RESEARCH

BMC Women's Health



A mixed-methods preliminary evaluation of an innovative treatment for cervical precancer in El Salvador's screen-and-treat program

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Abstract

Background Cervical cancer remains a leading cause of cancer death for women worldwide. Screen-and-treat programs are a key strategy to reduce disease burden in low and middle-income countries (LMICs). Thermal ablation (TA) has emerged as a portable alternative to cryotherapy, the treatment typically used in screen-and-treat initiatives. Interest in TA is growing, but there is limited research on its implementation in public health settings. Here we present results from a preliminary evaluation of the barriers and facilitators of TA in El Salvador, one of the first countries to adopt a national HPV screen-and-treat program.

Methods This mixed-methods study took place between August 2022 to February 2023 across five clinics. The Practical, Robust Implementation and Sustainability Model (PRISM) was utilized to map findings to contextual factors that impact implementation and sustainability. Participants were frontline providers and women who presented for treatment after a positive HPV test. Providers took part in semi-structured interviews while women completed questionnaires. Additional data were collected from clinic records. Quantitative data were analyzed using inferential statistics and a rapid qualitative analysis approach was used for interviews.

Results Providers perceived TA as easier to use and more comfortable for patients, but cryotherapy was utilized 20% more frequently during the study period (cryotherapy treatments = 133 vs. TA treatments = 100). Although the two treatments have the same contraindications, a greater proportion of women were deemed eligible for treatment with TA vs. cryotherapy (95% vs. 79%, p < .001). There were discrepancies in provider and women's perceptions of pain and side-effects. While > 80% of women received counseling during the screen-and-treat process, misconceptions regarding screenings results and treatment remained.

Conclusions The new treatment (TA) was highly acceptable to participants. However, there may be a need for additional provider training to support TA adoption and fidelity to program guidelines, while patients would benefit from more effective counseling. As LMICs strive to meet cervical cancer elimination targets set by the World Health Organization, it is expected that innovations will be quickly introduced to clinical practice. Thus, it is critical to understand the factors that impact their implementation and sustainability in these settings.

Keywords Cervical cancer, Screen-and-treat, Thermal ablation, Cryotherapy, LMIC, El Salvador

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Background

Although preventable, cervical cancer remains a leading cause of cancer death in low- and middle-income countries (LMICs) [1]. Vaccination against the human papillomavirus (HPV), the leading cause of the disease, has only reached 12% of the eligible population worldwide, and this is concentrated in high-income settings [2, 3]. Thus, screening and treatment of precancerous lesions will remain essential to reduce incidence and mortality in the coming decades. Screen-and-treat interventions (i.e., treating screen-positive women without histopathologic diagnosis) are considered essential strategies to increase access to prevention in resource-limited settings [4–6]. There is significant interest in the implementation and sustainability of such initiatives [7-10], and this has been amplified by the call to eliminate cervical cancer launched by the World Health Organization (WHO) in 2018 [11]. While research on the implementation of the screening component of screen-and-treat programs has grown [10, 12-14], treatment has received far less attention [7, 15]. Here, we present results from a preliminary evaluation of the barriers and facilitators of an innovative treatment in the context of El Salvador's screen-and-treat program.

Screen-and-treat approaches typically rely on ablation therapy (i.e., using extreme temperatures to destroy precancerous lesions). Globally, the most widespread ablation treatment for cervical precancer is gas-based cryotherapy. This technique, which has long been part of WHO guidelines [16], achieves freezing temperatures via compressed gas. Although effective, the difficulties of gas procurement and transportation have widely been recognized as limiting factors for scale-up and sustainability [17, 18]. These challenges have spurred interest in thermal ablation (aka cold coagulation, thermoablation) [19], another ablative treatment that uses heat instead of cold. A desktop device unit that runs on electricity has been used for decades [20-23] but in recent years several portable models that operate on rechargeable batteries have been brought to market [24]. Portable thermal ablation (henceforth TA) has been shown to be safe, effective, and acceptable to users [25-27]. There is considerable enthusiasm for TA as a point-of-care solution that does not require a consumable good. Following the WHO's endorsement of the treatment in 2019 [28], TA devices have been rapidly introduced into several LMICs through a combination of research, donation programs, and government investment [10, 29-31]. However, there is remarkably little data on the implementation strategies, processes, or outcomes of these initiatives.

El Salvador has been an early adopter of cervical cancer control innovations. In 2011, the Ministry of Health (MoH) partnered with Basic Health International (BHI), a non-profit organization, to conduct a demonstration project of a screen-and-treat algorithm using a low-cost HPV test (careHPV, Qiagen, Gaithersburg, MD) paired with cryotherapy [32-34]. Eventually the country became one of the first LMICs in the world to implement such a program at the national level [35, 36]. HPV tests have been included in the MoH budget since 2022 and TA was added to the country's cervical cancer control guidelines the same year [37]. Similar updates are underway in other LMICs, although the use of TA in public health systems remains limited. Although the present study was designed prior to the introduction of TA to El Salvador, the country received a donation of 70 devices from an international aid agency at the same time. Thus, some aspects of the study were integrated with MoH preparations for roll-out of the new treatment.

Methods

Conceptual framework and intervention

The Practical, Robust Implementation and Sustainability Model (PRISM) [38-40] was identified as an appropriate framework to contextualize study findings and connect them with eventual efforts to maximize adoption, implementation, and sustainability of the TA intervention. This model was chosen for various reasons: it is easily generalizable to diverse settings, it considers all stages of the implementation process from pre-implementation to maintenance, and it is an extension of the RE-AIM framework, which facilitates future evaluation of implementation outcomes. PRISM is divided into three main components: contextual factors, implementation strategies, and implementation outcomes. Here we will focus on contextual factors, a set of four domains that encompass multiple settings and actors at various levels and which impact implementation and sustainability of the intervention (see Fig. 1).

In this context, ablation treatment is only one element of a multi-component intervention, i.e., the screen-andtreat program. In El Salvador, the program is available for women between the ages of 30 and 59 with no previous HPV test in the last five years. Screening takes place at 717 municipal health units around the country. After 30 days, women with a positive HPV test attend one of 77 regional treatment centers. This second appointment encompasses delivery of HPV test results, counseling, assessment for treatment eligibility, and same-day ablation treatment (or referral to colposcopy for ineligible women). This study focused on this visit and, more narrowly, on ablation treatment. Referral to colposcopy and subsequent management were not addressed.



Fig. 1 The Practical Robust Implementation and Sustainment Model (PRISM) [38, 40]. Contextual factors are shown on the left

Training workshops

At the beginning of the study, a series of TA training workshops designed by the MoH in partnership with BHI were delivered to staff at participating centers (collaborative trainings have been an implementation strategy of the program since its inception). Trainings were integrated in broader preparations to introduce TA to the program. For physicians, training consisted of a didactical group session followed by supervised treatment of patients. For nurses and community health promoters (CHPs), training consisted of one-day sessions that covered HPV and cervical cancer prevention, TA as a new treatment (including device use, disinfection, etc.) and counseling of patients with HPV positive results. Once training was completed, single TA devices (C3 WiSAP Medical Technologies, GmbH, Brunnthal, Germany) were provided to each participating treatment center to use alongside cryotherapy as part of routine care.

Setting and subjects

The study was a mixed-methods evaluation of barriers and facilitators of TA treatment in the screen-andtreat program. It took place between August 2022 to February 2023 at five treatment centers in the Paracentral region (four in rural areas and one in a peri-urban zone). These sites were selected by the MoH as part of their plan to gradually incorporate TA into the screening program. Upon arrival at the treatment center, clinical procedures followed routine practice. Women received their HPV results and counseling from a nurse. They were then offered a speculum exam by a general practitioner. The exam includes visual assessment for treatment (VAT) to confirm eligibility for ablation, and if no contraindications are found, immediate treatment. Cryotherapy and TA are applied in a similar manner using a probe that is placed on the cervix. National guidelines specify a cryotherapy "double-freeze" modality (i.e., 3-min freeze, 5-min thaw, 3-min freeze) while TA application consists of a 30-40 s application followed by 20-s applications until the squamocolumnar junction (SCJ) is fully covered [37]. Contraindications are the same for both treatments (i.e., lesion that is larger than 75% of the cervix, lesion that goes into the endocervical canal, SCJ not fully visible, obstructions such as polyps or condylomas, or suspicion of cancer) The treatment that each woman received was determined internally at each clinic as this is the level at which individual treatment decisions are typically made. Immediately after treatment, women received recommendations to follow for the next 4 weeks (i.e., avoidance of sexual intercourse, submerging the body in water, douching, and using tampons). Women were scheduled to return one year later for repeat HPV testing. In addition to women with positive HPV results, participants were frontline providers including general practitioners who perform treatment, nurses who conduct result delivery and counseling, and CHPs who recruit women and schedule appointments (CHPs are not permitted to deliver screening results).

Data collection and analysis

Data collection occurred on scheduled treatment days. The goal was to obtain data on at least 100 patients per treatment type. Women first attended a consultation with the clinic nurse for intake procedures, including delivery of HPV results. Immediately after, research assistants conducted informed consent procedures and a background questionnaire. Women then continued to the exam room for the speculum exam and possible ablation treatment. During the exam, a checklist was completed which included a treatment pain evaluation using the Wong-Baker scale [41]. At the end of the appointment, women were administered an acceptability survey. Four weeks later, a phone call assessed side-effects and satisfaction with the treatment received. The call was attempted three times before marking data as missing. Semi-structured interviews were also conducted with subsets of women during treatment days and with providers from participating centers at the end of the study period (results from interviews with women will be presented elsewhere). The interview guide for providers is provided as a supplementary file.

Quantitative data were analyzed using inferential statistics as appropriate. Open responses to two shortanswer questions for patients were coded for content analysis using an inductive approach. To simplify interpretation, each response was assigned a single code associated with the first meaningful segment of text (most answers were very short). Provider interviews were analyzed by bilingual team members in Spanish using a rapid qualitative analysis approach developed by Hamilton [42, 43]. First, a "summary template" was created where interview questions and additional recurring themes were each identified by a unique domain name. Then, a template form was filled out for each interview by summarizing participant's responses under the appropriate domain name and this information was transferred into a matrix (participant x domain). The matrix was then utilized to identify common and particularly relevant themes under each domain.

This research and all consent to participate procedures were reviewed and approved by the El Salvador National Ethics Committee for Health Research (CNEIS). The datasets analyzed during the current study are available from the corresponding author on reasonable request and subject to approval by CNEIS.

Results

Two of the PRISM contextual domains (characteristics and perspectives on intervention) focus on the organization that plans or delivers the intervention (e.g., organizational managers, leaders, staff, etc.) and on those who receive it (e.g., patients, families, caregivers, etc.). The other two include the implementation and sustainability infrastructure and the external environment in which the intervention occurs. Each of these domains encompasses multiple elements that play a role in implementation outcomes, although not all may be activated or evaluated in any given study. Below we describe study findings associated with each of these domains.

Recipients (organizational and patient characteristics)

Screen-and-treat facilities and staff are part of a single national public health system under the MoH. A total of 10 providers and 243 HPV-positive women participated in the study (cryotherapy=132, thermal ablation=110). Sociodemographic characteristics as self-reported by patients are presented in Table 1. Providers who took part in interviews were 4 doctors, 4 nurses, and 2 CHPs, all with extensive experience in the program (at each participating center, there were 4–5 providers involved in screen-and-treat). Providers were between the ages of 30 and 53 and all but 2 individuals were female (one doctor and one CHP were male). In interviews, they described the patient population as mostly rural but including a range of ages and formal education. Providers also

Characteristic	Overall N=242	Cryotherapy N = 132	Thermal ablation N = 110	<i>p</i> -value ^a
Age, median (IQR)	36 (32, 45)	36 (32, 45)	36 (33, 44)	0.98
Marital status, n (%)				0.57
Single	70 (29)	33 (25)	37 (34)	
Married/Cohab	158 (65)	90 (68)	68 (62)	
Partner (live separately)	4 (2)	3 (2)	1 (1)	
Divorced	2 (1)	11 (1)	1 (1)	
Widowed	8 (3)	5 (4)	3 (3)	
Education in years, median (IQR	8 (4, 11)	8 (4, 11)	9 (4, 11)	0.31
Employment, n (%)				0.04
Yes	95 (39)	44 (33)	51 (46)	
No	147 (61)	88 (67)	59 (54)	
Travel time to clinic in min- utes, median (IQR)	30 (20, 60)	30 (25, 60)	30 (20, 60)	0.08
Household size, median (IQR)	3 (2, 4)	3 (2, 4)	4 (2, 4)	0.2

 Table 1
 Sociodemographic characteristics of patient participants

^a Wilcoxon rank sum test; Fisher's exact test; Pearson's Chi-squared test

mentioned patient-level barriers including competing demands (e.g., childcare, work) and various sociocultural beliefs and misconceptions, as described more fully below.

Intervention (Organizational and patient perspectives)

Provider perspectives were elicited via semi-structured interviews. Common themes to emerge from matrix analysis are presented on Table 2. Overall, the training workshops were viewed as adequate and useful, but physicians expressed a desire for increased TA practicum time. Both treatments were believed to be effective and safe, but providers at all levels expressed a preference for TA as simpler to use and disinfect, faster and more comfortable for patients, and resulting in fewer pain complaints. Seven mentioned problems with the cryotherapy gas supply that sometimes resulted in postponed treatments. There was a surprising lack of awareness of side-effects of either treatment type, with six providers explicitly stating that neither treatment presented any significant symptoms.

Providers mentioned different barriers associated with screening and treatment. Transportation was viewed as a major challenge for treatment because centers are few and far between compared to primary health units where screening takes place. Lack of childcare and difficulties obtaining permission to miss work were also mentioned in connection to treatment visits. For both screening and treatment, uptake challenges included lack of information of HPV and cervical cancer, resistance to male doctors performing pelvic exams, stigma (e.g., fear of disclosure of HPV status), and various fears and misconceptions (e.g., procedures are painful or cause infertility).

In terms of patient perspectives, close-ended surveys revealed high levels of satisfaction and no differences between treatments. Overall, 97% of women (197/203) reported feeling very satisfied with their treatment and feeling extremely or very confident that the treatment worked. At the 4-week post-treatment survey, overall satisfaction remained unchanged at 98% (98/100) and the same proportion reported they would recommend the treatment to a friend. However, answers to short-answer questions reflected more complicated perceptions. In response to "What do you think a positive HPV test means?" women primarily expressed negative emotions, rather than understanding of the purpose or results of the test. Only 4% (9/242) of women specifically linked their test results to HPV, a virus, or an infection. These women tended to relate their results to the need for treatment and frame the experience more positively (see Table 3).

Regarding treatment ("What treatment did you receive and what was it for?"), 86% (209/242) of women had some knowledge of the treatment they received or its purpose ("The freeze is to eliminate the damaged cells", "A burn to kill the virus", "A treatment to take away the bad thing I have"). An additional 9% (22/242) did not receive a sufficient explanation ("They didn't explain anything", "They just told me they would do a treatment, but they didn't explain which one"), and 5% (11/242) stated they did not remember or provided other descriptions ("They only told me they would do an exam with an acid", "They told me they would apply a cream").

Implementation and sustainability infrastructure

In the context of the El Salvador public health system, there are various facilitating features for innovation implementation and sustainability in the cervical cancer space. Over the last decade, the MoH has demonstrated strong political will to prioritize this health area. Openness to collaborate with research partners ("bridge researchers") has contributed to the adoption of various innovations, including HPV testing and self-sampling [34, 35]. The screen-and-treat intervention is now well-established with multi-disciplinary, dedicated teams in every region of the country. Providers at all levels in this study demonstrated high levels of commitment to the program (see Table 2). However, current findings suggest that challenges related to TA treatment remain or may emerge as the treatment is scaled-up. Main considerations to emerge from interviews and program indicators are:

Adoption of TA treatment

It is yet unknown if the long-term plan for the country involves de-implementation of cryotherapy in favor of TA, and comprehensive data on the performance of each treatment option will be important to make such determination. Providers indicated a preference for TA as easier to use and more comfortable for patients, but cryotherapy was selected 20% more frequently during the study period (cryotherapy treatments=133 vs. TA treatments=100). As in other LMICs, cryotherapy has been in use for years and there are hundreds of providers with extensive experience using this treatment. Interviews with physicians point to issues that may impact TA adoption:

"I have more experience, since I've been doing cryos for years...that's why I feel like a lot of confidence... look, like I said, it's not a problem, but it was adapting from one to the other because it was hard to turn [the TA device] on and I had to learn that they were different regarding the protector and all that, but thank God, all good." (female, 50y).

"For me it was more comfortable to use cryo because it's the only thing that I knew until I learned thermo...honestly, at first I was afraid. I was afraid and I would say, oh my God, I said, this, this is heat, I'm going to burn." (female, 46y).

Domains	Common/salient themes	Illustrative quotes ^a
Training perceptions	-Positive views of training (useful, new knowledge) - Materials and supplies -Desire for longer/more extensive practicum (physicians)	"It has been very illuminating because things that I really did not know about and this has led me in one way or another to research a little bit more about it." Physician, male, 52y "I think it was all very good because they showed us a bit more about how to give the treatments and how to approach the user directly when she has a positive result." Nurse, female, 35y "Well, maybe the materials should be updated, right? Because we have been working with materials from some years back and it would be good to be able to implement new materials and that they are more suitable for a population that can't read or write." CHP, male, 41y
Cryo vs. TA (equipment)	-Cryotherapy more complicated (e.g., gas valve regula- tion, leaks) -Problems with gas supply -TA easier to use	"Of course, sometimes, when the doctor applied it to freeze the gas, it would come out on the other side. It leaked." Nurse, female, 33y ^b "[TA] is not like the cryotherapy gun that you have to turn it on, have to turn it off, and have to be evaluating that the needle doesn't go up into the red area, right? So with thermal ablation you don't see that. With thermal ablation you just place the probe and the doctor starts and that makes it much more practical." Nurse, female, 33y ^b "At first [cryotherapy] was a bit difficult for me because of the valve regulation and it was also difficult because we use to have only the nurse and myself, and sometimes the nurse was not available at that moment. She would come and go and it would fail a little bit and when we had to pull it out it would get blocked, like stuck, but then apart from that, everything fine." Physician, female, 34y "Well, the [TA] equipment is quite simple, very simple, once it's charged and wait until the device is stabilizes and it turns on properly and then measure the seconds that the treatment has to be applied. To me it seems very simple and the time is shorter" Nurse, female, 53y.
Cryo vs. TA (treatment)	-Both are safe and effective -TA more comfortable for patients (e.g., less painful, shorter duration) -TA clinical considerations (e.g., can treat entire area) -Lack of awareness of longer-term side-effects	"The advantage is that recovery with thermo is much faster. The disadvantage with cryo is that the time that the patient has to be lying down receiving the treatment is long. The other practi- cally one or two minutes, exaggerating, and the other is 11 min. Safe. Both methods are safe. Both methods are efficacious. But the patient feels more comfortable with a thermo than a cryo." Physician, female, 46y "[TA] is effective and safe and they [patients] have been satis- fied, they have not felt major side-effects or major pain like with the other one. A little heat, some said. And for me it's better because it's easier, faster, and it also has the advantage that if the whole area is not treated, a second cycle can be done and that is good." Physician, female, 50y "What I liked about [TA] is that for the user, from what I observed, is that it is less painful. The wait times are also shorter. The treatment is faster. And for the users, I could observe that they don't feel a lot of pain." Nurse, female, 33y ^b

Table 2 Domains and themes to emerge from matrix analysis of provider interviews

Table 2 (continued)

Domains	Common/salient themes	Illustrative quotes ^a
Patient-level barriers	-Transportation (barrier to treatment but not screening) -Sociocultural barriers for screening and treatment (e.g., avoidance of male providers)	"The majority of times, it is always transportation. There are communities that we have that only have one bus and if that bus breaks down, they can't come [for treatment]." Nurse, female, 35y "There's population that still depends on their partner to be able to do the exam and also from their family or what the neighbors will say." CHP, female, 30y "There is always the neighbor that says, look, don't go. Like I told you before, they say that if they have the [HPV] test, she will be sterilized and won't be able to have children, so don't go, that has happened or sometimes we have the stereotype of the husband that is also a barrier that prevents them from coming. Why? Because of the fear that a man will do the exam." CHP, male, 41y "In the case of women they always come with the fear that it is a man that will perform the cryotherapies, and that if it is a man, I won't go. But then when one says that a female doctor will be there, well in my case that I will be there, then they say ok then yes and they are more calm." Physician female. 34y
Commitment to the program	-Efforts to ensure adherence -Appreciation for the experience	"To this date I have not had a woman that tells me no, I'm not going. They always attend, even if I have to spend one or two hours giving them a talk, because sometimes when one gives them the result, many women think, I'm going to die, right? So then, one has to explain to them that this is not about dying if they don't get the treatment, maybe it can happen, but the best thing is to receive the treatment." CHP, female, 30y "It has been very positive for me to learn, know more about this topic and this empathy for people too, because I'm a woman. Apart from that, really, this also creates more awareness for me and especially for all women that, thank God, I have the honor to serve in this health facility." Nurse, female, 33y ^b "Well, truly I want to thank, thank for the experiences they have given us also of being able to do something to help women because the truth is that it is hard to lose someone to cancer so being part of this team that is doing something or being part of the team that is fighting this situation, well it's truly excellent." Physician, male, 52y

^a Selected quotes do not illustrate every theme under each domain

^b Two interviewees were nurses with the same age

"What was more difficult for me with the thermal ablation equipment was placing the applicator in the adequate zone without it moving. Because it is not like with cryotherapy that it freezes and it sticks, it doesn't move. But with this one you have to take care to put it in the right place and hold it and that it doesn't move, but apart from that, nothing." (male, 52y).

Clinical training

Although cryotherapy and TA are applied in a similar way, some physicians felt that a more extensive clinical practicum was needed. One noted that she had performed supervised treatments with only 6 patients. Other comments were along similar lines: *"Well, maybe the thermal ablation [could be improved]. Because it was only a few times." (female, 36y).*

"I remember that when they trained us for cryotherapy we spent a week, a whole week...seeing lots of women, it was practically impossible not to learn because there so many cases of so many things that one could, in reality, have very well illustrated, and that was what I wanted, I was surprised." (male, 52y).

Procurement and maintenance

Since TA was introduced to treatment centers via a largescale donation, some upfront expenses were avoided. Other costs associated with expansion, such as probe replacements or device repairs, are currently unknown.

Code	Frequency (%)	Illustrative quotes
Worried/nervous	71 (29)	"It's something that worries me, but I'm calm that I will get treatment." "I was very nervous but I got calmer when they explained and that's why I came to my appointment today." "I'm worried, I don't know about this topic."
Afraid/frightened	28 (12)	"I was frightened but I decided to come to see what I had." "I was afraid, I thought it was something complicated but then I calmed down because they explained that it was a lesion and that I should come today and follow the recommendations." "I have a lot of fear, they don't give us a lot of information."
Shocked/surprised	21 (9)	"I didn't expect it, but I will take the treatment they give me." "I was very surprised, I didn't expect this." "I felt shocked, with fear even though I had heard about that problem."
Other negative emotion (e.g., bad, sad, etc.)	35 (14)	"Very bad, but I wanted to come because I love my daughters and want to be well for them." "I feel very sad, I never imagined they would do that to me." "I felt like my world collapsed."
Neutral or positive (incl. 9 women with fac- tual statements about the HPV test)	43 (18)	"I think that it's good because they detect it on time and that way they can treat it." "I am willing to receive the treatment for my own good." "Excellent because it prevents a serious illness in the long term." "That I have the virus that can cause a cancer."
Cancer-focused	19 (8)	"I can get cancer if I don't get treated." "I thought that maybe it was cancer." "I thought it was a symptom of cancer."
Reference to sexual relations	7 (3)	"It happens due to not being careful with partners." "I think it was my husband, because I did it 5 years ago and it came out fine." "The doctor told me it was due to sexual relations."
Other	18 (7)	"We don't know what God will send us." "I think it's serious, I think it's a fungus." "I don't know about this, I don't know what it is."

Table 3 Content analysis of patient responses to short-answer question: What do you think a positive HPV test means?

At least one nurse mentioned a consideration related to maintenance that emerged during training, which highlights the need to align equipment and supplies with locally available resources:

"In the moment when we were trained, the colleague [who gave the training] had material, well, equipment to put it that way, for disinfection, that currently the Ministry of Health doesn't have." (female, 33y).

The only two device failures during the study were linked to cryotherapy (a gas leak and a probe that did not defrost properly). Maintenance needs of TA are not yet known, but a plan for such contingencies will be essential to ensure sustainability of this innovation.

Program indicators

The study was not designed or powered to measure implementation outcomes, but performance indicators provide preliminary data (Table 4). There were some discrepancies between program guidelines and observed processes. Salient among these were time periods between screening and result delivery that were significantly longer than 30 days, heterogeneity in the result delivery process, and adequacy of patient counseling after a positive HPV test. Providers perceived TA as less painful than cryotherapy and there were no significant differences in median pain between the two treatments reported by women. However, 12.2% of women in the TA group reported moderate to severe pain levels (>6) compared to 6.9% in the cryotherapy group. As expected, mean duration of speculum exams (including VAT and treatment if eligible) was twice as long with cryotherapy than with TA (in minutes, 20 vs. 9, p < 0.001, respectively).

Eligibility criteria are identical for both treatments; however, a significantly larger proportion of women in the cryotherapy group vs. the thermal ablation group were deemed ineligible for treatment (21% vs. 6%, p < 0.001). To better understand this difference, we examined the reasons for ineligibility indicated by physicians. Among the 28 women ineligible for cryotherapy, the most common contraindications were a SCJ that was not fully visible (10), lesions that extended into the canal (4), and lesions larger than 75% of the cervix (3). The remaining 11 included women with various other contraindications (e.g., polyps, atrophied cervix) (7), unspecified

Variable	Overall N = 242	Cryotherapy N=132	Thermal ablation <i>N</i> = 110	<i>p</i> -value ^a
Months since previous screening, median (IQR)	59 (45, 80)	56 (41, 71)	63 (52, 87)	0.002
Missing	4	1	3	
Days to result delivery,median (IQR)	39 (24, 59)	34 (20, 51)	49 (29, 69)	< 0.001
Missing	4	4	3	
Staff who delivered HPV result, n (%)				0.082
Doctor	70 (29)	40 (30)	30 (27)	
Nurse	146 (60)	73 (55)	73 (66	
Health promoter	26 (11)	19 (14)	7 (6)	
Referral to treatment method, n (%)				0.14
At local health unit	116 (48)	65 (49)	51 (46)	
Received phone call	96 (40)	46 (35)	50 (46)	
Received home visit	28 (12)	19 (14)	9 (8)	
Other	2 (1)	2 (2)	0 (0)	
Counseling at referral, n (%)				0.7
Yes	205 (85)	113 (86)	92 (84)	
No	37 (15)	19 (14)	18 (16)	
Counseling at arrival, n (%)				.026
Yes	226 (93)	119 (90)	107 (97)	
No	16 (7)	13 (10)	3 (3)	
Pain during procedure, n (%)				0.4
0	27 (14)	17 (17)	10 (10)	
2	104 (52)	56 (54)	48 (49)	
4	51 (26)	23 (23)	28 (29)	
6	11 (6)	5 (5)	6 (6)	
8	7 (4)	2 (2)	5 (5)	
10	1 (1)	0 (0)	1 (1)	
Missing	41	29	12	
Duration of speculum exam in minutes, median $({\rm IQR})^{\rm b}$	13 (9, 21)	20 (16, 24)	9 (8, 12)	< 0.001
Missing	7	4	3	
Eligibility for ablation, n (%				< 0.001
Eligible (no contraindications)	208 (86)	104 (79)	104 (95)	
Not eligible (contraindications)	34 (14)	28 (21)	6 (5)	
Received recommendations, n (%)				0.47
Yes	217 (90)	116 (87)	101 (93)	
Yes but didn't understand/remember	6 (3)	4 (3)	2 (2)	
No	18 (7)	12 (9)	6 (5)	
Missing	1	0	1	

Table 4 Preliminary indicators of implementation performance

^a Pearson's Chi-squared test; Fisher's exact test; Wilcoxon rank sum test

^b Including VAT and treatment, if eligible

contraindications (3), and one suspicion of cancer. In contrast, of 6 ineligible women in the TA group, reasons were a SCJ that was not visible (4) a lesion extending into canal (1), and polyps (1). Other contraindications were not mentioned. Finally, across treatments, 10% of women reported either not receiving or not understanding post-treatment recommendations.

Another consideration is potential treatment sideeffects. Some providers alluded to headaches or dizziness experienced immediately after the procedure and 17 (7%) women reported vasovagal symptoms at the time. This was more frequent for women in the cryotherapy than the TA group (11% [14] vs. 3 [3%] respectively, p = 0.01). However, a patient assessment at 4 weeks post-treatment revealed other side-effects (Table 5). The most frequent was watery discharge with almost half of all women reporting intensity as severe but lasting significantly longer in cryotherapy than TA patients (median 21 vs. 15 days, p < 0.001). Bleeding or spotting, on the other hand, was experienced by a larger proportion of women who received TA than cryotherapy (32% vs. 16%, p = 0.061) but mostly described as low intensity. Cramping and malodorous discharge were similar in frequency, intensity, and duration between the two treatments. The impact of side-effects on treatment adherence and patient choice merits further investigation.

External environment

The 2018 WHO call to eliminate cervical cancer has influenced global decision-making by governments, researchers, aid organizations, and funding agencies. It has accelerated the development of new technologies and may facilitate the global implementation of innovations in cervical cancer prevention, including TA. It is less certain how the initiative will impact sustainability, particularly in low-resource settings. However, the overall role of the WHO in cervical cancer control efforts in LMICs cannot be underestimated. Since many countries closely follow WHO recommendations, the inclusion of TA in the agency's cervical precancer treatment guidelines has already spurred change in the regulatory environment. El Salvador updated its own national guidelines in 2022, which made possible the introduction of TA devices into the public health system. Similar guideline changes have occurred or are anticipated in other countries [28, 44], allowing for the implementation of new initiatives that can increase access for vulnerable populations (offering treatment at mobile clinics, for example).

Other crucial actors in the external environment include the manufacturers and distributors of technologies at the center of screen-and-treat interventions (e.g., screening tests, treatment equipment). In the case of TA, the three companies that currently market these devices are relatively small. Future challenges may include the ability to meet growing demand and the need for regional representatives that can negotiate prices, facilitate procurement, and undertake export and import processes. A lack of marketing and distribution infrastructure has the potential to hinder expansion and scale-up of this innovation.

Finally, an understudied factor are community resources that can help mitigate existing barriers to treatment adherence such as stigma or misconceptions about screening and treatment. Although conditions will vary in every context, there are recent examples of leveraging assets at the community level to increase uptake to cervical screening and treatment [45–48].

Discussion

The WHO cervical cancer elimination initiative is a unique window of opportunity to accelerate cervical cancer control in LMICs. As member countries have recently reaffirmed their commitment to reach elimination targets [49, 50], new initiatives are in development to increase global HPV vaccination, validate low-cost screening methods, and implement or expand screen-and-treat programs [51–54]. Implementation science (IS) has an essential role to ensure that health systems are ready to receive and sustain innovations. In Fig. 2, we summarize barriers and facilitators of ablation treatment that emerged from this study and map them to PRISM contextual factors. These findings can help develop strategies to support the implementation and sustainability of TA in El Salvador and other LMICs.

In many ways, El Salvador is an optimal environment to ensure that a cervical cancer control innovation is successfully integrated into the health system. There is a track record of political will, an established program with a strong infrastructure and dedicated staff, and a history of successful implementation strategies (e.g., training workshops, tracking of patients by CHPs, etc.). Transportation to treatment facilities is challenging, but the MoH has steadily opened more clinics since the program started (from 70 to currently 77) and the portable nature of TA may alleviate this issue. In addition, interviews suggest that providers are highly motivated and find TA acceptable and comfortable for patients. On the other hand, familiarity with cryotherapy may hinder widespread adoption of TA and this may account for differences in the use of each method during the study period. There are also outstanding sustainability questions related to the procurement and maintenance of TA equipment. Finally, there are significant education gaps, including women's understanding of the screening test. Since delivery of HPV results and the offer for treatment occur at the same time, uncertainties surrounding the test may impact women's uptake and experience of treatment.

There are areas where program fidelity may need to be improved, specifically the length of time of result delivery and the adequacy of patient counseling. An important discrepancy to emerge was the increased eligibility for treatment with TA compared to cryotherapy. Unlike cryotherapy which involves a fixed number of applications, TA allows for multiple applications at the judgment of the clinician. This may result in patients with larger or otherwise ineligible lesions being treated with TA when instead they should be referred to other colposcopy and alternative treatment. Further research will be necessary to investigate this possibility, but it will be important to address maintenance of TA treatment quality in future physician trainings. On the other hand, previous research has indicated that up to 70% of patients referred to colposcopy may not attend follow-up

Side effect	Overall N=242	Cryotherapy N=132	Thermal Ablation $N = 110$	<i>p</i> -value ^b
Cramps, n (%)				0.48
Yes	34 (34)	15 (31)	19 (37)	
No	66 (66)	34 (69)	32 (63)	
Missing	142	83	59	
Intensity, n (%)				0.69
Low	9 (26)	3 (20)	6 (32)	
Moderate	11 (32)	6 (40)	5 (26)	
Severe	14 (41)	6 (40)	8 (42)	
Duration, median (IQR)	6 (2, 8)	6 (2, 15)	6 (3, 7)	0.97
Watery discharge, n (%)				0.2
Yes	87 (89)	40 (83)	47 (94)	
No	11 (11)	8 (17)	3 (6)	
Missing	144	84	60	
Intensity, n (%)				0.79
Low	11 (13)	4 (10)	7 (15)	
Moderate	35 (41)	17 (44)	18 (38)	
Severe	40 (47)	18 (46)	22 (47)	
Duration, median (IQR)	15 (10, 28)	21 (15, 30)	15 (7, 20)	< 0.001
Malodorous discharge, n (%)				0.93
Yes	16 (16)	8 (16)	8 (16)	
No	84 (84)	41 (84)	43 (84)	
Missing	142	83	59	
Intensity, n (%)				0.99
Low	7 (44)	4 (50)	3 (38)	
Moderate	2 (13)	1 (13)	1 (13)	
Severe	7 (44)	3 (38)	4 (50)	
Duration, median (IQR)	8 (5, 15)	15 (5, 18)	7 (5, 13)	0.31
Bleeding, n (%)				0.026
Yes	24 (24)	7 (14)	17 (33)	
No	76 (76)	42 (86)	34 (67)	
Missing	142	83	59	
Intensity, n (%)				0.58
Low	12 (55)	5 (71)	7 (47)	
Moderate	5 (23)	1 (14)	4 (27)	
Severe	5 (23)	1 (14)	4 (27)	
Duration, median (IQR)	5 (3, 11)	5 (2, 8)	5 (4, 15)	0.28

 Table 5
 Side effects reported by patients at 4 weeks post-treatment^a

^a For all side effects, intensity and duration only apply for those who experienced the symptom

^b Wilcoxon rank sum test; Fisher's exact test; Pearson's Chi-squared test

care [33]. The use of TA may reduce the number of referrals and thus, the loss to follow-up for this group of women.

As more patients become familiar with the different treatments, other factors may become important in treatment choice. There is evidence that TA is more painful, and this has been reported as a concern in previous studies [26, 27, 55]. Indeed, while the median level of pain reported by patients in this study did not differ according to treatment, a larger proportion of patients treated with TA reported moderate to severe pain. However, patients

found both treatments highly acceptable and 8/10 providers specifically mentioned less pain as an advantage of TA. This discrepancy may be due to the longer duration of cryotherapy being experienced as more uncomfortable than TA, regardless of pain during the treatment procedure. Another suggestive finding is the lack of discussion of side-effects among providers. These are welldocumented among patients and there are differences in frequency and duration that may render one treatment preferable over the other.



Fig. 2 Main barriers and facilitators of TA implementation mapped to PRISM contextual factors

Limitations of the study are the small sample size and scope of this project. Findings are preliminary but suggest new research avenues to understand the factors that impact adoption of the new technology, determinants of sustainability, and existing gaps in the program. The study focused on patients with HPV positive results that presented for appointments at treatment centers; thus, it is yet unknown to what extent these factors prevent women from undertaking screening or treatment in the first place. Another weakness is that no data was collected to investigate how decisions were made to treat women with one or another of the available treatments. Understanding the factors that impact adoption of the new technology is an important question for future research in this arena.

Conclusion

There is increased interest in applying the theories and frameworks of IS to global cervical cancer prevention, but significant research gaps remain [5, 7, 56, 57]. The WHO call for elimination has generated rapid change in many LMICs, and IS can make a significant contribution to ensure the current momentum is not a missed opportunity. In the case of TA, there are initiatives to deploy this treatment across diverse contexts but there is virtually no data on the use of this technology in public health systems. As many LMICs have made commitments to meet elimination targets, other innovations are expected to move quickly into clinical practice. Thus, it is imperative to identify gaps, evaluate readiness, and put in place strategies that can support implementation and sustainability. This study takes a step in that direction. Findings can help identify determinants that maximize adoption, implementation, and sustainability of TA, and can help evaluate the use of this technology in other settings.

Abbreviations

- BHI Basic Health International
- CHP Community health promoter
- CNEIS Comité Nacional de Etica de la Investigación en Salud
- HPV Human papillomavirus
- IS Implementation science
- LMIC Low and middle-income countries
- MoH Ministry of Health
- PRISM Practical, Robust, Implementation and Sustainability Model
- SCJ Squamocolumnar junction
- TA Thermal ablation
- VAT Visual assessment for treatment
- WHO World Health Organization

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s12905-025-03638-x.

Supplementary Material 1.

Acknowledgements

Not applicable.

Authors' contributions

MS contributed to the design of the study, analysis and interpretation of data, and drafted the manuscript. LL and JRP contributed to study design, data acquisition, and interpretation of data. GCR contributed to study design, data analysis and interpretation, and manuscript review. KP and JMV contributed to study design and interpretation of data. EM, RM, and MC contributed to study design, interpretation of data, and manuscript revision. KA contributed to study design, data acquisition and interpretation, and manuscript revision of this manuscript review. All authors have approved the submitted version of this manuscript.

Funding

This research was funded by a grant from Prevent Cancer Foundation Global Grants Program.

Data availability

The datasets analyzed during the current study are available from the corresponding author on reasonable request and subject to approval by CNEIS.

Declarations

Ethics approval and consent to participate

This research and all consent to participate procedures were reviewed and approved by the El Salvador National Ethics Committee for Health Research (CNEIS). All clinical procedures were conducted in accordance with El Salvador national guidelines and regulations. All participants provided informed consent to participate. The research was conducted in compliance with the principles outlined in the Helsinki Declaration.

Consent for publication

Not applicable.

Competing interests

Montserrat Soler is a paid research consultant for Basic Health International (BHI). Miriam Cremer is President and Founder of BHI and on the Speaker Bureau for Merck and Organon. Rachel Masch is on the Speaker Bureau for Organon.

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Received: 10 December 2024 Accepted: 26 February 2025 Published online: 13 March 2025

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