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Patient and provider factors associated with endometrial Pipelle sampling failure

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HIGHLIGHTS

- Pipelle sampling failure rates were identified in a large healthcare system.
- Clinically important risk factors were identified for Pipelle sampling failure.
- Postmenopausal bleeding as a biopsy indication is the key risk factor.
- Prior history of biopsy failure is risk factor for Pipelle sampling failure.
- Further research is warranted to improve Pipelle efficiency in high risk patients.

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ABSTRACT

Objective. To explore risk factors associated with sampling failure in women who underwent Pipelle biopsy.

Methods. A consecutive sample of 201 patient records was selected from women who underwent Pipelle biopsy procedures for suspected uterine pathology in a large healthcare system over a 6-month period (January 2013 through June 2013). Personal and medical data including age, BMI, gravidity and parity, and previous history of Pipelle biopsy were abstracted from medical records for each patient. Logistic regression analyses were used to determine factors associated with biopsy sampling failure.

Results. Pipelle biopsy sampling failed in 46 out 201 women (22.89%), where 8 (17.39%) were due to inability to access the endometrium, 37 (80.43%) were inadequate samples, and 1 (2.18%) was due to unknown reasons. Personal and medical factors found to be related to sampling failure included: postmenopausal bleeding as biopsy indication (OR 7.41, 95% CI 2.27–24.14); history of prior biopsy failure (OR 23.87, 95% CI 3.76–151.61); and provider type (physician vs. midlevel provider) (OR 9.152, 95% CI 2.49–33.69).

Conclusion. We identified several risk factors for biopsy failure that suggest the need for particular care with Pipelle sampling procedures among women with certain characteristics, including postmenopausal bleeding and a history of prior failed Pipelle biopsy. Our finding of a significantly higher risk of sampling failure based on personal and clinical data suggests that providers must take into account additional considerations to improve sampling success.

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1. Introduction

Endometrial cancer is the most common gynecologic malignancy in the developed world [1], with the highest incidence in the US and Canada [2]. Endometrial biopsy plays a significant role in early cancer diagnosis, preoperative assessment, and treatment planning [3,4], with Pipelle biopsy emerging as the most common method for sampling endometrial tissue in patients with suspected endometrial cancer [5,6]. Pipelle sampling is a cost-effective [7] procedure and has similar sampling adequacy and histopathological results as dilation and curettage (D&C) [8]. In contrast with D&C, Pipelle biopsies are better tolerated and can be easily performed in an out-patient setting [9]. The increasing

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incidence of endometrial cancer [10] highlights the importance of Pipelle biopsy for timely cancer diagnosis.

Despite the wide utilization of Pipelle biopsy for diagnosis of uterine pathologies, few studies have assessed the rate of sampling failure and the factors associated with the failure of Pipelle sampling procedures. A meta-analysis by Dijkhuizen et al. in 2000 found a 10.4% sample size-weighted failure rate across 15 studies that used Pipelle sampling [5], whereas a systematic review by Clark et al. in 2002 reported only an 8% failure rate among 7 studies [11]. However, individual studies over the years have reported up to 33% Pipelle sampling failure rates depending on the study characteristics and the participant inclusion criteria [9,12–16]. In a previous research study conducted by our group, Pipelle biopsy sampling had a sampling failure rate of 38% with severely obese (BMI ≥ 35) bariatric surgery candidates [17]. Primary reasons for biopsy failure reported in the literature are inability to access the uterine cavity or an insufficient amount of tissue collected for histological analysis [16].

Therefore, the aim of the present study was to fill an important gap in the literature by examining factors associated with the rate of failure in a sample of women who underwent Pipelle biopsy in a large healthcare system. Elucidating the factors associated with increased risk of biopsy sampling failure is important, as this information can potentially provide clinicians with additional tools to identify appropriate candidates for outpatient biopsy and to consider using alternative diagnostic options for women with high risk of failure.

2. Methods

After approval from the University of Pittsburgh Institutional Review, a consecutive sample of 201 patient records was selected for women who underwent Pipelle biopsy procedures for suspected uterine pathology in a large healthcare system over a period of 6 months (January–June 2013). Patient records were identified through CoPath, a pathology information system, using keywords “Pipelle”, “Endometrial” and “biopsy”, and were accessed through the UPMC Center for Assistance in Research eRecord team, per UPMC policy. Based on literature review and clinical experience, the following information was obtained from a medical records review: history of prior biopsy success/failure, age group (categorical: 22–54 and ≥55), body mass index (BMI) group (categorical: normal weight (<24.9), overweight (25.0–29.9), and obese (≥30.0), history of smoking, history of hormone use, history of sexually transmitted diseases, gravidity, parity, indication for current biopsy, reason for current biopsy failure, and the type of the healthcare provider performing the Pipelle procedure (physician vs. other (Certified Registered Nurse Practitioner or Physician Assistant)). We have used STRAW + 10 staging system which defines the reproductive stages in a woman's life from premenopause to the late postmenopausal period to approximate age criteria for the early and late menopausal transition [18]. In accordance with the STRAW + 10 guidelines women in this study were dichotomised into postmenopausal ≥55 years ($n = 64$ (31.84%)) and pre-menopausal 22–54 years ($n = 137$ (68.16%)) groups based on age as proxy variable, and, roughly corresponding to atrophic endometrium and non-atrophic endometrium respectively.

The data abstracted from the medical records is assumed to be reliable for all information collected within UPMC facilities and all procedures conducted at the UPMC facilities. Over 60% of women residing in Allegheny County use UPMC facilities for their medical care, with a large percentage of genecology patients solely relying on UPMC facilities for their care. While information on personal factors like gravidity, parity, STDs, etc., is not necessary collected at the biopsy visit, it is confirmed at each consultation visit and/or medical encounter leading to the biopsy appointment.

Biopsy failure was defined as a dichotomous outcome (biopsy failure/success) based on the following definition: 1) the clinician was unable to introduce the Pipelle curette into the uterine cavity; or 2) an insufficient amount of tissue was obtained during Pipelle biopsy procedure for histological evaluation. This definition was utilized for current biopsy attempt and for the history of previous biopsy failure. All collected endometrial tissue samples were examined by pathologists who determined sample adequacy for histological diagnosis and provided a pathology report.

Descriptive statistics were used for initial data analyses. In our models, we assessed each one of the above factors using univariate logistic regression to determine if they were significantly associated with sampling failure. To control for possible confounding factors we used multivariable logistic models adjusting for age and BMI, as these factors have been associated with biopsy success/failure in the literature and in our clinical practice [17,19].

Variables that were significant in the multivariable models and were reported as factors influencing sampling success in the clinical practice of our healthcare system were then tested for interactions to identify any effect modification in our logistic regression models, while adjusting for BMI and age. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC) with α level set at <0.05 (two-sided). Missing values were excluded from the analysis. Statistically insignificant risk factors (P-value > 0.05) were excluded from the final model.

3. Results

The characteristics of the study participants are presented descriptively in Table 1. Briefly, the majority were white, between the ages of 22–54, and overweight or obese. The Pipelle sampling failure rate among physicians was 39 out of 185 (21.08%) compared to 7 out of 16 (43.75%) failure rate among non-physician providers. Univariate regression (Table 2) demonstrated that older age (OR 4.15, 95% CI 2.04–8.45, $P < 0.001$), history of failed Pipelle biopsy (OR 15.01, 95% CI 2.65–84.94, $P = 0.002$), postmenopausal bleeding as an indication (OR 3.68, 95% CI 1.34–10.09, $P = 0.015$), and non-physician provider type (OR 5.37, 95% CI 1.69–17.07, $P = 0.004$) were significant predictors of sampling failure of Pipelle biopsy. Multivariable logistic regression modelling demonstrated that a history of prior biopsy failure (OR 23.87, 95% CI 3.76–151.61, $P < 0.001$), an indication for biopsy of postmenopausal bleeding (OR 7.41, 95% CI 2.27–24.14, $P = 0.002$), and provider type (OR 9.15, 95% CI 2.49–33.69, $P = 0.001$) were significantly associated with a higher risk of having a failed Pipelle biopsy, while age group was no longer significant (Table 2). Hormone use was not significantly associated with biopsy failure. While BMI was not a statistically significant predictor of Pipelle sampling failure, it is important to point out that women who were obese had a higher percentage of Pipelle biopsy failure 24 (27.27%) compared to women of normal weight 9 (16.67%). We tested interaction terms in our multivariable models; however, no significant interactions were observed.

4. Discussion

Among the women who underwent Pipelle biopsy procedures at a major healthcare system, a consecutive sample of 201 patients demonstrated an approximately 23% sampling failure rate for the Pipelle biopsy, which is within the range of failure rates reported in previously published literature. We found that ≥55 age group, postmenopausal bleeding as indication for sampling, history of prior biopsy failure, and type of provider are important factors that were associated with Pipelle biopsy sampling failure.

Factors influencing sampling failure rates for Pipelle biopsies have rarely been investigated. Gordon & Westgate suggested that Pipelle biopsy sampling failure results predominantly from the insufficiency of collected samples for histological diagnosis, whereas a small proportion of failures can be attributed to barriers preventing physical access to the endometrial cavity [16]. McCluggage suggested that patients' histories, including menopausal status and hormone use, are important in

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