Experience with a new cervical smear sampling device

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The cervical smear is effective in detecting the precursor lesions of cervical cancer. With appropriate treatment invasive carcinoma may be prevented. A major cause of a non-diagnostic smear is poor sampling. A new sampling device, the Cervex-Brush, has been touted as being capable of producing a superior specimen compared with the modified Ayre's spatula, which is the most widely used cervical sampler in Hong Kong. When evaluated on 500 women, the Cervex-Brush was found to produce a good quality sample as judged by the presence of endocervical and/or metaplastic cells, lack of blood, and the thickness of the cell sample. In the drive to ensure that cervical smears are of the highest quality, the Cervex-Brush is worthy of further evaluation for routine use. Although it is significantly more expensive, the extra costs could be offset by the substantial savings that can accrue from having a smaller number of substandard samples and the need to repeat smears.

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Introduction

Cervical cancer is the most common lower genital tract malignancy in Hong Kong women and in 1994 there were 459 new cases and 144 deaths. These figures are probably low, as reporting cancer cases is not mandatory and the statistics quoted may not reflect the true incidence. Nevertheless, cervical cancer is a preventable disease if women have a regular smear test. A well-performed cervical smear is effective in detecting precursor lesions that can progress to cervical cancer and if appropriate treatment is undertaken, the cancer may be prevented from developing. Unfortunately, cervical intraepithelial neoplasia (CIN), the forerunner of most cervical cancers, is not only an asymptomatic lesion but is also invisible to the unaided eye. Hence, the cervical smear is a "blind" procedure.² However, if the transformation zone (TZ) (the region of the cervix where the majority of cancers develop) is adequately sampled then CIN lesions can be detected by a cervical smear.

wooden Ayre's spatula, which was first introduced in 1947.⁴ In Hong Kong, most smears are taken with a modified Ayre's spatula that has a more tapered tip (Fig 1). Recently, a new sampler, the Cervex-Brush (Rovers BV, Oss, The Netherlands) has become available for evaluation and this report examines the quality of cervical smears obtained with this device.

Materials and methods

The Cervex-Brush sampler was used to obtain smears from 500 women who attended the newly-established

An optimal cervical smear should contain endocervical epithelial cells (EEC) and/or metaplastic cells

(MC), an indication that the TZ has been sampled.³ To

improve the collection of cells, a number of new sam-

pling devices have been designed to replace the

from 500 women who attended the newly-established Community Cervical Cancer Prevention Clinic set up at the Sir Yue Kong Pao Cancer Centre, Prince of Wales Hospital. To reduce errors associated with sampling, all the smears were collected by one person and the same steps were followed for each patient. The 20 cm long Cervex-Brush (Fig 1) consists of 57 flexible plastic bristles that are grouped together in a broom-like configuration, 2 cm wide, which is attached to a flexible plastic handle. Each bristle has a flat surface on one aspect and a convex surface on the other (Fig 2) and those in the centre are longer than the more peripherally-placed ones. The longer central bristles are

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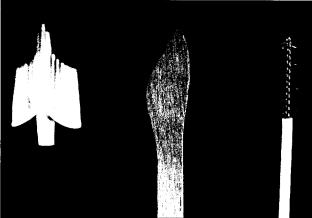
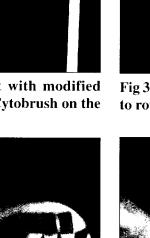


Fig 1. Cervex-Brush on the left with modified Ayre's spatula in the centre and Cytobrush on the right



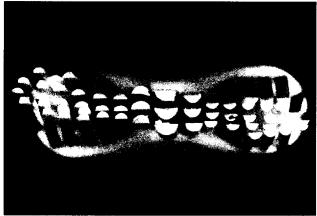
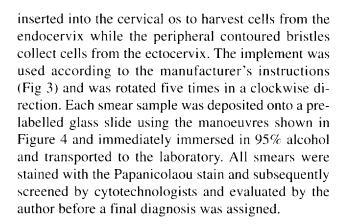


Fig 2. Close-up view of bristles. Those in the centre have been cut for photography. The flat and convex surfaces can be seen.



To assess the adequacy of each smear, the following points were recorded. Firstly, the presence of at least two clusters of well-preserved EEC and/or MC, with each cluster having a minimum of five cells. Secondly, the evenness of the cell sample on the slide and the degree of dissociation of cell clusters. Thirdly, the

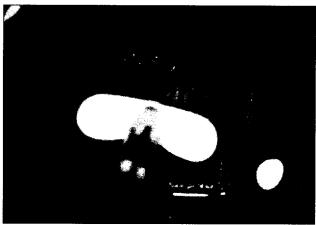


Fig 3. The Cervex-Brush applied to the cervix prior to rotating it five times in a clockwise direction

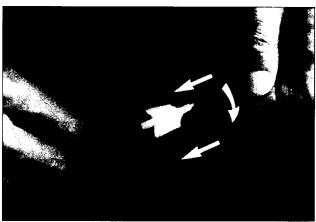


Fig 4. First one side of the Cervex-Brush is wiped by drawing it firmly longitudinally down the slide and then rotating the brush 180° to wipe the opposite side on the slide surface

amount of blood present. Finally, whether or not wellpreserved and well-visualised squamous epithelial cells covered more than 10% of the glass slide surface.

Results

A total of 500 smears were analysed. Table 1 details the salient findings regarding the quality of the smears from a laboratory perspective. The majority of the smears (485) [97%] were satisfactory and only 15 (3%) lacked EECs or MCs. Despite having EECs, six smears were bloody and three had thick areas, so screening was more difficult. In two cases, the cellularity was low and barely 10% of the slide surface was covered with squamous cells. Table 2 details the abnormalities detected and the Bethesda System³ was used for reporting all the smears. There were four low-grade squamous intraepithelial lesions (LSIL) and three highgrade squamous intraepithelial lesions (HSIL). Two

Table 1. Table showing the quality of smears obtained using the Cervex-Brush method

Cellularity	No. of cases
Adequate	
- Endocervical cells pressent	485
- Bloody	6 *
- Thick in areas	3 *
Inadequate	
- No endocervical cells present	15
* still screenable despite bloody	or thick areas

patients had minor changes that were classified as atypical squamous cells of undetermined significance (ASCUS). Nine smears had *Candida* spp. present and 10 had non-specific inflammatory changes. In six (1.2%) women there was light spotting after the smear procedure.

Discussion

When cervical smears are performed by different individuals, using different techniques, there is ample opportunity for discrepancy. In this study, however, all 500 samples were taken by one person thus ensuring that the smears were of a uniform quality. Studies have shown that sampling errors can lead to a false-negative rate that may be as high as 30%. 5-8

The results indicate that the TZ can be adequately sampled by the Cervex-Brush when it is used according to the manufacturer's instructions. A previous study indicated that a maximal cell sample can be obtained by rotating the Cervex-Brush five times in a clockwise direction. The insistence on the accurate sampling of the TZ (supported by the presence of EECs or MCs in a smear) stems from the fact that when reviewed, many women with cervical cancer but negative cytology had smears that lacked EECs. 10-13 Hence, these lesions had escaped detection because of inadequate sampling.

The use of a modified Ayre's spatula and a separate Cytobrush was a significant advance and one study¹⁴ indicated that this yields an optimal smear but this usually results in the production of two slides, which substantially increases laboratory workload.^{2,15} If great care is taken, and an aerosol spray fixative is used, it is possible to place both samples on a single

Table 2. Results of the smear diagnosis showing the proportion and categorisation of abnormal findings

Diagnosis		No. of cases (%)
Normal		457 (91.4)
Abnormal		28 (5.6)
- CIN I* ±	HPV† (LSIL)‡	4 (0.8)
- CIN II-II	II (HSIL)§	3 (0.6)
- ASCUS		2 (0.4)
- Candida	spp.	9 (1.8)
- Inflamm	ation	10 (2.0)
Inadequate	smears	15 (3.0)
Total		500
* CIN † HPV ‡ LSIL	cervical intraepithelial neoplasia human papillomavirus low grade squamous intraepithelial lesion	
§ HSIL	high grade squamous intraepithelial lesion	
¹¹ ASCUS	atypical squamo mined significan	us cells of undeter-

slide but this is a more involved procedure.² However, the Cytobrush, because it is more abrasive, often produces undesirable bleeding.¹⁶ If a Cytobrush is employed it should be used after the Ayre's spatula sample so that the ectocervical specimen is less likely to be contaminated with blood.² Unfortunately, a sample obtained with the Cytobrush alone represents an inadequate examination as the TZ and the adjacent ectocervix are not sampled and lesions may remain undetected. Hence, use of the Cytobrush requires that a second sample with the Ayre's sampler be performed in most circumstances.

An adequate cervical smear depends on not only a good specimen, but also on appropriate labelling and identification of the specimen slide. Relevant clinical information should also accompany the smear.² The minimum data that should be supplied include the patient's age and date of the last menstrual period. Unfortunately, this information is often not recorded. If an adequate cervical smear is obtained by the clinician and is evaluated by competent laboratory staff, then the smear as a diagnostic procedure has a high level of accuracy and sensitivity. Despite being a simple procedure, however, a significant number of smears sent to the laboratory for evaluation are of a poor quality and this greatly lessens their diagnostic value.

A relaxed patient can make the procedure less of an ordeal and also allow a better sample to be obtained. Women prefer to be given an explanation of the various procedures and as much privacy as possible, including being offered the cover of a sheet or towel.² The warming of the speculum, and a demonstration of the apparatus can also help to engender good rapport. For some ethnic groups, cervical screening is not a concept with which women are familiar or necessarily comfortable, and in the author's experience, this is particularly so with many Chinese women. Some women feel embarrassment, while for others the genital region is sacred, and special care should be taken to provide a trusting environment. Recognising cultural differences and individual preferences shows concern for the woman's comfort and ease.² The importance of the smear test in preventing cervical cancer should be stressed during this discussion with the patient.

The gender of the smear-taker can be important and many women in this study appreciated having a woman take their smear. Other studies confirm that many Western women also prefer having a woman smear-taker. A recent Hong Kong study indicated a possible role for nurses to help increase the uptake of cervical cytology screening among Hong Kong women and nurses could also be employed for taking smears. 19

Although there have been no published Hong Kong studies on the quality of cervical smears and the incidence of false-negative smears, there have been assertions made of misdiagnosis because of poor standards in Hong Kong laboratories.²⁰ It is essential that laboratories evaluating cervical smears have high standards and this means well-trained staff who are not subjected to unreasonable workloads. Good quality control programmes must also be in place to maintain high standards. In many overseas countries, laboratory registration and accreditation is mandatory and this ensures that laboratories perform at an acceptable standard—both features should be introduced in Hong Kong.

With the cost of medical care escalating at an alarming rate, two factors are of paramount importance in any health expenditure—cost-effectiveness and cost containment. Therefore, should the Cervex-Brush, which is substantially more expensive, be used instead of the modified Ayre's spatula? Each Cervex-Brush costs approximately HK\$1.80 to \$2.50, depending on the supplier, while the wooden spatula costs from 5 to 25 cents, depending on the country of manufacture. Even with mass produc-

tion techniques and bulk purchasing, the price of the Cervex-Brush is unlikely to approach the modest price of the wooden Ayre's spatula. However, there can be substantial savings if the number of inadequate smears that lack EECs or MCs can be reduced. Having to repeat a smear because of a previously inadequate sample not only requires a woman to present for a further examination but also involves further nursing, medical, and staff laboratory time and effort. In addition, there are added stresses for the patient and more importantly, an inadequate sample may mean an undetected lesion and the development of a cancer in the future.

As this study did not directly compare the Cervex-Brush and the Ayre's spatula, it cannot be concluded that the former is a better sampling device. However, an Australian study that compares the two samplers in a carefully controlled trial shows that smears collected with the Cervex-Brush have significantly more endocervical cells (P<0.0001) than do those taken with the Ayre's spatula.21 Another study from Holland indicates that the Cervex-Brush is able to decrease the number of unsatisfactory smears by 50%, thus reducing the number of women that need a repeat smear.²² Because of the contoured shape of the Cervex-Brush, the smear obtained is comparable to one that would require the combined use of an Ayre's spatula and an endocervical brush sampler. 16 There is also overwhelming clinician preference for the Cervex-Brush over the Ayre's spatula because the former is easier to use, 16.21 even in older women and those with iatrogenic scarring of the cervix.²³

A group of medical experts have concluded that "with the exception of stopping the population from smoking, cervical cytological screening offers the only major proved public health measure for significantly reducing the burden of cancer today."²⁴ Therefore, to fully exploit the diagnostic potential of the cervical smear, it is imperative that optimal samples be submitted to the laboratory. This will be assisted by the use of effective sampling devices and the Cervex-Brush warrants further evaluation for routine use.

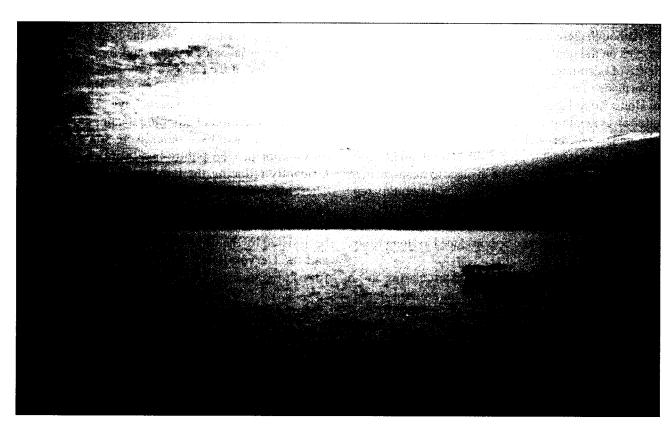
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M Smith, Sunset on the beach at Krabi, Thailand.