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Prevalence, characteristics, and outcomes of HIV-positive women diagnosed with invasive cancer of the cervix in Kenya

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Abstract

Objective: To determine the prevalence of invasive cervical cancer (ICC) and assess access to, and outcomes of, treatment for ICC among HIV-infected women in Kisumu, Kenya.

Methods: We performed a retrospective chart review to identify women diagnosed with ICC between October 2007 and June 2012, and to examine the impact of a change in the referral protocol. Prior to June 2009, all women with ICC were referred to a regional hospital. After this date, women with stage IA1 disease were offered treatment with loop electrosurgical excision procedure (LEEP) in-clinic.

Results: Of 4308 women screened, 58 (1.3%) were diagnosed with ICC. The mean age at diagnosis was 34 years (range, 22–50 years). Fifty-four (93.1%) women had stage IA1 disease, of whom 36 (66.7%) underwent LEEP, 7 (12.9%) had a total abdominal hysterectomy, and 11 (20.4%) had unknown or no treatment. At 6, 12, and 24 months after LEEP, 8.0% (2/25), 25.0% (6/24), and 41.2% (7/17) of women had a recurrence of cervical intraepithelial neoplasia 2 or worse, respectively.

Conclusion: Most HIV-positive women diagnosed with ICC through screening had early-stage disease. The introduction of LEEP in-clinic increased access to treatment; however, recurrence was high, indicating the need for continued surveillance.

Keywords

Cervical cancer screening; HIV; Kenya; Loop Electrosurgical Excision Procedure; Resource-limited settings

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Conflict of interest
The authors have no conflicts of interest.

1. Introduction

Cancer of the cervix is a common malignancy and a leading cause of death in women worldwide [1]. Approximately 500 000 new cases occur annually, 80% of which are reported among women in low-income countries [1-3]. Although highly preventable, cervical cancer remains a major public health challenge in Sub-Saharan Africa, where the mortality to incidence ratio is up to 80% [1,4,5]. Infection with HIV is associated with an increased incidence and recurrence of human papillomavirus (HPV) infection and HPV-associated cervical intraepithelial neoplasia (CIN) [6-8]. In addition, the majority of HIV-infected women reside in resource-limited settings, where access to cervical cancer screening is limited.

The management of cervical cancer is a major challenge in Sub-Saharan Africa [8]. In a survey of East, Central, and Southern African countries [1], surgical facilities for women with cervical cancer were available in only 46% of provincial hospitals, with only 21% of the hospitals having a gynecologist to perform the procedure. Only 22% of these countries had access to anticancer drugs, and the number of surgical oncologists and radiotherapists in tertiary hospitals was inadequate [1,5]. Late presentation with advanced disease, incomplete or poor treatment, and high rates of loss to follow-up also contribute to the high mortality [9].

Kenya's cervical cancer incidence is estimated at 29–200 per 100 000 women annually, with a 2- to 4-fold higher risk among HIV-infected women [7]. Currently, the prevalence of HIV among women aged 18–49 years in Kenya is estimated at 8.9% [7]. Without a functional national cancer registry, little is known about women diagnosed with cervical cancer in Kenya, including treatment access and outcomes. Treatment options for late-stage disease are severely limited because only 1 public facility, in the capital city of Nairobi, provides radiation therapy.

Low-cost screening strategies have the potential to improve access to cervical cancer prevention for both HIV-infected and HIV-uninfected women in resource-limited settings. With increased access to screening, more HIV-infected women will be diagnosed with early-stage disease, potentially increasing their treatment options. The standard of care for the treatment of early-stage disease is generally surgical, ranging from cone biopsy for stage IA1 disease to radical hysterectomy with lymph node dissection for stage IB or IIA [1,5]. Recently, treatment of stage IA1 disease using excisional techniques with close follow-up has been explored for women desiring fertility or seeking less radical surgery [10,11]. Expanding access to treatment, especially in resource-limited settings, should also be considered as a justification for excisional treatment. Loop electrosurgical excision procedure (LEEP) can be safely performed by trained non-physician healthcare providers in this setting [12], and if offered as treatment for stage IA1 cancer, it could potentially increase access to treatment in settings where availability of inpatient surgery is limited.

We sought to establish the prevalence, access to treatment, and out-comes of HIV-infected women diagnosed with invasive cervical cancer (ICC) at the Family AIDS Care and

Education Services (FACES) HIV clinic in Kisumu, Kenya, specifically focusing on the management and short-term outcome of women diagnosed with stage IA1 disease.

2. Materials and methods

The present study was a retrospective chart review to establish the number and characteristics of women diagnosed with cancer of the cervix at the FACES clinic, Kisumu. Located in Nyanza province, Kisumu is Kenya's 3rd largest city, with a population of 400 000 [12]. The HIV prevalence in Kisumu is 15%, twice the national average [7]. At FACES, women are screened for cervical cancer with visual inspection with acetic acid, followed by colposcopy with biopsy when necessary [13]. A pathologist at the University of Nairobi interprets the biopsy samples obtained during either colposcopy or LEEP. Cervical cancer staging is done as per guidelines from the International Federation of Gynecology and Obstetrics [12], using a combination of clinical and pathologic evaluation. A diagnosis of stage IA1 disease is made if there is no visible lesion and there are no changes in the contour of the cervix, but the pathology results indicate invasion of squamous cell carcinoma beyond the basement membrane. Clinical staging of advanced disease is based on pelvic examination performed by a gynecologist in-clinic or at the referral hospital.

Treatment for stage I or IIA invasive cancer is available at the 2 referral hospitals in Kisumu, where the standard of care is a simple or total abdominal hysterectomy (TAH) performed by a gynecologist. Women with more advanced disease are referred to Nairobi for radiation and chemotherapy. Women with stage IA1 disease were referred to a local hospital until the middle of 2009 (referral-only period: October 1, 2007, to June 30, 2009). However, the uptake of referral care was low because of uncertain waiting times and the associated financial burden. Therefore, the decision was made to offer these women either LEEP in-clinic at no fee or referral for standard care (referral or in-clinic treatment period: July 1, 2009, to June 30, 2012). Women treated with LEEP were re-screened with colposcopy at 6, 12, and 24 months, and those with CIN 2, CIN 2/3, or stage IA1 disease during follow-up were offered repeat LEEP.

Women diagnosed with histologically confirmed invasive cancer were identified by review of the electronic records of cervical cancer programs, and by a manual search through the pathology results from inception of the screening program on October 1, 2007, until June 30, 2012. Two investigators who reviewed and reconciled all cases performed this process. The records for all HIV-positive women screened for cervical cancer at FACES were evaluated for inclusion. No specific exclusion criteria were used. Clinical and demographic information and abstracted data on treatment and outcomes were obtained from the patient files or by contacting referred patients who were no longer being seen at the FACES clinic.

The disease prevalence was calculated by dividing the number of women with cervical cancer by the total number of women screened during the specified time period, as determined from a unique identification number in the electronic records. Recurrence of the disease was defined as a diagnosis of CIN 2 or worse during follow-up. The *t* and χ^2 tests were used to explore univariate associations between recurrence and predictors of interest, with the plan to build a multivariable model using predictors with a statistically significant

association. The cumulative recurrence rate was determined by dividing the number of women with a recurrence by the total number of women seen during the same time period. The time to recurrence was established using Cox proportional hazards models because of variation in the exact time of follow-up. The duration of follow-up was determined by subtracting the date of the follow-up examination at which recurrence was detected from the date of treatment. The statistical analysis was performed with Stata 12 (StataCorp, College Station, TX, USA). $P < 0.05$ was considered statistically significant.

The Institutional Review Boards of the Kenya Medical Research Institute (Nairobi, Kenya) and the University of California in San Francisco (San Francisco, CA, USA) approved the present analysis. The participants provided written informed consent.

3. Results

Among 4308 women screened at FACES between October 2007 and June 2012, 58 (1.3%) were diagnosed with invasive squamous cell cervical cancer. The majority of the women (37/47 [78.7%]) had no prior history of cervical cancer screening (Table 1). At screening, 46 (92.0%) patients with stage I disease had a colposcopic impression of CIN 2/3 (Table 2). The diagnosis of invasive cancer was made on colposcopically directed biopsy for 24 (41.4%) women and on the LEEP specimen for 31 (53.4%) women; the remaining 3 (5.2%) women had visible lesions suggestive of ICC at screening. The 31 women who were diagnosed with invasive cancer on examination of the LEEP specimen were all thought to have CIN 2/3 at the time of their colposcopic biopsy.

During the referral-only period, 17 women were diagnosed with ICC. Of these, 15 (88.2%) women had stage IA1 disease, 1 (5.8%) had stage IB disease, and 1 (5.8%) had stage IIIB disease. Of the 15 women with stage IA1 disease, 4 (26.7%) underwent a TAH at a referral hospital in Kisumu and 3 (20.0%) had sought treatment but decided against it, all citing financial constraints as barriers to receiving a TAH at the referral facility. For the remaining 8 women with stage IA1 disease, information on access to treatment was unknown because these women were lost to follow-up (n = 5) or transferred out after referral (n = 3). The woman with stage IB disease underwent a TAH 5 months after referral and was still in care at the time of writing. The woman with stage IIIB disease received radiation and chemotherapy at Kenyatta National Hospital in Nairobi; within a few months, a recurrence was detected on examination and the woman passed away while in hospice care. Hence, during the referral-only period, 6 of 17 (35.3%) women accessed care in the form of TAH (n = 5) or radiation and chemotherapy (n = 1), including 4 of 15 (26.7%) women with stage IA1 disease and 2 of 2 (100.0%) women with disease that was more advanced than stage IA1; 3 (17.6%) women did not access care despite a referral, and 8 (47.1%) women were lost to follow-up and no information on care was available (Table 3).

During the referral and in-clinic treatment period, 41 women were diagnosed with ICC. Of these, 39 (95.1%) had stage IA1 disease, 1 had stage IB disease, and 1 had stage IIIA disease. Information on treatment was available for all 39 women with stage IA1 disease. Thirty-six (92.3%) women underwent LEEP as their primary treatment; in 23 women, LEEP had also served as the diagnostic tool, whereas 13 women underwent LEEP after ICC

diagnosis by colposcopic biopsy. The remaining 3 (7.7%) women underwent a TAH after referral. The woman diagnosed with stage IB disease was referred to the regional hospital and was continuing to wait for treatment at the time of writing. The woman diagnosed with stage IIIA disease was referred for radiotherapy but died while awaiting treatment. Thus, during the referral and in-clinic treatment period, 39 (95.1%) women with ICC accessed treatment, including all women diagnosed with Stage IA1 disease (Table 3).

Follow-up data were available for 29 (67.4%) of the 43 women with stage IA1 disease who received treatment, including 25 (69.4%) of the 36 women who received LEEP and 4 (57.1%) of the 7 women who had a TAH. At 6, 12, and 24 months after LEEP, the cumulative rates for the recurrence of CIN 2 or worse were 8.0% (2/25), 25.0% (6/24), and 41.2% (7/17), respectively (Table 4). The hazards of recurrence at 6, 12, and 24 months were 120, 384, and 240 events/1000 person-years, respectively (Fig. 1).

Age at diagnosis, CD4+ count, WHO stage, use of highly active anti-retroviral therapy (HAART), and duration of HAART use were not significantly associated with recurrence on univariate analysis; therefore, no multivariate analysis was performed.

All women with a recurrence of CIN 2, CIN3, or stage IA1 disease during follow-up underwent repeat LEEP. For the 4 women with follow-up data who had initially undergone a TAH, the total duration of follow-up was 143 months, with a mean follow-up of 35.6 months (range, 21.1–44.1 months) after the procedure. All had a normal pelvic examination with no signs of local disease recurrence at the follow-up visit.

4. Discussion

In the present population of HIV-infected women who underwent cervical cancer screening in western Kenya, the prevalence of ICC was 1.3%, with the majority having had stage IA1 disease at the time of diagnosis. In a study conducted in Kiambu, Kenya [14], ICC was detected in 7 of 715 HIV-positive women screened at an HIV clinic, resulting in a prevalence of 0.98% in a similar patient population. Prior studies [15,16] have found that the majority of HIV-infected and uninfected women diagnosed with ICC in resource-limited settings have late-stage disease. In Tunisia, only a third of the women diagnosed with ICC during 1994 had early-stage disease [15], whereas stage I disease accounted for less than 10% of ICC cases at another Kenyan hospital [16]. The higher proportion of early-stage disease in the present study can probably be explained by the availability of screening. Increasing access to screening in resource-limited settings may shift the pattern of disease stage at diagnosis to one where the proportion of more treatable, early-stage disease is higher.

The mean age of the women diagnosed with ICC in the present study was younger (34 years) than that seen in other studies in resource-limited settings [17,18]. Moodley et al. [17] found mean age of 39.8 years among 672 HIV-positive women with ICC presenting to a South African hospital, and another similar study from South Africa [18] found a mean age of 41 years. Data on the mean age at ICC diagnosis from a screening population in a low-resource setting are not available. The young age at diagnosis in the present study may

reflect the fact that screening programs enable the detection of early-stage disease before it progresses to the symptomatic stages seen in referral programs. Additionally, the results may reflect the accelerated progression from HPV infection to CIN to ICC among HIV-infected women [16,19,20].

The majority of women in the present study had no prior history of cervical cancer screening, consistent with many other studies from resource-limited settings that show little screening coverage [1,2,5,18]. Of note, more than half the women in the present study had a diagnosis of CIN 2/3 on colposcopically directed biopsy, but were found to have ICC on LEEP specimens. This has implications for see-and-treat programs using cryotherapy: it indicates that a number of women with early-stage ICC could remain undiagnosed because of a lack of histopathology sampling at cryotherapy, and may therefore receive inadequate treatment.

In the present study, access to treatment for ICC was limited for patients who were referred outside the HIV clinic. During the referral-only period, only a third of the women with ICC received a TAH, with more than half having received no treatment or being lost to follow-up. Long waiting times, sizeable co-payments, and lack of staff availability all contributed to the lack of treatment access. When offered LEEP in-clinic or referral for the treatment of stage IA1 disease, all eligible women chose LEEP performed in-clinic at no cost. The recurrence rates during follow-up were similar to those seen after excisional treatment for CIN 2/3 among HIV-positive women at this clinic (9.2% at 6 months [13]) and elsewhere (up to 50% after 6 months [21]). No studies of HIV-positive women with stage IA1 disease from resource-limited settings report on recurrence after local excision; however, a study of HIV-negative women outside Sub-Saharan Africa [22] has reported lower recurrence rates, ranging from 2.7% to 9.0%. The fact that most women with recurrent disease in the present study had CIN 2/3 meant that the majority of recurrences could be treated with repeat LEEP. This procedure can also be used as a bridge to accessing TAH for women with a recurrence. Further follow-up of the women with recurrent disease is required to determine the 5-year outcomes.

The present study is limited by the relatively small number of women with ICC seen at the study clinic and the limited availability of post-treatment information because of loss to follow-up. Additionally, the clinical protocol did not include an immediate post-treatment biopsy to ascertain whether disease found at follow-up was truly recurrent or attributable to treatment failure. We were also unable to assess the margin status—a known predictor of disease recurrence—in the LEEP specimens. Finally, in both the inpatient setting and the clinical setting, clinical staging was based on pelvic examination by a trained gynecologist because anoscopy and cystoscopy were not available.

The present study examined access to, and outcomes of, treatment for ICC among a screening population of HIV-infected women in a resource-limited setting. The majority of the women diagnosed with ICC in the present population had early-stage disease. Providing immediate LEEP in-clinic for stage IA1 disease rather than referral to a local hospital increased access to treatment, with recurrence rates similar to those seen after CIN 2/3 treatment for HIV-positive women. However, the recurrence rates for both CIN 2/3 and

stage IA1 disease were high, indicating that HIV-infected women need more surveillance than HIV-negative women.

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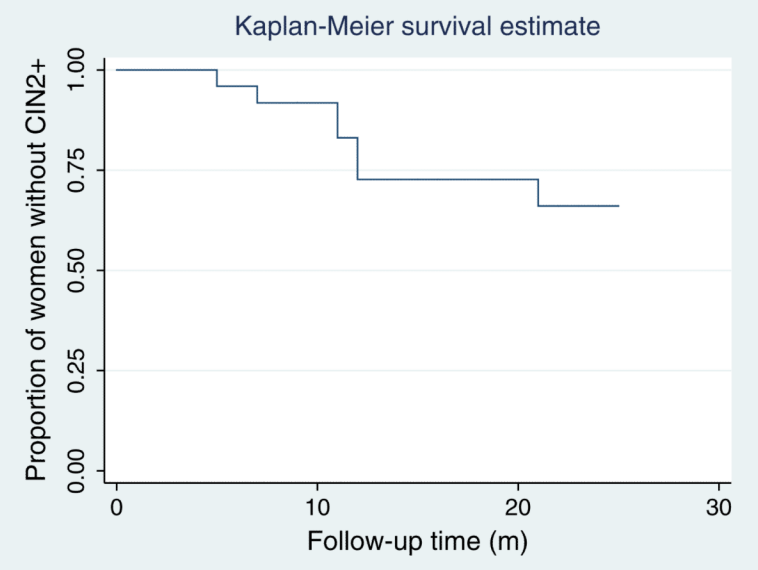

Fig. 1.

Kaplan–Meier survival curve for the recurrence of cervical intraepithelial neoplasia 2 or worse after loop electrosurgical excision procedure for stage IA1 disease Abbreviation: CIN 2+, cervical intraepithelial neoplasia 2 or worse.

Table 1

Demographic and clinical characteristics of 58 women diagnosed with cervical cancer between October 2007 and January 2012 in Kisumu, Kenya.[a]

Characteristic	Value
Age, y (n = 57)	34.0 ± 6.7
Marital status (n = 50)	
Married	42 (84.0)
Single, divorced	8 (16.0)
Parity (n = 49)	2.5 ± 1.5
Barrier/Hormonal contraception use (n = 51)	27 (52.9)
CD4+ count (n = 57)	367.5 ± 202.4
CD4+ category (n = 57)	
≤200 cells/mm^3	13 (22.8)
201-500 cells/mm^3	31 (54.4)
≥501 cells/mm^3	13 (22.8)
WHO stage (n = 52)	
Stage 1	14 (26.9)
Stage 2	19 (36.5)
Stage 3	12 (23.1)
Stage 4	7 (13.5)
Currently on HAART (n = 56)	38 (67.9)
Duration of HAART, mo (n = 47)	14.2 ± 15.4
FIGO clinical stage (n = 58)	
Stage 1A1	54 (93.1)
Stage 1B	2 (3.4)
Stage II	0 (0.0)
Stage IIIA/B	2 (3.4)
Stage IV	0 (0.0)
Prior history of screening (n = 47)	10 (21.3)
Mode of diagnosis (n = 58)	
Colposcopy-directed biopsy	24 (41.4)
LEEP specimen	31 (53.4)
Visual inspection	3 (5.2)

Abbreviations: FIGO, International Federation of Gynecology and Obstetrics; HAART, highly active antiretroviral therapy; LEEP, loop electrosurgical excision procedure.

[a] Values are given as mean ± SD or number (percentage).

Table 2

Colposcopic findings of women diagnosed with stage IA1 or IB cervical cancer in Kisumu, Kenya.

Characteristic	Number (percentage)
Visual colposcopic impression (n = 50)[a]	
Unsatisfactory	1 (2.0)
CIN 1	2 (4.0)
CIN 2/3	46 (92.0)
Suspicious for cancer	1 (2.0)
Satisfactory colposcopy (n = 47)	
Yes	34 (72.3)
No	13 (27.3)
Lesion extends into endocervix (n = 48)	
Yes	6 (12.5)
No	42 (87.5)
Punctation (n = 43)	
Yes	3 (7.0)
No	40 (93.0)
Mucosal bleeding (n = 49)	
Yes	8 (16.3)
No	41 (83.7)
Lesion >2.5 cm (n = 21)	
Yes	4 (19.1)
No	17 (80.9)

Abbreviation: CIN, cervical intraepithelial neoplasia

[a] Colposcopic impression was available for 50 of 54 women with stage IA1 or IB disease.

Table 3

Tables Access to treatment for invasive cervical cancer during the referral-only period versus the referral or in-clinic treatment period.[a]

Referral only		Referral or in-clinic treatment			
Disease stage	**Accessed treatment**	**Disease stage**	**Accessed treatment**	**LEEP**	**TAH**
Stage IA1 (n = 15)	4 (26.7)	Stage IA1 (n = 39)	39 (100)	36 (92.3)	3 (7.7)
Stage IB (n = 1)	1 (100.0)	Stage IB (n = 1)	0 (0.0)	0 (0.0)	0 (0.0)
Stage IIIA/B (n = 1)	1 (100.0)	Stage IIIA/B (n = 1)	0 (0.0)	0 (0.0)	0 (0.0)
All women with ICC (n = 17)	6 (35.3)	All women with ICC (n = 41)	39 (95.1)	36 (92.3)	3 (7.7)

Abbreviations: ICC, invasive cervical cancer; LEEP, loop electrosurgical excision procedure; TAH, total abdominal hysterectomy.

[a] Values are given as number (percentage).

Table 4

Cumulative incidence of biopsy-proven recurrence of CIN 2 or worse after treatment with loop electrosurgical excision procedure for stage IA1 cervical cancer.

Follow-up interval	Total number	New CIN2 or worse recurrences[a]	Cumulative recurrence rate	Instantaneous hazard rate
6 months	25	2	0.08	120 cases/1000 person-years
6–12 months	22	4	0.25	384 cases/1000 person-years
12–24 months	11	1	0.41	240 cases/1000 person-years

Abbreviation: CIN, cervical intraepithelial neoplasia.

[a] All patients with a recurrence had CIN 2/3, with the exception of 1 patient at 6–12 months who had stage IA1 disease and 1 patient at 12–24 months who had stage IB disease.