MINI-REVIEW

Self-Collection Tools for Routine Cervical Cancer Screening: A Review

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Abstract

Sub-optimal participation is a major problem with cervical cancer screening in developing countries which have no organized national screening program. There are various notable factors such as 'embarrassment', 'discomfort' and 'no time' cited by women as they are often also the bread winners for the family. Implementation of self-sampling methods may increase their participation. The aim of this article was to provide a survey of various types of self-sampling tools which are commonly used in collection of cervical cells. We reviewed currently available self-sampling devices and collated the advantages and disadvantages of each in terms of its acceptance and its accuracy in giving desired results. In general, regardless of which device is used, self-sampling for cervical scrapings is highly acceptable to women in most of the studies cited.

Keywords: Self-sampling - cervical cancer - Pap smear - review

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Introduction

In developing countries, cervical cancer is one of the commonest cancers in women. The paradox, many developing nations do not have organized cervical cancer screening. In Malaysia for example, despite the country offering Pap smears for free since 1995, only 47.3% of Malaysian women have been screened (Othman and Rebolj, 2009). Out of 1432 cases of cervical cancers diagnosed in one teaching hospital, less than 10% of the cases have had pap smears within 3 years of cancer development (Othman et al., 2009). Among the factors cited are "Never heard about it" (36.2%), "Shy" (10.4%), "Afraid to do it" (13.1%), and "I am busy" (3.6%) (Othman et al., 2009). In general, urban women have better acceptance to cervical cancer screening. In one study urban Malaysian women are less likely to state "Lack of time" as the reason for not having Pap smear done (Dunn and Tan, 2010).

Currently, Pap smears are taken by health personnel. However, reduction of patients who come voluntarily for screening is the major problem that needs to be solved. Many studies have been conducted on acceptability of women towards Pap smear for cervical cancer screening (Rositch et al., 2012; Rashwan et al., 2011). There are some misconceptions and barriers to doing Pap smear especially in developing nations (Al-Naggar et al., 2010).

For these nations the approach is to find feasible, affordable, and essential method for detection of cervical cancer (Sahasrabuddhe et al., 2012). Self-sampling is a method to collect cervical specimen by using a special designated device to collect cervical cells at squamous-columnar junction by the user themselves without assistance of medical personnel. Studies have shown that using self-sampling method increases participation of non-responders in screening programs (Bosgraaf et al., 2014a; Piana et al., 2011; Sancho-Garnier et al., 2013). Self-sampling samples have also been shown to be suitable for HPV testing (Sancho-Garnier et al., 2013; Scarinci et al., 2013; Tamalet et al., 2013; Othman and Othman, 2014) even in a in a large-scale (Harper et al., 1999).

There are many self-sampling devices which have been clinically approved such as swabs, cervical brushes, tampon, and cervico-vaginal lavages (Harper et al., 1999; Schmeink et al., 2011). The collected materials taken from the self-sampling devices are submitted to laboratories and treated as per routine samples for cytopathology examination and for HPV detection (Pengsaa et al., 2003; Okayama et al., 2012).

Different Types of Self-Collection Methods

Swab self-sampler

Swab is a type of device consists of small piece of soft material sometimes on the end of a small stick that is use for applying medicine or cleaning a wound. There are two types of swab available in the market; dry swab which is usually Dacron swab with a plastic bag and wet

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swab which is a flocked swab with a tube filled with 1 ml of liquid transport medium (ESwab®, Copan, Brescia, Italy). Wet and dry swab show good agreement (85.7%) in its function and maintain specimen integrity (Eperon et al., 2013). Swab self-sampler mainly collect cervical and vaginal cells (Schmeink et al., 2011).

The most commonly used brand for swab self-sampler is Dacron swab or cotton swab (Moscicki et al., 2010; Cerigo et al., 2012; Karwalajtys et al., 2006; Gravitt et al., 2001). It is small, easy to use and can be processed in a similar technique as to those collected by physicians (Zehbe et al., 2011). After collection, the swab can be either inserted into the accompanying dry plastic tube or suspended in preservative (Eperon et al., 2013), sterile cryovials (Forney et al., 2010), phosphate buffered saline (Eperon et al., 2013) and specimen transport medium (Moscicki et al., 2010). In addition, sending and returning the swabs through the mail is feasible, thus these devices can be home-based (Baay et al., 2009).

However, there are some limitations of using swab as a self-sampling tool. There is a higher rate of microscopic blood contamination which may disturb HPV DNA results. Self-sampling with a cotton tip swab can miss 50% more cancers than physician sampling, indicating that the cotton tip technique is not a safe method for the collection of samples aimed at primary cervical cancer screening (Lorenzato et al., 2002). The majority of studies using Dacron swab have used liquid-based storage and transport which is impractical because the fluid may leak (Cerigo et al., 2012). Moreover, the swabs need to be kept in cold box until the sample is sent to the lab for processing (Forney et al., 2010).

Brush self-sampler

Brush is a type of device that needs women to insert the bristles into the vagina. Cytobrush is the most well-known brush tool to collect self-sampling materials. The market also has variety of brush-types self-sampling devices such as Evalyn brush, Viba-brush, conical shaped brush (cervical sampler) and Femipap. Similar to swab self-sampler, brush self-sampler mainly collect cervical and vaginal cells (Schmeink et al., 2011).

The self-collected samples from Evalyn brush shows 85.5% agreement for high risk HPV detection when compared to physician-taken samples (van Baars et al., 2012). In addition, the pink colour of Evalyn brush is attractive to women. Another study which compare Evalyn brush and lavage device named Delphi screener showed that that the participation rate in the brush based self-sampling device group was higher than in the lavage based group (Bosgraaf et al., 2014b). This study also found that the participation rate is vary marginally with age; in the brush group (31.3-37.8%) and the lavage group (30.1-34.7%) (Bosgraaf et al., 2014b).

There are many advantages of using brush self-sampler. It can be used for dry transport and storage (van Baars et al., 2012). Brushes are flexible and easy to use, can be processed in the same way as physician-obtained smears, and are suitable for sending by mails (Schmeink et al., 2011). Many studies which use brush for self-collection have demonstrated a higher sensitivity for cervical intraepithelial neoplasia grade two or worse than studies using Dacron or cotton swab A (Belinson et al., 2003; Szarewski et al., 2007; Gok et al., 2012b). Offering a brush based device to non-responder in cervical cancer screening programme is non inferior to lavage based device in term of participation (Bosgraaf et al., 2014b).

The limitation of brush-types self-sampling device is the amount of cells collected is at least three times lower than obtained by the Delphi cervico-vaginal lavage self-sampler (Bosgraaf et al., 2014b). Brush self-samples primarily contain vaginal cells, thus making it less suited for additional molecular tests for disease markers (Gok et al., 2012b).

Tampon self-sampler

Tampon is a cylindrical mass of absorbent material, primarily used as a feminine hygiene product. At present, tampons are designed to be easily inserted into the vagina during menstruation and absorb the user's menstrual flow. Tampons come in two basic types; with applicators, or a plastic tube that will help to push the tampon up into the vagina. Tampon can collect a sizable cellular pellet that the swab cannot which could increase the possible variability in cell concentration aliquot from each tampon sample for PCR purposes. The market also has variety of tampon-types self-sampling devices such as Fournier self-sampling device.

Women are more familiar and comfortable with tampons than with other self-sampling methods, and the use of tampons is an attractive self-sampling option for women. Tampon self-sampler can collect mainly squamous epithelial cells from the wall of the vagina together with shed cervical cells (Schmeink et al., 2011). In women with CIN, detecting high-risk HPV in samples is comparable regardless of tampon use duration, from as low as 10 seconds to overnight exposure (Harper et al., 2002). A study which compare tampon or swab and paired clinician-obtained specimen found that tampons combined with Hybrid Capture 2 testing did not perform well in with a sensitivity of only 60% and a $\varkappa$ of only 0.55 compared to clinician sampling combined with HC2 testing (Jones et al., 2007).

There is some limitation of using tampon. A condition called toxic shock syndrome may affect some women (Dixit et al., 2013; Parsonnet et al., 1996; Gupta et al., 1994). Toxic shock syndrome is an extremely rare but potentially fatal consequence of leaving a tampon in for too long. HPV DNA by using tampon self-sampler is available but the samples need to be processed more extensively to get DNA extraction. Therefore, DNA extraction from tampons is time consuming and inefficient (Zehbe et al., 2011).

Cervico-vaginal lavage self-sampler

Cervico-vaginal lavage is a type of device that releases liquid into the vagina and re-collects the fluid. Cervico-vaginal secretions are often used in reproductive health studies. Cervico-vaginal lavage may have the advantage of increased sampling surface area and collection of a large sample volume, which can be fractionated for various analyses (Lorenzato et al., 2002). The examples

Table 1. Characteristics of Self Sampling Devices

Types of Device	Swab Self-Sampler	Brush Self-Sampler	Tampon Self-Sampler	Cervicovaginal-Lavage Self-Sampler
Criteria	A type of device consists of small piece of soft material sometimes on the end of a small stick that is use for applying medicine, cleaning a wound, etc.	A type of device that need women insert to the bristles material into the vagina and is turned around to collect cells	A cylindrical mass of absorbent material, primarily used as a feminine hygiene product.	A type of device that releases liquid into the vagina and re-collects fluid
Storage	Dry plastic tube or suspended in preservative for examples Preservcyt solution, sterile cryovials, specimen transport medium, phospahate buffered saline	Specimen transport medium but dry storage available	Specimen transport medium for examples PreservCyt	Specimen transport medium for example: Cervatec medium
Transportation via mail	Yes	Yes	Not convenient	Not convenient
Type of cell collected	Cervical and vaginal cells	Cervical and vaginal cells	Mainly collect squamous epithelial cells from the wall of the vagina together with shed cervical cells.	Mainly collect squamous epithelial cells from the wall of the vagina together with shed cervical cells
HPV DNA	Available	Available	Available but need to be processed more extensively to get DNA extraction	Available
Sensitivity overall	74-81% (14)	74-81% (14)	Less well, between 67-94% (14)	Less than 81% (14)
Duration of collection	Fast, less 10-20 seconds	Fast, less than 1 minute	Longer-10 seconds to overnight	1 to 8 hours or more
Position during collection	Lying down, standing as well as in sitting position.	Either standing with one foot on the toilet or bathtub, or standing with legs apart and knees slightly bent (Squat position)	Either standing with one foot on the toilet or bathtub, or standing with legs apart and knees slightly bent (Squat position)	Lying down, standing as well as in sitting position.
Example of brand available in the market	Dacron swab, Flocked swabs, emery paper-swab	Cytobrush, Evalyn brush, Viba-brush, cervix brush, conical shaped Brush (Cervical Sampler)	Fournier self-sampling device	Pantarhei screener, Kato device, Mermaid sels-sampling device

of frequently used self-collection method which can rinse the upper vagina and cervix to obtain cervico-vaginal material are the Delphi screener, Pantarhei screener, Mermaid self-sampling device and Kato self-sampling device. Nobbenhuis, MA, et al used an irrigation syringe, a disposable female urine catheter, and a container with 15 ml sterile phosphate buffered saline (PBS) for irrigation (Nobbenhuis et al., 2002).

Delphi screener is noted to be easy to handle, excellent user acceptance and high sensitivity in detecting high risk HPV (Delere et al., 2011). There are two generation of Delphi screener, the first generation and the second generation. In first generation, the limitation is easy leakage, which is later resolved in the second generation. Instead of a syringe-like mechanism for which the thumb is needed to push the plunger, the second generation is designed to improve both the grip and strength to push the plunger. However, this method also was associated with higher rates of microscopic blood contamination (Delany et al., 2008).

Several studies have been done by using Kato self-sampling device (Pengsaa et al., 2003; Okayama et al., 2012; Nabandith et al., 2012; Sanchaisuriya et al., 2004). In a study 78% of women prefer Kato self-sampling compared to samples collected by gynaecologists (Nabandith et al., 2012). Kato device is generally acceptable to women with regardless of educational background (Sanchaisuriya et al., 2004). The advantage of this device is the sponge for cell collection is wider; therefore, if the specimen is collected according to the instruction manual, the number of cells should be sufficient to satisfy the Bethesda system criteria 2001 for reporting cytological diagnoses, resulting in a decrease in the number of indeterminate specimens and a much higher positive cytology rate (Okayama et al., 2012).

There are some limitations of using cervico-vaginal lavage. Some women dislike the lavage because the liquid seemed messy and unsanitary (Richman et al., 2011). In addition, cervico-vaginal lavage needs to dilute before collection. Dilution reduces the sensitivity of most assays, and the extent of dilution is often difficult to determine, making quantification of the initial in vivo concentrations difficult. Therefore, dilution of the samples reduces the sensitivity of the assay. Another main disadvantage is that cervico-vaginal lavage specimens are not convenient to be sent by mail.

A summary of these devices and their characteristics is given in Table 1, with individual studies listed in Table 2.

Table 2. Characteristic of Studies by Using Different Types of Self-Sampling Device

References	N	Place	Inclusion Criteria	Exclusion Criteria	Self-Sample Brands	Physician Sample Brands	HPV Test
Swab self-sampler							
Cerigo et al., (2012)	93	Nunavik, Quebec,	Age 18-69 years	NA	Dacron swab	Dacron swab	PGMY-primer PCR protocol and genotyping with the linear array method
Moscicki et al., (2010)	537	San Francisco	Age of 13–21 years and had less than 5 years of sexual experience	Planning to move within 3 years, immunosuppressed, currently pregnant or had a history of ablative or surgical therapy of the cervix.	Dacron swab	Lavage	PCR amplification with PGMY09/11 primer system
Moscicki et al.,[18]	377	Gambia, Africa	Had previously accepted a speculum examination	Pregnant	Dacron swab	Cytobrush	PCR and HPV typed (ELISA) and monospecific probes.
Karwalajtys et al.(2006)	307	Canada	Age 15-49 years, follow up HPV testing	NA	Dacron swab	Cervical sampler brush	Hybrid Capture 2
Gravitt et al.,(2001)	268	Eastern United States.	Recruited as part of a matched, multicenter, case-control study of adenocarcinoma and SCC of the uterine cervix	Missing swab samples	Dacron swab	Dacron swab	PCR
Tamalet et al.,(2013)	9334	Marseille (Vitrolles and Marignane)	Aged 25-69 years without a Pap smear recorded in the National Insurance Registry for more than 2 years	NA	Flocked swabs	NA	PCR (MYR09/MY11primers)
Brush Self-Sampler							
Daponte et al.(2006)	137	Larissa, Greece	Referred for colposcopy because of abnormal cervical cytology	NA		Cytobrush	PCR
van Baars et al.,(2012)	134	The Netherlands	Age 18 years and above visiting the gynecological outpatient clinics for colposcopy because of abnormal cervical cytology	NA	Evalyn brush	Rovers Cervex-Brush	PCR SPF10-DEIA-LiPA25 andGP5_/6_-LQ-test.
Dannecker et al.,(2004)	560	Munich, Germany	With no history of hysterectomy.	NA	Cytobrush	Cytobrush	Hybrid Capture 2
Dijkstra et al.,(2012)	135	The Netherlands	Age 20–68 and referred for colposcopy	NA	Viba-brush	Viba-brush	GP5+/6+- PCR EIA, with genotyping by reverse line blotting (RLB).
Gok et al., (2012)		The Netherlands	Had not attended the organised cervical screening program	NA	Viba-brush	Viba-brush	Hybrid Capture 2
Bosgraaf et al.(2014)	35,477	The Netherlands	Had received a pre-invitation letter and could "opt out" of this trial	Previous hysterectomy, being follows up by gynaecologist because of abnormal cytological result less than 2 year before inclusion and pregnancy.	Evalyn brush	NA	GP 51/61 PCR
Tampon self-sampler							
Jones et al.,(2007)	450	Gugulethu, South Africa,	Age 18 years or older, sexually active, self-reportedly not pregnant, and willing to comply with the protocol and gave written informed consent	Had taken antibiotics in the previous 4 weeks, were participating in a study evaluating a vaginal product, or had a history of sensitivity to latex	Tampon	Cervical sampling brush	Hybrid Capture 2
Harper et al.,(2002)	103	Boston, Massachusetts	Referred to colposcopy at least 18 years of age, and were not pregnant.	NA	Tampon	Dacron swab*	MY09/MY11 PCR primer system with reverse line blot detection strips
Coutlee et al., (1997)	274	Que´bec, Canada	Participating in the Canadian Women's HIV study	NA	Tampon	Cervicovaginal Lavage	PCR
van de Wijgert et al.,(2006)	450	Gugulethu, South Africa,	Age 18 years or older, sexually active, not pregnant, and willing and able to comply with the study protocol	Had taken antibiotics in the 4 weeks before study enrolment, were participating in a study evaluating a vaginal product, or had a history of sensitivity to latex.	Tampon	Swab	Hybrid Capture 2
Barbee et al.,(2010)	362	Miami, FL.	Haitian women, 21 years of age and older; no prior history of cervical cancer or surgical hysterectomy; no recent Pap smear	Reported recent Pap smear screening	Fournier	NA	NA
Gage et al, (2011)	252	Mississippi State	Nonpregnant, non-hysterectomized women aged 26 to 65 years without history of treatment	Inability to speak English, perceived mental incompetence, and visualization of an overt cancerous lesion at the clinical exam.	Fournier	Dacron swab	Hybrid Capture 2, Amplicor, and Linear Array
Castle et al., (2006)	137	Miami, Florida	Nonpregnant, non-hysterectomized women were recruited from the colposcopy and general gynecology clinics	NA	Fournier	Cytobrush	Hybrid Capture 2
Cervico-vaginal self-sampler							
Jentschke et al., (2013)	152	Hannover, Germany	Referred for colposcopy	NA	The vaginal lavage	NA	PCR and Hybrid Capture 2
Gok et al., (2010)	28 073	The Netherlands	Age 30-60, Non-attendees living in the countries of Noord-Holland or Flevoland	Previous hysterectomy	Cervicovaginal lavage	NA	Hybrid Capture 2
Hesselink et al., (2014)	27,792	The Netherlands	Age 30-60, had not responded to the regular 5-year screening invitation	NA	Delphi screener	NA	Quantitative methylation-specific PCR.
Nobbenhuis et al., (2002)	75	Amsterdam, The Netherlands	Age 20-63, referred to colposcopic clinic	NA	An irrigation syringe	Cervex brush	GP 5+/6+ PCR
Jones et al.,(2012)	198	New York City	Age at least 18 years old, attended one of three ambulatory clinics	Pregnant, breastfeeding, hysterectomy, or discomfort reading on their own in Spanish or English.	Delphi Screener	liquid-based cytology	Hybrid Capture 2
Brink et al., (2006)	96	The Netherlands	Age 18 to 59 referred to thegynecologist for colposcopy-directed biopsy and healthy volunteer	NA	Mermaid	Endocervical brush	GP5_/6_ PCR-enzyme immunoassay (PCR-EIA)

Advantages and Limitations of Self-Sampling

There are many advantages of using self-sampling in cervical cancer screening. The use of self-sampling may lead to higher acceptability to screening (Gok et al., 2012a; Wikstrom et al., 2011). Self-sampling is more attractive for the non-attendees in countries which have organized screening and from rural women in countries which have limited resources (Sancho-Garnier et al., 2013). It can be an alternative method to women who are reluctant to undergo pelvic examination due to shyness (Scarinci et al., 2013) or too busy looking after the family which is often the case amongst Asian women (Othman and Rebolj, 2009). In addition, it may reduce cost on the 'patients' and on 'hospitals' as no visits to clinicians are needed (Darlin et al., 2013; Scarinci et al., 2013). It is of interest to note that self-sampling is also acceptable to men in studies using self-obtained rectal specimens (Dodge et al., 2012; Wiley et al., 2013). With minimal education on how to take the samples, the women can produce samples just as good as physician samples. All these devices come with good easy to follow manual. The sampling can be done at the women's convenience.

Previous studies have examined the sensitivity and predictive value of HPV detection by comparing self-collected and clinician collected samples for HPV testing (Cerigo et al., 2012; da Silva Rocha et al., 2012). Studies have shown that self-sampling yields more often HPV-positive results compared to physician-collected samples (Cerigo et al., 2012). It can also be an additional method instead of only conventional cytology screening which often is associated with sampling, processing and screening error (Schmeink et al., 2011). The use of liquid-based cytology enables preservation of both cellular morphology and nucleic acids. Theoretically, this allows cytological examination and HPV testing on the same sample because the DNA is also preserved (Yoshida et al., 2013).

In term of cytology testing, physician-collected specimens mainly contain endocervical and ectocervical cells, whereas self-collected specimens generally represent mixture of vaginal and cervical cells (Schmeink et al., 2011). The sensitivity of cytology on self-obtained samples is low, probably due to the fact that self-obtained samples mostly contain vaginal cells and only a few cervical cells (Brink et al., 2006). Other interesting study shows that self-collected vaginal swabs reflect the same microbial diversity as physician-collected vaginal specimens (Forney et al., 2010). There are high rates of microscopic blood contamination in self-sampling specimens (Delany et al., 2008) but this can be solved using liquid based cytology (Yoshida et al., 2013). Validation on the reliability of HPV self-sampling procedures for screening purposes shows that this testing is acceptable to women and valid for assessing the risk of CIN2+ (Dijkstra et al., 2012). However, the specificity of cytology on cervico-vaginal self-obtained samples for the detection of CIN2, CIN3, or cervical cancer is quite high, especially when combined with high risk HPV testing (Brink et al., 2006).

The vast majority of studies assessing self-sampling have used liquid-based storage and transport media (Moscicki et al., 2010; Yoshida et al., 2013). However, the use of self-sampling device without any of these also shows good results (Cerigo et al., 2012; Darlin et al., 2013). The sampling device such as brush self-sampler and swab self-sampler can be sent out and returned to laboratories by mail. Leakage problem need to be considered when using self-sampling device with liquid-based storage and liquid transport media. Dry self-sampling device with no liquid-based storage or transport media may be more convenient and less expensive. Self-sampling device with dry-storage is highly recommended to avoid such problem (Cerigo et al., 2012; van Baars et al., 2012; Eperon et al., 2013). A dried material on a solid carrier is neither hazardous nor flammable like FTA cartridges also can solve storage and transportation problems (Lenselink et al., 2009). For low resource settings, standard transport medium may be impractical and unavailable, because of the cost.

Some limitations of self-sampling; using self-sampling method alone in screening for cervical cancer may deprive women of pelvic examinations usually done by physicians before the procedure. Lack of confidence in self-sampling results is the most common reason why women prefer clinician-sampling (Guan et al., 2012). The self-sampling devices are not customised to slight anatomical variation of female genital tracts. The transformation zone area in elderly women is higher than younger women thus may be difficult to reach by the devices giving rise to unsatisfactory or inadequate samples. There is also a potential risk in traumatising and perforating the mucosa of the vagina and cervix in the process of getting the samples in women who do not follow the instruction. In such instances, if the women are suffering from bleeding tendencies, this may lead to medical catastrophe.

Women must have a minimal level of education in order to read and understand the manual (Forrest et al., 2004). They need to clearly follow the instruction in order to get satisfactory samples. Some women complained that they have difficulty to understand the instruction because of medical terminology used in the pamphlet (Howard et al., 2009). Their understanding improves when the video is shown. Some women especially those who have never used tampon may have anxiety to insert the device. Some devices look bulky which may add to anxiety. In the context of cytological examination, the main limitation of self-sampling is inability to get endocervical cells in the majority of the smears (Schmeink et al., 2011).

In addition, big size or obese women may have difficulty in inserting devices into their vaginas. The self-sampling devices which do not have variety in sizes like speculum may also limit collection of cervical scrapes because of varying anatomical differences. There is need in future to create a self-sampling device which caters for various body types of women.

Conclusion

Most of the studies thus far indicate positive experience with self-sampling. It is easy to perform and 'friendly' to women. There is good correlation between cervical cells obtained by self-sampling and physician

sampling. Cytological examination and HPV testing can be done on the samples. Self-sampling could be the answer to non-attendees in screening programs. There are several devices available in the markets; the consumers would have to decide the device of their liking. In future, there is a potential that self-sampling may replace conventional method of taking samples. More clinical trials in a large screening population are needed.

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