International Journal of Gynecology and Obstetrics 125 (2014) 116–120

Contents lists available at ScienceDirect

International Journal of Gynecology and Obstetrics

journal homepage: www.elsevier.com/locate/ijgo

CLINICAL ARTICLE

Sheathed versus standard speculum for visualization of the cervix

David A. Hill *, Michael L. Cacciatore, Georgine Lamvu

Department of Obstetrics and Gynecology, Florida Hospital Graduate Medical Education, Florida Hospital Orlando, Orlando, USA
Department of Obstetrics and Gynecology, University of Central Florida College of Medicine, Orlando, USA

ARTICLE INFO

Article history:
Received 7 August 2013
Received in revised form 24 October 2013
Accepted 28 January 2014

Keywords:
Bivalve
Cervix
Gynecologic examination
Speculum
Vaginal sidewall

ABSTRACT

Objective: To determine whether modifying a plastic speculum with a flexible sheath would improve visualization and decrease pain during vaginal examination. *Methods:* We conducted a prospective randomized controlled trial of 136 women undergoing vaginal speculum examination at an outpatient obstetrics and gynecology faculty practice. Patients underwent examination via a standardized technique with either a medium-sized plastic speculum (standard) or an identical speculum modified with a flexible polypropylene sheath (sheathed). Investigators recorded the percentage of the cervix visualized. After speculum insertion, patients recorded pain using a 10-cm visual analog scale. *Results:* There were no substantial demographic differences between the standard (n = 67) and the sheathed (n = 68) groups. Investigators were able to visualize a significantly greater percentage of the cervix using the sheathed speculum compared with the standard speculum (95.1% ± 8.2% vs 78.2% ± 18.4%; $P < 0.001$), representing a 21.6% improvement in visualization, and were able to visualize the entire cervix in 42 (61.8%) patients when using the sheathed speculum compared with 11 (16.4%) patients undergoing standard speculum examination ($P < 0.001$). Patients undergoing examination with the sheathed speculum reported a nonsignificant decrease in pain scores (1.0 vs 1.2; $P = 0.087$). *Conclusion:* A sheathed speculum significantly improves visualization of the cervix, without compromising patient comfort.

ClinicalTrials.gov: NCT01670630

1. Introduction

Speculum examination is used to obtain cervical cytology screening, perform gynecologic procedures, and evaluate patients with vaginal and cervical disorders. A successful speculum examination requires adequate visualization of the cervix in the gentlest manner possible. Throughout history, there have been almost 600 new or modified vaginal speculum designs, although very few were developed with rigorous study to determine whether they improved visualization or altered patient comfort [1]. Performing examinations with bivalve specula can be challenging owing to difficulty visualizing the cervix and upper vagina because of lateral vaginal wall laxity. To overcome this, some clinicians will cut off the ends of an examination glove finger or the end of a condom and slide these over the speculum blades, creating a sheath to retract the lateral vaginal walls [2,3]. Another option is to use a larger speculum, which may increase pain. These modifications can make it difficult to open the speculum blades and may cause pain when tension from the glove finger or condom pinches the blades against the cervix when withdrawing the speculum. Using a flexible sheath to improve visualization has not been studied.

The aim of the present study was to determine whether using a speculum modified with a flexible polypropylene sheath would improve visualization and decrease patient discomfort compared with the use of a standard speculum.

2. Materials and methods

A randomized single-blind trial was conducted at the Department of Obstetrics and Gynecology, Florida Hospital, USA, from August 17, 2012, to February 28, 2013. Consecutive patients between the ages of 18 and 50 years who presented to the outpatient obstetrics and gynecology faculty practice with conditions requiring vaginal speculum examination were screened for participation. The Florida Hospital Institutional Review Board approved the study, which was conducted according to Consolidated Standards of Reporting Trials guidelines [4]. Investigators informed participants of the risks and benefits of the study and obtained written informed consent. All patients volunteered to participate without incentives.

The primary goal of the study was to determine whether a sheathed speculum would improve the examiner's ability to visualize more of the patient's cervix. Therefore, because vaginal delivery can lead to increased lateral vaginal wall laxity, participation also required at least 1 vaginal delivery equal to or greater than a gestational age of 20 weeks and the presence of a cervix. Pregnancy can also cause patulous vaginal sidewalls, making speculum exams difficult, so we also offered participation to pregnant women who met the enrollment criteria. Demographic information was also collected (Table 1).

* Corresponding author at: 235 E. Princeton Street, Suite 200, Orlando, FL 32804, USA. Tel.: +1 407 303 1449; fax: +1 407 303 1424.
E-mail address: d.ashley.hill.md@flhosp.org (D.A. Hill).

0020-7292/$ – see front matter
http://dx.doi.org/10.1016/j.ijgo.2013.10.025

Table 1
Participant demographics.[a]

Characteristics	Sheathed (n = 68)	Standard (n = 67)
Age, y	36.3 ± 6.2	36.9 ± 6.6
Body mass index[b]	26.9 ± 5.1	27.5 ± 6.5
Number of vaginal deliveries >20 weeks	1.57 ± 0.74	1.81 ± 1.13
Pregnant	5 (7.4)	8 (11.9)
Indication		
Well-woman examination	55 (80.8)	53 (79.1)
Cervical cultures	7 (10.3)	6 (9.0)
Pap test only	1 (1.5)	2 (3.0)
Uterine or cervical procedure	5 (7.4)	5 (7.5)

[a] Values are given as mean ± SD or number (percentage).
[b] Calculated as weight in kilograms divided by the square of height in meters.

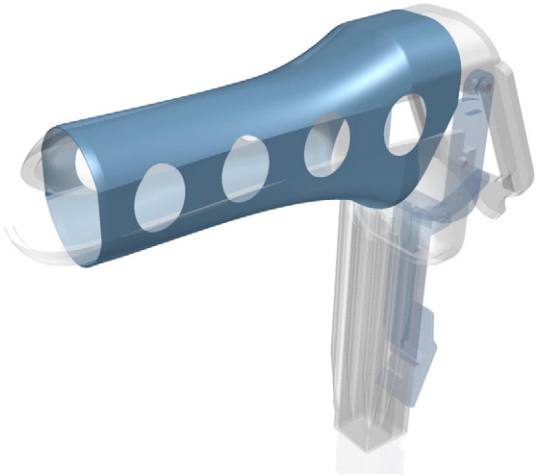

Fig. 1. Illustration of the sheathed speculum.

Screening excluded women who had vulvar atrophy, pain or lesions, vestibulodynia, vaginitis, dyspareunia, interstitial cystitis, or chronic pelvic pain, and women who were menopausal (as determined by amenorrhea for 12 months or more, use of hormone therapy, or elevated follicle-stimulating hormone levels) because these conditions can cause pain during speculum examination. Patients not fluent in English were also excluded from participation.

After enrollment, participants were randomly assigned to either the standard or the sheathed speculum arm using a permuted-block, computer-generated schedule (blocks of 4, which were sealed in opaque envelopes in sequential order unknown to either the participants or the investigators).

Patients underwent speculum examination (by either D.A.H. or M.L.C.) via a standardized examination technique identical for each patient. For the standard arm, investigators used a medium-sized plastic bivalve (Graves) speculum (KleenSpec; Welch Allyn, Skaneateles, NY, USA). Patients in the sheathed arm underwent examination with a nearly identical speculum modified with a single-use, flexible, transparent polyurethane sheath designed to retract the vaginal sidewalls (ClearSpec; ClearSpec, Boca Raton, FL, USA) (Figs. 1 and 2). ClearSpec provided the sheathed specula for the study. The polyurethane sheath was latex-free, wrapped completely around the blades of the speculum, and was attached with adhesive. It compressed flat when the blades were closed to facilitate insertion (Fig. 2) and contained circular openings on each side to enable visualization of the vaginal sidewalls and collection of vaginal sidewall samples. Both specula measured 3 cm across the tip of the blades and had a halogen light, which inserted into the base.

Patients were placed on an examination table in the dorsal lithotomy position with their feet in stirrups and buttocks just over the edge of the table. A privacy drape prevented patient visualization of which speculum was used. Investigators placed 0.3 mL of room-temperature sterile lubricant (Surgilube; Savage Laboratories, Melville, NY, USA) on each speculum by smearing a thin coating of lubricant over both blades in order to reduce pain during speculum insertion [5]. All speculum examinations were performed the same way, using a standardized insertion technique. Investigators educated participants prior to examination that 0 represented "no pain" and 10 "the worst pain imaginable," then patients were instructed to make a single vertical mark on a 10-cm, non-hatched visual analog scale (VAS) to indicate their level of pain. After a pause to allow the patient to mark her score, any other procedures such as cervical cultures/cytology screening or speculum removal were performed without marking the VAS.

In order to determine what percentage of the cervix was visualized, we used a standardized diagram of a cervix superimposed on a grid of equal-sized squares for each patient (Fig. 3). Immediately after opening the speculum, investigators drew the amount of cervix visualized onto the diagram. Two independent observers blinded to the type of speculum used counted the squares that represented the amount of cervix visualized, then calculated the percentage of visible cervix. The mean of the 2 values was used as the final measurement of cervix visualization.

Based on a pilot study at the Florida Hospital Department of Obstetrics and Gynecology, we estimated that the mean percentage visualization

Fig. 2. Photograph of flexible sheath in open and closed positions.