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Efficacy of Cryotherapy in Treatment of Benign and Premalignant Cervical Lesions

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Abstract

Introduction: Benign cervical lesions, such as cervical erosion and chronic cervicitis, frequently present with symptoms like vaginal discharge, pelvic pain, dyspareunia, and abnormal bleeding. These symptoms significantly impact women's quality of life, often leading to ineffective outpatient treatments. Additionally, premalignant cervical lesions pose a risk of progression to cervical cancer, which is a leading cause of cancer-related deaths in India.

Aim & Objective: This study evaluates the efficacy of cryotherapy in treating benign and premalignant cervical lesions.

Methods: An interventional analytical study was conducted in the Department of Obstetrics and Gynaecology at SMS Medical College, Jaipur, from March 2023 to March 2024. A total of 250 women aged 18 to 60 with complaints of chronic vaginal discharge, postcoital bleeding, or dyspareunia, cervical erosion or CIN1 were included. Cryotherapy was done using the double-freeze technique, and follow-up assessments were conducted at 2, 6 and 12 weeks post-treatment.

Results: The majority of participants were aged 25-35 years (44%) and predominantly from rural backgrounds (60%). A notable 64.8% women had history of treatment taken for pelvic inflammatory disease as an important risk factor and 40% patients had cervical erosion on per speculum examination. Before treatment 87.2% patients reported vaginal discharge, 50.4% experienced pelvic pain, 16.4% had dyspareunia and 13.2% reported backache. There was a significant reduction of vaginal discharge from 87.2% to 6.4% 12 weeks after cryotherapy ($p<0.0001$). A complete resolution in pelvic pain, dyspareunia and backache was seen at 12 week follow up. Minimal side effects were observed, primarily transient discomfort and watery discharge.

Conclusion: Cryotherapy is a highly effective and safe treatment for benign and premalignant cervical lesions, associated with minimal complications. This cost-effective procedure can be integrated into routine outpatient care, potentially reducing morbidity and mortality linked to these conditions.

Keywords: Cryotherapy, cervical lesions, cervical cancer, CIN1, vaginal discharge, regression of lesion.

Introduction

Benign cervical lesions such as cervical erosion and chronic cervicitis commonly present with symptoms like vaginal discharge, pelvic pain, dyspareunia, post coital bleeding, abnormal bleeding, vaginal discharge and pelvic pain being most common. These symptoms significantly affect women's quality of life, often leading to multiple outpatient visits and prolonged antibiotic treatment without relief. In gynaecology outpatient department (OPD) one in four women report vaginal discharge. Globally, one in ten women experience vaginal discharge annually.[1]

Cervical erosion affects 15%-17% of women visiting gynaecology OPD. It results when the endocervical columnar epithelium extends onto the vaginal portion of the cervix, undergoing squamous metaplasia. Hormonal changes, use of oral contraceptives, and infections are key causes. Although often asymptomatic, cervical erosion can lead to postcoital bleeding, persistent vaginal discharge, and pain; necessitating prompt diagnosis via Pap smear or biopsy to rule out more serious conditions like CIN or cancer. Chronic cervicitis, marked by ectocervical inflammation, can result in complications such as low-grade squamous intraepithelial lesions (LSIL) in up to 20% of cases.[3]

Premalignant lesions of cervix are critical as they can progress to cervical cancer over a decade if left untreated. Cervical cancer is the second most common cancer and a leading cause of cancer-related deaths in India.[2] Cervical cancer remains a significant global health issue, with around 6,04,000 new cases and 3,42,000 deaths reported in 2020.[6] In India, cervical cancer is responsible for 1,30,000 new cases annually, accounting for 20% of all female cancer deaths.[4] Human papillomavirus (HPV) is the primary cause, progressing to cancer in about 5% of cases when not cleared by the immune system. This progression offers a window for screening and timely intervention, such as the World Health Organization's screen-and-treat approach.[5]

Treatment options for benign and precancerous cervical lesions include ablative and excisional methods. Cryotherapy is a simple, affordable, and effective ablative treatment, especially suited for low-resource settings. It has a treatment efficacy rate between 85%-97% and minimal complications, making it a preferred outpatient procedure. Though cryotherapy's effectiveness is well-documented in developed countries, there is limited data from developing nations, where complaints like persistent vaginal discharge are more prevalent.[6]

Therefore, this study aims to evaluate the effectiveness of cryotherapy in treating benign and premalignant cervical lesions, potentially reducing morbidity and mortality associated with these conditions.

Materials and Methods

This interventional analytical study was conducted in the Department of Obstetrics and Gynaecology at SMS Medical College, Jaipur. The study began in March 2023 and continued for one year. Participants included women aged 18 to 60 attending the gynaecology outpatient department with complaints of chronic vaginal discharge, postcoital bleeding, dyspareunia, backache or found to have Cervical Intraepithelial Neoplasia 1 (CIN1) or cervical erosion, The sample size of 250 was based on previous studies showing 87.8% and 91% healing

efficacy at 6 and 12 weeks post-cryotherapy, ensuring 80% power with a 0.05 alpha error and 10% absolute error.

Inclusion criteria: Women aged 18–60 years presenting with chronic vaginal discharge, postcoital bleeding, dyspareunia or found to have cervical erosion or CIN1 and giving written informed consent.

Exclusion criteria: Women with lesions extending into the endocervical canal, genital malignancy, lesions too large for cryotherapy probes, active vaginal bleeding, pregnancy and genital infections or infections like Herpes, HIV, VDRL were excluded.

Methodology

All eligible women aged 18–60 meeting the inclusion criteria were explained about the nature and purpose of study. After taking written and informed consent detailed history was taken, general and systemic examinations were conducted, followed by necessary investigations. Information was recorded in a pre-designed proforma and entered into Microsoft Excel. A bivalve speculum was used to expose the cervix and a Pap smear was taken. A 5% acetic acid solution was applied and the cervix was inspected for acetowhite lesions and Swede score was calculated. After applying the inclusion and exclusion criteria, patients were selected for cryotherapy and consent was taken. The procedure involved cryocauterization with nitrous oxide, maintaining a temperature of −55 to −58°C to create a 2 mm frost margin. The double-freeze technique was used, with 3-minute freeze, 3-5 minute thaw, followed by another 3-minute freeze. Post-procedure, patients were monitored for side effects and advised on aftercare, including avoiding sexual contact and tampons for 6 weeks. Follow-up visits were scheduled at 2, 6 and 12 weeks. At 12 weeks a VIA (Visual Inspection by Acetic Acid) test was repeated to assess lesion regression and symptom improvement was noted. The efficacy of cryotherapy was determined by regression of lesion in terms of absence of VIA positivity and symptom resolution, with hospitalization recommended for severe complications.

Results and Observation

The study included women primarily aged 25-35 years (44%) followed by 32.8% between 35-45 years and 23.2% above 45 years with majority residing in rural areas (60%). Socio-economic status distribution showed majority belonging to lower middle class (44%) and middle class (37.6%). In terms of education, 39.2% were illiterate. Early onset of sexual activity was reported by 45.2% patients. In a significant number of patients 64.8%, history of treatment taken for pelvic inflammatory disease was noted as a risk factor. Smoking, use of oral contraceptive pills and history of sexually transmitted diseases were other risk factors. None of the patients had received HPV vaccination. Per speculum examination findings revealed that 75.2% patients had vaginal discharge, 40% had cervical erosion and 18.8% had cervicitis.

Table 1: Distribution of cases according to Visual Inspection with Acetic Acid (VIA) and Visual Inspection with Lugol's Iodine (VILI)

Parameter		No. of Patients (N)	Percentage (%)
VIA	Positive	236	94.4
	Negative	14	5.6
VILI	Positive	236	94.4
	Negative	14	5.6

94.4% patients had positive lesions on VIA (Visual Inspection with Acetic Acid) and VILI (Visual Inspection with Lugol's Iodine).

Table 2: Distribution of cases according to resolution of symptoms before cryotherapy and at 2week, 6week and 12 week follow up

Parameter	Before cryotherapy		Follow up at 2 week		Follow up at 6 week		Follow up at 12 week		P-Value
	No. of Patients (N)	Percentage (%)	No. of Patients (N)	Percentage (%)	No. of Patients (N)	Percentage (%)	No. of Patients (N)	Percentage (%)	
Vaginal Discharge	218	87.2	179	71.6	37	14.8	16	6.4	<0.0001
Foul Smelling Discharge	2	0.8	Nil	-	Nil	-	Nil	-	0.89
Abnormal Bleeding	6	2.4	Nil	-	Nil	-	Nil	-	0.03
Post-Coital Bleeding	8	3.2	1	0.4	Nil	-	Nil	-	0.003
Post-menopausal Bleeding	3	1.2	Nil	-	Nil	-	Nil	-	0.56
Dyspareunia	41	16.4	3	1.2	Nil	-	Nil	-	<0.0001
Pelvic Pain	125	50	22	8.8	19	7.6	Nil	-	<0.0001
Backache	33	13.2	6	2.4	5	2	Nil	-	<0.0001

Before cryotherapy procedure, 218 patients (87.2%) reported vaginal discharge, 2 patients had foul-smelling discharge, 6 patients experienced abnormal bleeding, 8 patients had post-coital bleeding, 3 patients had post-menopausal bleeding, 41 patients experienced dyspareunia, 125 patients had pelvic pain and 33 patients reported backache. At 2-week follow-up, vaginal discharge was reported by 179 patients, with no cases of foul-smelling discharge or abnormal bleeding. Only 1 patient had post-coital bleeding. Dyspareunia was no longer reported and 22 patients experienced pelvic pain, while 6 patients reported backache. By the end of 6-week, only 37 patients reported vaginal discharge, with no cases of foul-smelling discharge, abnormal bleeding, post-coital bleeding or post-menopausal bleeding. Pelvic pain had resolved for most, leaving only 19 patients with ongoing pelvic pain and 5 patients with backache. At the 12-week follow-up, only 16 patients (6.4%) reported vaginal discharge complete resolution of abnormal bleeding, post coital bleeding, post-menopausal bleeding, dyspareunia, pelvic pain and backache.

Graph 1: Distribution of cases according to resolution of symptoms before cryotherapy and at 2week, 6week and 12 week follow up

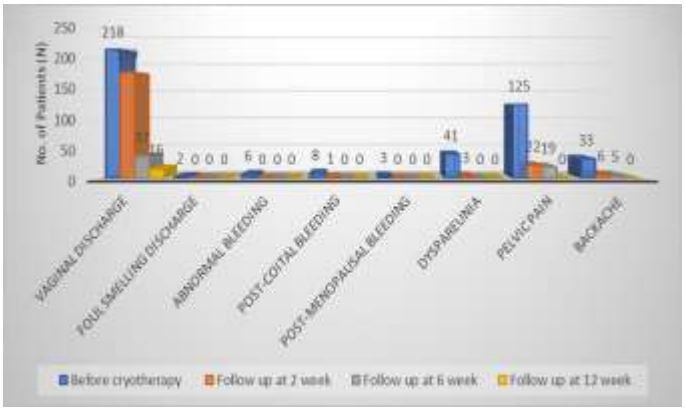

Table 3: Distribution of cases according to regression of VIA positive lesion at 12 week follow up

Regression of lesion	No. of Patients	Percentage
Complete	234	93.4
Incomplete	16	6.6
Total	250	

Following cryotherapy treatment, 234 (93.4%) patients experienced complete regression of their lesions.

Graph 2: Distribution of cases according to regression of VIA positive lesion at 12 week follow up

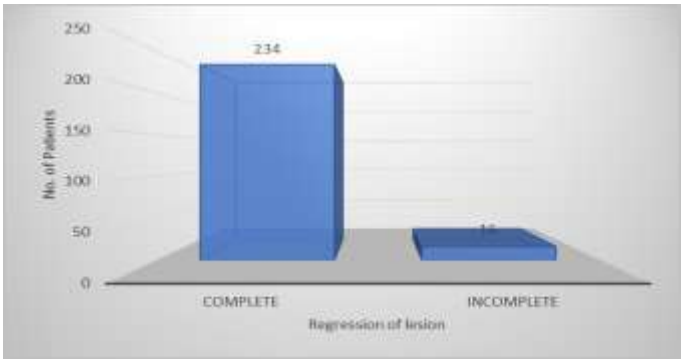

Figure 1: VIA positive lesion in a patient

Figure 2: Immediately after cryotherapy

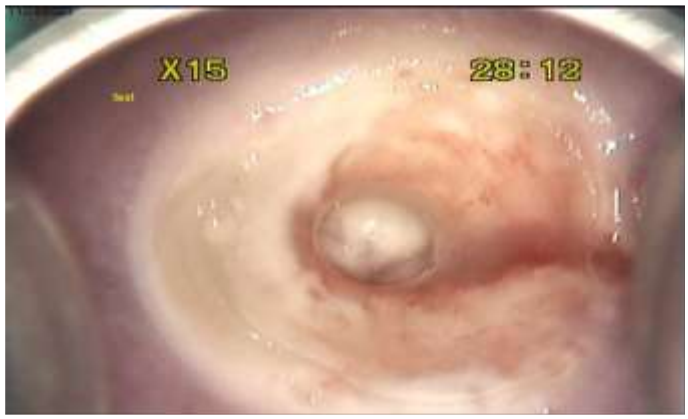

Figure 3: VIA Negative at 12 week follow up post cryotherapy

Discussion

Numerous benign and premalignant cervical lesions, such as ectropion and cervicitis, commonly present with vaginal discharge, pelvic pain, dyspareunia, backache, postcoital bleeding, and abnormal bleeding. These distressing symptoms often lead to multiple OPD visits and prolonged antibiotic use without relief. While many cervical lesions may be asymptomatic, concerning symptoms like postcoital bleeding necessitate thorough evaluation to distinguish benign conditions from more serious issues, including infections or cervical intraepithelial neoplasia (CIN). Cryotherapy is an effective treatment for these cervical changes, with efficacy rates between 85% and 97%, involving the freezing of abnormal tissue to facilitate its removal and promote healing.[7]

In our study (Table No 2); 218 (87.2%) patients reported vaginal discharge, including 2 (0.8%) with foul-smelling discharge. Abnormal bleeding was noted in 6 (2.4%), post-coital bleeding in 8 (3.2%), and post-menopausal bleeding in 3 (1.2%). Dyspareunia affected 41 (16.4%), 125 (50%) experienced pelvic pain, and 33 (13.2%) reported backache. Agah J et al. (2019)[9] reported pre-intervention leucorrhea in 88.0% of the cryotherapy group and 80.3% of the placebo group, along with vaginal itching, pelvic pain, dyspareunia, and post-coital bleeding, with no significant differences between groups. Patel K D et al (2021)4 found that among patients with cervical inflammation and LSIL (CIN1), abnormal vaginal discharge was reported by 94.59% of those with inflammation and 88.46% of those with LSIL (CIN1). Abnormal bleeding, dyspareunia, post-coital bleeding and pelvic pain were also reported, though with varying frequencies

In our study (Table 2), at the 2-week follow-up, 179 patients (71.6%) had vaginal discharge, with no foul-smelling discharge or abnormal bleeding, and 22 (8.8%) experienced pelvic pain. By the 6-week follow-up, 37 patients (14.8%) reported vaginal discharge, with no abnormal symptoms. At the 12-week follow-up, 16 patients (6.4%) reported vaginal discharge, 1 (0.4%) had post-coital bleeding, 3 (1.2%) experienced dyspareunia, and 19 (7.6%) reported pelvic pain; 5 (2%) had backache. There was a significant reduction of vaginal discharge from 87.2% to 6.4% 12 weeks after cryotherapy (p value <0.0001). A complete resolution in pelvic pain, backache and dyspareunia was seen at 12 week follow up (p value <0.0001). Also patients presenting with foul smelling discharge, abnormal bleeding and postmenopausal bleeding had significant relief. These findings highlight the effectivity and efficacy of cryotherapy. Patel K D et al (2021)4 observed that, among patients with cervical lesions and LSIL (CIN1) before and after cryotherapy, abnormal discharge decreased significantly from 94.5% before cryotherapy to 7.57% at 12 weeks. Abnormal bleeding, initially reported by 6.75%, was eliminated post-cryotherapy. Dyspareunia dropped from 20.2% before treatment to 3.03% at 6 weeks and was completely resolved by 12 weeks. Post-coital bleeding, initially at 5.40%, was eradicated by 2 weeks. Pelvic pain decreased from 32.4% to 1.51% by 12 weeks. For patients with LSIL (CIN1), abnormal discharge reduced from 88.46% pre-cryotherapy to 8.33% at 12 weeks. Abnormal bleeding, reported by 15.38%, dropped to 3.84% at 2 weeks. Dyspareunia reduced from 34.61% to 4.16% by 6 weeks and was resolved by 12 weeks. Post-coital bleeding, initially at 11.53%, was resolved by 2 weeks. Pelvic pain decreased from 23.07% to 8.33% at 6 weeks and was resolved by 12 weeks.

Agah J et al (2019)24 found that post-intervention, the incidence of leucorrhea decreased to 57 participants (76.0%) in the cryotherapy group and 42 participants (55.3%) in the placebo group (p=0.006). Vaginal itching and pruritus decreased to 38 participants (50.7%) in the cryotherapy group and 15 participants (19.7%) in the placebo group (p<0.001). Pelvic pain decreased to 40 participants (53.3%) in the cryotherapy group and 25 participants (32.9%) in the placebo group (p=0.009). Dyspareunia decreased to 37 participants (49.3%) in the cryotherapy group and 21 participants (27.6%) in the placebo group (p=0.005). Post-coital bleeding decreased to 18 participants (24.0%) in the cryotherapy group and 8 participants (10.5%) in the placebo group (p=0.023). Katakdhond et al (2017)56 and Mohanty et al(1985).28 Mohanty et al(1985) 28 recorded that cryotherapy eliminated enhanced vaginal secretion and pain in 98% of patients 12 weeks after treatment. In the present study (Table 3) following the cryotherapy treatment, 234

patients (93.4%) had complete regression of their lesions, while 16 patients (6.6%) had incomplete regression. 90.4% had complete regression of lesion at 12 week follow up implying high efficacy of cryotherapy in treatment of benign and premalignant cervical lesions. In a study by Yasemin Çekmez et al (2016)26 ectopy completely disappeared in 119 (95.9%) patients after 6 weeks. The most common follow up side effect after cryotherapy was watery discharge per vaginum (71.6%) at 2 weeks. The discharge decreased at 6 week follow up (14.8%) and a significant decrease was seen at 12 week follow up (only 6.4% patient reported vaginal discharge). Very few patients reported bleeding, abdominal cramps, pain or discomfort which were completely absent at 12 week follow up. None of the patient had fever. These findings imply cryotherapy has a good safety profile with very less side effects and complications.

Conclusion

Cryotherapy is highly effective for treating benign and premalignant cervical lesions, with minimal side effects and complications. It is a simple, cost-effective, and safe procedure suitable for routine outpatient practice. This method can be adopted as a screening and treatment approach to reduce morbidity and mortality associated with these lesions.

References

1. Khadawardi, F.R.C.S., K. Prevalence of Abnormal Vaginal Discharge among Pregnant Women. The Medical Journal of Cairo University, 2020; 88: 677-683.
2. Sathishkumar K, Sankarapillai J, Mathew A, Nair R A et al. Survival of patients with cervical cancer in India–findings from 11 population based cancer registries under National Cancer Registry Programme. The Lancet Regional Health- Southeast Asia 2024;24: 100296.
3. Patel KD, Karnavat RD, Viramgama DG, Dalal RK. Evaluation of efficacy and safety of cryotherapy in benign and premalignant cervical lesion.Int J Reprod Contracept Obstet Gynecol 2021;10:3066-71.
4. Kumar K, Iyer VK, Bhatia N, Kriplani A, Verma K. Comparative evaluation of small cytology and hybrid capture for diagnosis of cervical cancer. Indian J Med Res 2007; 126:39-44.
5. de Kok IM, van der Aa MA, van Ballegooijen M, Siesling S, Karim-Kos HE, van Kemenade FJ, et al. Trends in cervical cancer in the Netherlands until 2007: has the bottom been reached? Int J Cancer. 2011;128(9):2174–81.
6. World Health Organization. WHO guidelines: use of cryotherapy for cervical intraepithelial neoplasia. Geneva: World Health Organization; 2011.
7. Jahic M. Cryotherapy of Erosion of Cervix and Low Grade Squamous Intraepithelial Lesion. Materia Socio Medica. 2018;30(4):294.
8. Katakdhond S, Samant P. Cryotherapy for cervical lesions: efficacy and patient satisfaction. Int J Reprod Contracept Obstet Gynecol 2017; 6:2331-6.
9. Agah J, Sharifzadeh M, Hosseinzadeh A. Cryotherapy as a Method for Relieving Symptoms of Cervical Ectopy: A Randomized Clinical Trial. Oman Med J. 2019 ;34(4):322-326.
10. Matányi S. Side effects and complications of cervical cryotherapy. Acta Chir Hung. 1992-1993;33(1 2):157-62.
11. Mohanty KC, Rand RJ, Berry B. Cryotherapy in the management of cervical ectopy. Genitourin Med 1985;61(5):335-337.