Effect of the Size of Extended, Modified Ayre's Spatula on Endocervical Cell Yield in the Postmenopausal Women

Wallobh parnpoonsarp MD, FRTCOG*,
Piyawan Ploarsa RN*, Arpakorn Vongterat PN*

** Department of Obstetric & Gynecology, Faculty of Medicine, Srinakarinwirot University, Nakorn Nayok, Thailand*

Background*: The extended tip of modified Ayre's spatula often was not inserted into the cervical os of some menopausal women. This study investigated in the postmenopausal women by reducing the size of extended tip of modified Ayre's spatula to prove the better outcome of cervical smears.*
Objective*: To compare the efficacy of the new design spatula with the regular used spatula on endocervical cell yield in the postmenopausal women*
Materials and Methods*: The postmenopausal women who came for cervical cancer screening (pap smear) were allocated into two groups by random. The screening for cervical cancer of the first group was performed by using the conventional modified Ayre's spatula and the second group by using the new-design extended tip modified Ayre's spatula. The slides contain endocervical cell of both groups were statistically compared.*
Results: *Two hundred postmenopausal women were recruited in this study. Overall average of the endocervical cell yield is 46.5%. The endocervical cell yield of the new-design extended tip modified Ayre's spatula is 46% and of the control group is 47%. The cell pick up tool that all length of the extended tip inserted into the cervical os of the postmenopausal women is only fifty-seven percent of the first group and sixty-six percent of the second group. Bleeding from cervical os after taking the cells from the cervix is 38.6% of the new-design extended tip modified Ayre's spatula and 61.4% of the convention modified Ayre's spatula.*
Conclusion: *No statistic difference on the endocervical cell yield between groups in this study. The endocervical cell yield is related to the design and the insertion into the cervical os of the extended tip of spatula. Additional study of the smaller taper extended spatula tip is required. Using only one model of the extended tip, modified Ayre's spatula to pick up cell for pap smear in everyone who come for cervical cell carcinoma screening might be not appropriate.*

Keywords: *Spatula, Endocervical, Endocervix, Yield, Menopause, Postmenopause, Postmenopausal, Women, Cervical, Cancer, Papanicolaou, Ppap, Smear*

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The cause of high false-negative result of Pap smear (Papanicolaou smear) comes from many factors such as the techniques and screening tools to pick up the specimen or the cytologist's interpretation[1-3]. In Thailand, modified Ayre's spatula is used as the conventional cell pick up tool for cervical cancer screening. Many researches showed the cytobrush combined with the Ayre's spatula can pick up more slides containing the endocevical cells than the extended tip, wooden spatula or modified Ayre's spatula alone[4-7]. But the cytobrush with modified Ayre's spatula is more expensive than the conventional cell pick up tool for taking the specimen for pap smear in Thai population.

In the postmenopausal women, the transformation zone of the endocervix which is the best area to pick up the cells for a diagnosis of cervical cell abnormality always move into the cervical canal[8]. The researches showed the cervical smears obtained from the postmenopausal women often contained no endocervical cells and the rate of false-negative of pap

Correspondence to: Parnpoonsarp W, Department of Obstetric & Gynecology, Faculty of Medicine, Srinakarinwirot University, Ongkarak, Nakorn Nayok 26120, Thailand.

smear in postmenopausal women is higher than the general population[9]. Also, the authors showed the cervical smears which contain the endocervical cells would reduce the number of repeated tests and have a significantly higher number of atypical epithelial changes[10-120]. In our experience, at the HRH Princess Maha Chakri Sirindhorn Medical center, often the insertion of the extended tip of modified Ayre's spatula into the cervical os of some menopausal women could not be done. So this research is designed to study in the postmenopausal women by reducing the size of extended tip of modified Ayre's spatula (Fig. 1) to prove the hypothesis of reducing size of extended tip of modified Ayre's spatula might pick up more the endocervical cells on the cervical smears than the conventional modified Ayre's spatula.

Objective

To compare the efficacy of the new-design extended tip of modified Ayre's spatula with the conventional spatula on endocervical cell yield in the postmenopausal women

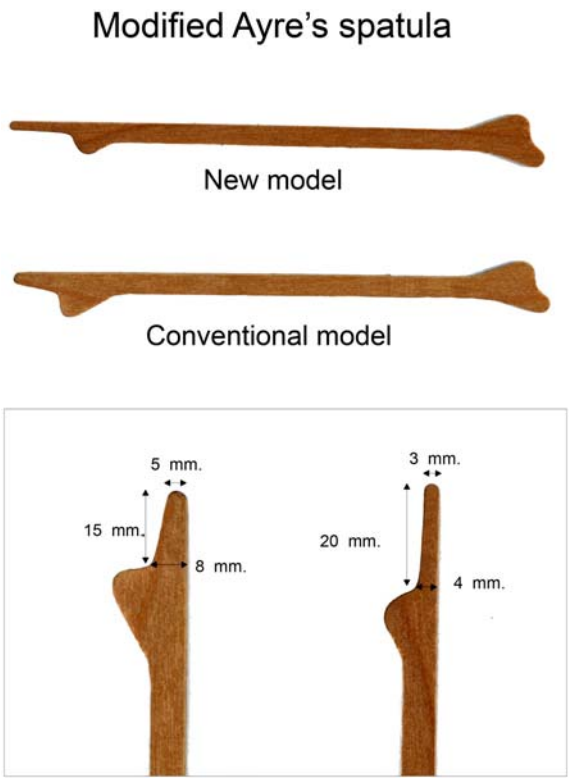

Fig. 1 The new design extended tip modified Ayre's spatula vs. the conventional extended tip modified Ayre's spatula

Material and Method

As prospective randomized study, after the project is approved by the ethic committee, two hundred postmenopausal women with no vaginal bleeding and cervical lesions who came for the cervical cell carcinoma screening (pap smear) at the HRH Princess Maha chakri Sirindhorn Medical center and consented to be in were allocated into 2 groups, one hundred cases per group, by randomized running number sealed in the envelope. The cervical cancer screening of the first group was performed by using the conventional modified Ayre's spatula and the second group by using the new-design extended tip modified Ayre's spatula. The number of the sample size was calculated by "PC calculation program for sample size on window XP" using type one error (∞) = 0.05, power of study = 80%, p_0 = .3, p_1 = .5, m = 1. The doctors who took the sample for pap smear were trained to be the same technique. All of the cervical smears were masked the status of the study group and interpreted by one cytologist. The slides contain the endocervical cell of both group were statistically compared by Chi-square, Fisher's exact test for categorical data; unpaired T-Test, Mann-Whitney test for continuous data, statistic significant when $p < 0.05$.

Results

Two hundred postmenopausal women were recruited in this study. The age is between 46-83 years and the average age is 58.53 $\pm$ 6.79 year. The age of beginning to be the menopause is between 37-57 year and the average age is 49.96 $\pm$ 3.36 year. The duration of postmenopausal period is 6 months-31 years, the average is 8.95 $\pm$ 7.08 years. The number of childbirth is between 0-14, the average is 3.03 $\pm$ 1.976. No statistically significant difference of the age of the postmenopausal women, duration of postmenopausal period, number of children, the ratio of using hormone therapy and the ratio of the gynecologist to general doctor who took the samples between both groups (Table 1). Only the average age of beginning to be the menopause is statistically significant difference between groups, however when classified in age interval of beginning to be the menopause we found no statistically significant difference between both groups (Table 2) and the average age of beginning to be the menopause of both groups had no effect on the statistic difference of the number of cervical smears contain the endocervical cells (Table 3). The number of cervical smears contains endocervical cells is statistically correlate to the depth

Table 1. General characteristics

	Control group	Study group	p-value
Average age (yrs)	58.26 ± 5.61 (49-74)	58.80 ± 7.81 (46-83)	0.575
Average age of beginning to be the menopause (yrs)	50.69 ± 2.93 (40-57)	49.22 ± 3.66 (37-57)	0.002
Postmenopausal period (yrs.)	7.76 ± 6.15 (0.5-29)	9.44 ± 7.84 (0.5-31)	0.094
Number of childbirth	3.19 ± 2.08 (0-14)	2.86 ± 1.86 (0-12)	0.239
History of usinghormone therapy	13	6	0.091
Gynecologist: general physician	67:33	69:31	0.762

Table 2. The age interval of beginning to be the menopause

	Age interval of beginning to be the menopause (yrs)					Total
	35-40	41-45	46-50	51-55	56-60	
Control group	1 (20.0%)	6 (31.6%)	40 (46.0%)	50 (59.5%)	3 (60.0%)	100
Study group	4 (80.0%)	13 (68.4%)	47 (54.0%)	34 (40.5%)	2 (40.0%)	100
Total	5	19	87	84	5	200

p = 0.079

Table 3. The correlation between the age interval of beginning to be the menopause and the cervical smears contain endocervical cells

Endocervical cell	Age interval of beginning to be the menopause (yrs)					Total
	36-40	41-45	46-50	51-55	56-60	
Absence	4 (80.0%)	11 (57.9%)	46 (52.9%)	43 (51.2%)	3 (60.0%)	107 (53.5%)
Presence	1 (20.0%)	8 (42.1%)	41 (47.1%)	41 (48.8%)	2 (40.0%)	93 (46.5%)
Total	5	19	87	84	5	200

p = 0.784

of extended tip of cell pick up tools inserted into the cervical os (Table 4). The slides contain endocervical cells of the study group is forty-six percent of the cases which are no statistically significant difference from forty-seven percent of the control group. Table 5 show no statistically significant difference of the number of cell pick postmenopausal women (Table 6) but not related to the duration of postmenopausal period and history of using hormone therapy of the post-menopausal women (Table 7, 8). The amount of blood loss from cervical os after the new design extended tip modified Ayre's spatula inserted into is less than of the conventional modified Ayre's spatula. (38.6% of new-design extended tip of modified Ayre's spatula vs. 61.4% of the conventional spatula).

Table 4. The correlation between the cervical smears contain endocervical cells and the depth of extended tip of cell pick up tools were inserted into the cervical os

The length of the extended tip of the cell pick up tools insert	Endocervical cell		Total
	Absence	Presence	
Total	58 (29.0%)	65 (32.5%)	123 (61.5%)
More than half	24 (12.0%)	9 (4.5%)	33 (16.5%)
Less than half	19 (9.5%)	18 (9.0%)	37 (18.5%)
No	6 (3.0%)	1 (0.5%)	7 (3.5%)
Total	107 (53.5%)	93 (46.5%)	200 (100%)

p = 0.018

Discussion

The researches show the cervical smears which contain the endocervical cells would reduce the number of repeated tests and have a significantly higher number of atypical epithelial changes[10-12]. The percentage of smears contains endocervical cells also vary with the cell pick up screening tools[5,7]. By extended tip spatula alone, they reported the cervical smears contain endocervical cells were between twenty-seven to sixty percent[5-6,9]. The slides of cervical smears contain endocervical cells in this research are forty-six to forty-seven percent which is concordant with the results of other research. The result also show the number of slides contain endocervical cells are correlated to the extended tip of spatulas inserted into the cervical os. However, the cervical smears contain endocervical cells of study group are not different form the control group. One of the causes is no difference in the spatulas inserted into the cervical os between both groups. So, additional comparative study of the smaller taper extended tip of spatula is required.

Only fifty-seven percent of the conventional spatula of which all the length of extended tip was inserted into the cervical os of the postmenopausal women, so using the cell pick up tool with only one model extended tip to pick up cell for pap smear in everyone who come for cervical cancer screening might

Table 5. The number of extended tip of cell pick up tools were inserted into the cervical os

	Of the extended tip of the cell pick up tools inserted				Total
	Total length	More than half	Less than half	None	
Control group	57	17	23	3	100
Study group	66	16	14	4	100
Total	123	33	37	7	200

p = 0.4

Table 6. The correlation between the extended tip of cell pick up tools were inserted into the cervical os and the number of the childbirth of the postmenopausal women

Number of the childbirth	The length of extended tip of the cell pick up tools inserted				Total
	Total	More than half	Less than half	None	
more than 3	54 (27.0%)	9 (4.5%)	6 (3.0%)	1 (0.5%)	70 (35.0%)
less than 3	69 (34.5%)	24 (12.0%)	31 (15.5%)	6 (3.0%)	130 (65.0%)
Total	123 (61.5%)	33 (16.5%)	37 (18.5%)	7 (3.5%)	200

p = 0.006

Table 7. The correlation of the extended tip of cell pick up tools were inserted into the cervical os and the duration of postmenopausal period

Postmenopausal period (yrs)	Of the length of extended tip of cell pick up tools inserted		Total
	More than half	Less than half	
less than 5	67	18	85
6 to 10	45	14	59
11 to 15	18	6	24
16 to 20	14	4	18
21 to 25	6	0	6
26 to 30	5	2	7
more than 30	1	0	1
Total	156	44	200

p = 0.901

Table 8. The correlation of the extended tip of cell pick up tools were inserted into the cervical os and the history of using hormone therapy of postmenopausal women

History of using hormone therapy	The length of extended tip of cell pick up tools inserts		Total
	More than half	Less than half	
Yes	15 (7.5%)	4 (2.0%)	19 (9.5%)
No	141 (70.5%)	40 (20.0%)	181 (90.5%)
Total	156 (78.0%)	44 (22.0%)	200

p = 1

be not appropriate. Finally, this research shows the smaller taper extended tip of modified Ayre's spatula is also causes less bleeding.

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ขนาดของ extended tip ของ modified Ayre's spatula กับผลการเก็บตรวจเซลจากปากมดลูกของสตรีวัยหลังหมดระดู

วัลลภ ปานพูนทรัพย์, ปิยะวรรณ พลอาษา, อาภากรณ์ วงศ์เทวราช

***ภูมิหลัง**: สตรีวัยหลังหมดระดูที่มารับการตรวจมะเร็งปากมดลูก บ่อยครั้งพบว่าไม่สามารถสอดอุปกรณ์เก็บตรวจเข้าไปภายในปากมดลูกได้ งานวิจัยนี้ได้ออกแบบการศึกษาโดยการพัฒนาส่วนเก็บตรวจของอุปกรณ์เก็บตรวจให้มีความกว้างที่น้อยกว่าเดิมทั้งนี้เพื่อหวังว่าจะเพิ่มประสิทธิภาพในการเก็บตรวจให้ดีขึ้นโดยเฉพาะในการเก็บตรวจเซลเพื่อวินิจฉัยมะเร็งปากมดลูกในสตรีวัยหลังหมดระดู*

***วัตถุประสงค์**: เพื่อศึกษาเปรียบเทียบประสิทธิผลของ modified Ayre's spatula ที่ได้รับการปรับเปลี่ยนขนาดของ extended tip กับ modified Ayre's spatula ที่ใช้อยู่ปกติในปัจจุบัน ในการเก็บตรวจ endocervical cell ของสตรีวัยหลังหมดระดู*

***วัสดุและวิธีการ**: สตรีวัยหมดระดูที่มารับบริการตรวจคัดกรองมะเร็งปากมดลูกถูกสุ่มตัวอย่างแบ่งออกเป็น 2 กลุ่ม โดยกลุ่มแรกจะได้รับการตรวจโดย modified Ayre's spatula ขนาดมาตรฐานที่ใช้อยู่ กลุ่มที่สองจะได้รับการตรวจโดยใช้ modified Ayre's spatula ที่ได้รับการปรับเปลี่ยนขนาดของ extended tip ผลการตรวจจะถูกรวบรวมนำมาศึกษาเปรียบเทียบอัตราการตรวจพบสไลด์ที่มี endocervical cells โดยใช้เครื่องมือทางสถิติ*

***ผลการศึกษา**: จากสตรีวัยหลังหมดระดูจำนวน 200 คน ผลการศึกษาพบสไลด์ที่มี endocervical cells เฉลี่ยร้อยละ 46.5 โดยอุปกรณ์เก็บตรวจชนิดออกแบบใหม่สามารถเก็บตรวจพบสไลด์ที่มี endocervical cells ร้อยละ 46 และอุปกรณ์เก็บตรวจชนิดเดิมที่ใช้อยู่ตรวจพบร้อยละ 47 ส่วนเก็บตรวจเซลของอุปกรณ์เก็บตรวจชนิดเดิมที่ใช้อยู่สามารถสอดผ่านปากมดลูกของสตรีวัยหลังหมดระดูได้สุดร้อยละ 57 และชนิดออกแบบใหม่สามารถสอดผ่านปากมดลูกของสตรีวัยหลังหมดระดูได้สุดร้อยละ 66 ภาวะเลือดออกภายหลังการเก็บตรวจเซลมะเร็งปากมดลูกพบร้อยละ 38.6 ในกลุ่มที่ได้รับการตรวจด้วยอุปกรณ์เก็บตรวจชนิดออกแบบใหม่ และร้อยละ 61.4 ในกลุ่มที่ได้รับการตรวจด้วยอุปกรณ์เก็บตรวจชนิดเดิมที่ใช้อยู่*

***สรุป**: การศึกษานี้ไม่พบความแตกต่างของจำนวนสไลด์ที่ตรวจพบ endocervical cells ระหว่างสองกลุ่มศึกษา การตรวจพบ endocervical cells สัมพันธ์กับการสอดอุปกรณ์เก็บตรวจผ่าน cervical os ควรมีการศึกษาเปรียบเทียบเพิ่มเติมโดยออกแบบส่วนเก็บตรวจเซลของอุปกรณ์เก็บตรวจให้มีขนาดเรียวเล็กกว่าที่ออกแบบในการศึกษานี้ การใช้อุปกรณ์เก็บตรวจที่มีขนาดส่วนเก็บตรวจเซลเพียงขนาดและรูปแบบเดียวในการเก็บตรวจผู้มารับบริการตรวจคัดกรองมะเร็งปากมดลูกทุกคนน่าจะไม่เหมาะสม*