Integration of Visual Inspection with Acetic Acid as a Screening Tool for Cervical Premalignant Lesion into the Primary Health Care Programme in a Southwestern State of Nigeria: Report of a Pilot Study

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Abstract

Objectives: *The aim of this pilot study was to determine the feasibility of integrating cervical cancer screening into the health programmes of the local government using direct visualisation of the cervix with dilute acetic acid with immediate treatment of positive cases to maximize treatment adherence. Other objectives were to determine the acceptability of a "see and treat" approach among women diagnosed with cervical premalignant lesions in Ekiti state and tolerability and side effects of treatment with cryotherapy*

Method: *The pilot study was carried out in Ekiti state in the south western part of Nigeria. Forty doctors drawn from all the 16 Local Government Areas' primary health facilities across the state were trained for a period of one week on how to screen for cervical premalignant lesions of the cervix using direct visualization with dilute acetic acid and how to treat screened positive women with cryotherapy.*

Results: *A total of 1431 women were screened with Visual Inspection with Acetic Acid (VIA) . Their ages ranged from less than 20 years but sexually active to women who were over 60 years. Majority of the women were traders while 22% were house wives. The parity of the women ranged from zero to e"6. Forty-four (3.1%) were VIA positive, while 1318 (92.1%) were VIA negative, 6 (0.4%) had suspicious looking cervix and 63 (4.4%) were referred for Pap smear because their entire Squamo –columnar junction could not be visualized.*

Conclussion: *Cervical cancer screening can be successfully incorporated into the health programmes of the local government in Nigeria.*

Introduction

Cervical cancer is the most common gynaecological malignancy and the second leading cause of cancer deaths among women[1]. Worldwide, about 529,000 new cases are diagnosed every year with approximately 274,000 deaths and over 80% of the new cases and approximately 85% of deaths occur in developing countries[2, 3]. The disparity in this disease burden between developed and

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developing countries is attributable to the organized screening programme in developed nations for the detection of premalignant lesions of the cervix, treatment and adequate follow-up of detected cases[4, 5]. According to WHO, Nigeria has a population of 40.43 million women aged 15 years and older who are at risk of developing cervical cancer[6]. It is estimated that every year 14,550 women are diagnosed with cervical cancer in Nigeria with 9,659 deaths from the disease[6]. WHO also projects a 25% increase in the next decade in the absence of widespread interventions[6].

Among gynecologic cancers, cervical cancer offers great potential for prevention, early detection, and cure due to its long preinvasive phase. Cervical cancer arises via a series of four necessary steps. These include human Papilloma virus (HPV) transmission, viral persistence, progression of clone of persistently infected cells to precancer and invasion. The whole of this process takes between 10-15 years. The backward steps occur also, namely clearance of HPV infection and the less frequently, regression of precancer to normalcy[7].

The method of cervical cancer screening introduced by Papanicolaou several years ago and currently called Pap smear or conventional cytology is the mainstay of cervical cancer screening programmes in most developed countries of the world[4,5]. A cervical cancer screening programme based on the Pap smear depends on high-quality sampling, well-trained cytologists, adequate follow-up and further diagnosis of women with a positive cytology results. There is significant variation on positive rates, as well as cytological analyses of Pap smear results even among experts[8]. The Pap smear involves making many visits to the hospital before treatment can be administered. For these reasons it is costly and associated with a high loss to follow-up rate[9]. Therefore in low resource settings of developing nations, the method can hardly be used for screening due to high cost and non availability of Pathologists in the rural areas. Cytological-based cervical cancer screening programs are well established in developed countries but the success is based on repeated screening of women which is not feasible in many developing countries. In cytological-based screening programs for cervical cancer, women with abnormal screening results are usually referred for colposcopy for further evaluation and direct biopsy for histology if lesions are seen. However, colposcopy is not widely available in the country as only few centres have it and are mainly in the teaching hospitals which are often far from the rural areas [10].

The recognition of the limitations of cytology-based approach in low-resource settings has encouraged the development of alternative approaches to screening. One of the most widely evaluated screening approaches is Visual Inspection with Acetic Acid (VIA). The advantages of VIA over conventional cytology are that the results of the test are immediately available and if this is combined with treatment options such as Cryotherapy in the so-called "see and treat" will significantly reduce the loss to follow up rate which often characterize cervical cancer screening in developing countries. In addition, virtually all the materials for VIA are cheap and can be sourced locally thereby reducing the cost of screening program. In low resource settings, VIA could be a realistic screening method when the only alternative is no screening[11, 12]. In order to reduce the incidence and mortality from cervical cancer in low resource settings like Nigeria, what is required is a program that reduces the number of visits that a woman makes to the health facility and which is also linked to immediate treatment of detected cases. Essential components of such program are high coverage rate and immediate, effective treatment of positive cases (to minimize loss to follow-up).

In the VIA method, dilute acetic acid (3-5%) is applied to the transformation zone after exposing the cervix with a speculum. The acetic acid transiently coagulates the abundant nucleoproteins in the abnormal dividing cells, obscuring the blood vessels below the basement membrane and thus appearing as

acetowhite area. In a study done in South Africa, VIA detected more than 65% of high-grade lesions and invasive cancer[12] . Similar study was done in Zimbabwe using services of Nurses and Midwives, and the sensitivity and specificity of VIA in detecting high-grade lesion were 77 and 64% respectively compared to 43% and 91% for Pap smears[13]. In a study done by Jose Jeronimo *et al,* of the 15 women with histologically confirmed diagnosis of CIN 2 or 3, Pap smear detected 5 while VIA detected 11 of these cases [14]. A meta-analysis on the VIA revealed a sensitivity of 66–96% and a specificity of 64–98% [15].

Screening alone does not reduce the incidence and mortality from cervical cancer but adequate treatment of the detected lesions. There are various treatment modalities. These can broadly be divided into excision or ablative methods. Cryotherapy is a common ablation method that can be used particularly with VIA in a low resource setting. Cryotherapy is a low cost ambulatory procedure that can be performed without anesthesia or analgesia. It is ideally suited for low resource settings like rural Nigeria. It is as effective as many excisional methods[16,17]. Occasionally following cryotherapy, patients may experience discomfort, but it is seldom of a severity to require discontinuation of the treatment. Self-limiting vasomotor reactions characterized by light-headedness and flushing is common. After cryotherapy, patients will usually have 10 to 14 days of watery vagina discharge that may require use of sanitary napkins. Unprotected coitus and intravaginal tampons are not recommended during that time.

Objectives

1. The feasibility of incorporating cervical cancer screening into the primary health care program at the state level.
2. Acceptability of a "see and treat" approach among women in Ekiti state
3. Tolerability and side effects of treatment with cryotherapy.

Materials and Methods

The pilot program took place in Ekiti state in southwest part of Nigeria. Ekiti state has a population of 2,398,957 according the 2006 national population census. There are about 500,000 women in the state who are within the reproductive age and are susceptible to cervical cancer. A state wide mobilization was carried out by the Government to encourage women to take opportunity of the screening. Forty doctors drawn from all the 16 Local Government Areas' primary health facilities across the state were trained for a period of one week by Gynae-Oncologists from the Obafemi Awolowo University Teaching Hospital, (OAUTHC) Ile- Ife. The training was done using the training manual of the International Agency for Research on Cancer (IARC) [18]. Medical Officers from each of the local government areas of the state were trained for one week on screening for cervical premalignant lesions using VIA and how to perform cryotherapy to treat cervical pre-malignant lesions and the possible side effects of cryotherapy as well as how to manage the side effects of cryotherapy.

The training focused on:

1. Aetiopathogenesis of cervical cancer
2. Passing a vaginal Cusco's speculum and recognizing a normal cervix as well as the transformation (TZ) zone as well as the physiology of the TZ
3. Perform direct visualization of the cervix using dilute (3%) acetic acid (VIA).
4. Mobilise and counsel women for cervical cancer screening as well as for cryotherapy including limitations and side effects of treatment.

For the purpose of this pilot study, criteria for a positive VIA are:

- Distinct, well-defined, dense (opaque, dull- or oyster-white) acetowhite areas with regular or irregular margins, close to or abutting the squamo-columnar junction in the transformation zone or close to the external os if the squamo-columnar junction is not visible.

- Strikingly dense acetowhite areas are seen in the columnar epithelium
- The entire cervix becomes densely white after the application of acetic acid
- Condyloma and leukoplakia occur close to the squamo-columar junction, turning intensely white after application of acetic acid.

In this pilot study, criteria for using cryotherapy are:

- Cryotherapy probe tip must cover the entire lesions to be treated and must not be more that three-quarters of the ectocervix.
- Lesion does not extend into the cervical canal
- There is no visible sign of invasive disease
- The squamo-columnar junction is seen in its entirety
- Lesion does not extend into the vaginal fornix
- The cervix is not severely distorted
- There is no obstructing polyp
- There is no ulceration

After the training, the health workers were provided with materials for the screening and were sent back to their primary health care centres to start the screening exercise. Women were invited for screening through the use of mass media and radio jingles. Each woman was counseled and informed consent was taken before the screening and treatment. Socio-demographic information was obtained from each woman after which they were taken to a private room where they were placed in lithotomy position and a bivalve speculum was passed to expose the cervix. The cervix was examined to see if the entire transformation zone (TZ) could be visualized. Those whose TZ could not be entirely visualized were referred for Pap smear. Freshly prepared Acetic acid (5%) was then applied to the TZ and this was examined after one minute with a handheld flash light for colour changes. Positive result was the present of acetowhitening at the squamo-columar junction. The result was recorded on the questionnaire. All positive cases were confirmed by the Gynae-Oncologists as a quality control measure before treatment was offered. Those with aceto-whitening were counseled about cryotherapy and the possible side effects. The women that agreed to be treated also signed an informed consent form. Cryotherapy was administered using N_20 after which the women were instructed not to engage in unprotected sexual intercourse for 3 weeks and to come back if they developed fever, bleeding par vaginam or malodorous vaginal discharge. Women without acetowhitening at the squamo columnar junction (Negative test results) were asked to repeat the test 3 years later and women with lesions suspected to be cancer were referred to the Gynae-Oncology unit in O.A.U.T.H.C; Ile-Ife for standard management.

The trained Health workers were dispatched to the selected health facilities across the state. Information obtained at the end of the study was processed by Statistical Package for Social Science (SPSS) version 17. Descriptive statistics such as means, frequencies and percentages were used to summarize variables

Results

A total of 1431 women were screened across 16 Local Government Areas of the state during the 2 weeks period that the exercise lasted. Women screened ranged between those less than 20 years but sexually active to those well over 60 years (Table 1). Majority of the women were traders while 22% were house wives. The

Table 1. Age characteristics of screened patients

Age (Years)	Frequency	Percentage
<20	28	2.0
20-29	265	18.5
30-39	391	27.3
40-49	489	34.2
50-59	228	15.9
≥ 60	30	2.1
Total	1431	100

parity of the women ranged from zero to 6 (Table 2). Forty-four (3.1%) were VIA positive, 1318 (92.1%) were VIA negative, 6 (0.4%) had

Table 2. Parity characteristics of screened patients

Parity	Frequency	Percentage
0	213	14.9
1	110	7.7
2	177	12.4
3	254	17.7
4	268	18.7
5	212	14.8
≥ 6	197	13.8
Total	1431	100

suspicious lesions on the cervix and 63 (4.4%) were referred for Pap smear because their squamo-columnar junction could not be visualized (Table 3).

Table 3. Result of screening

Outcome	Number	Percentage
VIA Positive	44	3.1
VIA Negative	1318	92.1
Suspicous for Cervical Cancer	6	0.4
Referred for Pap Smear	63	4.4
Total	1431	100

Side effects of treatment were minimal and consisted mainly of cramps during treatment and watery vaginal discharge. No case of excessive bleeding was reported. These side effects were accepted by the women once prior explanation was given. Acceptability of treatment was high as over 98% of women who were screened positive agreed to be treated.

Discussion

In this pilot study we have been able to demonstrate that cervical cancer screening by VIA is feasible and can safely be incorporated to primary health care programs at the local government level. This pilot study showed that women will make use of screening facilities if the awareness is created and the services are made available. The pilot sudy also shows that cryotherapy is an acceptable method of treating cervical premalignant lesions among women in Ekiti state judging from the number of women who agreed to be treated.

We recorded a rather low positivity rate with VIA. Reasons for the lower positivity obtained from this pilot study could be due to the facts that the screening was done by medical Doctors and all positive cases were re-examined by the Gynae-Oncologist from OAUTHC before treatment was offered. At least one study has shown that reported high positivity for VIA were performed by other health workers other than Physicians[19]. In a comparison study of VIA among physicians and nurses, there was moderate agreement between the doctors and the nurses with the nurses having more VIA positive cases than doctors with Physicians having a higher specificity (69.81% versus 54.85%) compared to Nurses [19]. In addition to the variability in the positivity rate of VIA between Nurses and Physicians, Ajenifuja *et al* also demonstrated that even within the same category of health workers positivity of VIA varies significantly[20]. In Tanzania, Ngoma *et al* (2010) showed that the variability of VIA is also time-dependent with peak positivity occurring shortly after training[21].

Apart from the positive cases, 6 women (0.4%) had obvious lesions on the cervix and were promptly referred to the teaching hospital for appropriate management. This is one of the benefits of cervical cancer screening because though the purpose of cervical cancer screening was to detect pre malignant lesions, cancer detected during screening exercises are more likely to be in the early stages where the chances of survival is higher compared to when the patients presents to the health facility after she started having symptoms. This study also showed that women are more willing to be treated once they are properly counseled and told that they had lesions of their cervices.

In a low resource setting like ours, where ironically, the incidence of cervical cancer is on the increase, with late presentation of patients and attendant high mortality, cervical cancer screening can be incorporated into the health program at the Primary Health Care (PHC) level with VIA until such a time when our infrastructure and human resources can support the conventional cytology or HPV DNA testing.

Conclusion

The results and logistic lessons learnt during this exercise showed that VIA is a veritable tool for reduction of cervical cancer as it could be carried out in the remotest Local Government area of the state. It is a simple, easily learnt and low-cost technology. It also showed that when VIA is used as a tool for screening, there is the need to put in place quality control measures to reduce the false positive rate and the wastes associated with overtreatment. In a low income country like Nigeria, low and middle cadre health workers can be taught to screen for cervical premalignant lesion. Visual Inspection with Acetic acid is an acceptable method of screening for cervical cancer in rural part of Nigeria. See and treat is also acceptable to women in Nigeria. The success of this pilot program demonstrated that cervical cancer screening using VIA can be successfully incorporated into the health care program of the local governments in Nigeria.

Limitations

The limitation of this study was that there was no histological confirmation before treatment was offered. However, it should be noted that see and treat in this was associated with little or no short time morbidity.

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