

The importance of cryosurgery in gynecological practice

Kriochirurgia w praktyce ginekologicznej

Rokita Wojciech

Department of Obstetrics and Gynecology St Alexander City Hospital, Kielce, Poland

Abstract

Cryosurgery is a destructive technique that was introduced to gynecology in the late 1960s to treat CIN (cervical intraepithelial neoplasia). Tens of thousands of patients have been treated with cryotherapy, which has proved to be a predictable, reliable treatment technique, with limited side effects and morbidity. This method is used to treat cervical, vaginal, endometrial and vulvar lesions.

This study aims at determining the current state of knowledge on the place of cryosurgery (cryotherapy) in gynecological practice. Research was carried out to find current data on indications, contraindications, techniques of treatment and equipment necessary to perform cryosurgical procedures in gynecology.

Cryosurgery is a safe, relatively inexpensive and easy to perform procedure for treating women with lower genital tract pre-malignant diseases without impairing their fertility.

Key words: **cryosurgery / gynecology / treatment / premalignant lesions /**

Streszczenie

Kriochirurgia jest ablacijną metodą leczenia wprowadzoną do praktyki ginekologicznej pod koniec lat 60-tych ubiegłego stulecia, początkowo tylko do leczenia śród nabłonkowej neoplazji szyjki macicy. Od tego czasu zakres wskazań dla tego typu terapii uległ znacznemu poszerzeniu i do chwili obecnej na całym świecie wykonano tysiące zabiegów kriochirurgii ze wskazań ginekologicznych.

Celem pracy jest przedstawienie aktualnego stanu wiedzy na temat tej metody terapeutycznej oraz określenie jej miejsca w nowoczesnej praktyce ginekologicznej.

Słowa kluczowe: **kriochirurgia / ginekologia / leczenie / wskazania /**

Adres do korespondencji:

Wojciech Rokita
Department of Obstetrics and Gynecology St Alexander City Hospital, Kielce, Poland
Kościuszki 25, 25-315 Kielce, Poland,
e-mail: rokita@kielce.com.pl

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Introduction

Cryosurgery is a destructive technique that was introduced to gynecology in the late 1960s to treat CIN (cervical intraepithelial neoplasia). Tens of thousands of patients have been treated with cryotherapy, which has proved to be a predictable, reliable treatment technique with limited side effects and morbidity [1].

History

Therapeutic use of cold temperature has existed for a long time in the medical setting, first and foremost for its anaesthetizing effects. But the damage that cold can do has also been noted from the earliest times and has been mentioned in both civilian and military sources, including historical accounts discussing the effect of cold climates on various body tissues [2]. The first successful treatments of malignant diseases using cold were reported in England between 1845 and 1851 by James Arnott (1797-1883), who used iced saline solutions at temperatures of -18°C to -24°C to treat advanced breast and uterine cancer [3]. Cryosurgery was first reported to be used in the therapy of cervical intraepithelial neoplasia (CIN) by Crisp [4]. It was quickly adopted as the major form of therapy for cervical intraepithelial neoplasia lesions (CIN) after appropriate diagnosis. Two decades later, Benedet and associates also reported excellent results in cryosurgery for CIN 3 lesions with a failure rate of only 5,5% [5]. Similarly, Collins and colleagues [6] and Ostergard and associates, used cryosurgical techniques in patients with gynecologic inflammatory diseases to treat chronic cervicitis [7].

Historically, the use of cryoablation to treat the endometrium was first described in 1967 by Cahan and Brockunier [8]. Drogemueller performed a series of cases in the early 1970s [9] and Pitroff treated 67 women in the early 1990s [10]. A decade later, CryoGen Inc developed the Her Option[®] Cryoablation Therapy System which was approved by FDA for endometrial ablation in April 2001.

Principles of cryosurgery

Cryosurgery involves cooling the tissue until cryonecrosis occurs. An important principle of physics is that the heat is transferred between entities, as opposed to cold being added to an entity. During the cryotherapy of the cervix, heat is removed from the cervix to the cryoprobe tip at a rate faster than heat can be delivered to the cervix through blood flow from the cervical branches of uterine arteries. Hypothermia is achieved by passing compressed refrigerant gas (carbon dioxide or nitrous oxide) through a small orifice at the tip of cryoprobe, the Joule Thomson effect. Temperatures of less than -20°C are required for tissue necrosis [11]. During cryotherapy freezing of tissue appears after formation of an iceball. The cellular membranes are pierced by the ice crystals that form, releasing the intracellular contents and causing vascular thrombosis and microcirculatory failure anoxia and ischemia [12]. A double freeze (freeze-thaw-freeze) treatment is more effective than a single-freeze procedure [13].

A method of rapid freeze and a slow defrost is the most effective method of inducing tissue damage. The temperature of cryoprobe tip, using a nitrous oxide system, is approximately -65 to -75°C during cryotherapy. The temperature at the edge of the frozen tissue will be around -20°C . The mean probe tip temperature should be -60°C [14].

During cryotherapy two clinically relevant temperature zones

are produced within the iceball. The lethal zone is the frozen area located between the cryoprobe tip and -20°C isotherm. Tissues in this area will not survive the freeze. The more peripherally located zone is represented by frozen tissue with temperatures between -20°C and 0°C . Tissue in the recovery zone is temporarily frozen during the procedure but will remain viable after defrosting. The recovery zone generated by most cryosurgical units represents the most peripheral 2mm rim of frozen tissue adjoining the leading margin of the iceball [15]. The direct thermal effect of cryotherapy determines eventual treatment success. Neoplasia within the lethal zone is readily destroyed by cryonecrosis. However, adjoining tissue temporarily frozen in the recovery zone and more peripherally positioned non-frozen residual minor neoplasia may regress following cryotherapy through the actions of the immune system. After cryotherapy a large central viral (HPV) load is debulked and the immune system may be better able to eradicate a limited amount of surrounding low-grade residual disease [16].

Equipment

Cryosurgery can be performed using carbon dioxide or nitrogen oxide as the coolant. Carbon dioxide is cheaper than nitrous oxide but the temperature achieved by nitrous oxide is lower than that obtained by carbon dioxide. Hence, the depth of tissue destruction is greater with nitrous oxide and it is the preferred coolant [17]. The equipment needed for cryosurgery of the cervix is listed in table I.

Table I. The equipment needed for cryosurgery (cryotherapy) [18].

The equipment required for cryosurgery
<ul style="list-style-type: none"> • Cryogun • Large nitrous oxide tank with a pressure gauge and at least 20 psi of pressure in the tank • Various sizes and shapes of cryotips • Water-soluble lubricating gel • Vaginal speculum • Colposcope • 3 to 5% acetic acid or vinegar • Vaginal wall retractors • Disinfectant for cryoprobes

Nitrous oxide tanks with a pressure gauge should have high-strength gas lines pretested 2000 PSJ. This will allow for a faster and more effective freeze. It is also important to have several cryoprobe tips available to choose from, including an assortment of shapes and sizes. This will allow the clinician to choose the appropriate size and maximize the chances of cure success [18]. The choice of a cryoprobe to be used depends on the size of the lesion and the morphology of the transformation zone. Use of a flat cryoprobe or one with a small central nipple diminishes the possibility of cervical stenosis. This type of probe will also be less likely to cause the squamous cellular junction to recess into the endocervical canal, resulting in an unsatisfactory colposcopy in following examination [19]. The best option for the sake of maximizing patient cure is to use a nipple-shaped probe tip with no more than a 5-mm nipple extension for most initial freezes.

Indications for cryosurgery

Cryosurgery is a technique used for treating cervical, vaginal, endometrial and vulvar lesions. This method is mainly used to treat cervical changes. The main indications for cryosurgery of cervical lesions can be divided into two groups: benign indications and premalignant indications. The benign group of indications for cervical cryosurgery includes: recurrent cervicitis and cervical erosion (ectropion). If women are to receive cryosurgery due to such benign indications, the cytologic and colposcopic assessment is essential prior to the procedure to exclude significant neoplasia. Normal Papanicolaou (Pap) smear is not sufficiently sensitive to guarantee normality. The premalignant indication for cervical cryotherapy is a biopsy-confirmed premalignant cervical lesion (CIN1-CIN3). It is probably best reserved for small sizes lesions and LSIL (low grade squamous intraepithelial lesions) [16].

Cryosurgery of CIN

The International Agency for Research on Cancer (IARC) states that cryosurgery (cryotherapy) can be used in the treatment for CIN provided that:

- the lesion is in the ectocervix without extension to the vagina and/or endocervix
- the lesion is entirely visible and does not extend more than 2-3 mm into the cervical canal
- there is no evidence of invasive cancer or glandular involvement and the endocervix is normal
- the lesion can be adequately covered by largest available cryoprobe tip of 25 mm diameter [13]

The American Society for Colposcopy and Cervical Pathology (ASCCP) in 2006 ASCCP guidelines stated that ablative therapy is acceptable provided that:

- colposcopy is satisfactory, the endocervical curettings are negative for CIN and cancer and it is not a recurrent lesion following prior therapy [20]
- cryotherapy is used, in cases of advanced stages of cervical cancer, to control the bleeding while awaiting conventional therapy [21]

The Polish Gynecologic Society Recommendations in 2009 state that performing cryosurgery of CIN is acceptable under the strictly outlined conditions that allow performing this type of procedures safely [22].

The cryosurgery of CIN is not recommended by the National Health Service Practice Guidelines due to higher failure rate [23].

Benedet et al. determined parameters that are necessary to increase success rates in the treatment of CIN [24]:

- minimal endocervical extension of the transformation zone
- fully visible lesion margins
- excellent probe – epithelium contact
- satisfactory iceball formation extending 3-4 mm beyond the lesion margins
- adequate cryotherapy gas pressure

Cryosurgery is a safe, useful, inexpensive procedure that should be considered for any patient (particularly young and nulliparous) with CIN 1 or 2, confined to one or two quadrants of the exocervix [1].

Cryosurgery of the vagina

Cryotherapy of vaginal lesions is not a popular method in treating vaginal intraepithelial neoplasia (VAIN). However, Townsend has reported treatment of VAIN by cryosurgery [25]. Due to possible post-therapeutic complications, he recommends a single freeze-thaw cycle with the iceball extending to 3 mm of colposcopically normal epithelium. Detailed colposcopic assessment is required for the management of such vaginal lesions. If the lesion cannot be covered by the probe tip, it should be subdivide for individual freezing with the iceballs overlapping. Effectiveness and safety of the cryosurgery in the treatment of VAIN has not been estimated.

Cryosurgery of the vulva

Vulvar lesions can be treated by cryotherapy. Townsend states that VIN (vulvar intraepithelial lesion) lesion less than 2 cm in diameter can be treated by cryosurgery. He recommends nitrous oxide, a single freeze-thaw cycle and extension of iceball at least 3 mm on to colposcopically normal epithelium [26]. Biopsy of the lesion and colposcopic assessment are the necessary elements of the management process. Nevertheless, CO₂ laser and ultrasonic surgical aspirator are currently most popular in VIN treatment [17].

Cryosurgery can be used as a palliative therapy in case of recurrent fungating cancer of vulva and perineum. In these cases cryotherapy can be also used to decrease bleeding, malodours discharge and patient discomfort [26].

Cryotherapy has been used on the vulva to eradicate small warts. The freezing induces localized tissue necrosis. Although healing usually is satisfactory and numbing effects induce analgesia, application is limited by the delivery system and probe tip sizes. Larger condylomatous masses are more difficult to treat by cryotherapy and in such cases excisional methods are more preferable [27].

Cryosurgery has also been used to treat urethral prolapse. The method is extremely effective in producing complete annular necrosis and healing of the prolapsed tissue. This procedure can be performed without anesthesia [28].

Cryoablatio endometrii

Cryoablatio endometrii is a cryosurgical technique for endometrial destruction. The uterine cryoablation therapy system consists of a 5,5mm cryoprobe that is inserted into the uterine cavity. Transabdominal sonography is used to confirm proper placement of the probe and to follow the growth of the iceball that forms during the treatment cycle. Once activated, the system circulates a mixed fluid through the probe to achieve intrauterine temperatures between -90°C and -110°C. The device is directed into the cornual regions, each of which is treated individually. Cryoablation of the endometrium is an effective therapeutic option for the management of menorrhagia. Later definitive surgery may be required in 6% to 20% of women after endometrial cryoablation [29].

In the pilot study authors used the cryoablation of the endometrium in 10 women with menorrhagia and obtained high therapeutic efficacy of this method. The advantage of this therapeutic method is the simplicity of its implementation, low cost and safety [30].

Contraindications for cryosurgery

In gynecology cryosurgery is mainly used in therapy of the cervical lesions. The contraindications to cryotherapy of the cervix include (table II):

Table I. Contraindication for the cryosurgery of the cervix.

Contraindication for the cryotherapy of the cervix
<ul style="list-style-type: none"> • presence of vulvitis, vaginitis, cervicitis and or pelvic inflammatory disease • cervical cancer • in-utero DES exposure • menstruation • unsatisfactory colposcopy • positive endocervical curettage • persistent CIN after previous cryotherapy • high-grade CIN • lesions larger than two cervical quadrants in size • lesions greater than 3 cm in diameter • lesions that extend more than 5 mm into the endocervical canal • exophytic, nodular or papillary cervical lesions • low grade CIN preceded by a cytology report of HSIL • discordance between review cytology, colposcopy and histopathology

(a) presence of vulvitis, vaginitis, cervicitis and/or pelvic inflammatory disease. The following should be adequately treated before performing cryosurgery [17], (b) cervical cancer, (c) pregnancy, (d) in-utero DES exposure because of an increased risk for cervical stenosis, (e) menstruation, (f) unsatisfactory colposcopy, (g) positive endocervical curettage, (h) persistent CIN after previous cryotherapy, (i) high-grade CIN, (j) lesions larger than two cervical quadrants in size, (k) lesions greater than 3 cm in diameter, (l) lesions that extend more than 5 mm into the endocervical canal, (m) lesions with irregular surface (exophytic, nodular or papillary) or obstetrical scars that hinder proper application of the cryoprobe tip to the cervical transformation zone [16], (n) low grade CIN preceded by a cytology report of HSIL (high squamous intraepithelial lesion) or AGC-NOS (Atypical Glandular Cells Not Otherwise Specified), i.e. discordance between review cytology, colposcopy and histopathology. In such circumstances a diagnostic excisional procedure is recommended [31], (o) a woman presenting with menstrual problems (especially intramenstrual bleeding) and a cervical ectropion. Endometrial disease has to be ruled out by endometrial biopsy before performing cryosurgery [16].

Complications of cryosurgery and side effects of treatment

Cryosurgery is the most acceptable of all the ablative techniques performed in gynecology. Cryotherapy of the cervix is usually accompanied by pain and cramping of varying degrees [32]. About 20% of patients after cryosurgery of the cervix experience a profuse watery discharge for 2 to 3 weeks after cryotherapy and some patients experience light spotting lasting for about two weeks. Late complications of cryosurgery are rare and consist principally of cervical stenosis in 1 to 4% of patients

[1]. Serious complications related to cryotherapy are rare. Possible complications include vasovagal episodes, infection, mucometria and bleeding. There is no evidence that cryotherapy has any adverse impact on fertility or pregnancy outcome [33]. After the cryotherapy treatment the cervix heals well and there is a characteristic appearance of radial ridging. The squamocolumnar junction (SCJ) is often found to be lying just within the external os. But in many patients cervical anatomy has been changed after cryosurgery and the SCJ may not be visible because of moving into cervical canal [34].

Results of treatment

Although patient acceptability is very high, cryosurgery is becoming less popular, largely as a result of published results indicating higher failure rates. Cryotherapy has a lower clearance rate than other conservative techniques. Some authors have claimed clearance rates of about 95% [35]. However, the general experience appears to be that a rate of 85% is more frequently seen [36]. Average cure rates in relation to severity of cervical dysplasia have been reported, 94% cure rate for CIN1, 93% for CIN2, and 84% for CIN3/CIS [37]. Like other local destructive methods, the size of the lesion and not the biologic stage of the CIN seems to influence the chances of success and of complete clearance. Although a long-term analysis of 2839 patients treated by cryotherapy demonstrated a negligible risk for residual disease [38], cervical cancer has been reported in women following cryotherapy of CIN [39].

At present cryosurgery of the cervix has lost ground to loop excisional procedures (LLETZ/LEEP), which can also be performed on an outpatient basis and provide a good specimen for histology [40].

Conclusions

In the past cervical neoplasia was managed primarily by excisional surgery: either cold-knife conization or hysterectomy. These surgical approaches conveyed a small but significant risk of inadvertent serious harm and morbidity. A profound reduction of surgical complications was noted following the implementation of cryotherapy to treat premalignant cervical diseases [16].

Modern cryosurgery achieves efficiency and effectiveness through good, uncomplicated surgical results, a high cure rate, and a high quality of life for patients. The "power of cold" needs to be understood and accepted by both surgeons and other therapists [41].

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