

Synthetic Hygroscopic Cervical Dilator Use in Patients With Unsatisfactory Colposcopy

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Objective: To assess the ability of a synthetic hygroscopic cervical dilator to make an unsatisfactory colposcopic examination satisfactory, thereby avoiding cervical conization.

Materials: From April 1991 to March 1993, 30 women with unsatisfactory colposcopic examinations underwent repeat colposcopy after a synthetic hygroscopic cervical dilator had been placed in the endocervical canal for approximately 2 hours.

Results: The reasons for initial unsatisfactory colposcopy in the 30 patients were squamocolumnar junction not seen in its entirety (18 patients, 60%), lesion not seen in its entirety (ten, 33%), and neither transformation zone nor lesion seen in their entirety (two, 7%). Complications were encountered in one patient from whom the dilator could not be removed completely. Of 29 patients undergoing repeat colposcopy, 23 (79%) had satisfactory examinations. In 15 of 30 patients, conization was avoided; it was required in six of 30 (20%) women for persistent unsatisfactory colposcopy (including the patient in whom the dilator broke) and in nine of 30 (30%) for other indications.

Conclusion: This experience suggests that a synthetic hygroscopic cervical dilator can be used in patients with an unsatisfactory colposcopy to achieve a satisfactory examination, thus avoiding cervical conization. (*Obstet Gynecol* 1995;85:30-2)

Patients with abnormal cervical cytology require evaluation to detect cervical intraepithelial neoplasia (CIN) and cervical cancer. Colposcopy, the first step in this evaluation process, is considered unsatisfactory if the entire squamocolumnar junction or the entire lesion cannot be seen. An unsatisfactory colposcopic examination occurs in 10-15% of all women under 45 years of age, and is even more frequent in postmenopausal women.¹ An endocervical speculum is not always help-

ful in allowing visualization of the squamocolumnar junction or the lesion. Thus, cervical conization is required for histologic diagnosis and the exclusion of cervical carcinoma.² Conization may be performed by cold knife, laser, or loop electrosurgical excision procedure. Cervical conization is not without complications. The procedure itself can be complicated by bleeding, infection, and anesthesia risks. Remote risks include premature labor and cervical incompetence. Future colposcopic examinations may also be compromised if the squamocolumnar junction recedes into the endocervical canal, making visualization difficult.¹ The financial cost of conization can also be substantial, particularly if the procedure requires a surgical facility and anesthesia.

The purpose of this study was to determine if the use of a hygroscopic cervical dilator, Dilapan (Gynotech, Lebanon, NJ), would facilitate visualization of the squamocolumnar junction and endocervical lesions in patients with unsatisfactory colposcopy, and to determine if cervical conization could be avoided in patients with unsatisfactory colposcopy.

Materials and Methods

During the study period, all patients undergoing evaluation for cervical dysplasia who had experienced unsatisfactory colposcopy were eligible for inclusion. They were enrolled at the University of Tennessee, Memphis, from April 1991 to March 1993, and at the Bowman Gray School of Medicine from December 1992 to March 1993. The eligibility criterion consisted of an unsatisfactory colposcopic examination despite the use of an endocervical speculum. Colposcopy was considered to be unsatisfactory if the squamocolumnar junction could not be seen in its entirety or if a lesion could not be completely visualized. Pregnant women and those with evidence of invasive cancer on a Papanicolaou smear or colposcopic examination were excluded.

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The evaluation protocol for the colposcopy clinic included repeat cervical cytology and colposcopic examination after application of 3% acetic acid. All colposcopic examinations were performed under direct faculty supervision. If the colposcopy was deemed to be unsatisfactory, an endocervical speculum was used in an attempt to achieve a satisfactory examination. Those who had persistent unsatisfactory colposcopy were offered entry into the study and the use of Dilapan. Informed consent was obtained from all patients enrolled in the study. The endocervical curettage (ECC) and cervical biopsies were performed after the Dilapan dilation.

The Dilapan dilator was placed into the endocervical canal for approximately 2 hours and held in place by a moistened gauze sponge. No pre-insertion medications were given, and subjects were allowed to remain ambulatory while the Dilapan was in place. On removal of the dilator, colposcopy was repeated immediately. Endocervical curettage and cervical biopsies were performed as indicated by the colposcopic findings. Inability to insert or remove the Dilapan, lack of dilation, and bleeding or tissue trauma were noted.

All colposcopic tissue specimens were reviewed at a weekly conference attended by the colposcopists and a single pathologist. At this conference, cytology, histology, and colposcopic findings were correlated. The ECC and biopsies were examined for disruption of epithelium interfering with diagnostic interpretation.

Results

Thirty subjects were enrolled in the study. Reasons for an initial unsatisfactory colposcopy were: squamocolumnar junction not seen in its entirety (18 patients, 60%), lesion not seen in its entirety (ten, 33%), and neither transformation zone nor lesion seen in their entirety (two, 7%). The mean age of the patients (\pm standard deviation) was 35 ± 12.4 years (range 15–65). The mean gravidity was 2.5 ± 2.4 (range 0–11), and the mean parity was 1.9 ± 2.0 (range 0–9). Twenty-nine of the patients were referred to the colposcopy clinic because of abnormal cervical cytology: squamous atypia (three patients), CIN I (11), CIN II (five), and CIN III (ten). One patient had undergone an endometrial biopsy for abnormal uterine bleeding, and squamous epithelium consistent with CIN I was found in the tissue sample. Five (16.7%) patients were taking oral contraceptives. There were 27 (90%) premenopausal and three (10%) postmenopausal women. Twelve (40%) patients had been treated previously for dysplasia: eight with cryotherapy, one with laser ablation, two with cold-knife conization, and one with unknown therapy.

Table 1. Colposcopic Outcome After Dilapan

Colposcopy after Dilapan	Groups by original colposcopic examination		
	Squamocolumnar junction not seen in entirety (N = 18)	Lesion not seen in entirety (N = 10)	Both (N = 2)
Satisfactory	13 (72%)	8 (80%)	2 (100%)
Unsatisfactory	4 (22%)	2 (20%)	0
Not repeated*	1 (6%)	0	0

* Dilapan broke on removal.

The Dilapan was inserted easily in all cases, although nine patients required use of a tenaculum to stabilize the cervix. Minimal, if any, patient discomfort was encountered. Complications interfering with colposcopic evaluation occurred in one patient in whom the Dilapan broke on removal, and the remaining fragment obscured the colposcopic examination. In two patients, there was minimal cervical dilation, and six patients had minor cervical bleeding, yet all had satisfactory repeat colposcopy. Gross tissue trauma was not noted. Histologic specimens lacked epithelial disruption interfering with diagnostic interpretation.

Table 1 outlines outcome of colposcopic examination according to reason for initial unsatisfactory examination. Colposcopy could not be performed in one patient because of the broken Dilapan. Twenty-three of 29 (79%) patients undergoing repeat colposcopy had satisfactory examinations.

In 15 of 30 patients, conization was avoided; it was required in six of 30 (20%) women for persistent unsatisfactory colposcopy (including the patient in whom the dilator broke) and in nine of 30 (30%) for other indications. Table 2 lists indications for those patients undergoing conization by either cold-knife conization or loop electro-surgical excision procedure.

Twelve patients had been treated previously for cervical dysplasia with either cryotherapy, laser ablation, or cold-knife conization. Ten of these patients had satisfactory colposcopy after use of the Dilapan. One patient who had previously undergone cold-knife conization had unsatisfactory colposcopy after the dilator was used, and the dilator broke in one patient who had had cryotherapy. The latter patient was unable to be reassessed with colposcopy.

Two of the three menopausal women had satisfactory colposcopy after use of the dilator. Twelve of the 15 patients referred for cytology of CIN II or III ultimately required conization. However, for those referred for squamous atypia or CIN I, 12 of 15 were able to avoid conization.

Six women had colposcopic lesions involving more than one quadrant of the cervix, of whom five had

Table 2. Indications for Conization After Dilapan

Indication for conization	Groups by original colposcopic examination		
	Squamocolumnar junction not seen in entirety (N = 8)	Lesion not seen in entirety (N = 6)	Both (N = 1)
Persistent unsatisfactory colposcopy	4*	2	0
Positive endocervical curettage	3	1	0
Lesion extending 2 cm into canal	0	1	0
Failed previous cryotherapy	0	1	0
Biopsy cannot exclude microinvasive carcinoma	1	1	1

* Includes patient with broken Dilapan.

biopsy-proven multifocal CIN II or III that required therapeutic conization despite satisfactory repeat colposcopy with the dilator. One of the six patients had histology of CIN I and was able to avoid conization.

Discussion

Dilapan is a hypan-polymer dilator currently approved for second-trimester pregnancy termination in the United States and several European countries. Cervical dilation with Dilapan occurs in two ways. The strongly hygroscopic polymer draws fluid from the cervical tissue into the rod, causing the cervical canal to soften. The rod expands uniformly in width only when absorbing fluid. This produces a strong outward radial force; the dilator expands rapidly from 3 mm to 8–10 mm. Because the polymer surface is soft, the tissue is not lacerated. Insertion of Dilapan is painless, and thus no pre-insertion pain medications are necessary.

Stern et al³ evaluated 18 women with abnormal cervical cytology in whom colposcopy was unsatisfactory despite the use of an endocervical speculum. The entire transformation zone was seen in 17 patients after 1–2 hours of Dilapan use; all of these women avoided conization. Golsis et al⁴ evaluated ten nulliparas who had abnormal lesions extending into the endocervical canal. Dilapan was inserted for 1 hour, and an average cervical dilation of 6.4 mm was attained. All ten patients had subsequent satisfactory colposcopic examinations and appropriate biopsies taken. Two underwent cone biopsies because of multifocal high-grade dysplasia. In these two studies, Dilapan use prevented conization resulting from an unsatisfactory colposcopy in 27 of 28 patients.

Endocervical curettage was not performed before

Dilapan placement to avoid potential compromise of the subsequent colposcopic examination. In this study, only four of the 30 patients had positive ECCs. Although conization could not be avoided in these four patients, post-Dilapan evaluation provided the colposcopist with information regarding the extent of treatment required.

The results of this study confirm that the use of Dilapan can convert an unsatisfactory colposcopy to a satisfactory examination. In this study, 23 of 29 (79%) patients undergoing repeat colposcopy had a satisfactory examination. Conization for unsatisfactory colposcopy was avoided in these patients. However, nine of 29 (31%) patients still required conization to treat multifocal disease or endocervical dysplasia, or to rule out the diagnosis of microinvasive carcinoma. Fifteen of 30 patients were evaluated for cytology of CIN II or III. The incidence of conization for indications other than unsatisfactory colposcopy may be lower in other clinical settings, where most patients undergoing colposcopic evaluation have squamous atypia or CIN I.

The Dilapan dilator is useful in avoiding conization for unsatisfactory colposcopy in pre- and postmenopausal women. Prior treatment for dysplasia does not alter its efficacy. In patients who also have multifocal disease or an endocervical lesion, and who will require conization for other indications, Dilapan may allow a shallower cone by assisting in visualization of the extent of endocervical disease.

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