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CRYOTHERAPY FOLLOWING VISUAL INSPECTION WITH ACETIC ACID AND LUGOL'S IODINE (VIA/VILI) IN KHWISERO, WESTERN KENYA: LESSON FROM THE FIELD AFFECTING POLICY AND PRACTICE

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ABSTRACT

Background: Cervical cancer can be prevented and mortality/morbidity reduced by early detection and referral. Developing countries are likely to benefit from more cost effective methods of screening and treatment. Visual inspection with acetic acid and Lugol's iodine (VIA/VILI) offers a see and treat solution thus an affordable and efficient way to identify pre-malignant lesions. Immediate treatment with cryotherapy can be offered if pre-malignant lesions are found on visual inspection. Cryotherapy is a simple procedure that is curative for dysplasia; it is likely to benefit cervical dysplasia cases picked early in resource poor settings, however there are several factors that hinder patients' access to this noble technique.

Objective: Determine hindrances to cryotherapy for patients following positive results of VIA/VILI after referral.

Design: Cross sectional Study

Setting: Khwisero, Western Kenya.

Subjects: Women attending a medical camp, willing to get screened for cervical cancer.

Results: One hundred and nine patients were screened; seventy three (66.97%) were negative for VIA/VILI, twenty one (19.26%) were positive and referred for cryotherapy. Reasons for lack of follow up were financial constraints, lack of medical personnel at referral centres and poor access to the referral facilities. 19.26% of women identified with positive lesions required intervention. No patient received cryotherapy following referral.

Conclusion: There is urgent need for availability of cryotherapy machines and training of personnel who can perform cryotherapy at the primary care level. Regional studies on knowledge attitudes and practices about VIA/VILI and cryotherapy are required to provide reasons for the poor uptake of this procedure.

INTRODUCTION

Each year cervical cancer is diagnosed in nearly half a million women, and more than 260,000 die of the disease (1). Screening programs and treatment of precancerous cervical abnormalities can reduce mortality, but have not been deployed effectively in the developing world (2). As a result, 93 percent of the overall mortality from cervical cancer occurs outside of the thirty-four wealthiest countries (3).

Within developing regions, Africa carries a larger burden of the disease (4). Africa experiences the highest number of new cases of and deaths from, cervical cancer in a year. According to the World Health Organisation (WHO), the incidence of cervical cancer in Africa is 80,419 while deaths

are approximately 53,334 per year (5). Although it is evident that the rate of incidence of cervical cancer is very high in sub-Saharan Africa, the incidence of cervical cancer in many African countries is unknown due to gross under reporting (6).

In SSA, cervical cancer affects mostly women in the 20-40 year age group. It accounts for 22.2% of all cancers in women and it is also the most common cause of cancer death among women it affects. Women in SSA lose more years to cervical cancer than to any other type of cancer and it affects women at a time in their life when they are critical to the social and economic stability of their families (5).

The incidence of cervical cancer and mortality rates have declined substantially in Western countries following the introduction of screening programmes.

Screening programmes in Africa, however, are often undeveloped or non-existent, thereby affecting the survival rate of women (4). The survival rate for cervical cancer in SSA in 2002 was 21% compared with 70% and 66% in the United States and Western Europe respectively (6).

Some of the risk factors or determinants of cervical cancer that contribute to the high mortality and low survival rates in Sub-Saharan Africa include: poor access to medical facilities (worst in the rural areas, where 60–70% of women who develop cervical cancer reside); poor nutrition and co-morbid conditions such as HIV infection (7); late presentation of the disease; large tumour at presentation; poor quality of care provided by many health services; and women not completing treatment due to challenges of poverty.

Developing countries are likely to benefit from more cost effective methods of screening and treatment. In developing countries, traditional pap smears have remained unaffordable for most and follow up of results from pap smears/biopsies are poorly handled in resource poor settings due to the scarcity of equipped laboratories and pathologists to review specimen (8). Various modes of treatment for premalignant lesions include LLETZ and cryotherapy. Seventy percent of pre-invasive and invasive cervical neoplasia (9) are associated with HPV type 16 and 18. Over eighty HPV types have been sequenced, although more than 200 types exist based on data from partially sequenced DNA fragments (10). HPV-16 accounts for more than 50% to 60% of cervical cancer cases followed by HPV-18 (10%–12%) and HPV 31 and 45 (4%–5% each) high risk types (11). HPV types associated with genital warts, such as HPV-6, and HPV-11, are referred to as low risk because they are rarely associated with malignant disease. Infection of the cervical epithelium with high-risk types of HPV plays a key role in the pathogenesis of cervical cancer and its precursor lesions, although very few women infected with HPV ultimately develop cervical cancer (12). HPV invades the basal cells of the cervical epithelium at the transformation zone. High-risk viral types usually integrate their DNA into the host genome. HPV viral oncogenes E6 and E7 inhibit the action of tumor suppressor genes p53 and the retinoblastoma gene; this activity prevents repair of DNA damage and programmed cell death, enabling proliferation of damaged cells and resultant tumorigenesis (13).

HPV infection in young women is frequent, but is transient in the large majority of women, persistence of high-risk types of HPV is a pre-requisite for the development of cervical intraepithelial neoplasia (CIN) 3 lesions and invasive cervical cancers although the biological reasons that determine persistence in individual women are poorly understood. Cofactors that further increase the risk of invasive cancer among HPV DNA positive women include old age, long-term

use of oral contraceptives (five or more years), high parity (five or more full-term pregnancies), smoking, and HIV infection (14,15). Many factors initially thought to be associated with cervical cancer—for example, number of sexual partners—likely are indicators of HPV exposure rather than independent risk factors.

There is strong evidence to support a multistep model of cervical cancer pathogenesis that involves, as the first step, infection with high-risk types of HPV. The median duration of HPV infection is about one year for high-risk types of HPV and shorter for the low-risk types (15). Many women with transient HPV infections will develop cytological abnormalities, although CIN 1 lesions have a high rate of spontaneous regression in the absence of treatment. CIN 3 lesions and carcinoma in situ have lower rates of spontaneous regression. The rates of progression and regression of CIN 2 lesions appears to fall between that of CIN 1 and CIN 3 lesions.

The latency period between HPV infection and the multistep process of development of dysplasia offers a golden opportunity to detect cervical cancer and possibly offer intervention. Methods of screening utilized include the Pap smear, Visual Inspection using Acetic acid / Lugol's iodine, Liquid based cytology and HPV-DNA tests. Since its introduction more than 50 years ago, the Pap smear has been used throughout the world to identify precancerous lesions for treatment or follow-up. Routine use of Pap smear screening in the industrialized world has contributed to the 70% to 80% reduction of cervical cancer incidence in developed countries (16). In the United States, where an overall decline in the number of cervical cancer cases has occurred, rates nonetheless remain high in impoverished areas (17). Lack of similar success in developing countries can be attributed to limited resources (i.e., supplies, trained personnel, equipment, quality control, health care infrastructure, and effective follow-up procedures) (21).

An accessible and affordable cervical cancer screening method is VIA/VILI. A patient who screens positive may be offered cryotherapy for treatment. An advantage to this is that VIA/VILI may be done by a variety of health care workers including doctors, nurses, midwives and clinical officers. It is inexpensive requiring a speculum, light source, acetic acid, Lugol's iodine and eliminates the need for expensive laboratory tissue diagnosis. A study by Mabeya and Orango 2009 (18), at Moi teaching and referral hospital Western Kenya compared the sensitivity and specificity of VIA versus Papsmear in HIV infected Women, they found Using cervical intraepithelial neoplasia (CIN) 2 or higher disease on biopsy as an end point, VIA had a sensitivity of 69.6% (CI=55.1–81.0%), specificity of 51.0% (CI=41.5–60.4%), PPV of 38.6% (CI=28.8–49.3%) and NPV of

79.1% (CI=67.8–87.2%). For conventional Pap smear, sensitivity was 52.5% (CI=42.1–71.5%), specificity 66.3% (CI=52.0–71.2%), PPV 39.7% (CI=27.6–51.8%), and NPV 76.8% (CI=67.0–85.6%).

Another study in Thailand 2002 (19) compared the costs and benefits of different strategies and their effectiveness in saving lives in a less developed country. They compared VIA, Human papilloma virus testing, and pap smear screening. It was found that VIA performed at five-year intervals in women aged 35 to 55 with immediate treatment if abnormalities were found was the least expensive option and saved the greatest number of lives.

Cryotherapy can be offered immediately at the same sitting after VIA/VILI provided a cryotherapy machine is available and in working order. VIA/VILI and cryotherapy offers a see and treat approach at a single sitting, curtailing the drawbacks of a pap smear that require high laboratory costs and need for follow up of results. This requires finances that are inaccessible to the lower socio-economic population at greatest risk.

The World Health Organisation currently recommends that cryotherapy should be used rather than no treatment in cases of CIN; especially in settings where LEEP is not available. A Cochrane review in 2013 on the effectiveness and safety of alternative surgical treatments for CIN revealed no significant difference in treatment failures or operative morbidity (20). Visual inspection with acetic acid and Lugol's iodine offers an affordable and efficient way to identify premalignant lesions followed by treatment with cryotherapy in a see and treat approach. The benefits of using cryotherapy to treat dysplasia in resource poor settings are several, first, it can be done by all cadres of health care providers including doctors, nurses, midwives, and clinical officers. Secondly, it does not require anaesthesia, electricity is not needed and finally it is relatively inexpensive (21).

A final report by Western Kenya cervical cancer prevention project in 2004 concluded that majority of women did not adhere to follow up due to travel costs, fear of cancer, its treatment and poor partner support (21). No studies are available regarding screening of women during a medical camp to establish follow up thereafter, majority of the work done stems from private and public collaborations and not free medical camps. We carried out a cross sectional study in Khwisero County; Western Kenya to establish the hindrances towards accessing treatment following referral when visual inspection with Lugol's Iodine and Acetic acid was positive.

MATERIALS AND METHODS

Cervical cancer screening was carried out using VIA/VILI among women who had been mobilised to attend a medical camp. VIA gives immediate results but requires training and supervision, all medical personnel undertaking the procedure at the medical camp were taken through refresher training on VIA/VILI and were certified by a senior lecturer and instructor from the Department of Obstetrics and Gynaecology Aga Khan University Hospital. A project in Harare Zimbabwe on VIA (22) required continued support supervision and attendance of more than one training session to ensure proficiency in provision of VIA. Other strategies to maintain standards on reporting included both in house and pre-service training of doctors and nurses within facilities (22). This underscores the importance of continuous and supervised training on VIA to ensure reproducibility of results during screening.

The procedure was carried out in a single room divided into two examination rooms. Each partition was equipped with an examination couch, desk, Lugol's iodine and acetic acid.

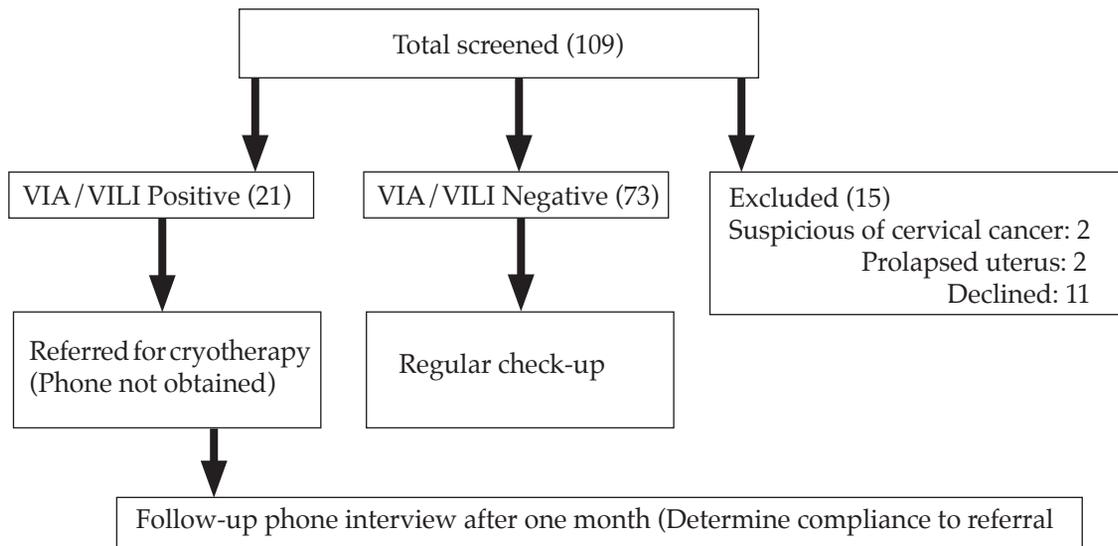
The health care provider undertaking the procedure had an 80 watt overhead lamp strapped across their forehead to aid in examination during a single examination.

We excluded all women who had obvious cervical masses, suspicious cancer, prolapsed fibroids or polyps.

We performed VIA/VILI and if the result was positive, referred them to the nearest centre which we offered cryotherapy (Kakamega provincial hospital) or recommended regular checks-ups if it was normal. Using standard interpretation guides, a positive VIA outcome was defined as "sharp, distinct, well-defined, dense (opaque, dull, or, oyster white) acetowhite areas with or without raised margins, abutting the squamocolumnar junction in the transformation zone" or "strikingly dense acetowhite areas in the columnar epithelium" or "condyloma and leukoplakia occurring close to the squamocolumnar junction turning intensely white" one minute after the application of a 5% acetic acid solution (15).

Those who had overt lesions suspect for cancer were referred for further care at the closest tertiary centre (Kakamega provincial hospital and Moi referral hospital). A follow up call at one month was made to find out whether they had gone for further care or not and reasons recorded.

Flow Chart of Screened Participants



RESULTS

We screened a total of one hundred and nine women who had availed themselves for a free medical camp. Majority of the women were in the age group of 26 and 55 years. Seventy two (72%) did not have any medical illnesses. Depo Provera was the most utilized form of contraception, 52% used no method at all. The population screened seemed to know their HIV status and spoke about it freely, Six patients who

were HIV positive reported good follow-up at the nearest HIV clinics.

Patients who screened positive for VIA/VILI were referred to tertiary facilities for cryotherapy. Out of the 21 patients referred, ten (47.67%) were unreachable on phone to enquire about follow-up, Seven (33.33%) did not follow through. In total eighty point nine five percent (80.95%) of women who had a positive VIA/VILI screen did not access cryotherapy treatment after referral.

Figure 1

Age distribution of women attending the medical camp for screening

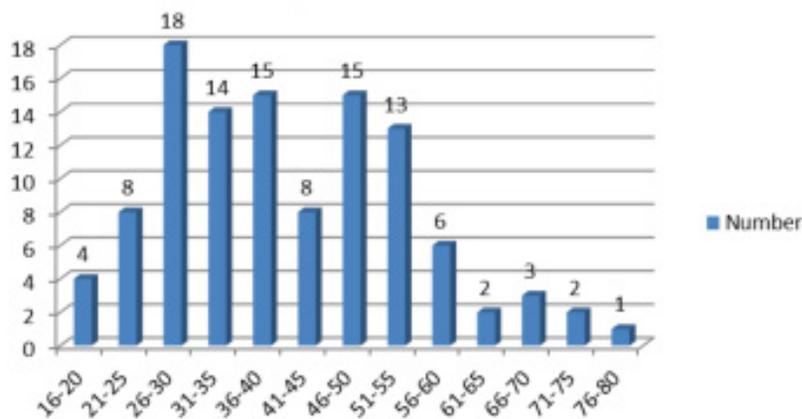


Figure 2
Marital Status

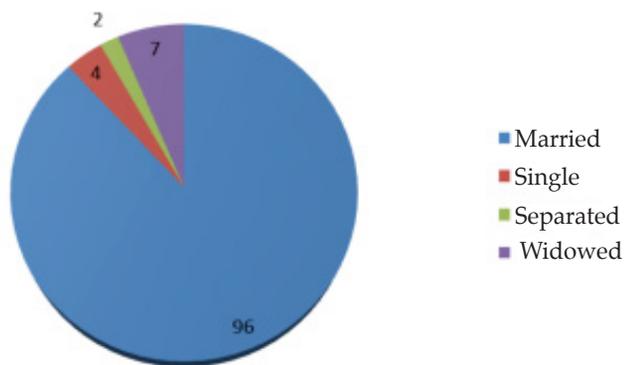


Figure 3
HIV-status of women screened

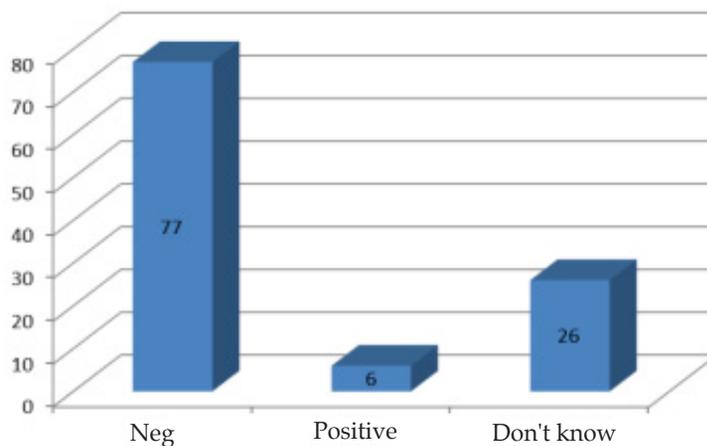


Figure 4
Use of Family Planning among screened women

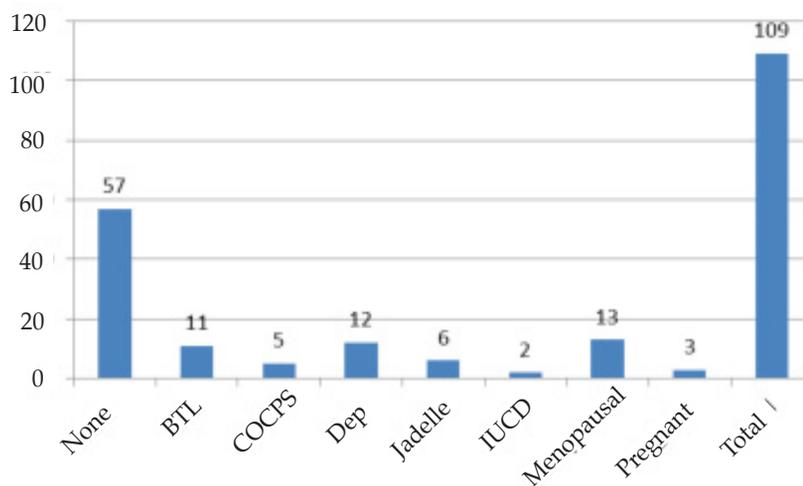


Table 1
Follow Up VIA/VILI Results

	Further Rx (yes/no & where)	Type of Rx	Reason for no Rx	Follow up arranged/ advised
1	Yes Kakamega	None	-No doctor in clinic	Advised to go back for follow up in 3 months.
2	No	-	Financial	-
3	Yes, Kakamega	Given oral medication	-	Advised on followup visit in 2 months
4	No	-	Time (still plans to go)	-
5	No	-	Financial	-
6	Phone not in use			
7	Phone not in use			
8	No		Separated from husband , Husband has phone and no idea on her whereabouts	
9	Yes (Kakamega)	Lab tests	Doctor not available on scheduled clinic day for review	Advised to book clinic in 2 months
10	No	-	Financial constraints	-
11	No	-	Financial constraints	-
12	Yes(Kakamega)	Repeat VIA	Went to both Kakamega and Busia district hospitals.Told she was ok	-
13	No	None	Financial constraints	-
14	No	None	Financial constraints	-
15	Phone not in use	-	-	-
16	Phone not in use	-	-	-
17	Phone not in use	-	-	-
18	Phone not in use	-	-	-
19	Phone not in use	-	-	-
20	Phone not in use	-	-	-
21	Phone not in use	-	-	-

DISCUSSION

Cervical cancer screening in developing countries is still a mirage and requires sustainable, affordable and feasible framework to deliver these services (7), the number of deaths annually due to cervical cancer can be prevented through VIA VILI and timely cryotherapy. Cryotherapy is carried out using a variety of cryotherapy devices that utilise frozen nitrogen or carbon dioxide gas and applied on suspicious positive lesions after a positive screening test.

Cryotherapy machines in the health centre where the medical camp was held were broken

down, instantly paralysing interventions for positive lesions requiring cryotherapy. Various types of machines have been utilised with different operational difficulties encountered, for example the Wallach cryotherapy equipment had a design flaw which caused temperatures above -20°C that led to product recall, and breakage without the availability of adequate repair and maintenance training (23). Details of machine breakdown at the health center could not be ascertained due to inaccessibility to the maintenance team at the health centre as well as poor understanding of machine breakdown intricacies. Good reliable reporting systems are required to facilitate timely repair and maintenance, healthcare

providers additionally require training on trouble shooting when machines malfunction as part of the training package.

Financial constraints was the leading cause for lack of follow up, millennium development goal one to eradicate extreme poverty and hunger by 2015 estimated that even by 2015 over 900 million people will still be living on less than one dollar a day (24); re-emphasising that extreme poverty will adversely affect healthcare seeking behaviour and worsen the vicious cycle of poor adherence to care; this is echoed in Western Kenya where travel costs was among the leading cause of lack of follow up in a similar setting (21).

Patient comprehension of cervical cancer is still poor, most women will not report to the clinic for screening due to the deceptive painless clinical course of the pre-cancerous stage (16), free medical camps offer healthcare providers a spring board to initiate the screening process and additionally offer patients counselling and knowledge about the disease. We noted procrastination of treatment by 4.8% of participants after referral.

Kenya is way below the recommended WHO doctor to patient ratio of 1 in 1000 (25). With approximately 40 million Kenyans, Kenya requires 40,000 doctors to meet that ratio. Among reasons for lack of follow up were unavailable healthcare personnel to review patients after referral; training and handsome incentivising of healthcare workers is key in the sustenance of service provision in rural areas of the country, the current total number of doctors is approximately 8,000 with approximately 2300 of them being in the public health sector. Even among the few in the public health sector, majority tend to conglomerate in the urban centers leaving rural Kenya in a perpetual health crisis (26). This emphasizes the need for health care providers at the primary setting i.e., nurses, and medical officers in dispensaries and subdistrict hospitals to not only be trained to perform both VIA/VILI and Cryotherapy but also be provided with the cryotherapy equipment to treat positive lesions immediately. VIA VILI and cryotherapy should be within walking distances to eliminate the factors identified in this report for lack of follow up for cryotherapy-money for transport, time, procrastination and unavailability of doctors.

It is imperative to invest in public awareness so as to empower patients on timely healthcare seeking. It is key to assess patients knowledge, attitudes and practices regarding cervical cancer and treatment modalities to set the stage for focused interventions.

A limitation of this report is that a majority of participants (42.9%) could not be contacted due to communication challenges as phones were no longer in use thus unable to ascertain their follow up.

This limitation of phone access stresses the need for immediate and accessible treatment with cryotherapy to minimise issues associated with follow up and referrals.

The good old papsmear initiated by Papanicolaou and Traut in 1941 is still not accessible to majority of women in poor resource settings due to cost, need for pathological assessment and further follow up appointments. The use of VIA/VILI is a simple, cost effective method that does not require the aforementioned pre requisites as in papsmear, but treatment of dysplasia by cryotherapy is faced with many logistical challenges. We noted financial restrictions (28.6%), intentional postponement of care after referral (4.8%) and unavailable doctor for review (9.5%) as major contributors to lack follow up.

In conclusion, cervical cancer is a public health problem in both developed and developing countries but is preventable and curable if identified at an early stage. It is the second most common cancer among women worldwide. Bridging the gap is paramount in healthcare service provision, patients need to be empowered on timely healthcare seeking, while government need to sustain services by enabling healthcare workers provide services in the most remote parts of the country. Strategies to eradicate poverty are required to help Kenya achieve millennium development goal one and by extension empower Kenyans to seek healthcare timely without hefty financial constraints.

There is urgent need for well maintained cryotherapy machines and training of personnel to perform cryotherapy at the primary care level. VIA VILI is an acceptable screening modality in resource poor settings, but without local availability of cryotherapy machines to treat dysplasia, the incidence of cervical cancer cases will not change. Multi regional studies on knowledge attitudes and practices about VIA/VILI and cryotherapy may offer targeted solutions for women and increase the uptake of this procedure for early diagnosis and timely treatment.

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