

Endocervical Curettage with the FemCerv Endocervical Sampler

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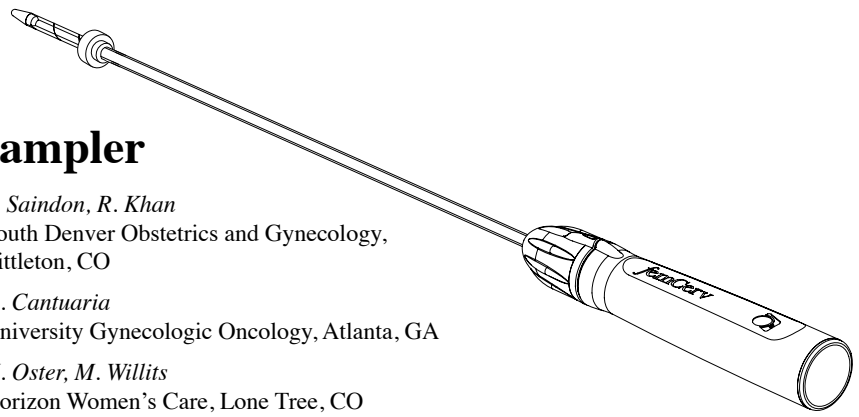
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Objective

To evaluate the FemCerv Endocervical Sampler when performing an endocervical curettage with respect to specimen adequacy for histological evaluation, observed patient discomfort, and ease of device insertion.

Methods

112 patients, ages 20-60, undergoing further evaluation of abnormal cervical cytology underwent an endocervical curettage with the FemCerv device at 6 clinical sites. Patient discomfort and ease of device insertion were assessed using a rating scale. All samples were submitted for histologic evaluation. Sample adequacy for diagnosis was determined by reviewing pathology reports.

Results

Of the 112 patients who underwent an endocervical curettage with FemCerv, 105 had samples that were adequate (94%) for performing a pathologic diagnosis, and 7 had samples that were not adequate for diagnosis. Physicians reported 95% of the patients experienced mild or no discomfort during the procedure and 92% of the physicians reported the device as easy to insert.

Of the 7 inadequate samples reported, 3 contained only endometrial tissue, 3 lacked intact epithelium, and 1 included fragment and mucous material (this patient had a previous inadequate sample collected using a Kevorkian curette 10 days prior).

FemCerv ECC Evaluation Data

Sample Adequacy, Patient Discomfort, Ease of Device Insertion

Patients (n = 112)

| Sample Adequacy | Patient Tolerance | Ease of Device Insertion |
|------------------------------------|----------------------------------|---|
| 94% Adequacy | 95% No/Mild Discomfort | 92% Easy to Insert (% = Difficulty of 4+5) |
| Adequate 105/112 | No Discomfort 57/112 | Insertion 1 03/112 |
| Inadequate 7/112 | Mild Discomfort 49/112 | Insertion 2 02/112 |
| Endometrial Tissue Only (3) | Moderate Discomfort 06/112 | Insertion 3 04/112 |
| Failed Kevorkian 10 Days Prior (1) | Severe Discomfort 00/112 | Insertion 4 07/112 |
| No Intact Epithelium (3) | | Insertion 5 96/112 |
| | | <i>1 = Difficult 5 = Easy</i> |

Conclusion

Endocervical curettage for the routine investigation of patients with abnormal cervical cytology was successfully conducted with the FemCerv Endocervical Sampler. The device typically provided adequate samples for histological evaluation. The device's rounded tapered tip was easy to insert in most patients. The procedure was well tolerated by almost all patients, who experienced mild or no discomfort.