Sampling endocervical cells on cervical smears: a comparison of two instruments used in general practice

CUMBRIAN PRACTICE RESEARCH GROUP

SUMMARY. The Aylesbury spatula and a newer plastic device, the Cervex® sampler(Steriseal), have been compared in a prospective study, to assess their ability to obtain endocervical cells on cervical smears taken in general practice. Twelve general practitioners in Cumbria took part in the study each taking equal numbers of smears from women with the Aylesbury spatula and the Cervex sampler. On average each practice took 20 smears with each instrument. All women attending for cervical smears for whatever reason were included in the study. Endocervical cells were reported in 62.8% of smears taken with the Aylesbury spatula and in 78.2% taken with the Cervex sampler (odds ratio 1.24, 95% confidence interval 1.10 to 1.41).

Increasing the percentage of smears which contain endocervical cells by using the Cervex sampler would reduce the number of repeat tests needed. This would cut down anxiety and inconvenience for the patient, and reduce costs for the health service.

Introduction

THE diagnostic accuracy of cervical smears depends on adequate sampling of the transformation zone of the cervix. An adequate sample of this area should contain endocervical cells.[1-3] A pilot study of all the cervical smears taken in one rural practice (three partners, 4500 patients) over a six month period using the standard technique with the Aylesbury spatula showed that 35% of smears did not contain endocervical cells.

Early cervical neoplasms can arise entirely within the endocervical canal and may therefore be missed if a smear is taken only from the ectocervix. The Aylesbury spatula has a pointed end which is inserted into the endocervical canal and thus overcomes this difficulty to some extent. However, small areas of abnormality may still be missed if the spatula is not in contact with tissue at all times, for example when the cervix is scarred and irregular. Endocervical and ectocervical samples should be collected to achieve the best possible chance of detecting abnormalities.[4] Dual sampling of the endocervix and the ectocervix using a brush together with a conventional spatula has been shown to improve the quality of cervical smears.[5] However, this involves taking two samples and inevitably takes longer.

The aim of this study was to assess whether the use of one of the newer smear taking devices provides a higher percentage of smears containing endocervical cells than the Aylesbury spatula. The Cervex® sampler (Steriseal) was chosen because it is designed to be used instead of the usual spatula, not in addition to it. This would increase its acceptability to general practitioners in busy practices. There is also good evidence of its efficacy.[6-8] The Cervex sampler is a plastic device with a soft fronded end shaped so that it can be inserted into the cervical os. The central fronds project 10 mm beyond the shorter outer fronds and are 20 mm in length. This means that the squamocolumnar junction which is on average 8–13 mm proximal to the tip of the cervix should be sampled in most women.[9]

E Roderick, MRCGP, J Anderson, MRCGP, I Birket, MRCGP, J Cox, FRCGP, C Donald, MRCGP, W Fakes, MB, BA, J Farndale, MRCGP, D Gardner, MB, P Gray, MRCGP, B Herd, MRCGP, A Horne, MRCGP, J Howarth, MRCGP, S Jay, MRCGP, R Jones, MRCGP, W G McKay, MRCGP, I Mitchell, MRCGP, M Stevenson, MRCGP, R Swindells, MRCGP, M Taylor, MRCGP, A Timney, MB, M Townend, MB, J N Westhead, MD, MRCPsych, MRCGP, P White, MRCGP, general practitioners, Cumbria.
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Method

Members of the Cumbrian practice research group agreed on a protocol. Twelve practices took part in the study; ethical approval was obtained from the ethical committee in each of the areas involved.

All women attending for cervical smears for whatever reason were asked to participate in the study and their written consent was obtained before they were included. The women were allocated alternately to the groups having their smear taken using the Cervex sampler or the Aylesbury spatula. Each practice took equal numbers of smears using each instrument, on average 20 with each. The smears were sent to one of two laboratories for analysis.

Detailed instructions on the method of taking smears were provided with each of the instruments in order to obtain uniformity of sampling. The instructions for use of the Cervex sampler were as supplied by the manufacturer while those for the Aylesbury spatula were a consensus by the members of the group on how the instrument was being used by the majority of doctors. The Aylesbury spatula had to be inserted into the cervical os and rotated 360 degrees clockwise and anti-clockwise; the Cervex sampler had to be inserted into the os in the same way but then rotated five times in one direction only. The practices were free to delegate the work to whichever practice member usually took smears. In many cases this was the practice nurse.

The following details were recorded by the doctor (or nurse) performing the smear for each woman participating in the study: age; whether pre- or post-menopausal; whether taking hormone replacement therapy or the oral contraceptive pill; whether there had been any previous procedure for cervical intraepithelial neoplasia, for example laser treatment, cryotherapy or cone biopsy; parity; whether pregnant at the time the smear was taken or within 12 weeks postpartum.

Confidence intervals for relative risks (odds ratios) were calculated as described by Morris and Gardner.[10]

Results

A total of 466 smears were taken — 232 using the Aylesbury spatula and 234 using the Cervex sampler. Fourteen patients were excluded from the study (nine in the Aylesbury group and five in the Cervex group) because the data recorded for these women was incomplete. Analysis of the patient details recorded revealed no differences between the two groups of women:

More of the smears taken using the Cervex sampler showed endocervical cells than of those taken with the Aylesbury spatula (Table 1) (odds ratio 1.24, 95% confidence interval 1.10 to 1.41). In addition, fewer smears taken with the Cervex sampler than

Table 1. Results of smears taken using the Aylesbury spatula and the Cervex sampler.

	% of smears taken using:	
	Aylesbury spatula ($n = 223$)	Cervex sampler ($n = 229$)
Endocervical cells present	*62.8*	*78.2*
Inadequate	*5.4*	*2.6*
Abnormal	*7.2*	*7.4*

n = total number of smears taken.

with the Aylesbury spatula were reported as inadequate (Table 1) (odds ratio 0.48, 95% confidence interval 0.18 to 1.27).

The number of smears reported as abnormal was very similar for both instruments (Table 1) (odds ratio 1.03, 95% confidence interval 0.53 to 1.92). This included all degrees of abnormality from mild inflammation to cervical intraepithelial neoplasia 3.

No difficulty was reported in the use of the Cervex sampler. In particular, no blood stained smears were reported.

Discussion

Some laboratories routinely report the presence or absence of endocervical cells in cervical smears to assist the clinician in deciding when a repeat test is necessary. Some cytopathologists recommend a repeat test in 12 months in all cases where no endocervical cells are seen; others leave the decision to the clinician. Studies have shown, however, that if no endocervical cells are present in the smear in women under the age of 45 years, then the test should be repeated sooner than the usual interval of three years.[11]

The results of this study have shown that using the Cervex sampler instead of the Aylesbury spatula increases the percentage of smears containing endocervical cells from 62.7% to 78.1%. Increasing the percentage of smears which contain endocervical cells would reduce the number of repeat tests needed. This would cut down anxiety and inconvenience for the patient, and reduce costs for the health service.[7] Cervex samplers, at about 20p each, are more expensive than the wooden Aylesbury type of spatulas which cost around 3p each. However, as the overall cost of a smear is between £5.00 and £15.00 savings would be made if fewer repeat tests were necessary. Yule has reported that the Cervex sampler can produce blood stained smears[8] but in this study no difficulties in the use of the sampler were reported.

The Cervex sampler has been shown by others[8] to increase the detection of abnormalities of the cervix significantly, although no such increase was found in this study. If more lesions were diagnosed and treated at an early stage the need for major surgery could be reduced.

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Address for correspondence

Dr E M Roderick, The Surgery, Caldbeck, Wigton, Cumbria CA7 8DS.