Original Article

Cervical cytopathology and sample suitability: a randomized controlled clinical trial

Citopatológico do colo uterino e adequabilidade da amostra: ensaio clínico randomizado controlado

Citológico del cuello uterino y adecuación de la muestra: ensayo clínico aleatorizado controlado

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Abstract

Objective: To assess two cervicovaginal collection techniques to sample suitability and the other findings of Pap smear.

Methods: The study was conducted from September 2018 to July 2019, in a school health center located in the city of Fortaleza - Ceará. The sample consisted of 365 women randomly divided, with 184 participants in the Control Group (technique in which the ectocervix smear was placed on the slide before endocervical material was collected) and 181 in the Comparison Group (in which the vaginal ectocervix smear was placed on the slide only after collecting the material from the endocervix). An instrument containing sociodemographic, clinical, sexual, reproductive and findings in cytopathological report was used. Women aged between 18 and 64 years, who had already started their sexual life and who underwent the cervical cancer prevention test during the data collection period, were included. Chi-square, Fisher and Kruskal-Wallis tests were used.

Results: There was no statistical association between cytopathological sample suitability for the two cervicovaginal collection techniques used and for the other clinical, sexual, reproductive and other variables related to the other findings in cytopathological report, obtaining a value of p>5% in all associations performed.

Conclusion: The two techniques for collecting cervical cells described in official manuals did not differ for obtaining an adequate cell sample, being equally effective and providing the guarantee of an accurate and timely Pap smear.

Resumo

Objetivo: Avaliar duas técnicas de coleta cervicovaginal à adequabilidade da amostra e aos demais achados do laudo colpocitopatológico.

Métodos: O estudo foi realizado no período de setembro de 2018 a julho de 2019, em um centro de saúde-escola, localizado no município de Fortaleza - Ceará. A amostra foi composta por 365 mulheres divididas aleatoriamente, sendo 184 participantes no Grupo Controle (técnica na qual o esfregaço da ectocérvice foi disposto na lâmina antes da coleta do material da endocérvice) e 181 no Grupo Comparação (no qual o esfregaço da ectocérvice vaginal foi disposto na lâmina apenas após a coleta do material da endocérvice). Utilizou-se um instrumento contendo variáveis sociodemográficas, clínicas, sexuais, reprodutivas e referentes aos achados no laudo citopatológico. Incluíram-se mulheres na faixa etária de 18 a 64 anos, que já tinham iniciado vida sexual e que realizaram o exame de prevenção do câncer de colo uterino no período da coleta de dados. Os testes do qui-quadrado, Fisher e Kruskal-Wallis foram utilizados.

Resultados: Não houve associação estatística entre a adequabilidade da amostra citopatológica às duas técnicas de coleta cervicovaginal empregadas e às demais variáveis clínicas, sexuais, reprodutivas e referentes aos demais achados no laudo citopatológico, obtendo-se valor de p>5% em todas as associações realizadas.

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Conflicts of interest: *Manuscript extracted from the dissertation entitled: "Eficácia das técnicas de coleta para a adequabilidade da amostra colpocitopatológica: ensaio clínico randomizado controlado", presented in 2019 to the Graduate Program in Nursing of the Universidade Federal do Ceará. Fortaleza, CE, Brazil.

Conclusão: As duas técnicas de coleta de células cervicais descritas em manuais oficiais não diferiram para a obtenção de uma amostra celular adequada, sendo igualmente eficazes e propiciando a garantia de um laudo colpocitopatológico preciso e oportuno.

Resumen

Objetivo: Evaluar dos técnicas de toma de muestra cervicovaginal con la adecuación de la muestra y con los demás resultados del informe colpocitológico.

Métodos: El estudio fue realizado durante el período de septiembre de 2018 a julio de 2019, en un centro de salud-escuela, ubicado en el municipio de Fortaleza, estado de Ceará. La muestra estaba compuesta por 365 mujeres divididas aleatoriamente, de las cuales 184 participantes estaban en el Grupo Control (técnica por la que el frotis del ectocérvix fue colocado en la lámina antes de la toma del material del endocérvix) y 181 en el Grupo Comparación (en el que el frotis del ectocérvix vaginal fue colocado sobre la lámina únicamente después de la toma del material del endocérvix). Se utilizó un instrumento con variables sociodemográficas, clínicas, sexuales, reproductivas y relativas a los resultados del informe citológico. Fueron incluidas mujeres del grupo de edad de 18 a 64 años, que ya habían empezado su vida sexual y que realizaron la prueba de prevención de cáncer de cuello uterino durante el período de la recopilación de datos. Se utilizaron las pruebas χ^2 de Pearson, Fisher y Kruskal-Wallis.

Resultados: No hubo asociación estadística entre la adecuación de la muestra citológica con las dos técnicas de toma cervicovaginal utilizadas y con las demás variables clínicas, sexuales, reproductivas y referentes a los demás resultados del informe citológico, y se obtuvo un valor de p>5 % en todas las asociaciones realizadas.

Conclusión: Las dos técnicas de toma de células cervicales que se describen en manuales oficiales no difirieron en la obtención de una muestra celular adecuada y son igualmente eficaces y favorecen la garantía de un informe colpocitológico preciso y oportuno.

Brazilian Clinical Trial Registry (ReBEC): RBR-2H4MPN.

Introduction

Pap smear (also known as cervical cytopathology) consists of taking samples of cells from the squamo-columnar junction (SJC) of the cervix, where the columnar epithelium is juxtaposed to the smooth squamous epithelium. In this area, squamous metaplasia occurs, a place where cellular growth and alteration can allow the entry of human papillomavirus (HPV), which causes more than 90% of cervical cancers.[1] It is a worldwide known and useful test for detecting precancerous and cancerous cells in the cervix, allowing the collection of cells from the transformation zone in search of an abnormal morphology.[2]

Currently, the test is divided into conventional smears and liquid-based preparation smears (LBP). Fluid-based preparation involves collecting cells from the cervical transformation zone using a brush and transferring these cells to a liquid preservative bottle. The conventional technique consists of collecting cells from the transformation zone using a brush and spatula, and then transferring them to a slide fixed with preservative. The liquid-based technique allows HPV, gonorrhea and chlamydia testing in a single collection.[3]

Theoretically, the liquid-based technique becomes more advantageous for having easier interpretation and less unsatisfactory results for filtering blood and debris from the sample. However, although some authors consider liquid cytology to be technically superior, the low cost and simplicity of conventional cytology analysis make it a method that will hardly be considered obsolete.[4]

Despite having reduced the cancer-associated mortality rate to 50-70%, its sensitivity (30-87%) is significantly affected due to sample quality and the considerable amount of time and external factors that permeate the exam quality,[5] such as mucus, red blood cells, debris and other cells.[6,7] Therefore, cytology is a highly subjective test and is dependent on the collector, with performance varying between laboratories and cytologists who analyze samples and report results, with the high rate of false negatives (14–33%) largely due to sampling limitations and smear preparation.[8]

In Brazil, in the most up-to-date primary guide for primary care professionals in the health system, which deals with cervical and breast cancers (Primary Care Report 13), published in 2013, there are several recommendations for performing the Pap smear, such as guidance that the collection of material should be performed in a single slide and that, after scraping the ectocervix using the Ayre spatula, professionals should not dispose of it at that moment, but reserve it to place on the blade only after the endocervical brushing with the Campos da Paz brush, fixing them in an associated way. However,

this recommendation is not included in Primary Care Report 13 of 2006, being introduced, without a justification note, in the most updated edition, in 2013.[9,10]

It is known that the number of unsatisfactory samples, in the form of a percentage, it is an indicator of cervical smear collection and preparation quality[11] and the importance of carrying out comparative studies of techniques for reducing these unsatisfactory samples, contributes to subsidize modifications aiming to obtain a cell sample in good conditions of analysis.[12]

Therefore, aiming at a conclusive and timely cytopathological report, with a direct influence on the quality of women's health care and health professionals' practice, this study aimed to evaluate two cervicovaginal collection techniques (conventional and currently recommended) and associate them with sample suitability and with the other findings of Pap smear report.

Methods

This is a randomized controlled trial (RCT), conducted in a local health unit (school health center) in the city of Fortaleza - Ceará, from September 2018 to July 2019. This research was conducted according to the Consolidated Standards of Reporting Trials (CONSORT) recommendations for trials evaluating non-pharmacological treatments,[13] registered on the Brazilian Clinical Trial Registry (REBEC) platform, with identifier RBR-2H4MPN.

This health-school center, located in a peripheral neighborhood of the city of Fortaleza, with the Human Development Index of 0.21, according to the census published by the City Hall of Fortaleza in 2010,[14] is a reference in care for women and children in the region, through consultations previously scheduled at the unit. Assistance is offered to women in pregnancy and puerperal phases, in reproductive planning, childcare and in gynecological nursing consultations. It is an internship field for nursing students and residents in obstetric nursing, in addition to having a permanent nurse and doctor from the health unit and professors from the UFC Nursing Department.

The study included women who spontaneously sought the service to perform the preventive examination in the age group of 18 to 64 years, with a sexual life already initiated. Regarding the exclusion of participants, these coincide with aspects that contraindicate the collection, as it cannot be carried out in the meantime, interfering with the objective proposed by this RCT: pregnant women, women with complaints of vulvovaginitis without previous treatment, women in their menstrual period and those who underwent total hysterectomy.

For sample calculation, we used the formula for studies with comparative groups,[15] and the following values were adopted: $Z\alpha$ = 95% (1.96), $Z\beta$ = 80% (0.84), d = 15% and p = 50% (because it is unprecedented, the proportion of occurrence of the adopted outcome was 50%). Thus, the values in the formula were replaced, revealing a sample size of 196 participants for each group, totaling 392 women.

However, due to the woman's spontaneous search for the health service, combined with the high rates of absenteeism from previously scheduled gynecological consultations, this research was completed with 184 women in the control group and 181 in the comparison group, totaling 365 participants. Figure 1 presents the flowchart representing the phases and follow-up of participants.

For data collection, a specific instrument was prepared containing questions about sociodemographic (age, marital status, education, neighborhood and monthly family income), clinical (presence of heart disease, diabetes, cancer, systemic arterial hypertension, alcohol consumption, cigarette use, history of infection sexually transmitted disease – and which), gynecological, sexual and reproductive profiles (previous Pap smear and frequency of performance, age at menarche, menstrual cycle, current contraceptive use, sexarche, number of sexual partners in the last three months, habits of oral, vaginal and anal sex, number of pregnancies and previous mode of delivery) and referring to the findings of Pap smear (sample adequacy, reason for unsatisfactory, represented epithelia, benign

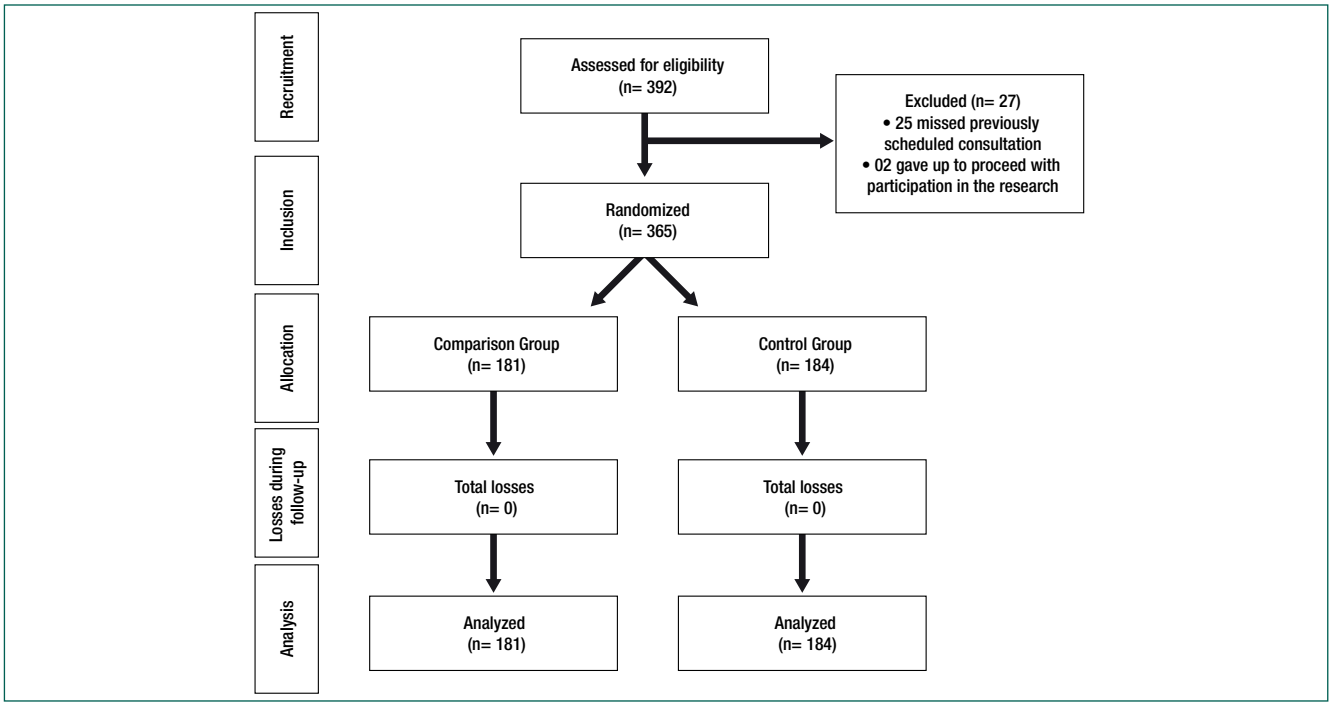

Figure 1. Representative flowchart of phases and follow-up of participants, according to the CONSORT Statement recommendations

or reparative cellular alterations, presence of atypia in squamous cells, glandular and of undetermined significance and presence of low (CIN I) and high-grade (CIN II/III) intraepithelial lesion.

The women, when spontaneously appearing at the health service to schedule gynecological prevention, were welcomed by the institution's professionals and by the researchers and evaluated regarding the inclusion and exclusion criteria of this research. After this observance, the participants who met the inclusion criteria were invited to participate in the study. The randomization scheme used was simple randomization, performed with the aid of a free online site [http://www.randomization.com].[16] This process was performed by a graduate student in nursing, without clinical involvement in the research.

After the random sequence generation, a sequential numbered list was generated for the allocation of women, stipulating six participants per day of data collection so that three belonged to the comparison group (ComparisonG) and three to the control group (ControlG). It is noteworthy that to ensure participant randomization concealment, their designation was only known to the responsible researcher immediately before cytopathological examination, when requested to the person responsible for randomization.

In Comparison Group (ComparisonG), the currently recommended technique described in Primary Care Report 13 of 2013[9] during examination, in the stage of collecting the cells from the ectocervix with the Ayre Spatula, the content obtained from this collection was reserved and only placed on the slide after material collection from the endocervix, with the Campos da Paz Brush, being, therefore, samples which were placed together and then on the slide.[9]

For the Control Group (ControlG), the conventional technique was applied, the collection being fixed at different times. The scraping from the ectocervix, as soon as it was obtained using the Ayre Spatula, was already placed on the slide. Then, the endocervix cells were collected with the Campos da Paz Brush and placed on the slide, which already contained the ectocervix material, according to Brazilian guidelines of Primary Care Report 13, 2006.[10]

It is worth noting that the smear arrangement was the same for both groups: the ectocervical sample was arranged in the transverse direction, in the upper half of the slide, and the endocervix sample

was placed in the lower half of the slide, in the longitudinal direction.[9] After performing gynecological examination, the slides containing the collected material were placed in individual bottles with enough alcohol to cover the entire smear. The samples were properly packaged and sent weekly to the analysis laboratory by professionals from the health institution.

The research was divided into two phases. The first consisted of women's gynecological consultation, with a complete anamnesis and filling in the institution's medical record and data collection form for this study. After the interview, the exam was carried out, according to the technique listed for the group belonging to the participant.

The second moment was related to the findings in the cytopathological report: after the scraping and fixation on the slide, these were sent to the clinical analysis laboratory and approximately 40 days were waited for the result to be available on the Ministry of Health website. With the result available, the cytopathological findings were transcribed to the data collection form, identified only with the card number of the Unified Health System (SUS - *Sistema Único de Saúde*)

This research involved a team composed of two nurses, a cytopathologist and a statistical professional. It is noteworthy that only the researcher responsible for the study was responsible for performing the Pap smear (in order to avoid measurement and friction allocated to obtain fluids). The other nurse was responsible for participant randomization.

Participants, statistician and cytopathologist were blinded. To this end, the assessor responsible for evaluating and granting the outcomes of this study, sample adequacy, blinding was instituted, in order to avoid performance and detection biases, in an attempt to limit and standardize potential co-interventions as much as possible, even knowing that blinding, in some cases, is difficult, either for technical reasons or for ethical reasons.[17]

The data obtained were compiled and analyzed with the help of Statistical Package for the Social Sciences (SPSS) version 22.0, using descriptive statistics and cross-references and, later, represented by tables. Fisher and Kruskal-Wallis were used to compare groups.

It is recommended that it be verified before the analysis of the association of the research outcome if there was really a similar distribution of patients (particularly the characteristics that can directly influence the result, as disease stage, age, weight, among others), because, in general, randomization techniques do not guarantee homogeneity of groups.[12] For this comparison between the groups, Pearson's chi-square test was used, considering statistically significant the values where p are less than 0.05 ($p<0.05$) and the Odds Ratio (OR) with 95% confidence interval.

For those women who agreed to participate, formalization took place by signing the Informed Consent Form (ICF) (it is worth noting that the same ICF was used for both groups, contributing to blinding the participants).

This research was submitted to the Research Ethics Committee of the *Universidade Federal do Ceará*, in the city of Fortaleza, Brazil, obtaining approval with Opinion 2,728,118 and CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 90654018.3.0000.5054. After approval, it was registered on the ReBEC platform, of the Ministry of Health, obtaining UTN U1111-1221-2303 and under registration RBR-2H4MPN.

Results

For participant sociodemographic data, as well as for clinical and gynecological aspects, it can be stated with a significance level of 5% that there was no statistical difference between the groups. The null hypothesis was accepted that the control (n= 184) and comparison (n= 181) groups were homogeneous in terms of the mentioned characteristics, as listed in Table 1.

On sample adequacy and detection of the findings in cytopathological report, contained in Table 2, it was demonstrated that both techniques of cervicovaginal collection (previous or currently recommended) are acceptable for obtaining adequate

Table 1. Comparison of groups according to sociodemographic, clinical and gynecological variables considering the control and comparison groups

Variables	Control Group (ControlG) (n = 184) n(%)	Comparison Group (ComparisonG) (n= 181) n(%)	p-value‡
Age (years)			0.362
18 to 29	62(33.6)	49(27)	
30 to 39	40(21.7)	50(27.6)	
40 to 49	44(24.1)	36(19.9)	
50 to 64	38(20.6)	46(25.5)	
Marital status			0.380
Single/without partner	59(32)	66(36.4)	
Married/stable union/with partner	125(68)	115(63.5)	
Years of study			0.125§
Zero	5(2.7)	4(2.2)	
< 9 years of study	48(26)	51(28.1)	
> 9 and <12 years of study	56(30.4)	43(23.8)	
>12 years of study	75(40.9)	82(45.3)	
Not reported	0(-)	1(0.55)	
Neighborhood			0.888‖
Near to the unit	172(93.4)	172(95)	
Far from the unit	12(6.5)	9(5)	
Diabetes Mellitus			0.514
Yes	9(4.9)	8(4.4)	
No	175(95.1)	173(95.6)	
Cancer¶			0.509
Yes	4(2.2)	3(1.6)	
No	180(97.8)	178(98.4)	
Hypertension			0.079
Yes	21(11.4)	31(17.1)	
No	163(88.6)	150(82.9)	
Alcohol consumption**			0.324
Yes	11(6)	14(7.7)	
No	173(94)	167(92.7)	
Cigarette use ††			0.571
Yes	11(6)	11(6)	
No	173(94)	170(94)	
STI history			0.455
Yes	21(11.4)	19(10.5)	
If so, which one? (n= 40)			0.508
HIV	1(2.5)	0(-)	
Syphilis	5(12.5)	2(5)	
Vaginal herpes	1(2.5)	3(7.5)	
Trichomoniasis	1(2.5)	0(-)	

‡p-value; §Fisher's exact test. ‖Fisher's exact test; Cancer = types reported: thyroid, stomach and skin; **Alcohol consumption = consumption of at least one can of beer (350 ml) at least three times a week; †† Cigarette use = the use of three packs of cigarettes per week was considered

Table 2. Association between sample adequacy and findings of cytopathological report to the collection techniques performed in the control * and comparison †groups

Report variables cytopathological	Control * n=184 n(%)	Comparison† n=181 n(%)	p-value‡
Sample adequacy			0.747§
Satisfactory	183(99)	180(99.4)	
Unsatisfactory	1(1)	1(0.6)	
If unsatisfactory, why?			0.496§
Intense cellular overlapping	0(-)	1(0.5)	
Not specified	184(100)	180(99.5)	
Epithelia represented			0.171‖
Only squamous	119(64.7)	109(60)	
Only glandular	14(7.6)	16(8.8)	
Squamous, metaplastic and glandular	45(24.4)	52(28.7)	
Not registered	6(3.3)	4(2.5)	
Benign or reparative cell changes			0.596‖
No	6(3.2)	5(2.8)	
Mild inflammation	55(30)	50(27.6)	
Moderate inflammation	81(44)	85(47)	
Severe inflammation	26(14.2)	25(13.8)	
Immature squamous metaplasia	0(-)	2(1.1)	
Atrophy with inflammation	10(5.4)	12(6.6)	
Not specified	6(3.2)	2(1.1)	
Atypical cells of undetermined significance			0.508‖
No	181(98.3)	179(98.9)	
Possibly non-neoplastic (ASC-US)	3(1.7)	2(1.1)	
Presence of atypia in squamous cells			0.226‖
No	181(98.3)	181(100)	
Low-grade intraepithelial lesion (HPV and/or CIN I)	1(0.5)	0(-)	
High-grade intraepithelial lesion (CIN II and III)	2(1.2)	0(-)	
Presence of atypia in glandular cells			0.504‖
No	183(99.5)	181(100)	
Adenocarcinoma in situ	1(0.5)	0(-)	

*Control = control group; † Comparison = comparison group; ‡ p-value; § Fisher's exact test; ‖ Chi-square test.

samples and for the detection of possible precursor lesions of CC, obtaining p>0.05 in all the listed variables.

When analyzing the sociodemographic characteristics of the two participants who obtained unsatisfactory samples, it was observed that one belonged to the age group from 30 to 39 years old, while the other from 40 to 49 years old; both were married/stable union or lived with a partner; one had even incomplete elementary education, while the other had completed it; both lived close to the health unit and had a family income of one to three wages. However, by associating the possible correlation of sociodemographic characteristics with sample adequacy, it was found that there was no statistical relationship, with p>0.05 in all variables.

The findings of this study showed that both cervicovaginal collection techniques are conducive to sample suitability for cytopathological analysis, not being significantly influenced by sociodemographic, clinical, sexual and gynecological conditions, under similar structural conditions.

The collection technique is an essential element for optimal Pap smear performance and smear suitability, being evaluated by the presence of squamous and/or columnar cells in the scraping. In Brazil, the

Cervical Cancer Control Program recommends that the collection be obtained from the transformation zone (ectocervix) using the Ayres spatula, which anatomically adapts to the region, and the endocervical brush, which can "sweep" the crypts located in the endocervical canal.[9]

Corroborating this research, previous studies also identified the non-statistical association in relation to the sample satisfactoriness, not varying with the woman's age,[19,20] despite the diagnostic limitation that permeates those over 60 years of age.[21]

Some authors discuss the potential link between smoking and other inappropriate health behaviors to cervical cancer incidence;[22,23] however, such studies do not demonstrate the association of cytopathological sample suitability with the habits mentioned above, basing the cause and effect relationship on health outcomes, being experimental, clinical and/or epidemiological documents.

In this study, in the comparison of two techniques for the detection of benign or reparative cellular alterations and atypia of undetermined significance, of squamous cells and glandular cells, no statistically significant differences were obtained, with all variables accepting the null hypothesis. It is worth mentioning that the frequency of detection of the most serious lesions such as HSIL, ASC-H and AGC varies with sample suitability, being three to four times more present in relation to smears with a limiting factor for analysis, with the main limitations related to collection quality.[24,25]

A high prevalence of cervical inflammation was identified among the participants of this study, which contributes to a significant number of inflammatory debris in the Pap smear, presenting great challenges in interpretation and reporting, due, in large part, to the limitations of sampling and smear preparation. Therefore, quality assurance in sample preparation, fixation, staining, reading and reporting is critical for accurate results.[8]

Studies describe that the main limitations of sample adequacy are directly related to collection quality, with the presence of smear with desiccation, pus, blood[24] and by organizational factors, professionals' skills and analysis laboratory size.[26] These same causes of sample inadequacy, in addition to the presence of insufficient cells in the smear, were reported in a previous study.[25]

New methods have been compared aiming at improving slide observation in the Pap smear, in particular material fixation quality and cellular distribution homogeneity in the smear, reducing the occurrence of unsatisfactory smears.[6] This could be mitigated with highly skilled pathologists allied to a good logistics system for collecting and guarding the cell sample, although it is challenging to implement them in countries with low resources.[8]

Cervical cell sampling and cervicovaginal microbiota diversity were also analyzed in previous research, comparing samples obtained using a rayon swab (a common device for microbial mucosal sampling) and a Cytobrush brush. The results of cells and microbiota were comparable at all taxonomic levels, as demonstrated by correlation coefficients of two groups, and no significant differences were identified between the two sampling techniques.[27,28]

In conventional Pap smear (CC) cytology, it is necessary to transfer the material from the brush to the slide, and in CBL, the impregnated brush is packaged directly in a bottle with fixative substance.[29] However, when conventional collection is performed according to established precepts so that it results in a good smear, studies show that the suitability of the two techniques is similar.[30]

When comparing smear quality after sampling only using the anatomical spatula (used to collect ectocervical cells) and the Cytobrush-Ayres spatula (used to collect endo and ectocervical cells), previous research concluded that there was no significant difference in smear quality using the two different methods, with a p-value of 0.2532. The anatomical spatula can be used as a unique device in conventional cytology.[31]

Knowing that unsatisfactory cervicovaginal samples represent a failure in screening for cervical cancer precursor lesions, in addition to causing inconvenience to women and wasting resources, sample adequacy is considered the most important component to ensure the exam quality.[9,32] For this, simple actions, such as communication between professionals working in cytopathology laboratories and those who collect material, can mitigate problems related to the sample in question,[28] given that

the main limitations of sample suitability are directly related to collection quality.[16,33]

Therefore, the application of the correct tool to prepare the gynecological examination must be implemented. In addition to technological advances in developed countries, in clinical settings and in developing countries, there are efforts by professionals to improve collection and reduce unsatisfactory samples, considering it necessary to know all existing techniques and modifications.[18] In the health unit where this study was conducted, in daily practice, there was a change in the collection technique, recommended by the Ministry of Health, and, empirically observed, health professionals were based on the old recommendation (2006)[10] versus the new recommendation (2013).[9]

Therefore, based on the proposal to test the two recommendations contained in the health manuals, in order to evaluate their effectiveness and origin in exam quality, knowing that a correct Pap smear involving all phases, especially collection, has a direct influence on the quality of women's health care, aiming at directing professionals' practice regarding the correct and most effective technique for performing preventive examination and obtaining the benefits of early cervical cancer screening. Since this procedure is also performed by other health professionals, the dissemination of findings can promote and strengthen, in relation to other categories, the scientific appreciation of nursing.

It was considered as limitations of this study conducting the research in a single health center and the sample loss of 27 participants, which restricted the generalization and the possibility of non-statistical significance of studied characteristics, as well as the performance of two different techniques, considering cervical sample adequacy, due to non-reaching the previously calculated sample. However, it is a pioneering RCT in the country, collaborating with data pertinent to the scientific literature and that adjustments in later research can be made.

Conclusion

It is concluded that the two techniques of cervical smear collection, described in the Brazilian manuals for the Control of Cervical and Breast Cancers, published in 2006 and 2013, are conducive to obtaining an adequate sample of cells and detecting microbiological findings, not impacting the reading and diagnosis of cytopathological report, and the professional who performs this exam can use the two techniques described. Therefore, in view of these results, it appears that colpocytopathological sample suitability and the detection of other findings in the report do not depend on sociodemographic, clinical and gynecological, sexual and reproductive aspects nor the type of technique used to collect cells from the uterine cervix.

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Collaborations

Freitas VCA, Soares PRAL, Nicolau AIO, Lima TM and Pinheiro AKB contributed to the study design, data analysis and interpretation, article writing, relevant critical review of the intellectual content and approval of the final version to be published.

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