An Alternative to Conization: Semilunar Biopsy-Repair

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□ Semilunar biopsy repair (SBR) provides a biopsy equal to conization and restores to physiologic function a lacerated, inflamed cervix with fewer complications. Unlike conization, SBR heals promptly.□

It is widely accepted that when a suspicious Papanicolaou smear is followed by a nondiagnostic punch biopsy, the more extensive procedure of conization must be done. This paper presents a suggested alternative to conization. We will review the disadvantages of the latter procedure as documented in the most recent literature, describe the alternative method we propose, and discuss the comparative aspects of the two operations.

Disadvantages of Conization

It is doubtful that any newly conceived operation with the same high incidence of complications as conization would receive the same general worldwide acceptance. Nonacceptance would be practically assured if any alternative operation were as ill-conceived from an anatomic, physiologic, or surgical point of view.

Conization is an incisional and excisional operation, not a procedure, in which the basic surgical techniques of cutting, ligating, and suturing are performed to achieve optimal healing. Sutures are used primarily for control of bleeding only. A cone is not adaptable geometrically to the frequently irregular-shaped multiparous cervix because of its fishmouth, unilateral, or stellate laceration, and to its rounded lips of hypertrophy or everted lips of ectropion (Figure 1). Uniform biopsy specimens are difficult, if not impossible, to obtain by conization, nor can the procedure be standardized. A trumpet-shaped channel is created in an organ whose natural canal is spindle-shaped or fusiform. Hence, the multifunctional protective mucus plug is more or less lost by removal of the cells that produce it and by enlarging the external os that retains it.

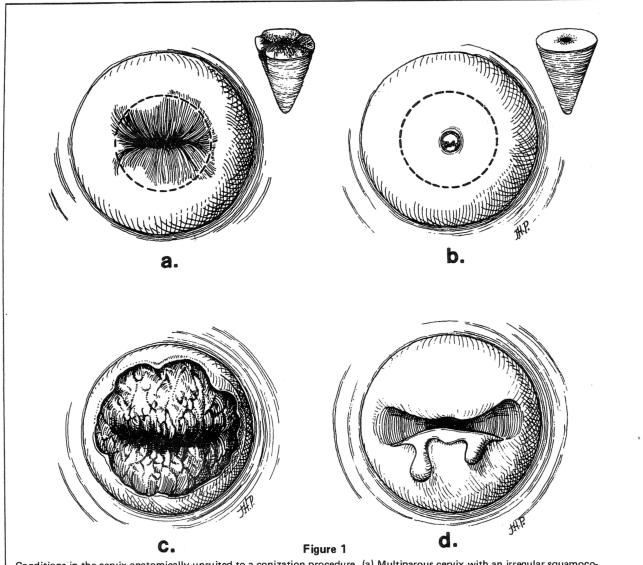
With a cone or ring biopsy, a circular, not infrequently rigid cicatrix is created, whereas the function of the cervix is to cyclically soften, lengthen, enlarge, contract, and dilate. Since the resulting wound cannot possibly be closed by accurate approximation of tissue, healing is necessarily prolonged, six to 10 weeks, by secondary intention. Because of the incidence of complications, conization is not lightly undertaken. It is indicated only when less traumatizing diagnostic methods fail to establish the diagnosis, e.g., repeat smears, repeated or multiple punch biopsies, directed punch biopsies by Schiller's solution, colposcopy, or radioactivity. Conization immediately following a single Papanicolaou smear is generally condemned.

Credit should be given to conization for the lower world-wide, crude death rate from cancer of the cervix by establishing a positive diagnosis as a basis of treatment. But what of those patients who did not have cancer, who in the same statistical period sustained some serious complication, even death, as a result of the operation itself?

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Conditions in the cervix anatomically unsuited to a conization procedure. (a) Multiparous cervix with an irregular squamocolumnar junction. A circular cone could easily miss portions of this line. (b) Virgin cervix where a cone would excise an excess of stroma, remove the columnar cells that produce the physiologically important mucus and enlarge the external os which normally retains it. (c) Ectropion and (d) fishmouth laceration, where an "adequate cone" would require what amounts to an amputation of the cervix.

It is not always easy to justify an individual misfortune on a statistical basis, as we are prone to do. What is needed is an adequate biopsy, simpler than the cone, which avoids its well-known disadvantages. We believe semilunar biopsy-repair meets these requirements.

Semilunar Biopsy-Repair

SBR furnishes adequate biopsy tissue and at the same time restores the cervix to a healthy, nulliparous state. A

modification in the method of suturing used in 72 more recently operated-on patients has so far eliminated the occasional occurrence of serious secondary hemorrhage (in 58 of 843 patients) which we previously reported. Minor bleeding encountered in these patients has been readily controlled simply by bed rest for one or two days. Most patients remain ambulatory throughout their convalescence but curtail their activities for about one week following the surgery. Our total experience with SBR, to

date, comprises some 1200 patients and extends over a period of 35 years (1938 to 1973) with an average follow-up of 10.6 years.

We present this summary of SBR (including the recent modification of suturing) for comparison with conization. Such a comparison should be of interest to all who care for women with symptoms of chronic cervicitis and who follow them with periodic Papanicolaou smears.

Method

The objective of SBR is twofold: (1) To obtain bilateral uniform-in-width semilunar strips of tissue, to include the important squamocolumnar junction, leaving a 0.5 cm. bridge of undisturbed tissue between their ends in the anterior and posterior lips; and (2) to restore the physiologically vital mucus plug by reconstructing from the intact tissue bridges a small caliber, virginal-type external os, 1 cm. in circumference.

The patient is selectively operated upon as soon after a menstrual period as possible. With the patient anesthetized and in the lithotomy position, a Papanicolaou smear is first taken. The perineum and vagina are then prepared with soap and water and povidone-iodine solution (Betadine, Purdue Frederick). A weighted speculum is inserted. With Allis forceps, the lips of the cervix are grasped at their centers, well within the cervical canal, for traction and immobilization. Care is necessary to avoid traumatizing the tissue bridges to be used for reconstruction of the new external os. The semilunar areas to be removed are first delineated by marking incisions. Each is then carefully excised in a uniformly thick intact piece by going over prominences and into crevices under direct visualization (Figure 2).

On occasion where there is considerable hypertrophy, a wedge of cervical stroma also must be removed, en bloc, with the semilunar biopsy as the base. The lips are then easily approximated as described. This is important, for if there is undue tension on the sutures, they will pull through in a few days, and the wound will fall apart. Triple sulfa cream (Sultrin, Ortho Pharmaceuticals) is introduced into the vagina immediately following surgery and daily thereafter by the patient to control local infection during the healing period. The patient is instructed to curtail activities for one week to prevent hemorrhage. Postoperative sounds or probes are unnecessary and should not be used since stenosis is not a problem. The approximated intact, untraumatized tissue bridges do not adhere to each other. Healing is complete within two weeks.

Followup care is minimal. The patient returns only for inspection and assessment of healing after one week, and again after two weeks. Normal sexual relations and

full activity may be resumed after the first menstrual period following surgery. A second Papanicolaou smear is taken after the third menstrual period to compare with the smear taken at the time of surgery.

Discussion

It is important to discuss the comparative aspects of the complications and characteristics of conization versus SBR.

Incidence of Complications

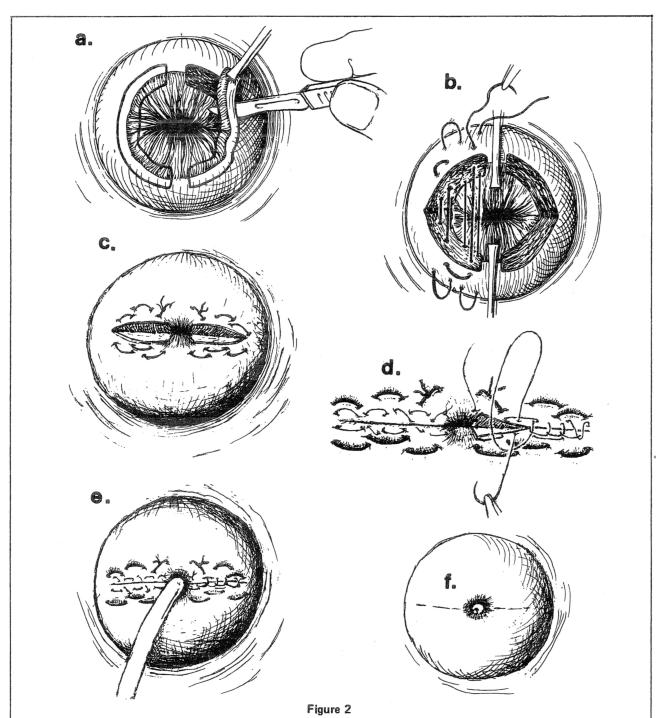
Slow healing by secondary intention, scarring, atresia, and stenosis are among the complications of conization which are deterrents to use of the operation in women of childbearing age. In our experience, SBR is essentially free of postoperative complications, including bleeding, when performed by the technique described. Furthermore, because of the restored, protective mucus plug, the endocervix is no longer exposed to the inflammatory influence of the acid and contaminated vaginal secretions.

Adequate Biopsy of the Squamocolumnar Junction

Biopsy of the cervix should include the squamocolumnar junction where carcinoma begins and from which it spreads. The more complete and certain is the excision of this tissue for histologic diagnosis, the better the biopsy. A presumed advantage of conization for biopsy is that it theoretically includes the entire squamocolumnar ring. Although simple in concept, under the best of conditions it would take a skilled artist to excise a well-proportioned cone of cervical tissue of a predetermined size using a flat, pointed instrument (e.g., a #11 Bard-Parker blade). With the constantly changing slant of the knife, but keeping its point precisely and blindly at the apex, it would be virtually impossible to excise a three-dimensional true, symmetrical, or accurate cone, even if a probe, dilator, or closed thumb forceps is used in the canal as an "aiming quide."

Conization becomes even more formidable when we consider that the uterus is a mobile structure and the cervical stroma so resistant that a to-and-fro "saw motion" is needed to accomplish excision without penetrating the uterine wall or injuring adjacent organs. Faced with such difficulties the advice is well taken that the operation should preferably be done by a skilled gynecologist.

In SBR, the 1 cm. length of the junction left undisturbed is at the most prominent, easily accessible site where it can be watched and studied with Papanicolaou or repeat biopsies as indicated. As a biopsy which includes most of this important squamocolumnar zone, SBR must be considered as equivalent, if not superior, to a cone,



Steps in a semilunar biopsy-repair (SBR): (a) Excision of biopsy tissue under direct visualization, with the squamocolumnar line centrally located. Note minimal amount of stroma excised. (b) A polyglycolic acid suture on a swedged, tapered needle is used first to approximate the columnar epithelium by placing the suture deep in the cervical stroma. Needle emerges always through the denuded area, close to the columnar layer, and returns through the mid-portion of the denuded area. (c) Columnar layer approximation completed. (d) A #00 Dexon suture is used to approximate the vaginal mucosa. Left side shows approximation using a continuous mattress suture; right side shows alternate use of a lock stitch. (e) Squamous layer approximation completed, with sound in the external os. (f) Shows virginal type cervix after healing is completed in less than two weeks.

and clearly superior to multiple punch biopsies.

Standardization of Surgical Procedure

Uniform cones may be obtained by coning instruments, but such cones are rigidly fixed as to size and shape according to the instrument used. Unfortunately, the contour of the cervix varies from patient to patient and an adequate cone must vary accordingly. If the coning instrument makes a thermal cut, the specimen may be well proportioned but the heat-altered tissue poses difficulty for the pathologist who must make the important diagnosis

Operators are widely divided in their opinions as to the proper method of doing a cone. These vary from a shallow, wide, deep or extended, or liberal cone, to a multiple biopsy cone. This confusion is illustrated by the "22 modes of conization" or more that have been suggested by Adelman and Hajan. Where such confusion exists it is probable that no particular cone can be accepted as standard.

Actually, a cone can no more circumscribe the irregularities of the usual multiparous cervix than a round peg can fit a square hole. A suggestion has been made that these irregularities be ironed out and the cervix made to fit the operation by "ballooning" it with an infiltrating solution, a feat difficult to accomplish in view of its dense resistant stroma. It is frankly stated that no universal method of conization can ever be achieved because of individual variations in contour of the cervix and the skill of the individual surgeon. Cone biopsies submitted to the pathologist are seldom alike.

Since SBR is done under direct visualization at all times, it is adaptable to any conceivable contour of the cervix. Requirements as to width, depth, and quantitative relationships to the squamocolumnar junction can be met easily and the pathologist consistently furnished with uniform biopsies properly oriented.

Choice of Surgical Procedure as a Method of Treatment

Conization, as first introduced in 1815, was used as a method of treatment of chronic cervicitis, infertility, dysmenorrhea, and erosion. It fell into disrepute in the mid-nineteenth century because of the immediate and long-range complications with which it was associated. When the Papanicolaou smear was accepted in 1943 as a screening procedure in cancer prevention, conization was resurrected to fill the need for a definitive biopsy and, it was hoped, as a method of treatment as well. Thus, when a smear indicated a suspicion of malignancy, the compli-

cations of conization were accepted by the profession as justified. However, the high incidence of residual cervical carcinoma found in coned uteri removed by hysterectomy (15 to 80 percent), plus recurrences following conization regardless of the type of cone used, should condemn the procedure as unsatisfactory for eradicating cervical cancer.

In application, the concept that a more extensive cone theoretically would be more successful was found to be erroneous in that it increased the severity of the complications proportionately without materially eliminating the incidence of residual carcinoma. Moreover, the scarring and not infrequent atresia or stenosis that is part of this operation can interfere with free exfoliation and make followup Papanicolaou smears unreliable. Accordingly, conization has come to be regarded not as a method of treatment, but primarily as a definitive diagnostic procedure to be used only when Papanicolaou smears or punch biopsies are equivocal. Hence, the average age at which a conization is done is at or near the menopause when atypical cells in smears are most common and the onset of carcinoma is most likely to occur.

SBR, on the other hand, not only furnishes an adequate biopsy but is a method of treatment as well. It corrects earlier benign lesions that are often associated with symptoms of abnormal bleeding and vaginal discharge in women with negative smears. These "high-risk" patients are relieved of their symptoms and are quickly converted into a "low-risk" category. An inflamed, discharging, lacerated multiparous cervix (or nulliparous cervix with eversive cervicitis) is restored to a clean, functioning virginal state generally recognized as resistant to the onset of cancer. Healing is rapid, with thin linear laterally placed scars beside a nonstenosed yet small external os retaining a protective clear mucus plug. Exfoliation can continue and followup Papanicolaou smears can be taken with complete confidence.

Papanicolaou Smear and Surgical Biopsy in Diagnosis of Cancer

A Class III, IV, or V Papanicolaou smear requires either an early repeat smear or immediate biopsy. A Class II smear does not indicate the need for a biopsy, but such cases bear careful watching. If repeat smears are unchanged or show increasing dysplasia, a biopsy is indicated. A Class I smear is considered to be of no concern. Yet it has happened that carcinoma *in situ* or invasive carcinoma has been discovered in the surgically removed uterus where only a Class I or II smear had been found.

In contrast, SBR is sufficiently free from complica-

tions to warrant its use in all age groups, as a biopsy check, regardless of the results of a Papanicolaou smear. And it serves as a method of treatment to convert high-risk patients to a low-risk category before significant changes in the Papanicolaou smear have taken place.

Management of the Patient with Positive Biopsy

When hysterectomy is indicated by conization, unless a hurried diagnosis by frozen section is made to permit hysterectomy within 24 to 48 hours, or preferably immediately, a delay of six to 10 weeks or more is otherwise required for complete healing to occur to avoid operating in a highly contaminated field. A frozen section is not the best way to make an accurate histologic diagnosis, and it leaves the tissue partially ruined for study in the ideal manner when an opinion based upon the frozen section is equivocal.

When indicated by SBR, which heals by primary intention, hysterectomy can be safely performed in two weeks or less, thus giving the pathologist the necessary

time to do his best work and sparing the patient the emotional trauma of waiting for the hysterectomy after the diagnosis is made.

Summary

Semilunar biopsy-repair (SBR) provides a biopsy equal to conization and restores to physiologic function a lacerated, inflamed cervix, with fewer complications. The procedure has been performed successfully in more than 1200 patients. Unlike conization, which heals by secondary intention, SBR heals promptly. In patients with chronic cervicitis, it restores the mucus plug, reestablishes physiologic function of the cervix, and relieves the symptoms with a meaningful degree of cancer prophylaxis.

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