

Clinical Evaluation of the Pipelle Endometrial Suction Curette for Timed Endometrial Biopsies

Jerome H. Check, M.D.
Jeffrey S. Chase, M.D.
Kosrow Nowroozi, M.D.
Chung H. Wu, M.D.
Rebecca Chern, R.N.

A clinical study was performed to determine the efficacy of the Pipelle in obtaining endometrial samples to be analyzed for luteal function. Patients' tolerance of this instrument and their willingness to undergo subsequent biopsies were also ascertained. An endometrial sample was obtainable from 1,278 women with the Pipelle, whereas 52 required the Novak curette and in 60 the sample could not be obtained with either instrument. Thirteen percent of the patients biopsied with the Pipelle stated that they would not allow a second such procedure to be performed. One percent of the samples were deemed inadequate for hormonal reading. The Pipelle seemed to be a safe, minimally traumatic method of sampling the endometrium for hormonal evaluation.

Introduction

The timed endometrial biopsy performed in the late luteal phase is still the best method of diagnosing luteal phase deficiency as a cause of infertility.¹ Luteal phase defects can be corrected with ovulation-inducing drugs^{2,3} or progesterone therapy in the luteal phase.^{4,5} The correction of the defect can be determined only by repeating the endometrial biopsy. Unfortunately, the standard instrument for the biopsy, the Novak curette, causes some women moderate to severe pain, and they are reluctant to have the test repeated.

The Pipelle Endometrial Suction Curette (Unimar, Inc., Wilton, CT) (Figure 1) is a new endometrial biopsy instrument that is thinner than the Novak curette, is devoid of serrated teeth and, because of its flexibility, usually does not require a tenaculum or straightening of the cervical fundal axis.

A study was performed to determine patient tolerance to the Pipelle and its efficacy in obtaining a sample large enough that a hormonal reading could be obtained.

Materials and Methods

Consecutive patients undergoing timed endometrial biopsies were included in this study until 2,000 biopsies were obtained. The study began with our fourth month of using the instrument. After the procedure the patients were asked about the degree of discomfort and whether they would be willing to undergo the same procedure again if necessary.

The Pipelle (Figure 1) is a flexible, clear plastic suction curette, 3.1 mm in outer diameter, consisting of two parts: (1) an outer sheath that is 23.5 cm in length with a lumen 2.6 mm in its inner diameter and a circular curette opening 4.0 mm proximal to its closed distal tip, and (2) an internal piston capable of traveling almost the entire length of the sheath when pulled by a knob at its proximal end. The piston is used to create negative pressure within the sheath of the instrument after its insertion into the uterine cavity.

From the Division of Reproductive Endocrinology and Infertility, Department of Obstetrics and Gynecology, Jefferson Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania.

Dr. Check is Associate Professor.

Dr. Chase is Clinical Assistant Professor.

Dr. Nowroozi is Clinical Assistant Professor.

Dr. Wu is Professor.

Rebecca Chern is Registered Nurse.

Address reprint requests to: Jerome H. Check, M.D., 1015 Chestnut Street, Suite 1020, Philadelphia, PA 19107.

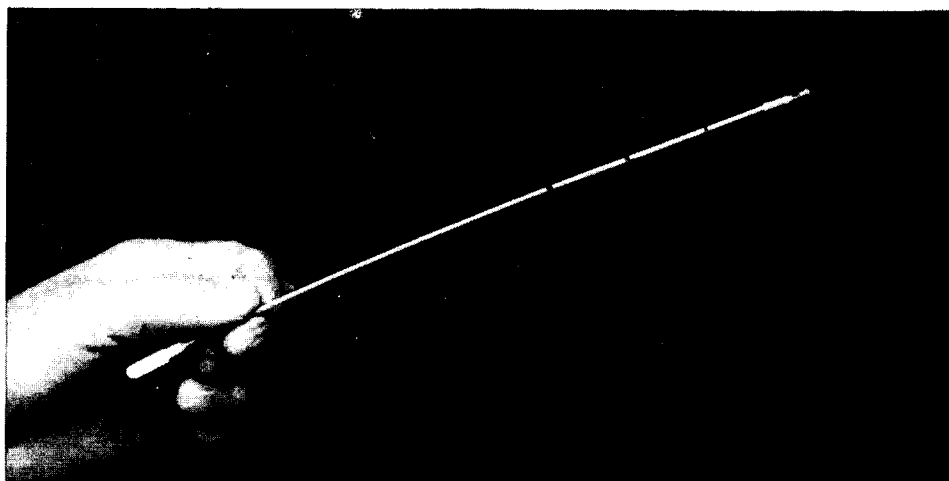


Figure 1
The Pipelle.

After standard preparation of the patient, the biopsy procedure with the Pipelle usually takes <30 seconds. With the piston of the Pipelle fully advanced to the distal tip of its sheath, the device is introduced through the cervical canal into the uterine cavity. Markings on the sheath at the 4-, 7- and 10-cm points provide a depth guide. Easily perceived tactile sensation provides additional control during insertion. The sheath is then stabilized with one hand, and the piston is drawn back completely in one continuous motion to create negative pressure within the lumen. The sheath is then simultaneously rotated between the thumb and forefinger (pill-rolling action) and moved in and out between the internal cervical os and the fundus of the uterus three or four times. These combined actions pass the curette opening through a helical arc against the walls of the uterus. During this passage the negative pressure within the sheath draws the endometrial tissue into the curette opening, where it is cut away and safely trapped within the lumen of the sheath. The Pipelle is then withdrawn, its extreme distal tip is cut off with scissors, and the sample is expressed into 10% buffered formalin by advancing the piston.

The endometrial biopsies were either sent to the Pathology Department, Thomas Jefferson University, to Damon Laboratories or to SmithKline Laboratories for processing the tissue and reading the biopsy.

Results

In 60 patients a sample was not obtainable with either the Pipelle or Novak curette. That probably was related to anatomic defects in the cervix or to

cervical stenosis or synechia. The 2,000 endometrial samples were obtained from 1,330 patients. Only 52 patients required a Novak curette to obtain the endometrial sample; 39 of those failures occurred after using Pipelles that were in a lot with a significant manufacturing defect subsequently rectified by the manufacturer.

In only 21 endometrial samples of the 1,948 obtained with the Pipelle (1%) was the quantity insufficient for dating; 16 of the 21 cases occurred with a Pipelle that came from the lot with initial product defects. Thus, in only 5 instances in the last 1,440 endometrial biopsies (0.3%) was the tissue insufficient for diagnosis. Cramps with the Pipelle sufficiently severe to preclude a second endometrial biopsy were reported by 174 patients (13%). By contrast, 31 of 52 patients (60%) experienced sufficiently severe cramps with the Novak curette to consider a second biopsy unacceptable (χ^2 test, $P < .01$).

Discussion

The Pipelle offers a quick endometrial biopsy technique (usually requiring <5 seconds and never >20) for obtaining a sample. The procedure was well tolerated by almost 90% of the patients.

The samples were sent to three different laboratories, including two commercial ones, and none of them had difficulty interpreting the biopsy with the amount of tissue obtained.

Another advantage of the Pipelle is that because it is made of flexible plastic, there is no risk of perforating the uterus. It comes sterilized and is disposable. As a single-use instrument, the Pipelle is cumulatively more expensive than the reusable

Novak curette, though the cost is partially offset by the elimination of cleaning and sterilizing time.

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