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Original Research Article

Acceptability & Safety of Thermal Ablation in VIA Positive Women to Prevent Cervical Cancer

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Abstract

Cervical cancer is a significant contributor to the incidence and mortality of cancer in women globally, ranking fourth worldwide. However, the establishment of screening programs has led to a significant decrease in cervical cancer rates. Thermal ablation, a novel ablative procedure for precancerous cervical lesions (CIN), also known as cold coagulation or thermocoagulation, aims to reduce the incidence of cervical cancer. This study evaluated the safety and acceptability of thermal ablation as a treatment for precancerous cervical lesions in women who tested positive on visual inspection with acetic acid (VIA) and Lugol's iodine (VILI). The study enrolled 50 VIA/VILI positive women, who underwent visual evaluation and thermal ablation therapy at a tertiary care hospital's Department of Obstetrics and Gynecology. Interviews were conducted after treatment and 4-6 weeks later to assess the participants' experiences with anxiety, discomfort, and pain during thermal ablation. The results showed that thermal ablation is a safe and widely accepted procedure among women. 90% of the patients did not experience any pain during the treatment, while 10% reported high pain. The most common mild side effect was vaginal watery discharge, and none of the participants experienced any severe adverse effects requiring hospitalization or urgent care. Additionally, 62% of the women were willing to repeat the procedure if necessary. These findings suggest that thermal ablation is a safe and minor surgical procedure that can improve screening and treatment in a single visit, thus optimizing cervical cancer control, particularly in low-resource settings. As a result, thermal ablation has the potential to be a valuable supplement to current cervical cancer screening and treatment options.

Keywords: Cervical cancer screening, Thermal ablation, adverse events, Visual inspection with acetic acid, Visual inspection with lugol iodine.

Introduction

Cervical cancer is a significant global public health issue, with over 311,000 women estimated to die from it annually, predominantly in low- and middle-income areas [1]. Due to ageing, demographic trends, and insufficient action, this number is expected to rise to 460,000 by 2040 [2]. Cervical cancer is the fourth most common

disease among women globally, and screening programmes have significantly decreased cervical cancer rates in high-income nations [3]. The World Health Organization (WHO) has set a target for screening programs to provide treatment to 90% of women with cervical disease as part of its call for action to eliminate cervical cancer [6]. In 2019, the WHO issued new guidelines recommending thermal ablation as a treatment for precancerous lesions.

Several alternative tests have been developed for cervical cancer screening, including visual inspection with acetic acid (VIA) and nucleic acid testing for human papillomavirus (HPV). However, in many low- and middle-income countries (LMICs), diagnostic confirmation services are limited, leading to a significant barrier in implementing effective screening programs. The World Health Organisation (WHO) published the first version of Comprehensive Cervical Cancer Control: A Guide to Essential Practise (C4GEP) in 2006 to address this problem and advocate the use of screen-and-treat algorithms. This strategy calls for administering ablative therapy, which entails obliterating the cervical transition zone, including any lesions, to women who test positive for a screening test. Through evidence-based reviews, the WHO approved cryotherapy, a type of ablative therapy, in 2011 and 2014 [4, 5].

Cryotherapy, a treatment for precancerous lesions in the cervix, has certain drawbacks that limit its effectiveness in low- and middle-income countries (LMICs) [7]. A major disadvantage of cryotherapy is the need for a refrigerant gas, such as N2O or CO2. However, the gas containers are bulky and heavy, making transport difficult. Furthermore, the gas is not always readily available in LMICs. Another challenge with cryotherapy is its cost, which includes the purchase or rental of tanks in addition to the treatment itself. These expenses can be prohibitive and result in delays or lack of treatment after a positive screening test, which is a significant setback to prevention efforts via a screen-and-treat approach.

Thermal ablation, commonly known as "cold coagulation" or "thermocoagulation", is a novel ablative treatment for cervical intraepithelial neoplasia (CIN). The World Health Organization (WHO) and the Guideline Development Committee have agreed that the term thermal ablation best represents the treatment [8]. Thermal ablation treatment is based on a 20-30 second application of a reusable metallic probe that is electrically heated to roughly 100°C, resulting in the destruction of the lesion's epithelial and stromal tissue [7].

Thermal ablation desktop devices typically weigh around 5 kg and are somewhat portable. Newer battery-powered handheld devices weigh less than 2 kg and are small enough to fit in a rucksack, making them easily implementable in low- and middle-income countries (LMICs) [9]. Furthermore, when compared to other methods, thermal ablation has a shorter treatment time. Thermal ablation, like cryotherapy, can be performed by a variety of competent healthcare staff, including primary care providers, and no anaesthesia is necessary. Thermal ablation cure rates have been shown in studies to be comparable to or better than cryotherapy cure rates. Thermal ablation allows women living in low-income countries with a positive screening test to be treated in a single visit. Thermal ablation equipment is tiny, portable, resilient, self-sterilizing, and simple to operate. Overall, thermal ablation appears to be a promising alternative to current ablative treatments for CIN, particularly in resource-constrained situations.

Methodology

The study was carried out at the Obstetrics and Gynaecology department of a tertiary care hospital. A total of fifty people were recruited and evaluated for eligibility, with

ages ranging from 20 to 50 and positive results for visual examination with acetic acid (VIA) and Lugol iodine (VILI). If the VIA test was positive, acetic acid, lugol iodine (VIA/, VILI), and TA were used for a visual assessment. After using VIA, visual assessment was evaluated with the naked eye. The choice to treat was based on the VIA/VILI evaluation, which regarded as positive any cervical whitening upon application of acetic acid as well as the occurrence of spontaneous cervical bleeding [10].

Thermal ablation (TA): After applying Lugol's iodine, a probe that had been heated to 100 degrees Celsius was used to thermally ablate (TA) the cervix in order to define the transitional zone. The whole anomalous region and transformation zone was covered by the application, which was repeated two or more times as necessary. There wasn't any local anaesthesia used. Women who could have cancer or lesions that extended into the cervical canal and couldn't be covered by the probe were disqualified but were given the proper care.

Women were urged to report any adverse effects, including cramping and discomfort in the abdomen, fever, bleeding, or vaginal discharge, at the follow-up appointment (4-6 weeks after treatment). Acceptability: Women were questioned immediately following treatment and 4-6 weeks later to determine if the technique was acceptable. The Wong-Baker FACES® scale was used to grade self-reported pain. This scale has been verified and has six distinct faces with a range of pain intensity from zero (no pain) to ten (worst), i.e., 0: no pain, 2: a little pain, 4: a little more pain, 6: even more pain, 8: a lot of pain, and 10: the worst pain. We then formed two subgroups: normal pain (score≤4), and mild pain (score> 4).

Safety: It was noted whether there were any adverse events (AEs) connected to the therapy within 30 days (4-6 weeks) following the operation. Mild discomfort was felt during daily activity, but there was no disruption to routine daily activity.

Result

Table 1: Demographic data

Parameter	N (%)
Age	
20-29	08 (16%)
30-39	32 (64)
40-50	10 (20)
Education	
Primary level	26 (52)
Secondary level	10 (20)
Illiterate	14 (28)
Parity	
0-1	03 (6)
2-5	38 (76)
>5	09 (18)
Age at Marriage	
<18	40 (80)
>18	10 (20)

Table 2: Acceptability by the participants

Parameter	Yes	No
Patient felt enough informed	47 (94)	3 (6)
Anxiety	30 (60)	20 (40)
Procedure performed as expected by the patient	44 (88)	6 (12)
Sufficiently informed about side effect of treatment	46 (92)	4 (8)
Would agree to repeat treatment if necessary	31 (62)	19 (38)
Pain rating scale	Range ≤ 4 45 (90)	Range > 4 5 (10)

Table 3: Safety levels and side effects

Side effects	N (%)
Bleeding	03 (6)
Faintness	05 (10)
hot flush	0
nausea	09 (18)
headache	06 (12)
Illiterate	14 (28)
Comfortable with treatment	06 (12)

All women were married, had single Partner and nonsmokers. Most of women belongs to age group of 30-40y (64%). A majority completed Primary education (52%). Age at first intercourse was less them 18 years in 80% of women. 76% women had 2-5 children's and 18% women had more than five children (table 1). Acceptability: 20% of them—10 people—reported having mild to moderate anxiety, which counselling helped to reduce. According to Wong-Baker faces, the most of them (90%) had low pain levels (4), however five women reported pain scores of 6–8/10. 92% of women felt sufficiently informed, 88% thought the surgery went as planned, and only 62% said they would consent to repeat the procedure if required (table 2).

There were no dropouts from the research due to adverse effects, including discomfort from the surgery. Only a small number of patients experienced mild side effects right away, such as bleeding (6%), dizziness (10%), headache (12%), and nausea (18%). 92% of patients reported feeling at ease throughout the operation. The most frequent adverse effect identified at 4-6 weeks after treatment was vaginal watery discharge, for which a simple antibiotic and vaginal passerines were administered. No severe adverse effects were noticed either immediately following the therapy or 4-6 weeks later. None of the individuals (table 3) reported experiencing any issues necessitating hospital admission or medical emergency visits.

Discussion

According to our survey, women tend to find TA extremely acceptable and overall satisfied. Only 62% of treated patients said they were satisfied with it (92%) and would accept it again if their disease recurred. The results agree with a study by Mungo *et al*. which was attended by a community of women living with HIV and in which the vast majority of participants said they would advise others to seek therapy. [11].

In our study, participants usually accepted the surgery well; over 90% of them reported minor or minimal discomfort (03/10) and few reported severe discomfort (68/10). While severe pain requiring hospitalization (Grade 3 or worse) was uncommon, other

investigators essentially reported mild pain [1216]. In Malawi, Campbell *et al*. used a screen and treat strategy with 381 subjects and they reported no major side effects associated with TA [17].

Most patients in our study had light vaginal discharge, supporting the idea that women should be made aware of this symptom during preoperative consultation. According to patients' expectations and wishes, TA was considered easy to perform, safe and acceptable. This issue is critical because when patients feel comfortable and happy, doctors may feel more confident [10]. The majority of patients tolerate TA, a minor surgical procedure, fairly well.

Conclusion

our results suggest that thermal ablation is a widely accepted and safe method to treat precancerous lesions of the cervix. Additionally, thermal ablation may become the preferred treatment option in resource-poor settings. This approach has the potential to improve the feasibility of screening and treatment in a one-visit approach, which could lead to optimization of cervical cancer elimination programs. Therefore, thermal ablation has the potential to make a significant contribution to the fight against cervical cancer.

References

1. IARC/WHO. GLOBOCAN 2019: Estimated cancer incidence, mortality and prevalence worldwide in 2019. Cervical Cancer Fact Sheet. Available at: https://gco.iarc.fr/today/data/factsheets /cancers/23-Cervix-Uteri-fact-sheet.pdf.
2. Impact of scaled up human papillomavirus vaccination and cervical screening and the potential for global elimination of cervical cancer in 181 countries, 2020-99: a modelling study. Lancet Oncol. 2019;20(3):394–407.
3. Arbyn M, Weiderpass E, Bruni L, et al: Estimates of incidence and mortality of cervical cancer in 2018: A worldwide analysis. Lancet Glob Health. 2020; 8: e191-e203.
4. WHO guidelines – use of cryotherapy for cervical intraepithelial neoplasia. Geneva: World Health Organization; 2011 (http://www .who.int/reproductivehealth/publications /cancers/9789241502856/en/, accessed 20 June 2019).
5. WHO guidelines for treatment of cervical intraepithelial neoplasia 2–3 and adenocarcinoma in situ: cryotherapy, large loop excision of the transformation zone, and cold knife conization. Geneva: World Health Organization, 2014 (https://www.who.int/reproductivehealth /publications/cancers/treatment_CIN_2-3/en/, accessed 20 June 2022). [Reference list]
6. World Health Organization: A Global Strategy for elimination of cervical cancer. https://www.who.int/activities/a-global-strategy-for-elimination-of-cervicalcancer
7. World Health Organization: WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions. https://www.who.int/reproductivehealth/ publications/ thermal-ablation-for-cervical-pre-cancer-lesions/en/.
8. WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions. Geneva: World Health Organization; 2019. Executive summary. Available from: https://www.ncbi.nlm.nih.gov/books/NBK549186/
9. WHO guidelines for the use of thermal ablation for cervical pre-cancer lesions. Geneva: World Health Organization; 2019. 1, Introduction. Available from: https://www.ncbi.nlm.nih.gov/books/NBK549179/
10. Pinder LF, Parham GP, Basu P, Muwonge R, Lucas E, Nyambe N, et al. Thermal ablation versus cryotherapy or loop excision to treat women positive for

cervical precancer on visual inspection with acetic acid test: pilot phase of a randomised controlled trial. Lancet Oncol. 2020;21(1):175-84.
11. Mungo C, Osongo CO, Ambaka J, et al. Safety and acceptability of thermal ablation for treatment of human papillomavirus among women living with HIV in Western Kenya. JCO Glob Oncol. 2020; 6:1024–33.
12. Viviano M, Kenfack B, Catarino R, Tincho E, Temogne L, Benski AC, et al. Feasibility of thermocoagulation in a screen-and-treat approach for the treatment of cervical precancerous lesions in sub-Saharan Africa. BMC Womens Health. 2017;17(1):2.
13. Dolman L, Sauvaget C, Muwonge R, Sankaranarayanan R. Meta-analysis of the efficacy of cold coagulation as a treatment method for cervical intraepithelial neoplasia: a systematic review. BJOG. 2014;121(8):929-42.
14. Levy J, de Preux M, Kenfack B, Sormani J, Catarino R, Tincho EF, et al. Implementing the 3T-approach for cervical cancer screening in Cameroon: preliminary results on program performance. Cancer Med. 2020;9(19):7293-300.
15. Banerjee D, Mandal R, Mandal A, Ghosh I, Mittal S, Muwonge R, et al. A prospective randomized trial to compare safety, acceptability and efficacy of thermal ablation and cryotherapy in a screen and treat setting. Asian Pac J Cancer Prev. 2020;21(5):1391-8.
16. Cubaka VK, Schriver M, Cotton P, Nyirazinyoye L, Kallestrup P. Providers' perceptions of communication with patients in primary healthcare in Rwanda. PLOS ONE. 2018;13(4):e0195269.
17. Campbell C, Kafwafwa S, Brown H, Walker G, Madetsa B, Deeny M, et al. Use of thermo-coagulation as an alternative treatment modality in a screen-and-treat programme of cervical screening in rural Malawi. Int J Cancer. 2016;139(4):908-15.