

Use Effectiveness Of The Cytobrush™ In The Primary Care Setting

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Abstract: Background: Numerous studies indicate that Papanicolaou smears contain better cellular material when the technique for collecting the sample employs the Zelsmyn Cytobrush™. Few studies, however, have examined its ability to increase the percentage of abnormal Papanicolaou smear results in actual clinical practice.

Methods: This study looked at 7999 Papanicolaou smears done by 46 primary care physicians to determine the percentage of abnormal results during two different periods. The Cytobrush™ technique was then implemented; and after 6029 Papanicolaou smears, the percentage of smears with abnormal findings was recalculated.

Results: The proportion of Papanicolaou smears demonstrating significantly abnormal cells remained constant during the three observation periods: 1.81 percent during the first period, 1.96 percent during the second period (before the Cytobrush™ technique was implemented), and 1.96 percent during the third period (after the Cytobrush™ technique was implemented).

Conclusions: It seems logical that Papanicolaou smears containing better cellular material from the squamocolumnar junction would increase the yield of Papanicolaou smears with cancerous and precancerous cells. Our study, however, did not confirm this supposition. While evaluation of Papanicolaou smear technique based on quantity and quality of cellular material is important, we believe the effectiveness of any technique must be evaluated from another perspective — the actual practice setting. (J Am Board Fam Pract 1991; 5:365-8.)

For more than 40 years, the Papanicolaou smear has been used to screen for cervical cancer.^{1,2} The extensive literature on cervical cancer discusses various aspects of the Papanicolaou smear as a screening tool and can be broken down into four basic categories:

1. Types of cytologic findings that have the most sensitivity and specificity^{3,4}
2. Identification of women at high risk (e.g., multiple sexual partners, early age of intercourse, history of sexually transmitted disease, infrequent previous Papanicolaou smears in older women)⁵⁻⁸
3. Frequency and cost of Papanicolaou smears — annually, biannually⁹

4. The various techniques of taking Papanicolaou smears^{1,2,10,11}

The literature on Papanicolaou smear techniques is considerable. Sampling technique has been identified as a major determinate of Papanicolaou smear adequacy^{11,12} and is directly related to the high false-negative rate (estimated between 20 percent and 45 percent).¹¹ Various techniques have been proposed in the past to reduce the false-negative rate of the Papanicolaou smear. One of the newer collection techniques uses the Zelsmyn Cytobrush™ (International Cytobrush, Inc., Hollywood, FL), which has been shown to yield a larger amount of cytologic material.^{2,10,13}

Many studies that compare yield do so by measuring the amount of cellular material originating from the squamocolumnar junction, where cancer of the cervix originates. It would seem logical that smears with a greater amount of cellular material from this area would yield more cancerous and precancerous cells, although not all studies have confirmed this supposition.^{11,14-16} To

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date, most previous studies using the Cytobrush™ have relied on improvement in the quantity of cellular material from the squamocolumnar junction to determine its superiority over other techniques.¹⁷ Rather than focus on the adequacy of the cellular content controversy, we analyzed the actual yield of abnormal cells on Papanicolaou smears in the practice of 46 primary care physicians before and after the Cytobrush™ technique was initiated.

Methods

Scott & White is a large, multispecialty clinic (315 physicians) in central Texas with 11 regional clinics spread over a seven-county area that includes both rural and urban sites. All of the Papanicolaou smears are read at the Scott & White Cytology Laboratory, and the results are stored in log books.

Because of recent reports of improved yields with the Cytobrush™, physicians of eight regional clinic practices unanimously agreed to adopt the Cytobrush™. The following technique was recommended by the Scott & White Division of Gynecologic Oncology: (1) The brush is placed into the endocervical canal and rotated one-half to one turn, and the contents are placed on a slide by rotating the brush across the slide. (2) A wooden spatula is then placed in the canal and also rotated, and the contents are smeared over the original material. (3) The Cytobrush™ is not used with pregnant women.

Arbitrarily, the first log books from 1987 (Papanicolaou smears from 13 January to 16 June 1987) and 1988 (1 February to 31 June 1988) were selected, and the findings from all of the Papanicolaou smears from the eight practices were tabulated. The Cytobrush™ was not in use during these periods.

Upon implementation of the new technique, results of 6029 consecutive Papanicolaou smears taken in these eight clinics between 1 January and 15 August 1989 were compared with those from the Papanicolaou smears taken earlier. The Papanicolaou smears were collected by 46 different physicians (45 family physicians and 1 internist) during the three collection periods.

Chi-square analysis was used to evaluate the data for significant differences between Papanicolaou smear results obtained before and after the initiation of the Cytobrush™ technique.

Results

During the 1987 collection period, of 3094 consecutive Papanicolaou smears done in the eight clinics, 406 (13.12 percent) contained cells considered to be abnormal (Table 1). During the second observation period, 615 (12.54 percent) of the 4905 consecutive Papanicolaou smears contained abnormal cells. After the Cytobrush™ technique was adopted, during the 1989 observation period, 6029 Papanicolaou smears done in the eight clinics resulted in 788 Papanicolaou smears (13.07 percent) that contained abnormal cells.

Of the total number of Papanicolaou smears in each observation period, 11.31 percent of the first group, 10.58 percent of the second group, and 11.11 percent of the Cytobrush™ group had reactive cells.

The proportion of Papanicolaou smears yielding significantly abnormal cells (from very mild dysplasia to cancer of the cervix) during the three observation periods also stayed surprisingly constant, with 1.81 percent in 1987, 1.96 percent in 1988, and 1.96 percent of the 1989 Cytobrush™ group yielding significantly abnormal cells.

Chi-square analysis showed no statistically significant difference between Papanicolaou smear results obtained before and after the initiation of the Cytobrush™ technique.

Figure 1 graphically displays the results of the three observation periods with percentages rounded. As shown, the actual yields were striking in their similarity.

Discussion

Though this study has the minimum number of controls, there are some strong points. On the positive side, because we did review smears from actual family practices using unselected patients from many providers who did not know that the

Table 1. Percentage of Papanicolaou Smears Yielding Abnormal Cells.

| Study Period | Total No. | Smears with Abnormal Cells No. (%) |
|----------------------------|-----------|------------------------------------|
| 13 January to 16 June 1987 | 3094 | 406 (13.12) |
| 1 February to 31 June 1988 | 4905 | 615 (12.54) |
| 1 January to 31 June 1989 | 6029 | 788 (13.07) |

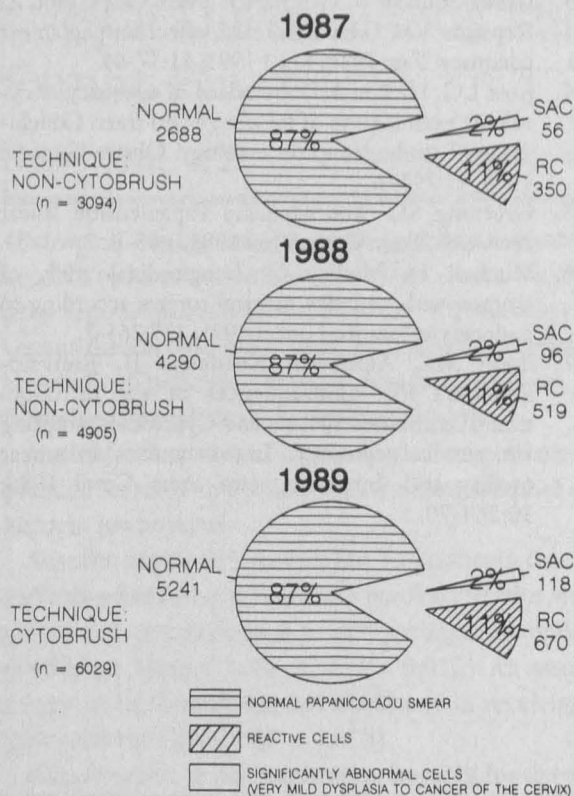


Figure 1. Comparison of Papanicolaou smear technique results across three study periods.

Papanicolaou smear results were being analyzed at either phase in the study, the study reflected real-life results. Because the physicians were totally unaware of the study, there is no halo effect, Hawthorne effect, or other experimental bias. We think this blinding lends some validity to the study.

While we believe this type of analysis gives us some insight into the use effectiveness of this new instrument and technique, we recognize some weaknesses in the study as well. Realistically, the Papanicolaou smear collection technique could vary somewhat among the physicians. It is unknown how this factor might affect the study. Also, the patients were unselected and came to the clinics for preventive medicine visits as well as illness visits. It is assumed that such a large number of Papanicolaou smears by the same physicians would include not only similar age groupings but a similar patient mix as well; but these data were not collected. Because the Papanicolaou smear results were being compared with the results of those done previously in the same practice, it is possible that the subsequent population

was reexamined, potentially yielding a lower rate. Comparison of the 1987 results with the 1988 results, however, does not indicate so.

For whatever reason, the Cytobrush™ technique did not improve our yield of abnormal cells obtained in Papanicolaou smears. Informally, the cytotechnologists believe that the smears do, in fact, have better cellular content and are easier and faster to read.

Other well-controlled studies have clearly demonstrated that improved cellular material is collected using the Cytobrush™ and the Cytobrush™ technique, and because this technique is easily performed and relatively inexpensive, on practical grounds we will continue using the Cytobrush™. Nevertheless, although the emphasis on cellular quality can be helpful in preliminary studies of new techniques, at some point the evaluation must prove to be more realistic in a practical sense, and the precision of theory must confront the realities of actual practice.

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