well in the cancer center with subspecialized pathologists and the 2 community hospitals with general pathologists.

Conclusion—Conization with frozen section analysis is an effective technique for intraoperative triage of patients to immediate simple or radical hysterectomy and can be accurately performed in both academic and community hospitals.

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Introduction

Cervical cancer is the second most common cancer and the third leading cause of cancer-related death among women worldwide. [1] The surgical treatment of cervical cancer varies greatly by stage at diagnosis and typically is based on clinical stage at diagnosis. Patients with stage IA1 disease (microinvasive disease, nonvisible lesion < 3 mm deep and < 7 mm wide) can usually be treated with conization or simple hysterectomy without removal of regional lymph nodes. Patients with stage IA2 disease (nonvisible lesion 3–5 mm deep and < 7 mm wide or stage IB1 disease (nonvisible lesion > 5 mm deep or 7 mm wide or visible lesion < 4 cm in size limited to the cervix) are often dispositioned to radical hysterectomy or radical trachelectomy with pelvic lymphadenectomy. [2] As the morbidity of radical surgery and lymphadenectomy is much greater than that of simple hysterectomy or conization, [3] accurate determination of depth of invasion (< or 3 mm) is critically important for triaging patients with nonvisible lesions to the proper surgical treatment.

As an office biopsy at time of colposcopic examination is often insufficient to accurately determine depth of invasion, in most patients with nonvisible lesions, a loop electrosurgical excisional procedure (LEEP) or cone biopsy must be performed to procure enough tissue to establish this critical prognostic factor. LEEP requires an office environment with adequate space, equipment, and support staff; cone biopsy requires an operating room with the associated costs and anesthesia risks. In addition, both approaches cause significant edema of the cervix starting 24 to 48 hours later, which makes surgical dissection difficult. Therefore, before performing definitive procedures after LEEP or cone biopsy, surgeons generally must wait at least 6 weeks to allow for swelling to recede, a delay in treatment that can cause substantial anxiety for patients. For those reasons, some centers offer conization with intraoperative frozen section analysis to determine depth of invasion followed by simple hysterectomy or radical hysterectomy/lymphadenectomy performed at the same surgery according to the intraoperative pathologic findings.

Other investigators have reviewed their experience with conization and intraoperative frozen section analysis and have reported that findings on intraoperative analysis and findings on examination of permanent pathologic specimens correlate 75% to 100% of the time. [4–9] However, these studies were limited to patients at single academic centers. The applicability of those findings to general practice remains unknown. The objective of this study was to review our experience with conization with intraoperative frozen section analysis and to compare the results from our tertiary cancer center with those from 2 community hospitals.

Methods

After approval was obtained from the MD Anderson Institutional Review Board, the records of all women who underwent conization with intraoperative frozen section analysis from January 1, 1997, to April 30, 2011, at The University of Texas MD Anderson Cancer Center, The Woman's Hospital of Texas, and St. Luke's Episcopal Hospital were reviewed. The start date of January 1, 1997 was chosen as this was when conization with intraoperative frozen section analysis was first performed at MD Anderson. This procedure was performed at the community hospitals starting in 2007. Only patients with a preoperative diagnosis of squamous carcinoma or adenocarcinoma in situ [AIS] or microinvasive cervical cancer (< 3 mm) were included. Patients with a visible lesion (by definition a stage IB1 cervical cancer) or a final diagnosis of a non-cervical primary lesion (e.g., stage II endometrial cancer with cervical involvement) were excluded. All frozen specimens were obtained in an operating room by either LEEP or cold knife conization under general anesthesia.

For frozen section analysis, the cone specimen was entirely submitted as radial sections following differential inking of the endocervical and ectocervical margins. One to two sections per slide were then placed on a brass chuck, and sections were covered in OCT (optimal cutting temperature). The chuck was placed in a freeze box packed with dry ice (-40°C) until the OCT material was opaque (30–45 seconds). Following transfer and cutting of thin sections (4–5 microns) in a cryostat (-20°C), the tissue was immediately fixed in methanol for 5 seconds. Once dry, slides were stained with hematoxylin and eosin in an automatic stainer and then read. At The Woman's Hospital of Texas and St. Luke's Episcopal Hospital, all specimens were reviewed by general pathologists. At MD Anderson Cancer Center, all specimens were reviewed by pathologists subspecialized in the area of gynecologic pathology.

For both squamous and glandular lesions, when analysis of frozen sections revealed no residual dysplasia, low- or high-grade dysplasia, or microinvasive carcinoma, a simple hysterectomy with or without a bilateral salpingo-oophorectomy was performed. When analysis of frozen sections revealed invasive carcinoma ($\geq 3\text{ mm}$), a radical hysterectomy and pelvic lymphadenectomy with or without bilateral salpingo-oophorectomy was performed.

Results on pathologic analysis of frozen sections, LEEP/conization specimens, and hysterectomy specimens were compared for each patient. Sensitivity and accuracy were also calculated. Finally, results from MD Anderson Cancer Center were compared to those from the 2 community hospitals. For cancer patients, recurrence rates were also assessed.

Fisher's exact test, the Mann-Whitney test, and the chi-squared test were used to evaluate differences between groups. Missing data were coded as "unknown," and those data points were excluded from the analysis. Unless otherwise noted, P values were not adjusted for multiple comparisons. P values of $<.05$ were considered statistically significant. All data were analyzed using SPSS 15.0 for Windows (SPSS, Inc., Chicago, IL).

Results

One hundred fifty-three patients met the inclusion criteria. For the entire group, the median age was 42.9 years (range 19.5–82.6), and the median body mass index was 26.9 kg/m^2 (range $17.5\text{--}49.7\text{ kg/m}^2$). For frozen section analysis prior to hysterectomy, 146 (95%) had a cold knife cone while the remaining 7 (5%) had a LEEP. Ninety-two patients (60%) were in the cancer center group, while 61 (40%) were in the community hospital group. Demographic data for both groups are shown in Table 1. There were no differences between the 2 groups in age, body mass index, prior pregnancies, menopausal status, ethnicity, or presenting symptoms.

Forty-four (48%) of 92 patients in the cancer center group had a previous extirpative procedure (LEEP or cone biopsy), compared to only 12 (20%) of 61 patients in the community hospital group ($P<.001$). In addition, 47 patients (51%) in the cancer center group had a preoperative diagnosis of at least a microinvasive carcinoma, compared to only 5 patients (8%) in the community hospital group ($P<.001$).

On pathologic review of permanent sections, 51 patients (55%) in the cancer center group had invasive carcinoma: 27 (29%) with stage IA1 disease and 24 (26%) with stage IA2/IB1 disease (Table 2). This rate of invasive carcinoma was significantly higher than the rate in the community hospital group, in which 8 patients (13%) had invasive carcinoma: 6 (10%) with IA1 disease and 2 (3%) with stage IB1 disease ($P<.001$). Accordingly, more patients in the cancer center group ultimately underwent at least an attempt at radical hysterectomy/

trachelectomy (26 [28%] vs. 2 [3%], $P<.001$). Seven patients in the cancer center group and 1 patient in community hospital group had the attempt at radical surgery aborted.

Table 3 compares findings on intraoperative frozen section analysis and final pathologic diagnosis by hospital type. Twenty-three patients had frozen sections showing no residual disease in the cervix. Of these, 3 patients (13%) had a final diagnosis of dysplasia, and no patient had a final diagnosis of invasive carcinoma. A frozen section finding of no residual disease was 100% correct in predicting who did not need a radical hysterectomy or radical trachelectomy (i.e., who did not have an invasive cancer ≥ 3 mm). The overall accuracy of frozen section analysis in detecting no residual disease was 96.5% (95% CI 86.9–100%).

Eighty patients had frozen sections showing squamous dysplasia in the cervix. Of these, 1 patient (1%) had a final diagnosis of microinvasive cancer. This patient had a single focus of carcinoma invading < 1 mm. No patient with dysplasia according to frozen section analysis had a final diagnosis of carcinoma invading ≥ 3 mm. A frozen section finding of squamous dysplasia was 100% correct in predicting who did not need a radical hysterectomy or radical trachelectomy. The overall accuracy of frozen section analysis in detecting dysplasia was 95.4% (95% CI 84.5–100%).

Twelve patients had frozen sections showing AIS in the cervix. The final diagnosis was AIS in all 12 of these patients. No patients with AIS on frozen section had an invasive carcinoma. A frozen section finding of AIS was 100% correct in predicting who did not need a radical hysterectomy or radical trachelectomy. The overall accuracy of frozen section analysis in detecting dysplasia was 98.7% (95% CI 92.7–100%).

Nineteen patients had frozen sections showing microinvasive carcinoma (< 3 mm) in the cervix. None of these patients had a final diagnosis of invasive carcinoma ≥ 3 mm. A frozen section finding of microinvasive disease was 100% correct in predicting who did not need a radical hysterectomy or radical trachelectomy. The overall accuracy of frozen section analysis in detecting microinvasion was 97.4% (95% CI 90.1–100%).

Nineteen patients had frozen sections showing invasive carcinoma (≥ 3 mm) in the cervix. None of these patients had a final diagnosis of microinvasive carcinoma. A frozen section finding of invasive disease was 100% correct in predicting who did need a radical hysterectomy or radical trachelectomy. The overall accuracy of frozen section analysis in detecting invasion was 100%.

For 55 patients, both margin status on frozen section analysis and margin status on final pathologic evaluation were reported. Twenty-three patients (42%) had a negative margin on frozen section analysis. Of these, 3 patients (13%) had dysplasia found in the final hysterectomy specimen. Twenty-four patients (44%) had dysplasia at the margin on frozen section analysis. Of these, 14 (58%) had dysplasia found in the final hysterectomy specimen, 9 (38%) had no residual dysplasia in the hysterectomy specimen, and 1 (4%) had a focus of invasive cancer (adenosquamous carcinoma, invasion ≥ 3 mm). Eight patients (15%) had invasive carcinoma at the margin on frozen section analysis. Of these, 7 (88%) had invasive carcinoma in the hysterectomy specimen, while 1 (12%) had no residual disease. There was no difference between the cancer center and community hospitals with respect to concordance of margin status between frozen section analysis and review of permanent sections ($P=.99$).

Thirty-three patients had stage IA1 cancer on frozen section analysis. Of these, 4 had dysplasia and 29 had microinvasive carcinoma on preoperative biopsy. Histologically, 27 patients (82%) had squamous carcinoma, and the remaining 6 (18%) had adenocarcinoma. At a median follow-up time of 75 months (range 7–160 months), there had been 2

recurrences in this group, and no patients had died of disease. Both patients with recurrence had squamous lesions. One patient had a nodal recurrence along the aorta 5 years after primary treatment, and the other patient had a vaginal recurrence diagnosed 10 years after primary treatment with a simple hysterectomy. Both were treated successfully with salvage radiation therapy.

Twenty-six patients had stage IA2 or IB1 cancer on frozen section analysis. Of these, 3 had dysplasia and 23 had microinvasive carcinoma on preoperative biopsy. Histologically, 14 patients (54%) had squamous carcinoma, 10 (38%) had adenocarcinoma, and the remaining 2 (8%) had adenosquamous carcinoma. At a median follow-up time of 49 months (range 12–143 months), there had been 2 recurrences in this group, and both patients had died of their disease. The first patient had a grade 3 squamous carcinoma with microscopic disease in the parametrium found on pathologic evaluation of the radical hysterectomy specimen. She received adjuvant chemoradiation but experienced simultaneous local and distant recurrence and died of disease 25 months after diagnosis. The other patient had a grade 3 squamous carcinoma with recurrence in the liver and died of disease 12 months later.

Discussion

Although conization with frozen section analysis was not perfectly precise in distinguishing dysplasia from invasive cancer, it was 100% accurate for triaging patients to simple or radical hysterectomy. In other words, no patient who should have undergone a radical hysterectomy (i.e., invasive carcinoma ≥ 3 mm) was missed, and likewise no patient who only needed a simple hysterectomy (i.e., with dysplasia or invasive carcinoma < 3 mm) underwent a radical hysterectomy. Furthermore, conization with frozen section analysis performed equally well in an academic cancer center with subspecialized pathologists and 2 community hospitals with general pathologists.

As conization with frozen section analysis should be employed as an intraoperative tool for determining whether patients should undergo simple or radical hysterectomy, the finding that it performs this task well is very reassuring. We recommend using the technique for this purpose only and not as a means to determine whether conization only is sufficient or if patients should undergo hysterectomy. In our series, 13% of patients with negative margins on frozen section analysis had residual dysplasia in the final hysterectomy specimen. This rate is much higher than what might be expected after conization. Reich et al. found that among patients with squamous carcinoma in situ who underwent conization and had negative margins on review of permanent sections, the rate of recurrence (all recurrences were CIN II/III) was only 0.35% after a median follow-up time of 107 months. [10] For women with AIS, multiple authors have likewise found low recurrence rates after conization with negative margins. [11, 12] Although these studies only looked at recurrence and did not evaluate hysterectomy specimens, we believe that residual disease, if any, must have been minimal if recurrence rates were so low. In addition, the common use of electrocautery to obtain hemostasis in the cone bed may also have an additional therapeutic effect of ablating residual dysplasia in the cervix thereby contributing to lower recurrence rates in these patients.

Furthermore, 1 (4%) patient in our study who had invasive carcinoma on frozen section analysis with only dysplasia at the cone margin was found to have invasive carcinoma in the hysterectomy specimen. Although this patient had invasion ≥ 3 mm and therefore would have been unlikely to be treated with conization only, this finding does raise concern regarding other patients with seemingly microinvasive disease for whom conservative therapy only might be considered. For such patients, we strongly recommend performing the

cone biopsy only and awaiting the results of review of permanent sections to determine whether conization only is adequate therapy.

Of particular interest, we found that conization with frozen section analysis can be performed accurately in community hospitals. Previous studies of this approach have all been from academic centers in the United States [4, 7, 8] and other countries [5, 6, 9], and presumably pathologists at academic centers had extra training or interest in gynecologic malignancies. At MD Anderson Cancer Center, all specimens were reviewed by 1 of 6 pathologists subspecialized in the area of gynecologic pathology and therefore spend the majority of their time reviewing gynecology cases. This is in stark contrast to the situation at the 2 community hospitals, where pathologists were required to review frozen sections from a wide variety of specimens—not only from all anatomical sites but also from both genders. This study shows, however, that after adequate training, conization with frozen section analysis can be performed by both general and subspecialized pathologists.

Although we found that both the cancer center and the community hospitals could accurately triage patients to simple or radical hysterectomy on the basis of conization with frozen section analysis, the patient populations differed greatly between the cancer center and the community hospitals. For example, of the 28 patients with adenocarcinoma-in-situ or invasive adenocarcinoma, 26 (93%) were seen at the cancer center where the specialized pathologists are located. This large selection bias was likely due to the acknowledged difficulty, even on permanent sectioning, in determining the presence or absence of invasion and the depth of invasion for adenocarcinoma-in-situ and invasive adenocarcinoma. [13, 14] We believe that conization with frozen section analysis of glandular lesions outside specialized centers should be undertaken with extreme caution. Frozen section analyses of squamous lesions, however, are likely to be performed accurately in community hospitals by skilled general pathologists.

In addition, fifty-five percent of patients in the cancer center group ultimately had invasive cervical cancer, compared to only 13% in the community hospital cohort. Furthermore, 26 (28%) of the 92 patients in the cancer center group underwent an attempt at radical hysterectomy based on frozen section, compared to only 2 (3%) of the 61 patients treated at community hospitals. This discrepancy reflects the nature of referrals to each of these practices. Gynecologic oncologists at community hospitals are referred a significant number of patients with cervical dysplasia for whom they assume complete care. Many of these patients have recurrent or complex disease requiring hysterectomy. The community hospital gynecologic oncologists, then, are often using conization with frozen section analysis to *rule out* the need for radical hysterectomy. In contrast, the gynecologic oncologists at the cancer center typically do not see patients with dysplasia (there is a separate clinic staffed by gynecologists specializing in benign disease) and therefore see a much higher percentage of patients with invasive carcinoma, for whom conization with frozen section analysis is a means to determine depth of invasion. The cancer center physicians, therefore, are often using this technique to *rule in* the need for radical hysterectomy.

Our findings are similar to those previously reported in the literature. Previous studies have reported an accuracy of 75–100% for conization with frozen section analysis in distinguishing dysplasia from invasive carcinoma. [5, 6, 8, 9, 15] Our overall accuracy in the evaluation of dysplasia was 95.4%. For microinvasive disease, the overall accuracy was 97.4%. This is similar to the 100% accuracy reported by Giuntoli et al. [7] in their evaluation of conization with frozen section analysis in the evaluation of microinvasive carcinoma.

Although no authors, including ourselves, have formally evaluated whether conization with frozen section analysis followed by simple or radical hysterectomy is a cost-effective approach for the treatment of high-grade dysplasia and microinvasive carcinoma, we remain convinced that it is. As shown here, the procedure is highly accurate and can be used to triage patients to simple or radical hysterectomy without error. Because of the retrospective nature of this study, we were unable to determine the additional operating room and anesthesia time required to perform the procedure. Other authors, however, have shown that the procedure adds an additional 30 to 45 minutes to the case. [6, 7] Certainly the benefits of avoiding the need for 2 separate procedures—conization followed by hysterectomy 6 weeks later—far outweigh this short additional operating time required for performing conization and definitive hysterectomy during the same procedure.

In summary, conization with frozen section analysis is an accurate means to help decide whether a patient needs a simple or radical hysterectomy. Furthermore, with proper education and training, the procedure can be performed as safely at a community hospital as at a major cancer center although we would caution the utilization of this procedure in patients with glandular lesions. As margin status on conization with frozen section analysis appears to be less accurate than margin status on analysis of permanent pathologic sections, conization with frozen section analysis should not be used to determine whether conization alone is adequate. Our findings show that conization with frozen section analysis is an effective technique for the intraoperative triage of patients to immediate simple or radical hysterectomy.

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Highlights

1. Conization with frozen section analysis for triage of patients to simple or radical hysterectomy was accurate in both an academic cancer center and community hospitals.
2. Inexperienced pathologists should undertake intraoperative assessment of glandular lesions with caution.

Table 1

Patient demographics and preoperative pathologic findings.

	Cancer center (n = 92)	Community hospital (n = 61)	P
Median age (range), years	42.9 (19.5–82.6)	42.9 (26.1–77.9)	NS
Median BMI (range), kg/m ²	26.5 (18.4–49.7)	28.3 (17.5–48.8)	NS
Median gravidity (range)	3 (0–12)	2 (0–11)	NS
Median parity (range)	2 (0–10)	2 (0–11)	NS
Menopausal, no. of patients (%)	25 (27)	14 (23)	NS
Ethnicity, no. of patients (%)			NS
Caucasian	62 (67.4)	42 (68.8)	
Hispanic	19 (20.6)	8 (13.2)	
African American	6 (6.5)	11 (18)	
Asian	5 (5.5)	0 (0)	
Presenting symptom, no. of patients (%)			NS
Abnormal Pap test	69 (75)	47 (77)	
Abnormal bleeding	21 (23)	12 (20)	
Unknown	2 (2)	2 (3)	
Preoperative diagnosis			<.001
Abnormal Pap test	4 (5)	17 (28)	
CIN II/III	27 (29)	33 (54)	
AIS	14 (15)	6 (10)	
Microinvasive cancer (< 3 mm)	47 (51)	5 (8)	
Method of diagnosis			<.001
Pap only	0 (0)	12 (20)	
Office biopsy	48 (52)	37 (60)	
LEEP/cone biopsy	44 (48)	12 (20)	

AIS, adenocarcinoma in situ; BMI, body mass index; CIN, cervical intraepithelial neoplasia; LEEP, loop electrosurgical excisional procedure; NS, not significant.

Table 2

Definitive treatment and pathologic findings.*

	Cancer center (n = 92)	Community hospital (n = 61)	P
Treatment			
Cone biopsy/simple trachelectomy	9 (10)	1 (1)	<.001
Simple hysterectomy	57 (62)	58 (95)	
Radical hysterectomy	19 (21)	1 (1)	
Aborted radical hysterectomy	7 (7)	1 (1)	
Surgical approach [†]			<.001
Laparotomy	38 (50)	6 (10)	
Laparoscopy	17 (22)	44 (75)	
Vaginal	11 (14)	9 (15)	
Robotic	10 (13)	0 (0)	<.001
Final pathologic diagnosis			
CIN I	2 (2)	6 (10)	
CIN II/III	28 (30)	41 (67)	
AIS	11 (12)	6 (10)	
Stage IA1 carcinoma	27 (29)	6 (10)	
Stage IA2 carcinoma	10 (11)	0 (0)	
Stage IB1 carcinoma	14 (15)	2 (3)	NS
Final histologic subtype (carcinomas)			
Squamous	34 (67)	7 (88)	
Adenocarcinoma	15 (29)	1 (12)	
Adenosquamous	2 (4)	0 (0)	

* Values in table are number of patients (percentage).

[†] For patients undergoing hysterectomy.

AIS, adenocarcinoma in situ; CIN, cervical intraepithelial neoplasia; NS, not significant.

Table 3

Comparison of frozen section analysis findings and final pathologic diagnosis, by hospital type.

Frozen section findings	Final diagnosis	Cancer center	Community hospital
No residual disease (n = 23)	No residual disease	12	8
	Dysplasia	2	1
	Invasion < 3 mm	0	0
	Invasion ≥ 3 mm	0	0
Dysplasia (n = 80)	No residual disease	1	2
	Dysplasia	33	43
	Invasion < 3 mm	0	1*
	Invasion ≥ 3 mm	0	0
Invasion < 3 mm (n = 19)	No residual disease	0	0
	Dysplasia	3	1
	Invasion < 3 mm	14	1
	Invasion ≥ 3 mm	0	0
Invasion ≥ 3 mm (n = 19)	No residual disease	0	0
	Dysplasia	0	0
	Invasion < 3 mm	0	0
	Invasion ≥ 3 mm	17	2
AIS (n = 12)	AIS	10	2

* Single focus of invasion < 1 mm

AIS, adenocarcinoma in situ.