RESEARCH ARTICLE

Out-reach Colposcopy Clinics and HPV Self-Sampling Decreases Loss to Follow up in a Community based Cervical Cancer Screening Programme

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Abstract

Objective: To introduce HPV self-sampling and out-reach colposcopy clinic as interventions to improve the follow-up of HPV positive women in a community based cervical cancer screening programme. Methods: This was a prospective observational study conducted during October 2017 to August 2019 and 2977 women underwent cervical cancer screening using CareHPV test. Follow up colposcopy for HPV positive women were conducted at the rural health center and alternatively as out-reach clinics in their own villages and default rates were compared. HPV positive women were followed up at one-year. They were given an option of either having a follow-up HPV test performed by a health care worker (HCW) or by self-sampling. Compliance to follow up in these two modalities were compared. A validated questionnaire was given to women who had given an HPV self-sample to assess their awareness about HPV and cervical cancer. Results: During our initial round of cervical cancer screening using HPV as a primary screening modality, our HPV screen positive rate was 7.05% (210 out of 2977 women screened). Our colposcopy rates following an initial invitation at the rural health centre was only 28.5%. Following this, we initiated out-reach colposcopy clinics at their own villages for HPV positive women and this increased colposcopy rates from 28.5% to 45.2%. The participation rate at one-year follow-up was increased from 40.5% to 60% by the introduction of self-sampling as a follow up option and 16.2% of women who were initially positive remained HPV positive at 12-14 months follow up. All women who were offered the option of self-sampling preferred it over a HCW collected sample. Conclusion: Our study showed that self-sampling could also be used effectively in the follow up of HPV positive women in the community. Outreach colposcopy clinics in their own villages enabled better follow up of HPV positive women.

Keywords: HPV- Follow-up- Self-sampling- Default- Out-reach colposcopy

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Introduction

Cervical cancer is the second most common cancer and the leading cause of cancer-related mortality among women worldwide. Majority of them have never had cervical cancer screening even once in their lifetime [1]. Cervical cancer deaths have devastating effects with very high human, social and economic costs, affecting women in their prime. Globally, cervical cancer occurs in the age group of 20 - 67 years, with a median age of 38 years [2]. India alone accounts for one-fourth of the global burden of cervical cancer and that is up to 17% of overall cancer-related mortality [3]. It is estimated that approximately one million women will be newly diagnosed with cervical cancer screening programmes 85% of cervical cancers are diagnosed at an advanced stage in India [4].

The World Health Organization (WHO), has recommended that every woman should have at least 2 high quality screening tests at 35 and 45 years of age and aims at global elimination of cervical cancer (<4 cases per 1,00,000 women in each country) by 2030 with 90-70-90 targets [5]. It has also emphasised that 90% of women diagnosed with cervical precancer or cancer should be appropriately treated [5]. Data from our previous pilot study on cervical cancer screening done in October 2017 revealed a high default rate (Percentage of HPV positive women who were lost to follow up) (59.5%) in HPV positive women attending a follow-up colposcopy clinic. This was in spite of providing transport to and from the villages to the colposcopy clinic at a nearby rural health centre (RC) and the colposcopy being done completely free of cost. Women who were HPV positive and had a

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negative colposcopy were invited to be rescreened with a repeat HPV test at 12 months. Our current study was undertaken to evaluate the use of out-reach colposcopy clinics and HPV self-sampling to reduce the default rate of HPV positive women in the community.

Materials and Methods

This was a prospective observational study. The initial part of the study was conducted in seven rural villages of Coimbatore district between October 2017 and August 2019. We used CareHPV for the primary HPV screening and 2977 women underwent HPV primary screening using CareHPV kit. This included both HCW collected samples and self- sampling. Women younger than 30 years and older than 60 years, those who were currently pregnant, or who had undergone hysterectomy or any treatment to the cervix were excluded from the study.

As part of triaging, we invited HPV screen positive women from initial three villages (1,2,3) to the rural health centre for colposcopy. As the loss to follow-up was high, we initiated colposcopy clinics in their own regions for villages 4 and 5. For HPV positive women in villages 6 and 7, an initial invitation for colposcopy at the rural center was sent. This was followed up after 3 weeks by an outreach colposcopy clinic in their own villages. The default rate (Percentage of HPV positive women who were lost to follow up) to colposcopy clinics in all these methods were evaluated. During the period of the study, women who were HPV positive and had a negative colposcopy were offered a follow up with a repeat HPV test in 12-24 months as per our clinic guidelines.

We chose to undertake the one-year follow-up of the HPV screen positive women (210 out of 2977 women) via door-to-door visits and the community oncology team reminded women of the importance of follow-up during the house visit. Each woman was given a choice of visiting a health centre for a HCW collected HPV sample or was given self-sampling kit and the acceptance of self-sampling was also evaluated.

A validated questionnaire was given to first 70 women who had given an HPV self-sample to assess their understanding about HPV and cervical cancer. The questionnaire was adapted from the cervical cancer screening belief survey originally developed by Byrd and colleagues [6]. The Health Belief Model (HBM) shows that an individual's decision to undergo health behaviour depends upon perceived susceptibility, severity, benefits and barriers towards that disease or procedure.

Data Analysis

For quantitative data, the mean and standard deviation were used in the descriptive analysis, while frequency and percentage were used for categorical variables. For groupwise analysis, participants were appropriately categorised. Analysis was conducted using IBM SPSS Statistics software (version 18.0, SPSSB Inc., Chicago, USA). Illustrations were made using Microsoft Excel-365, 2020.

Results

During the study period of two years, 2977 women were screened using CareHPV as primary screening. Two thousand and ten samples were health care worker (HCW) collected samples and 967 were collected by self-sampling. Overall, 210 of the 2977 women screened were HPV positive with a positivity rate of 7.05%. HPV positivity was 5.8% and 9.5% in the HCW and self-sampling groups respectively. At the same screening visit, all the women who had a HCW collected HPV test also had a VIA/VILI (N=2010) and 11.2% were found to be VIA VILI positive.

The screening area covered seven villages at distances of about 20-25 kms from a rural health centre (RC). Screen positive women from the first three villages were invited to the colposcopy clinic at a rural health centre. Only 43 of the 130 women who were HPV positive from these three villages attended the colposcopy clinic at the health centre and a high default rate (66.2%) was observed. We conducted out-reach colposcopy clinics in two villages (villages 4 and 5) and were able to improve colposcopy rates from 33.8% to 48.5%. In villages 6 and 7, we sent an initial invitation to women to attend the colposcopy clinic at the rural center. Three weeks after the initial invitation, out-reach colposcopy clinics were conducted in villages 6 and 7 and colposcopy attendance improved from 15.5% to 42.1% (Table 1). The colposcopy attendance interestingly was 67.1% from the HCW collection group and only 32.9% from the self-sampling group.

The majority (85.5%) of the 85 women who attended the colposcopy clinic had a normal colposcopy impression, whereas 10.5% had a colposcopy impression of LSIL and 3.5% had that of HSIL. Using a cut off of 6 on Swede's score, eight women had colposcopy-guided biopsies. One showed squamous epithelial atypia, two had squamous metaplasia, while the rest had cervicitis only on pathology.

In the one-year follow-up of 210 HPV positive women, only 126 out of 210 women provided a HPV self-sample (60%) and 16.2% of them were found to be HPV positive 12-14 months after their first HPV positive test. There was no significant difference (p>0.05) between the mean age group of HPV positive women (43.3±7.5) and HPV negative (43.5±8.1) women. The default rate in one year follow-up of primary HPV screen positive women even after offering HPV self-sampling was 40%. The percentage of self-sampling during the primary HPV screening study pilot study was 32.4% (N=967). However, all women who

Table 1. Comparison of Colposcopy Coverage Rate of HPV Positive Women at RC and Out-Reach Colposcopy Clinic

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Villages	1,2,3	4,5	6,7
Number of HPV positive women	130	35	45
Attended colposcopy clinic at RC N (%)	43 (33.8)	N/A	7 (15.5)
Attended Outreach colposcopy clinic N (%)	N/A	17 (48.5)	16 (42.1)

RC, Rural center; Village 1,2,3- Colposcopy at rural center; Village 4,5- Out-reach colposcopy clinic at their own village; Village 6,7-Initial invitation for colposcopy at rural center followed by out-reach colposcopy clinic in their own village

Table 2. One Year Follow-up of Primary HPV Screen Positive Women

	HPV positive in primary	1 year follow-up HPV sample by Self-sampling		HPV positive at 12–14-month follow-up
screening	HPV sample obtained	Loss to follow-up		
Number	210	126	84	34
Percentage	7.05%	60%	40%	16.20%

gave a second HPV sample at 12-14 months (N=126) preferred self-sampling over HCW collected samples. All women who provided self-samples at primary screening and at the one-year follow-up found the method to be entirely satisfactory. Many (40%) were not willing even to give a self-sample at the one year follow up (Table 2). Despite long conversations about the ease of the test and the importance of follow up, many responded as: "We will see when we develop any symptoms... Don't want any test now...". Other reasons why we couldn't contact the women for follow up included change of residence, current address unknown and a few of them had a hysterectomy following a positive HPV result (2.3%).

Knowledge of women regarding HPV, Cervical cancer, Screening and Treatment

With the aid of a modified, validated questionnaire, a survey was undertaken among 70 women who visited our screening clinic to evaluate perceived susceptibility, benefits, seriousness, and barriers for cervical cancer screening. Half of respondents thought that cervical cancer only develops in older women those over 50 years and that young women were not at risk. In the sample, 43% of respondents had little knowledge of HPV or its association to cervical cancer, and 34% were unaware that a virus could cause cancer. Majority (93%) of women believed that cervical cancer makes a women's life difficult as any other cancers, yet more than 50% presumed that it was not as serious as other cancers. Almost 64% agreed that screening test using either Pap smear or HPV DNA test and follow-up if found to be positive was important. Majority of women (91%) believed that if cervical precancerous lesions were diagnosed early, it was curable. On assessing perceived barriers, 30% of women would prefer not to be screened as waiting for results would make them anxious and worried. There was also a worry of what they would do if the HPV test results were positive. Family and childcare issues prevented 50% of women from being tested or followed up. Transportation to access health care was a difficulty experienced by 36% of women who has taken the survey (Table 3).

Discussion

Table 3. Data of Survey Conducted in Women (N=70), to Assess the Knowledge on Cervical Cancer, HPV and Barriers to Screening

Survey Questions	Agree N (%)	Disagree N (%)	Don't know N (%)
Perceived susceptibility			
Young women are also at risk of cervical cancer	25 (36)	42 (60)	3 (4)
I am not at risk of cervical cancer	19 (27)	41 (59)	10 (14)
Cervical cancer only happens in age > 50 years	37 (53)	16 (23)	17 (24)
Perceived seriousness			
HPV important risk for cervical cancer	16 (23)	24 (34)	30 (43)
There is effective treatment for cervical cancer	30 (43)	7 (10)	33 (47)
Cervical cancer makes women's life difficult	65 (93)	0 (0)	5 (7)
Cervical cancer not as serious as other cancers	37 (53)	13 (18)	20 (29)
Cervical cancer can be easily cured	31 (44)	9 (13)	30 (43)
Perceived benefits			
It is important to undergo PAP/HPV DNA test	45 (64)	0 (0)	25 (36)
It is important to follow up if found to have HPV positive	45 (64)	1 (2)	24 (34)
If cervical changes found out early, its curable	64 (91)	2 (3)	4 (6)
Perceived barriers			
I think procedure painful	15 (21)	30 (43)	25 (36)
Getting tested would only make me worry	21 (30)	49 (70)	0 (0)
I think it is expensive	14 (20)	49 (70)	7 (10)
My family don't want me to go for test or follow up	20 (29)	50 (71)	0 (0)
Don't have time (family/childcare issues)	35 (50)	35 (50)	0 (0)
Transportation difficulty/ health facility is too far	25 (36)	45 (64)	0 (0)

The questionnaire was adapted from the cervical cancer screening belief survey originally developed by Byrd and colleagues (Byrd et al., 2004)

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In our study, primary HPV screening of 2977 women using CareHPV kit showed a positivity of 7.05% compared to the previously reported 10.5% in a population-based study on the prevalence of HPV in three districts of Tamil Nadu [7]. The prevalence of HPV infection by Hybrid Capture 2 was found to be 6% in women between the ages of 30 and 65 in a pooled analysis on a previously unscreened population in India, which is comparable to the HPV positivity rates in our study [8]. At the same screening visit, all the women who got a HCW collected HPV test also had a VIA/VILI and 11.2% were found to be VIA VILI positive. Similarly in a study of 500 women at the Kasturba Gandhi Hospital in Tamil Nadu, it was observed that 30% of women tested positive for VIA/VILI [9]. The VIA VILI positivity rate in a subsequent study performed in Coimbatore Medical College in 2020 was 35%, but the trial was conducted on symptomatic women who complained of abnormal vaginal discharge [10]. Our study's substantially lower positive VIA VILI rates could be because it was conducted as a population-based screening programme on predominantly asymptomatic women.

A considerable loss to follow-up (59.5%) was seen among HPV positive women who were invited to the colposcopy clinic despite repeated phone calls. A study on the default rate in colposcopy at a university hospital in England found that only 17% of patients defaulted, which dropped to 10% after repeated calls or reminder letters [11]. When compared to our data, the default rate in Western countries seems relatively low. This is most likely due to the lack of education and awareness about the importance of cervical cancer screening in low resource settings. It is also possible that women do not feel empowered to make decisions on their own and still rely on male family members to drive them to appointments. Despite conducting out-reach colposcopy clinics to increase coverage, we were only able to reduce the default rate to 51.4% indicating the amount of work that needs to be done to increase awareness on cervical cancer prevention.

We offered self-sampling to HPV positive women to ensure that women would be followed up to track their current HPV status. All the women who consented to give a repeat HPV sample favoured self-sampling over HCW collection. A recent review on HPV self-sampling in LMIC reported a sensitivity rate of more than 91% and a specificity rate of 86-97% [12]. The feasibility and acceptability of self-sampling was found to be 89% when self -sampling was done at the participant's home [12].

Of the 210 HPV positive women in the primary screening, 126 women gave a repeat sample at12-14months follow-up and the follow up rate was 60% (Table 3). On one-year follow-up of HPV positive women with negative colposcopy, 16.2% women were again found to be HPV positive. A systematic review looked at patterns of persistent HPV infection in women who have not received treatment and found that the median duration (50% remained HPV positive) of HPV persistence was around 10 months [13, 14]. We used CareHPV for this study which only gave us a HPV positive or negative result. We were hence unable to differentiate if this was a persistence of an old HPV infection or a new infection. However, a repeat positive HPV test did put these women at a higher risk of developing cervical epithelial abnormalities. Majority of studies defined persistence of HPV infection as two HPV positive tests in 6-12 months and 80% of these studies detected HPV DNA using PCR technique [15]. In a systematic review on HPV persistence, Hoffman et al showed persistence of HPV infection post-treatment of CIN among 6,106 women, and noted that HPV persistence tended to decrease with increasing follow-up time after loop excision [14]. While three months post treatment follow-up showed 27% HPV persistence, it was 21%, 15% and 10% at 6, 12 and 24 months respectively. HPV persistence was found to be influenced by age, HPV type, method of detection, therapy, and post-treatment testing interval.

Most genital HPV infections remains asymptomatic and gets cleared within 1-2 years. Despite having a good understanding of the epidemiology of HPV infection, we still know relatively little about HPV re-infection. A prospective study raised two hypotheses, the first of which was that HPV infections picked up in childhood are not entirely cleared, become dormant and might get reactivated in later life. The second hypotheses states that even after clearance of the first infection by initial immune response, re-infection can happen later in life following a new exposure by sexual activity and it can be the same HPV or a new one [16]. In our study 73.01% became HPV negative in an average of 14.9 months. The HPV positive result 12-14 months after the initial positive test in our study (16.2%) could have been either due to persistence of the initial infection or a re-infection. Genital HPV infection is cleared in most women but remains latent in 10-20% of women. The persistent HPV infections may eventually progress to HSIL and invasive malignancy [17, 18]. Of all HPV strains, HPV16 infection is not only more likely to persist but also carried the highest risk of CIN3. The absolute risk for CIN3 was estimated as 50% at annual follow-up on HPV positive women [19].

The "screen and treat" approach treats a woman when the screening test results are positive without performing any confirmatory procedures such a colposcopy or biopsy, which lowers the risk of loss to follow-up [20]. According to a cross-sectional study by Singla and colleagues on the effectiveness and utility of "see and treat" in the Indian population, overtreating women with low grade cervical lesions is acceptable [20]. We would have overtreated women if we had offered them treatment after primary screen positivity as only 3.5% had HSIL on colposcopy in our study. The WHO currently recommends ablative treatment for HPV positive women with negative colposcopy to reduce default which we have now incorporated in our current screening programmes.

In our study, out of 84 women who did not participate in the follow-up, majority of women (41.6%) refused to give a repeat sample even after offering self-sampling. This shows a lack of public awareness on the importance HPV positivity and its role in progression to cervical cancer. While there are many studies that have looked at barriers to screening, very few have looked at barriers to follow up and more research needs to be done in this area. Studies in Chile and Netherlands have showed follow-up rate of screen positive women to be 85.5% and 90.4% respectively, however in France it was only 41% after a HPV self-sample [21-23].

Default is a significant concern in most medical specialties. A study showed a 34.0% default rate in cancer patients defining default as refusal, delay or discontinuation of treatment or visit [24]. A review on HPV self-sampling showed a subsequent increase in clinic follow-up after receiving a positive HPV test result by self-sampling [25]. Following a positive HPV self-sample, Chilean, Norwegian, Australian, Italian and Dutch women showed follow-up rates of 85%, 94.1%, 75.7%, 84.5%, and 90.4% respectively [25]. In comparison, a French study had only 41% follow-up rate following a positive HPV self-sample. A majority of under screened women who tested HPV-positive by self-sampling seemed more motivated to visit their doctor for follow-up treatment [23]. Our study showed a default rate of 67% for initial colposcopy and 40% for the one-year follow-up of screen positive women. Among the 35 women who were 'not willing' to give a repeat sample at the 12-14-month follow-up, 51.4% had given a HPV self-sample during the initial screening.

A systematic review on barriers affecting uptake of cervical cancer screening in low- and middle-income countries, showed that a majority (87.09%) reported lack of knowledge and awareness as the main reasons. The second frequently mentioned barrier were women's perception, that they only need to undergo screening when they are sick (48.38%) [26]. Embarrassment or shyness (45.16%), painful procedures (41.93%), fear of getting diagnosed with cervical cancer (35.48%) and anxiety or fear (38.7%) were also reported [26]. In our study at one-year follow-up, women refused testing as they were asymptomatic even after explaining the importance of follow-up. Religious objections or opposition to an HCW examining a woman's private area were not relevant in our study because women were reluctant to provide even a self-sampling.

The strength of this study is that it has looked at methods to reduce loss to follow up of HPV positive women. Apart from holding community out-reach colposcopy clinic, we have used self-sampling as a method of following up HPV positive women in the community. One of the limitations of our study was that we used CareHPV test for the one-year follow-up in the community. With the CareHPV test, we were unable to differentiate if the 16.2% repeat HPV positivity was due to persistent infection or a re-infection. The community out-reach clinics sets a successful example of cancer control activity for early detection and management of pre-cancers in low resource settings [27].

In conclusion, our study has shown that HPV selfsampling is convenient, women friendly and is preferred over HCW samples. It can be conveniently used not just for initial screening but also for follow up if required. HPV self-sampling is an ideal screening strategy and has to be included in any national cervical cancer screening programme. Wide spread use of HPV self-sampling along with initiation of out-reach colposcopy clinics have shown to bring down the default rates and in facilitating women to attend cervical cancer screening and subsequent follow-up.

Author Contribution Statement

The idea of the study was given by Dr. LB, the data collection was done by Dr. PT, CN, SS, RB, VS. All the authors contributed equally to writing and revising the manuscript. The authors declare that there is no conflict of interest.

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Ethical committee

The study was approved by our hospital scientific committee as part of a student thesis submitted to National Board of Exams, India. Ethical approval was obtained from the Institutional ethics committee, G Kuppuswamy Naidu Memorial Hospital, Coimbatore, Tamil Nadu.

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