Original articles

Evaluation of cervical thermal ablation for cervical precancer with high-risk HPV genotypes: Treatment effectiveness and HPV clearance at 12 months

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Abstract

Background: In Vietnam, there is currently a lack of evidence evaluating the effectiveness of cervical thermal ablation in the treatment of cervical precancerous lesions among women with high-risk HPV.

Objective: To evaluate the effectiveness of cervical thermal ablation in treating cervical intraepithelial neoplasia grade 1 (CIN1) and its clearance ability of high-risk HPV in women aged over 30 years.

Methods: A prospective cohort study of 74 patients aged ≥ 30 years with cervical high-risk HPV infection and histopathology-confirmed CIN1 at Tu Du Hospital, Vietnam, from August 2023 to December 2025.

Results: The mean age of participants was 39 ± 6.7 years. At 12 months after cervical thermal ablation, the clearance rate of overall high-risk HPV, HPV 16, and HPV 18 were 83.8%, 84.6%, and 75%, respectively. The cure rate at 12 months was 81.0%.

Conclusions: Thermal ablation not only resolves precancerous lesions but also promotes HPV clearance for high-risk types, which are the main causes of cervical precancer and cervical cancer. Further studies are needed to support wider application of cervical thermal ablation for treating precancerous lesions and HPV clearance in Vietnam.

Keywords: *Cervical precancer; cervical intraepithelial neoplasia; HPV clearance; thermal ablation; high-risk HPV.*

1. INTRODUCTION

Cervical cancer is the second leading cause of cancer-related death among women of reproductive age worldwide [1]. In 2020, the World Health Organization (WHO) proposed a global strategy to eliminate cervical cancer in order to accelerate progress toward its elimination. The targets for 2030 are: 90% of girls fully vaccinated against HPV by age 15, 70% of women screened with a high-performance test at least twice by age 45, and 90% of women identified with precancerous lesions or cervical cancer receiving treatment [2].

In 2021, the WHO recommended initiating a screen-and-treat approach for women from the age of 30, with treatment decisions based on an initial positive HPV DNA screening test followed by a second positive screening test (VIA or colposcopy), with or without histopathology results. The WHO recommends HPV DNA testing as the primary screening test rather than VIA or cytology in screen-and-treat approaches. In WHO's 2021 algorithm 2, women with a positive HPV DNA test who are eligible for treatment should receive ablative therapy (thermal ablation or cryotherapy) and be followed up after one year [3].

Several recommendations have been proposed for the management of cervical intraepithelial neoplasia. For patients with histopathology shows CIN 1, observation is preferred over treatment (evidence level 1B) [4]. However, immediate treatment rather than observation may be reasonable in patients who are difficult to follow long term, do not desire future childbearing, and are not concerned about potential obstetric complications. If CIN 1 persists after follow-up for high-grade squamous intraepithelial lesions or CIN 2, either treatment or continued observation is considered acceptable. For most patients, treatment rather than observation is generally recommended (evidence level 2C) [4].

Cryotherapy has been recommended by the WHO for the treatment of cervical precancerous lesions. In 2019, the WHO recommended thermal ablation as

an alternative to cryotherapy [5]. Cervical thermal ablation can overcome several barriers associated with cryotherapy, such as lower operating costs, a faster procedure, and no need for a gas supply [6].

Although many studies worldwide have reported promising results for the use of thermal ablation in treating cervical precancerous lesions and promoting clearance of cervical high-risk HPV, there have been no studies in Vietnam evaluating the effectiveness of thermal ablation for treating cervical precancerous lesions and HPV clearance at 12 months after treatment. This study therefore aims to assess the effectiveness of cervical thermal ablation in treating cervical intraepithelial neoplasia grade 1 (CIN1) and high-risk HPV clearance at 12 months after treatment in Vietnamese women aged over 30 years.

2. MATERIALS AND METHODS

2.1. Study design and participants

This was a prospective cohort study conducted on 74 patients at Tu Du Hospital, Vietnam, from August 2023 to December 2025.

We enrolled women aged ≥ 30 years who had a history of sexual intercourse, tested positive for cervical high-risk HPV, had histopathology-confirmed CIN1, had no history of cervical cancer or prior treatment for cervical precancerous lesions, were not pregnant, and provided informed consent. All women were eligible for cervical thermal ablation according to WHO criteria: the squamocolumnar junction was fully visible, cervical lesions involved < 75% of the cervix, and there were no lesions suspicious for cancer.

The sample size was calculated using the formula for estimating a proportion with absolute precision. The expected successful treatment rate of CIN1 with cervical thermal ablation was assumed to be P = 96%, with a significance level of α = 0.05 and an absolute error of d = 0.05 [7]. The minimum required sample size was 60 patients. We recruited 89 patients, and 74 completed the study at 12 months after cervical thermal ablation (Figure 1).

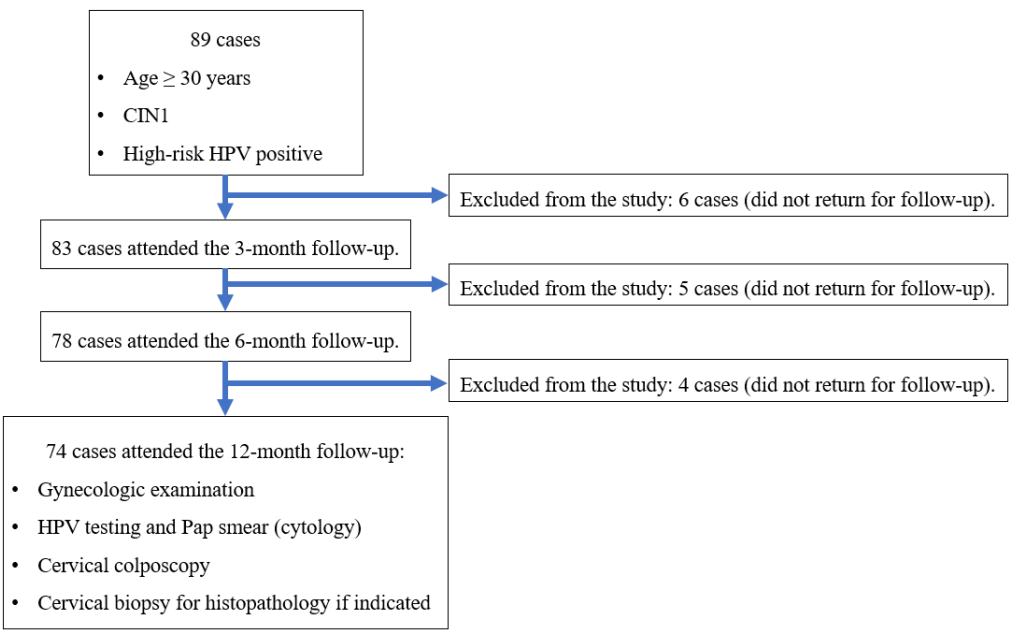

Figure 1. Study workflow

2.2. Cervical thermal ablation procedure

We used the Wisap C3 thermal ablation device (Wisap, Germany). A flat probe with a diameter of 17 mm or 20 mm was used for type 1 transformation zones, and a 20 mm nipple-shaped probe was used for type 2 transformation zones. The probe was heated to 100°C before being applied to the cervix. Each application lasted 40 seconds; if the lesion was extensive, multiple applications could be performed in a single treatment session to fully cover the lesion. After the procedure, patients rested in bed, and adverse events, satisfaction, and patient preferences were recorded immediately after treatment and 30 minutes post-treatment. All patients received 5 days of prophylactic oral antibiotics.

2.3. Follow-up

Patients were then scheduled for follow-up visits every 3 months to assess satisfaction, healing status, HPV clearance, and treatment effectiveness. At 3 months post-treatment, we performed a gynecologic

examination, assessed healing, and conducted HPV testing. At 6 and 12 months post-treatment, we performed a gynecologic examination, assessed healing, conducted cervical cytology and HPV testing, and performed colposcopy. Cervical biopsy for histopathology was performed when colposcopy showed abnormal findings requiring biopsy.

Cervical specimens were collected by rotating a cytobrush five times over the cervical surface and external os, then immediately rinsing the brush into Roche cell collection medium. The sample was used for cytology and HPV testing (Cobas 4800). Although samples could be stored for up to 6 months after collection, all samples were processed within 7 days to ensure optimal quality.

HPV testing was performed using real-time PCR on the Cobas 4800 HPV system. The Cobas 4800 HPV assay has a sensitivity of 94% and reports results across four channels: channel 1 detects 12 high-risk HPV types; channel 2 detects HPV16; channel 3 detects HPV18; and channel 4 is the internal beta-globin control.

Cytology slides were prepared from liquid-based cytology specimens using the ThinPrep 2000 system according to the manufacturer's protocol. Slides were stained using the Papanicolaou method and evaluated using the 2014 Bethesda System. Cervical cytology was interpreted by pathologists [8]. CIN1 was classified as low-grade squamous intraepithelial lesion (LSIL).

Colposcopy was performed using the Olympus OCS-500 colposcope. Acetic acid 3 - 5% (VIA) and Lugol's iodine (VILI) were used to guide directed biopsy when indicated. Colposcopy was conducted by experienced, certified colposcopists, and findings were assessed using the 2011 International Federation for Cervical Pathology and Colposcopy (IFCPC 2011) terminology [9].

2.4. Outcome definitions

After ablative treatment, complete healing was defined as disappearance of lesions with complete regeneration of the cervical epithelium. Partial healing was defined as reduction in lesion size without full restoration of normal cervical epithelium. Poor healing was defined as no reduction in lesion size with persistent bleeding.

Cervical high-risk HPV clearance was defined as successful if the HPV test was negative at 12 months post-treatment using real-time PCR on the Cobas 4800 HPV system.

Treatment effectiveness was defined as follows: cure was achieved when HPV testing was negative, normal cervical cytology test result and colposcopy did not indicate the need for cervical biopsy, or when colposcopy-guided biopsy showed no cervical precancerous lesions.

2.5. Statistical analysis

Data were analyzed using SPSS version 26 (IBM Corp., Armonk, NY, USA). Data were presented as frequency (n) and percentage (%), as well as mean ± standard deviation (SD). Categorical variables were assessed using the Chi-square test or Fisher's exact test as appropriate. A p value < 0.05 was considered statistically significant.

2.6. Research Ethics

The study protocol was approved by the Biomedical Research Ethics Committee of the University of Medicine and Pharmacy, Hue University (approval no. H2022/488, dated June 30, 2022).

3. RESULTS

From August 2023 to December 2025, we recruited 89 eligible cases for inclusion in the study. However, 6 cases did not return for the scheduled follow-up at 3 months after thermal ablation, 5 cases did not return at 6 months, and 4 cases did not return at 12 months. Ultimately, 74 cases completed the study.

3.1. General characteristics of the study population

Table 1. Baseline characteristics of the study population

Characteristic	Frequency (n =74)	Percentage (%)
Age (Mean ± SD, years)	39.2 ± 6.7	
30 - 45	61	82.4
46 - 64	13	17.6
Occupation		
Homemaker	24	32.4
Business	12	16.2
Farmer	5	6.8
Factory worker	16	21.6

Characteristic	Frequency (n =74)	Percentage (%)
Employee/Staff	17	23.0
Marital status		
Married	56	75.7
Divorced	8	10.8
Remarried	4	5.4
Widowed	2	2.7
Single	4	5.4
Age at menarche (Mean ± SD, years)	14.4 ± 1.4	
Age at coitarche (Mean ± SD, years)	22.2 ± 4.2	
< 18 years	4	5.4
≥ 18 years	70	94.6
Number of pregnancies		
0	5	6.8
1 - 2	34	45.9
3 - 5	31	41.9
> 5	4	5.4
Number of living children		
None	9	12.2
1 - 2	55	74.3
3 - 5	10	13.5
Smoking status		
Neither woman nor husband smokes	64	86.5
Husband only smokes	10	13.5

The mean age of the 74 women was 39.2 ± 6.7 years. The majority were married (75.7%). The mean ages at menarche and coitarche were 14.4 ± 1.4 and 22.2 ± 4.2 years, respectively, with almost all women initiating sexual activity at ≥ 18 years (94.6%). None of the participants smoked, and only 13.5% reported that their husbands smoked.

3.2. Clinical characteristics

Table 2. Clinical and laboratory characteristics of the study population.

Characteristic	Frequency (n)	Percentage (%)
Reason for visit		
General check-up	11	14.9
Vulvovaginal itching	42	56.8
Vaginal discharge	11	14.9
Postcoital bleeding	3	4.1
Prolonged menstruation	1	1.4
Other	6	8.1
HPV test		
HPV16	13	17.6
HPV18	4	5.4
Other 12 high-risk HPV types	50	67.6

HPV16 + other 12 high-risk types	3	4.1
HPV18 + other 12 high-risk types	4	5.4
HPV16 + HPV18	0	0
HPV16 + HPV18 + other 12 high-risk types	0	0
Cytology		
Normal	13	2.7
ASC-US	41	55.4
LSIL	20	27.0
Transformation zone		
Type 1	69	93.2
Type 2	5	16.8

Vulvovaginal itching was the most common reason for visit (56.8%). Regarding HPV genotype distribution, most patients were infected with one of the other 12 high-risk HPV types (67.6%), whereas HPV16 and HPV18 were detected in 17.6% and 5.4% of cases, respectively; co-infection with HPV16 or HPV18 and other high-risk types was uncommon. Cytology predominantly showed atypical squamous cells of undetermined significance (ASC-US, 55.4%). Most women had a type 1 transformation zone (93.2%).

3.3. Treatment outcomes at 12 months after cervical thermal ablation

Table 3. Treatment outcomes for cervical precancerous lesions at 12 months

Outcome at 12 months post-treatment	Frequency (n)	Percentage (%)
Lesion healing status		
Complete healing (cured)	74	100.0
Good/partial healing	0	0.0
Poor healing	0	0.0
Second ablation session	0	0.0
Cervical cytology		
Normal	66	89.2
ASC-US	7	9.4
LSIL	1	1.4
Colposcopy		
Normal	56	75.7
Mild acetowhite changes	10	13.5
Abnormal	8	10.8
Cervical biopsy performed	**9**	**12.2**
Histopathology results among biopsied cases (n = 9)		
Cervicitis/inflammation	5	55.6
Condyloma	1	11.1
CIN1	2	22.2
CIN1 + condyloma	1	11.1

At 12 months post-treatment, all 74 women (100%) achieved complete lesion healing on colposcopic examination, and no cases showed partial or poor healing; consequently, no second ablation session was required (Table 3).

Table 4. HPV clearance and cure outcomes.

HPV clearance and cure outcomes	HPV positive at baseline	HPV clearance status at 12 months		
		Positive	Negative	Clearance rate (%)
Overall HPV clearance	74	12	62	83.8
HPV16	13	2	11	84.6
HPV18	4	1	3	75.0
Other 12 high-risk HPV types	56	8	48	85.7
HPV16 + other 12 high-risk types	3	0	3	100.0
HPV18 + other 12 high-risk types	4	1	3	75.0
Cure			**62**	**81.0**

At 12 months post-treatment, the overall HPV clearance rate was 83.8%, with the lowest clearance rate of 75% in the HPV18 group (Table 4). Complete clearance was seen in all three women with HPV16 plus other high-risk types. Based on the predefined criteria, 60 women (81.0%) met the definition of cure at 12 months.

4. DISCUSSION

This is a clinical trial applying a new technique for the treatment of cervical precancerous lesions in Vietnam. In December 2024, the Vietnamese Ministry of Health issued the Guidelines for the Prevention and Control of Cervical Cancer, promulgated together with a ministerial decision, which mentions the use of thermal ablation in the treatment of cervical precancerous lesions [10].

Patient satisfaction, complications, adverse effects, treatment outcomes for cervical precancerous lesions, and cervical HPV clearance at 3 and 6 months after cervical thermal ablation were previously published in our article, "Efficacy of thermal ablation among women with cervical intraepithelial neoplasia grade 1 and high-risk human papillomavirus genotypes: The first prospective study in Vietnam" [11].

HPV infection is common among sexually active women, and persistent high-risk HPV infection can lead to progression to precancerous lesions and cervical cancer. HPV detected in women older than 30 years is more likely to represent persistent infection and therefore requires close follow-up to detect cervical precancerous lesions [12]. In our study, the mean age of HPV-positive women with cervical precancerous lesions was 39.2 ± 6.7 years, which is consistent with studies by Liqing Chen et al [13].

Cervicovaginal HPV infection is often asymptomatic; however, when patients present with symptoms such as vulvar itching or increased vaginal discharge, HPV may already have caused lesions in the vulva, vagina, or cervix. In our study, vulvar itching was the most common symptom (56.8%), whereas increased vaginal discharge accounted for only 14.9%. Colney et al. reported that the most common presenting symptom was vaginal discharge (14.9%), followed by chronic pelvic pain (13.9%), while postcoital bleeding was uncommon (1.3%) [14].

Cervical thermal ablation is a new method being used for the first time in Vietnam. In our study, cervical lesions treated with thermal ablation healed well at 12 months (100%), and no cases required a second treatment session. Wound healing occurs mainly within the first six weeks after ablation. Granulation tissue appears during the first 2 - 3 weeks after treatment, followed by re-epithelialization of the surface. Typically, the wound heals completely within 6 - 8 weeks after treatment [15]. Our findings are consistent with those of Manuela Viviano et al.: at 1 month after thermal ablation, cervical wounds had healed in 91.7% (95% CI: 84.9 - 95.8), while the remaining women had delayed healing and were treated with vaginal antibiotic therapy [16]. Similar results Christine Campbell et al. reported that more than 90% of cervices healed well at 3 months post-treatment [17].

Successful treatment of cervical precancerous lesions often leads to HPV clearance. HPV DNA testing may provide added value in monitoring disease progression [18]. In 2018, Mohamed Akaaboune compared high-risk HPV clearance after cervical thermal ablation versus no treatment. HPV clearance at 12 months was 84.1% in women treated with thermal ablation versus 70.2% in untreated women [19]. Our findings are consistent with this and other studies: the clearance rates for overall high-risk HPV, HPV16, and HPV18 were 83.8%, 84.6%, and 75%, respectively. In a study by Xuelian

Zhao et al., the HPV clearance rate was 80.4% among women treated with thermal ablation; clearance was lower for HPV16/18 than for other carcinogenic HPV types (67.6% vs. 85.7%) [20]. HPV testing had a negative predictive value of 98.7% for detecting CIN2+ at follow-up and a positive predictive value of 40.4%. Thermal ablation was effective for treating CIN and eliminating high-risk HPV. Zhao et al. (2021) also showed significantly higher HPV clearance in women treated with thermal ablation compared with untreated women (73.0% vs. 46.1%, P < 0.001), and higher clearance rates for HPV16, HPV52, and HPV58, with ORs (95% CI) of 2.8 (1.3 - 6.1), 3.2 (1.3 - 7.9), and 5.8 (2.1 - 15.6), respectively [21].

Cure at 12 months after thermal ablation was defined as a negative HPV test and no abnormal cytology, with colposcopy not indicating biopsy, or with colposcopy-directed biopsy showing no precancerous lesions. In our study, the cure rate at 12 months was 81.0%. (Tab 4) Our results are consistent with those of other authors. Dipanwita Banerjee et al. reported cure rates for CIN1+ and CIN1+/HPV+ after cervical thermal ablation of 81.0% and 81.8%, respectively [22]. Lower than that reported by Dolman et al. reported cure rates of 96% (95% CI 92 - 99%) and 95% (92 - 98%) for CIN1 and CIN2–3, respectively, with few adverse effects and no impact on fertility [7].

However, our cure rate was higher than that reported by Partha Basu et al. at 12 months: success rates were 74.0%, 71.1%, and 71.4% for thermal ablation, cryotherapy, and LEEP, respectively, demonstrating that thermal ablation was comparable to the other methods (P = 0.83) [23]. Evelyne Marie Piret reported mild side effects and high acceptability of cervical thermal ablation, suggesting that concerns about overtreatment should not hinder implementation of screen-and-treat programs [24]. Compared with alternative treatments, thermal ablation is feasible and effective for such programs.

Differences in cure rates across studies may be due to differing follow-up durations or varying definitions of cure. Overall, thermal ablation is effective for treating cervical precancerous lesions and clearing high-risk HPV. Our findings confirm that cervical thermal ablation is an effective option for Vietnamese women with CIN1 and high-risk HPV positivity. The method was recommended by the WHO in 2019 as an alternative to cryotherapy and reaffirmed in 2021, allowing immediate treatment in this patient group, especially in resource-limited settings where long-term follow-up may be difficult [3, 5].

The study was approved by the biomedical research ethics committee. As the first clinical trial conducted in Vietnam, it provides initial evidence on the effectiveness of cervical thermal ablation for treating CIN1 cervical precancerous lesions and promoting high-risk HPV clearance. It also introduces a new treatment option that is low-cost, easy to use, and portable, and does not require a cryogas supply, features that make it well suited for deployment in remote areas. Overall, the findings may be particularly applicable in resource-limited settings and in patient populations where long-term follow-up is challenging.

Because this is the first trial in Vietnam, there are no existing Vietnamese population data for direct comparison, and the study team faced early implementation challenges, especially in patient counseling and treatment delivery. In addition, most participants came from provinces outside Ho Chi Minh City, and transportation barriers likely affected follow-up. Finally, the study did not include a comparison arm against other treatment modalities; therefore, future studies with an appropriate control or comparison group are needed to more comprehensively evaluate outcomes.

5. CONCLUSION

This is the first clinical trial conducted in Vietnam evaluating cervical thermal ablation for cervical precancer in women aged ≥30 years. At 12 months, cervical thermal ablation effectively resolved CIN1 and promoted clearance of high-risk HPV, the primary cause of cervical precancer and cancer. These findings support cervical thermal ablation as an effective treatment option for CIN1 in cervical cancer prevention programs in Vietnam.

Conflict of interest: The authors have no conflicts of interest concerning the research, authorship, and publication of this article.

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