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ORIGINAL RESEARCH

Acceptability and safety of thermal ablation treatment for cervical cytological abnormalities in Pretoria, South Africa

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Background: Cervical cancer is one of the leading causes of cancer deaths in women, and 90% of the deaths occur in low- to middle-income countries (LMICs). Accessible cervical cancer screening and treatment options are an urgent priority. Thermal ablation (TA) is an alternative treatment option available for cervical premalignant conditions. The World Health Organization (WHO) has endorsed TA and published guidelines on its use. Most studies on the treatment's efficacy, safety, and acceptability are from high-income countries.

Methods: A prospective cohort study that recruited women who presented with abnormal cytology results from three hospitals in Pretoria, South Africa. Colposcopy examinations were done to assess patients' eligibility for TA. Post-treatment questionnaires were completed by participating doctors and women to assess the acceptability and safety profile of the treatment. Follow-ups were scheduled on day 7 to assess the safety profile further, and adverse events (AEs) were recorded.

Results: The analysis included 58 women. The mean age was 42.4 years. Our findings showed a safety rate of 91.4% and a patient satisfaction rate of 96.6%. All the participating doctors and women recommended the treatment. Most of our findings were consistent with those from previous studies.

Conclusion: Our study demonstrated TA as a safe and acceptable treatment method for cervical premalignant conditions in low-resource settings. The treatment does not require expensive infrastructure and can be performed by generalist doctors.

Keywords: cervical cancer screening, premalignant cervical conditions, colposcopy, punch biopsy, thermal ablation

Introduction

Effective screening for cervical cancer and treatment of precancerous lesions are pillars in the World Health Organization's (WHO's) strategy to eliminate cervical cancer.[1] Solving the preventable tragedy of cervical cancer by 2030 is also a frontline project of the International Federation of Gynaecology and Obstetrics (FIGO).[2] South Africa carries a high burden of cervical precancerous and cancerous lesions, with the resulting treatment load.[3-6] It is essential that generalists and trained nurse practitioners assist in managing pre-invasive/premalignant cervical lesions.

Standard treatment for premalignant cervical conditions includes cold knife conisation, large loop excision of the transformation zone (LLETZ), and laser conisation. Thermal ablation (TA) or coagulation is an alternative treatment option for outpatient settings but has not been implemented widely in South Africa. The WHO endorsed the method, published guidelines on its use, and recommends that trained nurses and midwives perform TA.[1,7,8]

Existing data show TA to be as safe and effective as LLETZ and cryotherapy for treating cervical intraepithelial neoplasia (CIN).[9-11] Ablative methods are generally indicated for low-grade squamous intraepithelial lesions (LSIL) or CIN1–2, showing high cure rates of 90–95%.[10,12] Cure rates were reported to be lower at 79–94% in high-grade squamous intraepithelial lesions (HSIL).[12] According to the WHO, no comparative studies between TA, other treatments, and no treatment are available for women living with human immunodeficiency virus (HIV, WLWH) with histologically confirmed CIN2–3. Some studies show TA cure rates to be similar between WLWH and HIV-negative women.[13] From a patient perspective, differences in benefits and harms between TA and cryotherapy seem trivial, but there are likely considerable resource savings using TA. Ablation may also be more acceptable and readily available; therefore, more feasible to implement than cryotherapy in many healthcare settings.[13]

This study evaluated the performance of TA before its routine use for treating cervical cytological abnormalities at the University of Pretoria Academic Hospital Complex. These hospitals in Gauteng Province, South Africa, provide public healthcare to a low- and middle-income population. We aimed to determine the acceptability and safety of TA in HIV-negative women and WLWH, as evaluated by patients and the doctors performing the procedures. The study was approved by the Research Ethics Review Committee of the Faculty of Health Sciences, University of Pretoria (reference number 463/2022) and approved by the hospitals and Gauteng Health Research Committee.

Materials and methods

Design, setting, and population

This prospective cohort study recruited non-pregnant women (aged 18 years and above) who presented with abnormal

cervical cytology results for colposcopy to Steve Biko Academic, Kalafong Provincial Tertiary, and Tshwane District hospitals from May to September 2023. Participants were screened for inclusion and exclusion criteria, and their informed, written consent was obtained.

Women with abnormal cytology results, including atypical squamous cells of undetermined significance (ASCUS), atypical squamous cells with high-grade squamous intraepithelial lesions not excluded (ASC-H), LSIL, and HSIL were screened with a visual inspection of the cervix after acetic acid application (VIA)/ Lugol's iodine application (VILI) and were subjected to colposcopy assessments to determine eligibility for TA treatment.

Exclusion criteria were previous surgical treatment of the cervix, lesions covering more than 50% of the cervix, extending beyond the cervix or out of reach of the probe, suspicion of invasion, or unsatisfactory visualisation of the transformation zone (TZ). Data were collected on all study participants, but only patients who received TA were included in the final analysis.

Participating healthcare workers (HCWs) included a medical officer, junior and senior registrars in the Department of Obstetrics and Gynaecology, and a junior registrar from the Department of Family Medicine. After colposcopy, a cervical block was performed using 1% lidocaine, and punch biopsies were taken from the lesions. Women without a visible lesion were considered eligible for treatment, in which case random biopsies were taken at 3 and 9 o'clock areas after receiving 1% lidocaine.

A MedGyn TA system (MTA-100) was used throughout the treatment in the implementation trial. The probe was preheated to 100 °C with a first treatment cycle length of 40 seconds. Cycles were repeated where necessary to cover the total lesion. The shortest cycle length was 20 seconds, the average length was 40 seconds, and the longest cycle length was 60 seconds. Standard operating procedures were adhered to for infection control and to reduce the risk of errors.

After treatment, questionnaires were administered to patients and HCWs to evaluate the participants' experience, safety, and acceptability of the treatment. Patients were advised on possible adverse events (AEs), good hygiene practices, and six weeks of abstinence. Patients also received a prescription for analgesia and antibiotics as per our LLETZ protocol. Telephonic follow-ups were done on day 7 to record AEs such as pain/cramps, dizziness, vaginal discharge, bleeding, and fever to assess the safety profile further.

Statistical analysis

All data was entered into Microsoft Excel and exported to Stata 11 (StataCorp LLC, College Station, United States) statistical software for analysis. Descriptive data analysis produced frequencies and percentages for categorical variables and means, standard deviations, medians, ranges, and interquartile ranges for numerical variables.

Results

Demographics and eligibility

A total of 76 women were screened for inclusion, with a mean age of 42.4 years (standard deviation 9.8) (Table I). Of these, 51 (67.1%) were WLWH, all on antiretroviral treatment, seven with a CD4 count < 200 cells/mm^3. Most women presented with HSIL/CIN2+. Among the 76 women who were screened, 60 (78.9%) were found to be eligible for TA during colposcopy; however, 58 (76.3%) met the study inclusion criteria and were treated with TA. Moreover, 37/58 (63.8%) of them were WLWH. Two of the 60 women screened positive on assessment, but one declined treatment, and the other previously had a surgical procedure on the cervix. All the women who did not meet the inclusion criteria were managed accordingly. Some women had more than one lesion characteristic that formed part of the exclusion criteria.

Table I: Lesion characteristics of all screened women (*n* = 76)

Variables		Number (*n* = 76)	%	Eligible for TA
Cytology results	ASCUS	13	17.1	Yes
	ASC-H	13	17.1	Yes
	LSIL/CIN1	15	19.7	Yes
	HSIL/CIN2–3	35	46.1	Yes
TZ fully visible		60	78.9	Yes
TZ not fully visible		16	21.1	No
Lesion size	No lesion visible	23/76	30.3	Yes
	Small, < 2/4 of the cervix	45/76	59.2	Yes
	Large, > 2/4 of the cervix	8/76	10.5	No
Position of lesion	No lesion	23/76	30.3	Yes
	Cervix only	49/53	92.5	Yes
	> 2 mm into endocervix	4/53	7.5	No
	Extend to vaginal wall	1/53	1.9	No
	Outside reach of probe	7/53	13.2	No

ASC-H – atypical squamous cells with HSIL not excluded, ASCUS – atypical squamous cells of undetermined significance, CIN – cervical intraepithelial neoplasia, HSIL – high-grade squamous intraepithelial lesion, LSIL – low-grade squamous intraepithelial lesion, TA – thermal ablation, TZ – transformation zone

Participating women and doctors' reported outcomes

Questionnaires used Likert scales to assess safety and acceptability. Variables used to assess safety were pain, heat sensation, bleeding, vaginal discharges, dizziness, vasovagal reaction, and accidental vaginal burns. Patient and doctor satisfaction with treatment duration and overall experience, patient and doctor recommendations, and the device's operability were variables used to assess acceptability.

Most women (87.9%) were satisfied with the treatment duration. Mild pain (very mild and mild) was experienced by 25 women (43.1%), lasting no more than 10 minutes (92.4%). Bleeding occurred in 17 women (29.3%) but was quantified as < 25% of the pad. Positive responses were given by 56 women (96.6%) regarding their overall experience, and all participants would recommend TA (Table II).

The 12 participating doctors completed a total of 58 questionnaires. The doctors found the device easy to operate,

even during this implementation study, where the median number of procedures was four. In 54 responses (98.2%), doctors reported the device as efficient, with patient safety ensured in most treatments (n = 53, 91.4%). There were four accidental vaginal burns (6.9%, none requiring intervention), and technical issues occurred in seven treatments (12.1%).

Doctors reported that most patients experienced very mild pain (n = 30, 51.7%), with bleeding mainly from biopsy sites, and one mild vasovagal reaction occurred (< 5 minutes). Most patients received one cycle (n = 29, 50.0%) or two cycles (n = 24, 41.4%) of TA, mostly with the timer set at 40 seconds. The patients tolerated the treatment well, and HCWs stated they would recommend TA administration by other HCWs or nurses in 57 questionnaires (98.3%). All participating doctors recommended introducing the treatment method for our unit (Table III).

Table II: Patients' immediate reported experience of TA procedures

Variables		Number (n = 58)	%
Satisfied with treatment duration	Definitely yes	46	79.3
	Partially yes	5	8.6
	No	7	12.1
Heat sensation in vagina	No	26	44.8
	Very mild	20	34.5
	Mild	8	13.8
	Moderate	2	3.4
	Severe	2	3.4
LAP/cramps during procedure	No	32	55.2
	Very mild	14	24.1
	Mild	11	19.0
	Moderate	1	1.7
	Severe	0	0.0
Duration of LAP/cramps (minutes) (Reported pain, n = 26)	< 5	13/26	50.0
	5–10	11/26	42.4
	20–30	1/26	3.8
	> 30	1/26	3.8
PV bleeding after procedure	None	41	70.7
	< 25% pad soaked	17	29.3
	> 25% pad soaked	0	0.0
Dizzy/faint during procedure	Yes	5	8.6
	No	53	91.4
Overall experience	Very satisfied	45	77.6
	Satisfied	11	19.0
	Other/fair	2	3.4
Recommend to friends/family/other patients		58	100

LAP – lower abdominal pain, PV – per vagina, TA – thermal ablation

Telephonic follow-up – day 7

Data was available from telephonic follow-ups of 43 participants (74.1%), of whom 37 (86.0%) reported mild AEs. The most common AEs were watery vaginal discharge (35/43, 81.4%), spotting to mild bleeding (< 1 week, 11/43, 25.6%), and mild pain (11/43, 25.6%). Severe abdominal pains lasting three days were reported by one woman (2.3%), but no one reported offensive discharge, prolonged bleeding, fever, or vasovagal reactions after treatment (Table IV).

Table III: Participating doctors' experience in performing TA procedures

Variables		Number (n = 58)	%
Device easy to operate	Yes	58	100
	No	0	0
Device allowed efficiency (responses, n = 55)	Yes	54/55	98.2
	No	1/55	1.8
Treatment duration (minutes)	< 5	47	81.0
	5–10	9	15.5
	10–20	2	3.5
Treatment cycles	1	29	50.0
	2	24	41.4
	3	4	6.9
	4	1	1.7
Timer settings (cycles, n = 93)	20 seconds	8/93	8.6
	40 seconds	84/93	90.3
	60 seconds	1/93	1.1
Device ensured patient safety	Definitely yes	53	91.4
	Partially yes	5	8.6
	No	0	0.0
Accidental vaginal burns	No	54	93.1
	Very mild	3	5.2
	Moderate	1	1.7
	Severe	0	0.0
Estimated bleeding (blood on gauze)	< 25% soaked	29	50.0
	25–50% soaked	29	50.0
	> 50% soaked	0	0.0
Pain estimate	No pain	19	32.8
	Very mild	30	51.7
	Mild	9	15.5
	Moderate	0	0.0
	Severe	0	0.0
Procedure tolerated by the patient?	Definitely yes	51	87.9
	Partially yes	7	12.1
	No	0	0.0
Technical problems	No	51	87.9
	Rarely	6	10.4
	Sometimes	1	1.7
Recommend for use by other HCWs/nurses	Yes	57	98.3
	No	1	1.7
Doctors recommending introduction for use in our unit	Yes	12	100
	No	0	0.0

HCWs – healthcare workers

Discussion

Data on the use and efficacy of TA for the treatment of pre-invasive cervical lesions among WLWH are limited, and there are several ongoing studies.[14] Currently, the recommendations

Table IV: Patients' experiences of TA – delayed report at day 7

Variables		Number (n = 43)	%
Adverse events	Yes	37	86.0
	No	6	14.0
Heavy vaginal discharge	Yes	7	16.3
	No	36	83.7
Watery vaginal discharge	Yes	35	81.4
	No	8	18.6
Spotting/mild/heavy vaginal bleeding	Yes	11	25.6
	No	32	74.4
Mild abdominopelvic pain/ cramps	Yes	11	25.6
	No	32	74.4
Intermittent vaginal pain/ cramps	Yes	5	11.6
	No	38	88.4
Severe abdominal pains (3 days)	Yes	1	2.3
	No	42	97.7

for HSIL management are similar for WLWH and HIV-negative women.[15] A large proportion (n = 37/58, 63.8%) of participating women in this study were WLWH. This is a true reflection of the high burden of cervical premalignant lesions and cervical cancer in this group, providing some promising preliminary data. In the current study, TA treatment was brief, lasting less than five minutes in 81% of the cases. Most participating doctors also found TA safe (91.4%) and easy to perform (100%). Positive responses were received after treatment from 96.6% of the women, all of whom recommended the treatment, proving TA to be highly acceptable in this study.

Importantly, TA was well tolerated by patients (87.9%) with no severe AEs. Most patients (55.2%) did not report pain, and those who had lower abdominal pain reported it as very mild (24.1%) or mild (19.0%). More than half of the participants (55.1%) experienced a warm sensation in the vagina during the procedure. The accidental vaginal burns (6.9%) that occurred during application or removal of the ablation device did not cause any bleeding or require any intervention.

Our research ethics board recommended cervical block using 1% lidocaine in this project, possibly contributing to the outcomes of no lower abdominal pain, very mild and mild pain. Similar to cervical cryotherapy, TA does not require regional or general anaesthesia.[7,13,14] In a study by Sandoval et al.,[16] the conclusion was that there is no need for pain medication for TA, and there was even confusion between pain from biopsy versus ablation. Piret et al.[11] also indicated that various medical providers can perform TA, and it does not require anaesthesia. TA does not commonly cause procedure-associated bleeding. In the study by Piret et al.,[11] bleeding during or immediately after treatment was rare and occurred in 2% of women. In our study, most of the bleeding during the procedure was attributed to the punch biopsies.

The main AEs associated with the procedure were reported as secondary bleeding and vaginal discharge, mostly occurring between one and six weeks after the procedure.[9] In this study, the most common AEs reported on follow-up were watery discharge (35%), abdominopelvic pain/cramps (11%), and spotting and mild bleeding (11%). In a study by Viviano et al.,[9] almost all treated women reported watery vaginal discharge, seldom with little blood, for about two weeks, while few reported abdominal pains.

No randomised or non-randomised studies evaluate the benefits and harms of prophylactic antibiotics in TA; therefore, we used our LLETZ protocol and prescribed prophylaxis.[13] No AEs suggesting infections were reported in the current study, but no conclusion can be made as the role of antibiotics was not studied.

Even in this early implementation phase, we showed high patient satisfaction rates with treatment duration and their experience (96.2%). Both groups (participating doctors and patients) would recommend the procedure (100%). This is consistent with the findings in the study by Mungo et al.,[17] showing a high rate of acceptability (98% satisfaction, and 100% would recommend TA to a friend). Pinder et al.,[18] when evaluating acceptability in low- to middle-income countries (LMICs), also found that 100% of treated women would recommend TA.

The current study supports the low morbidity of TA and the use of the procedure in a see-and-treat programme immediately after VIA/VILI, decreasing programme costs and loss to follow-up.[19] TA requires no consumables and provides a sustainable and feasible treatment option in LMICs.[20] The high acceptability rate and low pain scores support the standard practice of treating without anaesthesia, further reducing barriers to widespread implementation.[11,13,16,17,21-23]

The current study does not address treatment efficacy. However, during the planned follow-up phase of the current cohort, we will evaluate the persistence and recurrence rates of precancerous cervical lesions. Continued assessments of the side effects and acceptability are needed to support optimal implementation of the TA treatment modality in screen-and-treat programmes without analgesia use.[11]

Study strengths and limitations

In this prospective study, participating doctors and women gave mutually supporting positive feedback, recommending the use of TA to HCWs and friends/family/other patients. Several screened women did not meet the criteria for TA during colposcopy, providing a relatively small sample for analysis. There were 15 participants (25.9%) who could not be contacted for telephonic follow-up. We believe the procedure to be user-friendly, uncomplicated, and safe enough to expand the performance to trained nurses, but we did not recruit HCWs other than doctors for this study.

Conclusion

The benefits and mostly mild AEs associated with TA advocate for further promotion and integration into clinical practice. The see-and-treat strategy is a valuable option for sustaining a successful cervical cancer screening programme, especially in LMICs. TA has the safety and acceptability for widespread implementation. A follow-up study will focus on the method's treatment efficacy.

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Conflict of interest

The authors declare no conflict of interest.

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Ethical approval

Ethical approval was obtained from the University of Pretoria, Faculty of Health Sciences Research Ethics Committee (reference number 463/2022)

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