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Review

Comparison and acceptability of HPV self-collected cervical cancer samples versus doctor-collected samples in Africa: a systematic review

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Abstract

Self-collected cervical cancer (CC) samples might be considered alternative strategy and provided an equivalent comparable result on HPV (Human Papillomavirus) detection and acceptability with clinician-collected sampled in Africa. A systematic review was performed using four electronic bibliographic databases (Pubmed, Cochrane, WHO Global health library and Popline) to compared HPV detection rate and acceptability of HPV self-vs clinician collected sampling in Africa. Specific search keywords were used. The study only focused on research articles that compared self-vs clinician-collected samples based on HPV testing and its associated data. Eight research articles and a total of 3476 women were included from six countries in Africa continent. The mean age of women was 40.6 years with range of 16-89 years. Aggregately the high risk (HR)-HPV detection rate was 36% (7.2% -84.8%) and 35% (6.8% - 87.8) of self-vs clinician-collected sampling, respectively. The mean differences and variation in detection rates between sampling methods was 2.6% (SD =1.7). There was significant HR-HPV detection rate correlation between two sampling methods with value of R=0.997. The weighted average of kappa agreement was 0.71(0.47 to 0.89) was moderate. Overall women concluded that self-collected sampling method was a preferred method (86.3%), easy to obtained (77.8%), and 76.7% increased cervical cancer screening uptake. The acceptability of self-collected CC sampled HPV testing could be an alternative sampling method and increased the uptake of screening services. Introducing standardized self-sampling techniques and diagnostic assay study in Africa is paramount.

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Introduction

Human papillomavirus (HPV) is the main cause of cervical cancer [1]. In low and middle income countries (LMIC) implementation of HPV screening test could not be easy, simple and cost effective, however, Africa will be not ignore this methods introduced into its national cervical cancer screening programme [2,3]. Self-sampling has several advantages over physician-collected samples for detection of HPV genital infection. Self-collected samples can be more easily obtained in settings with limited resources, or in populations difficult to reach. Numerous studies have reported that vaginal/cervical self-obtained samples in women were accurate and suitable for Deoxyribonucleic Acid (DNA) testing [3-5]. Previous studies revealed that self-sampling might increase willingness to participate in cervical cancer screening programs as it reduces patient's financial and logistical burden; and increase sense of privacy and autonomy. Self-sampling therefore might remove some of the barriers that prevent women, especially those in low socioeconomic and minority populations, from participating in regular screening programs [4,6]. Overall, self-sampling is believed to improve the subjective patient experience, lead to increased screening participation and ultimately reduce morbidity and mortality related to HPV infection and cervical cancer [3,5,7].

In some countries self-sampling for HPV testing has already been adopted and evaluated to incorporate into national cervical cancer screening programs. Several studies have shown that the majority of women who have been under-screened but who tested HPV-positive in a self-obtained sample may have potential to visit a clinic for follow-up diagnosis and management [8-10]. The definition of HPV self-sampling is a process where a woman who wants to know whether she has HPV infection using a kit to collect a cervico-vaginal sample, which is then sent for laboratory analysis. Various collection methods were available which include lavage, brush, swab and vaginal patch. While HPV self-sampling cannot provide a diagnosis of cervical (pre-) cancer, it identifies those women at higher risk [10]

The aim of this systematic review was to reach consensus among different research articles outputs on the selected topics in Africa and to determine self-sampling acceptability and HPV detection comparability between self-collected sampling verses clinician-collected samples within Africa. We focused on detectability as the outcome of interest, i.e., any positive test, whether originating from self- or from physician-sampling. Our intent was on virological detection only, not on comparing collection methods as per their ability to distinguish HPV testing performances for detecting cervical precancerous lesions. This review addressed the following research question: Should HPV Self sampling testing considering as an alternative platform for resource limited countries in Africa? This study was to determine the level of agreement between self-vs clinician-collected sampling for HPV testing in Africa.

Methods

To answer our research question we performed a computerized literature search in multiple databases; Medline via PubMed, Embase (Excerpta Medica database), Google Scholar, Scopus, the Cochrane Library, OCLC, PAIS (Public Affairs International Service), International Database (EBSCO), WHO (World Health Organization) Global Health Library, and POPLINE (Population Information Online). The study was followed PRIMA systematic review procedures and flow diagram (Figure 1). PRISMA (Preferred Reporting Items for *Systematic Reviews* and Meta-*Analysis*) is an evidence-

based minimum set of items for reporting in systematic reviews and meta-analyses.

A combination of medical subject heading terms and free text terms relating to human papillomavirus or HPV and self-or patient-or auto-or physician-or clinician-or health professional-combined with collection or obtained or sampling or testing as both medical subject heading (MeSH) terms and text words in Africa were used. Reference lists of review articles and all articles identified in the systematic search were checked. An updated search was performed on September 2019. All abstracts were screened, checked and reviewed by two independent reviewers (HL and EL). The studies for which women visiting cervical cancer screening center for examination, sexually active populations and Human Immunodeficiency Virus (HIV) (+/-) populations, in Africa included. No exclusion criteria were setup in relation to commercially available HPV technology. Only studies analyzing vaginal and/or cervical HPV self-taken samples verses clinician HPV test results as a comparator where considered. The review focused on HPV detectability as the outcome of interest, i.e. any positive test, whether originating from self- or from physician-sampling.

Statistical analysis: the kappa statistic, concordance and the difference in the proportions of HPV detection between clinician and self-sampling were calculated. Strength of agreement was used according to Landis and Koch-Kappa <0: poor; poor; 0 to 0.20: slight: 0.21 to 0.40; fair, 0.4 to 0.60, moderate: 0.61-0.80:, substantial: 0.81 to 1.0, almost perfect. Convert extracted data to common representation (usually average and SD (Standard Deviation).

Current status of knowledge

A total of 250 articles were found through search engine and any duplication and irrelevant articles were cleared and removed. There were only 8 relevant articles with total population of 3476 female participants (Figure 1). Studies from six African countries were included in this systematic review Ghana (1 paper), Nigeria (2 papers), Egypt (1 Paper), Cameroon (2 papers), South Africa (1 paper) and Ethiopia (1 paper) [11-18]. The average age of women was 40.6 years with range of 16 - 89 years. One study presented an age group of 16 -17 years that included sexually active South African adolescent women [17]. A combination of cervico-vaginal sample collection strategy were used in almost all (87.5%) studies and only one study used different sample collection site for self- versus clinician in vaginal and cervical swab [17]. Four studies [11,12,16,17] used dry swab sample collection device whereas three used cytobrush devices for samples collection (Table 1). In this systematic review the overall detection rate of HR-HPV was moderately agreed between self-and clinician-collected samples. Although the presence of lesions may modify the ability to detect HPV, the agreement between self- and physician-obtained samplings was good regardless of the disease prevalence in the tested population [3,7,9,19]. Study inclusion criteria varied from general population to specific patient groups (Table 1), which included women who attended for cervical cancer screening service; HIV positive and negative women, and sexually active women. This is to our knowledge that first systematic review comparing the performance of self-collected cervical samples compared to clinician taken sample specifically focusing on Africa. P. Petignat *et al*. [20] published an article to compare the detection rate of genital human papillomavirus (HPV) infection in self- and physician-obtained samples around the globe. However, the objective, scope and period of this study were quite different from our study. The first focus was include only studies in Africa populations; secondary, the systematic review period included recent

studies and lastly we mainly focused on HR-HPV detection rate, results obtained from clinician-collected versus self-sampled. In this study we were included all type of population group without any restriction from general population to specific cases of HIV.

There was a high HPV prevalence difference observed between reviewed studies due to source of population where variation observed between HIV positive women versus general population. In the study with the highest HPV prevalence, 84.8-87.9% of women tested positive [13], while 6.2-9.8% were positive in the study with lowest prevalence [15]. There was variation (Mean=2.5, SD=1.7) among eight studies of HPV detection rate between self- sampling and clinician sampling (Table 2). Aggregately HR-HPV detection rate was 36% with a wide range of (7.2% - 84.8%) and 35% (6.8% - 87.8) for self- and clinician-collected sampling, respectively. The absolute median differences in detection rates between sampling methods was 1.9% (Table 2). In three articles HPV detection rate was highest for self-collected samples [11,17,18], whereas in the remaining five studies clinician taken samples had the highest detection rate. Comparatively a high rate of HR-HPV detection was found on three studies where source of population were sexually active and HIV positive women. Three papers from Ghana [12], Nigeria [14], and Ethiopia [18] compared acceptability and feasibility of self-collected samples over clinician-collected samples. Averagely 86.3%, 77.8%, and 76.7% of women reported that self-sampling techniques were preferred over clinician taken samples, easy to obtain, support cervical cancer screening, respectively. Most African women participating in the review articles concluded that self-sampling was a preferred choice which may decrease healthcare access challenge, health disparities, stigma, traditional cervical screening, providing samples at clinic which is uncomfortable, fear of doctors, fear of friends or family etc. Therefore, self-sampling could increase the uptake of cervical cancer screening in resource limited countries.

Most African women are not prone to visit clinic regularly for general check-up particularly for cervical cancer screening program, thus self-sampling could increase women participation in cervical cancer screening program and transmission studies of HPV infection [18,20]. There was significant HR-HPV detection rate correlation between sampling methods with R-value of 0.997, (Figure 2). The mean percentage difference of HR-HPV detection rate between self- vs clinician collection was 2.6% with range of 0.1% to 5.3%. Across all included studies there was no significant difference between HR-HPV detection rate between self- vs clinician collected samples. The greatest difference between the two samples methods was observed by 5.3% (Table 2), where detected in sexual active and HIV positive women [16]. This could be due to various reasons like difference observed on sample collection site, collection techniques, procedures, studies design, and source population, assay tests and clinical settings. This study also concluded as expected the prevalence was quite difference among different women source population where low in asymptomatic women attending screening program. Only two studies compared sample quality between self-and clinician-collected samples [12,18]. One study from Nigeria [12] showed that 2.7% of self-collected samples were rejected for further analysis due to poor quality, whereas none were rejected from clinician-collected samples (RNase p gene (cq values >40). However, study from Ethiopia [18] indicated 22.8% of self-collected samples and 30.1% of clinician collected- samples were rejected for analysis due to poor samples collection (<10 cells/ul).

This systematic review showed a moderate kappa agreement observed between two sampling methods and 62.5% of reviewed articles showed that a higher detection rate were observed in clinician-collected sampling (gold standard) over self-sampling. Thus, we are expecting such difference due to poor self collection instruction and insufficient collection procedural demonstration. However, self-sampling approach would help the uptake of cervical cancer screening program

and study HPV transmission and its impact on HPV vaccine in the Africa continent where all necessary awareness and education on self-sampling techniques provided to women. The average of studies trial of kappa agreement was 0.71 with range of 0.47 to 0.89 which was moderate. The overall agreement between self- and clinician collected HR-HPV detection rate was moderate with no significant variance (SD=0.16).

As this review study only focused on African based studies, there might be a number of concerns regarding fully introduction of self-sampling into the health care system. Most African countries still used PAP (Papanicolaou Test) smear and VIA (Visual Inspection of cervix with Acetic Acid) for cervical cancer screening program due to relatively cost effective and no major infrastructure required. Prior to introduce HPV detection based on self-sampling collection technique, at least some level of infrastructure is needed like equipment, reagents, electric power, and skilled manpower and so on. Therefore, a large scale standardized and comparison HPV study between two sampling methods across Africa countries might be need before introducing self-sampling into the cervical cancer program. Most African countries have at least HIV and/or Tuberculosis Bacillus (TB) diagnostic laboratory where equipped with lab infrastructure at hand, thus there would be possibility of sharing the resource for HPV detection at national or regional reference laboratories. If self -sampling devices were available at every health centers or in near future at pharmacy store, women could get it easily, take her samples and send to central laboratories for HPV detection and cytological analysis, which definitely know her status at early stage of disease and increased the uptake of screening. The best way to increase the women participation in Africa on cervical cancer screening service is availing rapid HPV diagnostic detection test at every clinic.

Conclusion

In conclusion, self-sampling could be considered as alternative best sampling methods which provide a reproducible and comparable HPV detection to that of clinician sampling methods. Introducing standardized self-sampling and diagnostic assay across Africa countries may be very useful and timely needs increase the uptake of cervical cancer screening coverage. We observed variations in study design; HPV detection methods and samples collection devices employed which could not fully permit adequate comparison across studies in order to make a generalized conclusion regarding the use of the self-sampling HPV testing. Therefore, it could be better to have a large scale study which includes different African countries by using same sampling devices and HPV detection tests. Further research is clearly needed to justified self sampling methods is an accurate and affordable approach in resource scarce setting.

What is known about this topic

- HPV testing between self verses clinician collected samples could have comparable results;
- Self sampling could be used as alternative cervical cancer screening;
- Self-sampling could be helpful to increase the uptake of cervical cancer screening because of easy to use, self-sampling acceptability and feasibility in terms of easy to obtain samples, preference method and increased cervical cancer screening uptake.

What this study adds

- This study was focused on African studies only and confirmed that self-sampling could be used as alternative platform to increase the uptake of cervical cancer screening which improve the very low screening coverage in Africa;
- Standardized self-sampling devices and easy collection procedures instruction could improve the

quality of samples and may help increase the uptake of service cancer screening program;

- Moderate agreement was observed between two sampling techniques which support the introduction of self-sampling in Africa continent as one of strategy. However, for better effectiveness of HPV self-sampling a large scale study in Africa could be designed through standardized sampling techniques, HPV assay, instrument, reagents and so on.

Competing interests

The authors declare no competing interests.

Authors' contributions

E.L., G.B., L.B, JP.B conceived and designed the study. E.L took part in data collection. E.L is performed data analysis. E.L and JP.B analyzed the data. E.L., L.B, JP.B and JP.V are performed data interpretation. E.L., G.B., JP.V, R.L, JP.B contributed to the writing of the manuscript. All the authors have read and agreed to the final manuscript.

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Table 1: characteristics of study populations of eight review articles

	Reference	Country	Sample size	Average age(yrs) /age range	Sample type (SS/CT)/sample quality control	Collection device (SS, CT)	Inclusion criteria	Exclusion criteria
1	Untiet *et al.*	Cameroon	789	44 (20-89)	Cervical samples	Flocked swab	Not pregnant women, aged between 20 and 89 years, having no previous cervical therapy or hysterectomy; women attending for routine cervical screening as well as hospital workers and wives of hospital employees	More than 6 months of stay
2	Modibbo *et al.*	Nigeria	400	40.8 (30 - 65)	Cervicovaginal (SS: RNase P gene level =n=5 (2.7%) excluded from further analysis, CT= n=0 (not excluded)	Dry flocked swab	Women with age group 30 to 65 yrs	Pregnant, planning to relocate within six months, HIV positive, had unexplained cervical bleeding, history of hysterectomy, mental illness or cervical cancer from the study.
3	Kamal *et al.*	Egypt	1601		Cervical samples	-		-
4	Obiri-Yeboah *et al.*	Ghanaian	191	44.1 (>=18 years)	Vaginal/cervical	CareHPV brush	HIV (+) and HIV (-) women or general OPD population	Currently menstruating, previous treatment of cervical cancer
5	Olusegun *et al.*	Nigeria	194	43.4 (23-75)	Cervical	Cytobrush (cervexR	NA	NA
6	Viviano *et al.*	Cameroon	188	38.7 (30-49)	Endocervical (for HIV + women)	Dry swab	NA	pregnancy and previous total hysterectomy
7	Adler *et al.*	South Africa	30	(16-17)	SS: Vaginal swabs; CT: cervical swab	Dacron© swab	sexually active South African adolescent females	
8	Eshetu et al.	Ethiopia	83	32 (20-65)	Vaginal/cervical SS:<10 cells/ul: 22.8% excluded; CT: <10 cells/ul: 30.1% excluded)	Cytobrush	An intact uterus, no history of cervica cancer	Less than 20 years

Table 2: comparison of HPV detection percentage between self-vs clinician collected cervical cancer samples							
Reference	**Country**	**Assay type**	**Type of HPV detect**	**HPV prevalence (%)**		**HPV prevalence (%) difference**	**Kappa value**
				SS	CT		
Untiet *et al.*	Cameroon	Abbott RealTime High Risk HPV assay (Abbott Laboratories, Abbott Park, IL)	HR-HPV	14.6	12.7	1.9	0.74
Modibbo *et al.*	Nigeria	GP5+/6+ Luminex system	HR-HPV	8.9	10.3	1.4	-
Kamal *et al*	Egypt	Hybrid Capture 2 (HC2) assay	HPV	84.8	87.9	3.1	0.89
Obiri-Yeboah *et al.*	Ghanaian	careHPV (Qiagen)	HR-HPV	78.0	78.1	0.1	0.88
Olusegun *et al.*	Nigeria	Hybribibo GenotArray	HR_HPV	6.2	9.8	3.6	0.47
Viviano *et al.*	Cameroon	GeneXpert HPV assay	HR-HPV	14.3	19.6	5.3	0.57
Adler *et al.*	South Africa	Roche Linear Array	HR-HPV/LR_HPV	47	43	4	0.80
Eshetu *et al.*	Ethiopia	Riotol qPCR	HR-HPV/LR_HPV	17.2	15.5	1.3	0.586

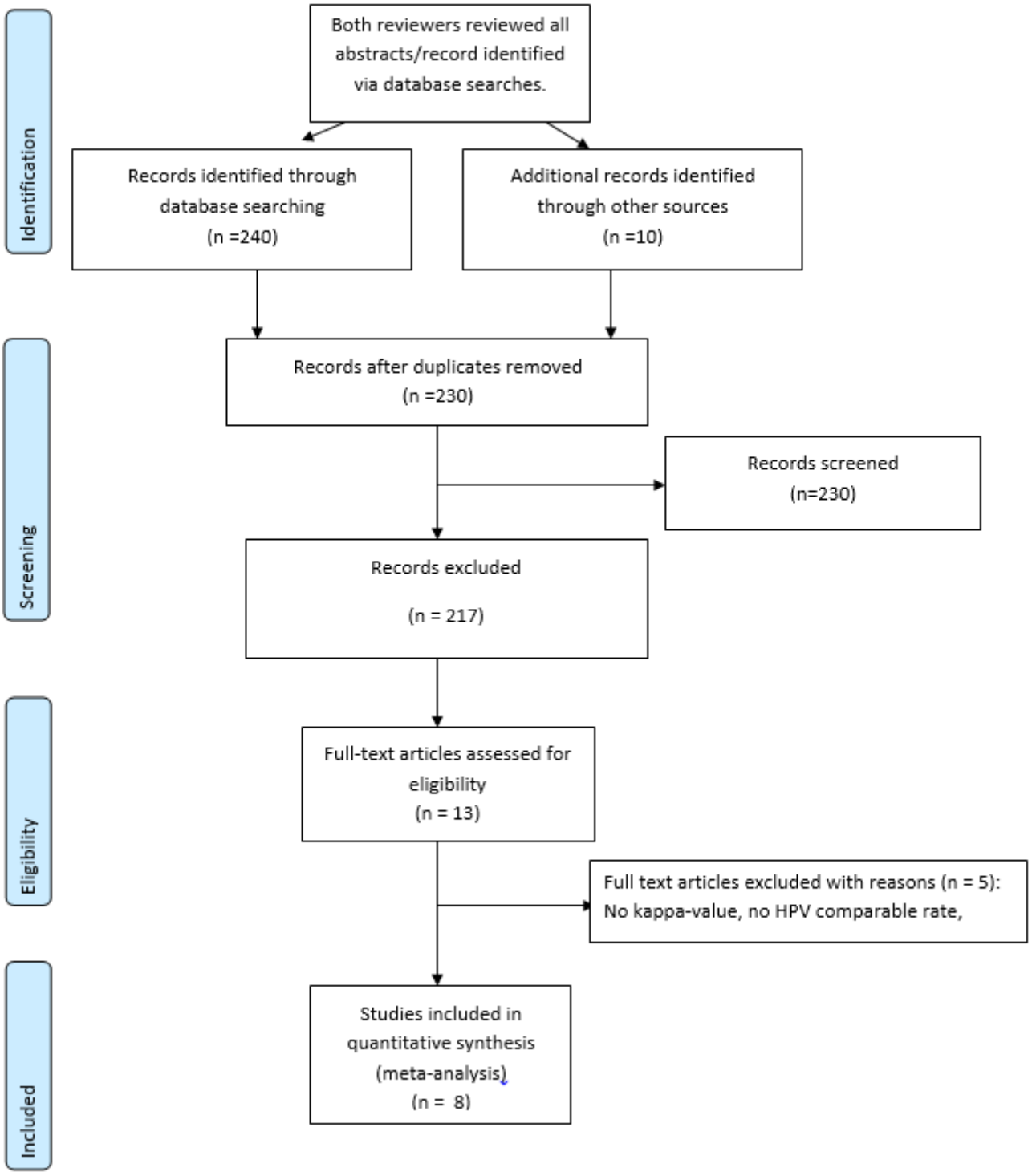

Figure 1: PRIMA systematic review processes

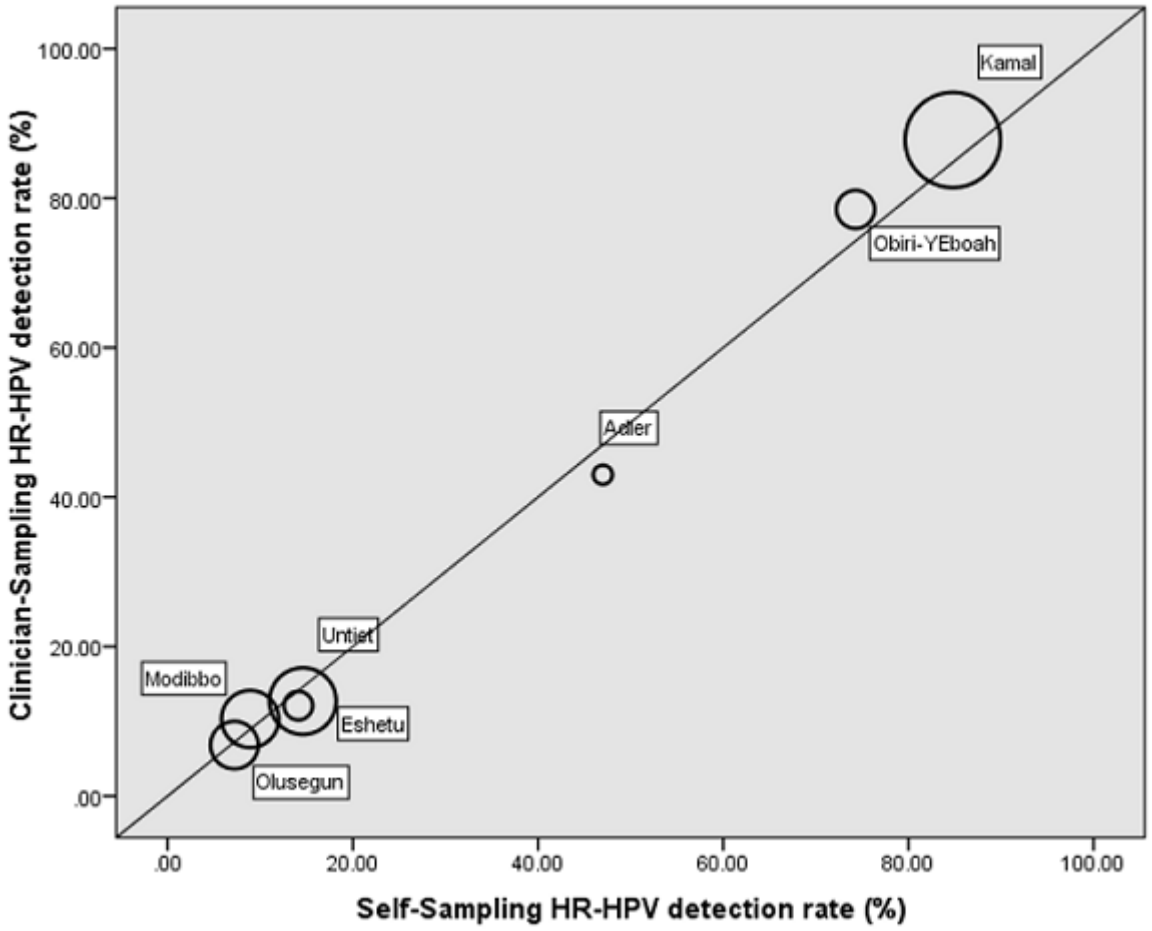

Figure 2: correlation of self- and clinician-sampling for high-risk HPV in trials with data from 3476 women. The sizes of the symbols are proportional to the sample sizes of the trials