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Spiral brush cervical biopsy experience in a community clinic

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Abstract. – OBJECTIVE: This article seeks to demonstrate the experience of implementing the spiral brush in several community clinic locales. Before the introduction of the spiral brush cervical biopsy in 2002 there were few alternatives to colposcopy directed punch biopsy when evaluating and managing abnormal dysplastic Papanicolaou (pap) smear or a visually abnormal cervix. Subsequent investigations validated the spiral brush usage but there are limited reports for its implementation in primary care colposcopy.

PATIENTS AND METHODS: Over a two year period (2004-2006) patients with internal referrals for colposcopy received the spiral brush cervical biopsy. Those that resulted in the diagnoses of high grade squamous intraepithelial lesion (HSIL) diagnoses (CIN2-3) were compared to the final pathology diagnosis from the loop excision specimen.

RESULTS: 15 cases of HSIL were identified with subsequent loop excision. Comparison of the pathology diagnosis from the loop excision and the spiral brush biopsy resulted in 13.3% (n=2) of cases differing. In both cases, low grade squamous intraepithelial lesion (LSIL) diagnoses (CIN1) were found whereas the remainder had the same diagnosis of HSIL.

CONCLUSIONS: These results showed acceptable rates of concordance with traditional pathology specimens which supports the use of this Food and Drug Administration (FDA) approved device within a primary care setting.

Key Words:
Colposcopy, Spiral brush, Pap smear, Primary care, Community clinic, Cervical biopsy.

Introduction

Up until the introduction of a disposable spiral brush biopsy instrument for cervical biopsy in 2002 and subsequent investigations validating its use in 2004, there was little alternative to traditional evaluation and management of an abnormal pap smear or a visually abnormal cervix other than colposcopy directed punch biopsy[1-4]. This device, using a spiral-shaped brush with stiff bristles, provides transepithelial samples that are rich in epithelial cells, including basal and parabasal cells, and can be studied using cytologic techniques. Since the spiral brush was initially introduced in the literature and its subsequent FDA approval, little has been reported as to its implementation for primary care colposcopists.

Although colposcopists are traditionally trained to punch biopsy lesions demonstrating features correlated with microscopic dysplasia, multiple studies have demonstrated difficulties with the biopsy sample representing the pathology seen on final excision specimens (cone or loop)[5-7]. Despite this limitation (the causes of which are multifactorial and beyond the scope of this paper), the incumbent pain and risk of bleeding or infection were considered necessary consequences to prevent cervical cancer.

There are few alternatives to a colposcopy-directed punch biopsy of suspicious lesions. Studies assessing a blinded, four-quadrant approach or aggressive sampling by multiple biopsies of suspicious lesions, yield pathologic correlation rates similar to the traditional punch biopsy, albeit with significantly reduced patient satisfaction[8,9]. Given the small size of the cervix, imaging modalities are of little use as well until very advanced disease. Additionally, studies bypassing the colposcopy directed biopsy to a "see and treat" from visual colposcopy alone to primary large loop excision of the transformation zone have been unreliably diagnostic and therapeutic[10-12], and is wrought with unwarranted complication risks since significant numbers of specimens are found to have no dysplasia on pathology[9,13].

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Thus some heralded the spiral brush biopsy sample as being an alternative given equivalent sampling ability to standard biopsies ostensibly without the same pain or bleeding seen with the a standard biopsy[14]. Monk et al[3] found patient reported pain and physician reported bleeding to be significantly less in the spiral brush group versus the punch biopsy group ($p < 0.001$). In general, the principle of obtaining similar results whether diagnostically or therapeutically with less invasive procedures or interventions is the hallmark of non-malfeasance. That said, since the introduction of this device and its subsequent FDA approval, little report of its use in primary care has been documented. We undertook implementing this into our practice and present herein a case series demonstrating our initial experience.

Patients and Methods

The disposable spiral brush biopsy instrument used was the SpiraBrush® (CDX Diagnostics, Newport Beach, CA, USA). The brush head is attached to a polystyrene plastic handle, which is scored just proximal to the brush head end. The bristles of the spiral brush head are each stiff and made of nylon laid in a double layer and protrude from a stainless steel wire spine. At the center, the end of each bristle is secured within a twisted wire backbone. One end of the twisted wire is attached to the handle, and the other end is bent at a 90° angle to the handle and then twirled into a spiral. The spiral brush was implemented via previously describe methods whereby it was first placed on the lesion and then the sample was obtained by applying firm pressure on the flat portion of the looped brush with whereby the operator then rotated one rotation clockwise and one rotation counterclockwise while firm pressure was maintained against the cervix for a minimum of three cycles. This protocol is recommended by the manufacturer to ensure an adequate sample (containing basal or parabasal cells). The spiral brush head was then snapped off at the scored mark and placed directly into a pre-labeled vial containing a preservative alcohol-based cytological solution.

The site was a community clinic setting over a two year period (2004-2006) serving two cities within a southern California locale whereby the patients were a population that typically remained within the community clinic setting for internal referral for colposcopy secondary to adherence to national treatment guidelines promulgated by American Society of Colposcopy and Cervical Pathology (ASCCP) guidelines for abnormal pap smears. Those that resulted in the diagnoses of HSIL (CIN2-3) were compared to the final pathology diagnosis from the loop excision specimen.

Table I. Spiral Brush Diagnostic Capabilities. Spiral brush cervical biopsy (Spiral Brush Biopsy) was used on patients that required colposcopy. Following identification of suspicious lesions, a loop excision was performed and the specimen was analyzed (Loop Excision) for comparison. SIL, Squamous Intraepithelial Lesions

Pathologic diagnosis	Spiral Brush Biopsy	Loop Excision
High Grade SIL	15	13
Low Grade SIL	0	2

Of note, currently and at the time of this study, the community clinic (Neighborhood Health) possessed no institutional review board (IRB) to review methodology of this study; however, given that the device was FDA approved for this purpose the need for IRB was waived.

Results

Over this two year period, 15 cases of HSIL diagnoses (CIN2-3) were identified that subsequently had a loop excision. Of these, 13.3 % of the excision specimens had a diagnosis that differed from the original spiral brush biopsy (n=2). In both cases, the diagnosis was LSIL (CIN1) whereas the remainder had the same diagnosis of HSIL.

Discussion

We demonstrate that this device has acceptable rates of concordance with traditional pathology specimens. Albeit this study did not have the power to remit to statistical analysis, it adds another data point to this very useful colposcopic tool. Although previous multicenter studies validate that it is safe and better tolerated in gynecologic-oncology clinics, we did not want to conclude a transition to this device in a primary care driven community clinic without a review of its applicability. Indeed, it was heralded in the journal American Family Physician that this could be a useful tool for primary care colposcopy but no

reports of its use have been disseminated. That said, FDA approval provides a medico-legal basis for changing practice though it requires a willingness to make changes to long held views and styles of practice management.

Conclusions

These results supported the use of this procedure at a community clinic level, and we have transitioned to use the spiral brush solely, and except in rare very advanced cases where we still offer the traditional punch biopsy. We hope this information will be valuable to primary care colposcopists elsewhere.

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Conflict of Interest

The Authors declare that they have no conflict of interests.

Financial Disclosures

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