

RESEARCH COMMUNICATION

A Comparison of Cytology with Pap Smears Taken by a Gynecologist and with a Self-sampling Device

Prasit Pengsaa¹, Supanee Sriamporn², Onanong Kritpetcharat³, Supot Kamsaard⁴, Krittika Suwanrungruang⁴, Sadamu Noda⁵, Kennichi Kakudo⁶

Abstract

Cervical cancer is the most common cancer in Thai women and as yet screening programmes are minimally effective. The Pap smear is the test accepted to be most appropriate for cervical cancer screening so far. One of the main reasons why women do not come to have Pap smear done is “shyness”, which weakens compliance with recommendations to undergo Pap smear with pelvic examination. The self-administered device by the Kato method was established to overcome this problem and the present study was carried out to confirm the adequacy of the specimens obtained with this technique in comparison with specimens collected by gynecologists. Two hundred women were invited to participate in the study voluntarily. Each was allocated to have a Pap smear conducted by a gynecologist and then instructed to produce a self-obtained smear using Kato’s device. The cytology results of Pap smears from both methods were compared to test for agreement using Kappa statistics.

There was agreement between the adequacy of smears collected by gynecologists and those self-sampled with the percentage agreement of 96.5% and a Kappa score of 0.43 (95% CI 0.33-0.54, P<0.001). There were 8 cases detected as epithelial cell abnormalities from the cervical cells collected by gynecologists and also with the self-administered technique. Good agreement for detection of cellular changes was found with a percentage of 78.0% and the Kappa’s score was 0.61 (95% CI 0.46-0.76, P<0.001). The results from this study provide convincing evidence that the self-administered device can be an alternative choice for women who are too shy to undergo pelvic examination or even for those who have limited time to visit health care centers or doctors to have a Pap smear test.

Key Words: Self-administered device - cervical cells - Pap smear

Asian Pacific J Cancer Prev, 4, 99-102

Introduction

Cervical cancer is a very common cancer in women worldwide, particularly in developing countries. Globally, one report documented 466,000 new cases per year with 231,000 deaths. Nearly 80 percent of malignant cases are in the developing countries as most patients present for care with the disease at a late incurable stage (Parkin et al., 2001). The death rate associated with cervical cancer is often equal to its incidence in countries where screening programmes are not well established or are minimally effective. In Thailand, cervical cancer continues to be the leading cancer among women with an age adjusted incidence rate 20.9 per 100,000 women, (Tables 1,2) (Deerasmee et al., 1999).

The implementation of Pap smear screening programs has proven to be effective in reducing the incidence and mortality rate in many developed countries but such

Table 1. Leading Cancers in Females in Thailand 1993

Site	ASR*
Cervix	20.9
Breast	16.3
Liver	15.5
Lung	11.1
Colon&rectum	7.5

*ASR: Age-standardized incidence rate per 100,000 (world standard population)

¹Department of Obstetric and Gynecology, Faculty of Medicine, ²Department of Epidemiology, Faculty of Public Health, ³Department of Pathology, Faculty of Medicine, ⁴Cancer Unit, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand, ⁵Osaka Cancer Prevention and Detection Center, Osaka, Japan, ⁶Department of Pathology, Wakayama Medical College, Wakayama, Japan
Corresponding Author: Ms Krittika Suwanrungruang, Cancer Unit, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand - Tel: (66) 43-243088; Fax: (66) 43-243088; e-mail: krisuw@kku.ac.th

Table 2. The Incidence of Cervical Cancer in Females in Different Regions of Thailand 1992-1994

Province	ASR
Thailand (estimated over all of the country)	20.9
Chiang Mai (Northern part)	25.7
Lampang (Northern part)	23.1
Khon Kaen (Northeastern part)	18.0
Bangkok (Central part)	18.5
Songkhla (Southern part)	15.8

programmes have not been established formally in Thailand. Low coverage rate for Pap smears is one important factor for the outcome of the screening program not only in the normal population but also in the health personnel (Kritpetcharat et al., 2003; Pengsaa et al., 1989). Those who do not cooperate and comply with advice to take the test often state that shyness is one reason for not having pelvic examination, while some have no time to come to health offices because of work responsibilities (Kritpetcharat et al, 2003). To cope with these problems, a self-administered device has been advised, known as the Kato method, and found to give 100% sensitivity and 99.6% specificity in detecting abnormal cells suspicious for malignancy (Pengsaa et al.,1997). To confirm the adequacy of the specimens in detecting the precancerous lesions of cervical cancer a study of efficacy and the acceptability of the device was here carried out in the primary health care unit in the Thakraserm Sub-district, Nampong District, Khon Kaen Province, Northeast of Thailand, in August, 2000.

Materials and Methods

Subjects

Women from Thakraserm Sub-district, age 20 years and above were invited to participate in the study voluntarily. Especially those who had never been screened for cervical cancer were encouraged by health personnel to take part with priority. The expected sample size was 200 subjects. Women who intended to participate were invited to write their name on the list at the health care center of Thakraserm Sub-district. The list was open up to 200 names. So the first 200 women on the list were invited to join the study. These 200 women were randomly divided into two groups. The first hundred women were first allocated to have a Pap smear done by gynecologists from the Faculty of Medicine, Khon Kaen University. Afterwards, they were instructed to obtain a self-administered smear using Kato’s device. The other hundred first made a self-administered smear and then underwent a Pap smear by a gynecologist.

Laboratory methods

The two hundred slides of Pap smears of cells obtained by gynecologists were processed, screened and interpreted by a team of cytotechnologists and cytopathologists at the Faculty of Medicine, Khon Kaen University, Thailand. The

slides from Kato’s devices were processed and interpreted at the Kato’s Institute, Nagoya, Japan. Both reports were compared and analyzed at Cancer Unit, Faculty of Medicine, Khon Kaen University, Thailand.

Statistical analysis

The agreement between the gynecologists specimens and self-administered specimens were statistically tested using percentage agreements, Cohen’s Kappa statistics, and Mcnemar test with Bonferroni’s adjustment for the adequacy of specimens and the overall result findings.

Results

From the total of 200 women with 400 specimens, the collection by gynecologists generated satisfactory specimens in 198 out of 200 cases (99.0%), satisfactory but limited in one specimen (0.5%) and one unsatisfactory (0.5%). The collection by Kato’s device obtained 192 satisfactory specimens (96.0%), 3 which were satisfactory but limited (1.5%) and 5 which were unsatisfactory (2.5%). The percentage of agreement was 96.5% with a Kappa score of 0.43 (95% Confidence Interval :CI 0.33 - 0.54) suggesting the level of agreement to be moderate but statistically significant (P<0.001) (Table3).

Results for detection of cellular changes are shown in

Table 3. Adequacy of Smears Collected by the Two Methods

Gynecologist	Kato Device Collection			Total
	Satisfactory	Satisfactory but limited	Unsatisfactory	
Satisfactory	192	3	3	198
Satisfactory but limited	0	0	1	1
Unsatisfactory	0	0	1	1
Total	192	3	5	200

Kappa = 0.43 (95% CI 0.33 - 0.54, P < 0.001)

Table 4. Findings for Detecting Abnormal Cells from Smears Collected with the Two Methods

Gynecologist	Kato Device Collection			Total
	Normal	Benign cellular Changes	Epithelial cell abnormalities	
Normal	82	19	4	105
Benign cellular Changes	18	67	2	87
Epithelial cell abnormalities	0	1	7	8
Total	100	87	13	200

Kappa = 0.61 (95% CI 0.46 - 0.76, P < 0.001)

Table 5. Infections Detected with Smears Collected by Gynecologists

Infection	Number	%
1. Trichomonas Vaginalis	4	9.3
2. Candida spp	28	65.1
3. Gardnerella vaginalis	3	7.0
4. Actinomyces spp	4	9.3
5. other	4	9.3
Total	43	100.0

Table 6. Infections Detected with Smears Collected with Kato Devices

Infection	Number	%
1. Trichomonas Vaginalis	7	19.4
2. Candida spp	28	77.8
3. Gardnerella vaginalis	1	2.8
Total	36	100.0

Table 7. Infections Detected with Smears by Both Methods with the Same Results

Infection	Trichomonas	Candida	Gardnerella	Total
Trichomonas Vaginalis	4	0	0	4
Candida spp	0	20	0	20
Gardnerella vaginalis	0	0	1	1
Total	4	20	1	25

Table 8. Squamous Cell Abnormalities Detected in Smears Collected by a Gynecologist

Squamous cell abnormality	Number	%
Atypical squamous of undetermined significance (ASCUS)	3	50.0
Low grade squamous intraepithelial lesion (LSIL)	1	16.7
High grade squamous intraepithelial lesion (HSIL)	2	33.3
Total	6	100.0

Table 9. Squamous Cell Abnormalities in Smears Collected with the Self-administered Device

Squamous abnormality	No	%
1. ASCUS	2	25.0
2. LSIL	5	62.0
3. HSIL	1	12.5
Total	8	100.0

Table 10. Squamous Cell Abnormality from Smears Collected by Both Techniques with the Same Result

Abnormality	ASCUS	LSIL	HSIL	Total
ASCUS	1	0	0	1
LSIL	0	2	0	1
HSIL	0	0	1	2
Total	1	2	1	4

Table 4. From the total of 200 slides, the gynecologists detected 105 cases of normal findings 87 cases of benign changes and 8 cases of epithelial cell abnormalities. With the self-administered device 100 cases were normal, 87 cases demonstrated benign cellular changes and 9 cases epithelial cell abnormalities. When matched together for agreement, this was the case for 82 cases with normal findings, 67 cases of benign cellular change and 7 cases of epithelial cell abnormalities with an overall value of 78% and a Kappa score of 0.61 (95% CI 0.46-0.76, $P < 0.001$), which suggested the level of agreement to be substantial.

Infections were detected in smears taken by gynecologists in 43 cases (Table 5) while the self-administered device detected 36 cases (Table 6). Out of this group, only 25 cases demonstrated agreement with the same infection in both groups (Table 7).

The gynecologists detected 6 cases of squamous cell abnormalities (Table 8) while the self-administered device could detect 8 cases of abnormalities (Table 9). When compared together, agreement was found for 4 cases (Table 10).

Discussion

Cervical cancer screening programmes based on exfoliate cervical cytology are known to be effective at reducing the incidence of and mortality from invasive cervical cancer (Hakama et al., 1986). Regular screening by Pap smear every three to five years can reduce the risk of developing an invasive cervical cancer by 80% to 90% for individual women. In a population programme with 80% compliance, an overall reduction in mortality and incidence of 60% would therefore be expected and has been observed in populations with effective centrally organized programmes (Laara et al., 1987; Hakama, 1982).

Since Thailand is one of the countries in which the incidence of cervical cancer is rather high, the screening programme should be considered to be high priority. One of the reasons for low coverage of the screening program is women are too shy to wish to undergo a pelvic examination (Kritpetcharat et al., 2003). In this case the self-administered device offers an attractive alternative choice for these women. As we found in this present study, the cytological tests from the two different methods of collective cervical smear are generally in agreement. However there were some differences in findings albeit not significant. The increase

in findings with smears from self-administered device may be explained by the fact that the smears by gynecologists are rather thick. The cells sometimes can not be read clearly. This points to a possible advantage of the self-administered device.

The different of screeners for the two sets of smear may be a shortcoming of the present study. However, with the basic assumption that both groups have same standard of academic level, this should be acceptable. From our study we would suggest that the self-administered should be provided for Thai women in the health service system. However, they are a number of issues of concern which remain. For instance, who will provide the knowledge of how to use the device and how to transfer the collected cells, and what laboratory should read cytology using what criteria. If the public health service system accepts this technique, the mentioned issues can be planned with appropriate discussion.

Acknowledgements

We would like to thank the medical and nursing staff of Srinagarind Hospital, and Numpong health personnel for their help in the conduct of this study, and Nagoya Preventive Medical Institute for their financial support.

References

- Deerasamee S, Martin N, Sontipong S, et al. (1999). Cancer in Thailand Vol. II, 1992-1994. *IARC Technical Report No 34*, International Agency for Research on Cancer, Lyon, France.
- Hakama M (1982). Trends in the incidence of cervical cancer in Nordic countries. In Magnus K, ed., *Trends in Cancer Incidence. Causes and Implications*, New York, Hemisphere, pp. 279-292.
- Hakama M, Miller AB and Day NE (1986). Screening for cancer of the uterine cervix. *IARC Scientific Publication No.76*, International Agency for Research on Cancer Lyon, France.
- Kritpetcharat O, Suwanrungruang K, Sriamporn S, et al. (2003). The Coverage of Cervical Cancer Screening in Khon Kaen, Northeast Thailand. *Asian Pacific J Cancer Prev*, (in press).
- Laara E, Day NE, Hakama M (1987). Trends in mortality from cervical cancer in the Nordic countries association with organized screening programmes. *Lancet*, **1**, 1247-8.
- Parkin DM, Bray FI, Devesa SS (2001). Cancer burden in the year 2000. The global picture. *European Journal of Cancer*, **37**, S4-S66.
- Pengsaa P, Vatanasapt V, Sriamporn S, et al (1997). A self-administered device for cervical cancer screening in Northeast Thailand. *ACTA CYTOLOGICA*, **41**, 749-54.
- Pengsaa P, Vatanasapt V, Titapant V, et al (1989). The impact of mass screening to cervical cancer in Khon Kaen Province. *Thai Cancer Journal*, **15**, 11-7.