



Research Article

Evaluation of the Quality of Cervico-Vaginal Smears at the Gyneco-Obstetric and Pediatric Hospital of Douala

Évaluation de la qualité des frottis cervico-vaginaux à l'Hôpital Gynéco-Obstétrique et Pédiatrique de Douala

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ABSTRACT

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Objective. Cervical cancer is likely to be the cancer that Cervico-Vaginal Smear (CVS) screening would be most contributive if performed under favorable conditions. In Cameroon, there is no quality control in the laboratories of Anatomy Cytology Pathology (ACP) and even less, there is no study on the quality of CVS sampling since its implementation in our country. However, in the laboratory, the quality of the sample determines the quality of the analysis and consequently the quality of the result and therapeutic orientations. The objective of our study was to evaluate the quality approach in the practice of CVS at the Gyneco-Obstetrics and Pediatric Hospital of Douala (GOPEHD). **Materials and methods.** We conducted a cross sectional retrospective descriptive study for a period from September 2015 to December 2016. We performed a quality control of CVS at the sampling level. We used the Bethesda System 2004 as a reference quality manual for evaluation. **Results.** A total of 508 CVS were reviewed. In this sample, 28.94% were satisfactory for the evaluation, while 43.31% were satisfactory interpretable with some limitations. The inadequate CVS rate was 27.76%. We also found that 65.31% of the CVS had no information regarding the quality of the sample. **Conclusion.** The quality of samples taken at GOPEHD is partially in line with Bethesda's recommendations, which implies that ACP professionals must truly engage in a process of improving quality in the practice of CVS.

RÉSUMÉ

Objectif. Le cancer du col de l'utérus est vraisemblablement le cancer dont le dépistage par le Frottis Cervico-vaginal (FCV) serait le plus contributif s'il était réalisé dans des conditions favorables. Au Cameroun, il n'existe pas de contrôle qualité dans les laboratoires d'Anatomie Cytologie pathologie et encore moins, il n'existe aucune étude sur la qualité des prélèvements des FCV depuis sa mise en pratique dans notre pays. Pourtant au laboratoire c'est la qualité du prélèvement qui conditionne la qualité de l'analyse et par conséquent la qualité du résultat et des orientations thérapeutiques. L'objectif de notre étude était d'évaluer la démarche qualité dans la pratique des FCV à l'Hôpital Gynéco-Obstétrique et Pédiatrique de Douala (HGOPED). **Matériel et méthodes.** L'étude transversale descriptive rétrospective a couvert la période de septembre 2015 à décembre 2016 où nous avons effectué un contrôle qualité des FCV au niveau du prélèvement. Le Système de Bethesda a été utilisé comme manuel qualité de référence pour l'évaluation. **Résultats.** Au total, 508 FCV réalisés en pratique clinique ont été réexaminés et au bout des analyses, nous avons obtenu 28,94% de FCV satisfaisants pour l'évaluation, 43,31% FCV satisfaisants mais avec des limites variables. Le taux de FCV inadéquats était de 27,76%. L'analyse des comptes rendu a révélé que 65,31% des FCV n'avaient aucune information concernant la qualité du prélèvement. **Conclusion.** La qualité des prélèvements à HGOPED est partiellement conforme aux recommandations de Bethesda ce qui implique que les professionnels ACP doivent véritablement s'engager dans une démarche d'amélioration de la qualité dans la pratique des FCV.

INTRODUCTION

Gynecologic cancers account for 19% of all cancers worldwide and in Africa the most common cancers of women are those of the breast and cervix [1]. With 528,000 new cases each year, cervical cancer is the second most common cancer in women worldwide with 80% of cases diagnosed in developing countries. The average age of onset is 52.2 years [2]. In the industrialized countries, the improvement of hygiene and living conditions and the appearance some fifty years ago of a cytological screening test, cervico-vaginal smear (CVS), made it possible to reduce the incidence and mortality of this cancer. Indeed, it is clear that the real problem in the prevention of cervical cancer is that women at risk escape screening. They live in less developed countries and those living in developed countries belong to the lower socio-economic classes [3]. In 2010, the World Health Organization estimated that nearly 75,000 women have been diagnosed with cervical cancer in Africa, with more than 50,000 who have died from this disease [4].

Cervical cancer is caused by persistent sexual infection with human papillomavirus (HPV). To date, two high-risk HPV types, 16 and 18 have been identified as responsible for approximately 70% of cervical cancer cases. Invasive cancer of the cervix is a rapidly progressive disease, fatal prognosis when diagnosed late, is the cause of widespread spread with metastases and great suffering somatic and psychological when there is no surgical management and adapted palliative care [5]. Ideal candidate for screening by its slow evolution and the existence of numerous curable pre-cancerous lesions, it is a cancer potentially becoming a rare disease. However, a significant proportion of women still have little or no screening [6]. In Cameroon, cervical cancer is the second most common gynecological cancer (23.4%) after breast cancer [7]. There are many prevention methods, including CVS, which is a screening test for precancerous and cancerous cervical lesions. This is the most widely used technique because it has dramatically reduced the incidence of invasive cancer. Mortality in most developed countries. However, this CVS screening will be valuable only if the sample taken meets the quality requirements of The Bethesda System (TBS). The search for quality and safety of results is nowadays a constant preoccupation of any professional practicing within a laboratory of pathological anatomy and cytology. The proper execution of the technical acts is one of the determining conditions of this quality [8].

In recent years, thanks to advances in science, expectations for continual quality improvement and monitoring of medical laboratories have increased significantly. However, the practice of cytopathology has long espoused the concept of quality management particularly as it is applied in gynecological cytology [9]. Several documents have been devoted mainly to quality control in gynecological cytology including the Bethesda System which provides a quality reference system throughout the chain of completion of a CVS, from sampling to writing the report. For example, the 2004 Bethesda Quality Manual discusses the validity criteria of

a sample and the quality criteria. Few studies have evaluated these sampling validity criteria in pathological anatomy and cytology laboratories, and even less so in pathological anatomy and cytology laboratories in Cameroon where, despite the resources and resources put in place to improve these laboratories, there is no quality control and there is no study on the quality of CVS sampling since it was put into practice in our country. The quality of the sampling is therefore essential because it determines the quality of the analysis and consequently the quality of the result and the therapeutic orientations.

The general objective of our study was to evaluate the quality approach in Cervico-Vaginal Smears, recognized as an excellent examination in the early detection of precancerous lesions of the cervix.

Specifically, it was about :

- ☞ Check compliance with the criteria for validity of a CVS specimen as specified in the 2004 Bethesda Quality Manual.
- ☞ Evaluate the quality criteria of the samples.
- ☞ Check the effectiveness of the mention "quality of samples" in the reports of CVS.

MATERIALS AND METHOD

Description of study

We conducted over a period of 16 months, September 2015 to December 2016 a retrospective study of descriptive type over a period of 08 months, December 2016 to July 2017 at the Gyneco-Obstetrics and Pediatric Hospital (GOPEHD) of Douala where we performed Cervico-vaginal smears quality control only at sampling level using the Bethesda System as a reference quality manual. The sample consisted of all CVS slides made during the study period. Included in our study were all slides collected and reviewed at GOPEHD, and reporting. Any unregistered and available slides or any recorded and unavailable slides were excluded from the study.

The study material consisted of data collection tool (Evaluation Sheet). The data collection was done at the Department of Anatomy Cytology Pathology and mortuary of the hospital.

For Data Analysis, we used SPSS 20.0 Software; Microsoft Office Excel and ACCES 2010. The chosen statistical analysis was Square KHI test (χ^2) with a significance level of $P < 0.05$. Our Sources of information was the Cervico-Vaginal Smear Registry for the collection of patient identification information and clinical information; Slides made during the study period for information on sample identification, technical quality, cell composition and other elements such as bleeding, inflammation, fixation; Cytological reports to check the presence of the mention "quality of sampling"; The Bethesda Quality Manual 2004. We chosen the Bethesda 2004 version because the recent versions apply to cervico-vaginal cytology in liquid medium, while in our country, we still use conventional cytology.

Variables

The variables consisted of different validity criteria and quality criteria:

Validity criteria:

- ☞ Patient identification and collection parameters (first and last name, contact or address, age and number of record);
- ☞ Clinical information (period of genital activity, contraceptives, age at first sexual intercourse, antecedents, screening history);
- ☞ Technical quality (Labeling, spreading, damage and blade assembly);
- ☞ Cellular composition (squamous component, endocervical and / or metaplastic component);
- ☞ Inflammation, bleeding, quality of fixation.

Quality criteria☞ **Satisfactory for the evaluation**

The following criteria must be applied:

- Correct identification and registration ;
- Complete clinical information ;
- A sufficient number of squamous cells well preserved and well visualized;
- An epithelial cell distribution greater than 10% of the blade surface.
- Endocervical and squamous component correct in the presence of the cervix; a minimum of two clusters of endocervical and / or metaplastic cells well preserved with at least 5 cells.

☞ **Satisfactory but limited by each of the following cases**

This criterion indicates that the sample provides useful information. However his interpretation may be compromised. This does not necessarily lead to repeat smears. The sample is satisfactory, interpretable but limited by ... "under one of the following conditions:

- No clinical information ;
- Partially haemorrhagic and / or inflammatory smear with thick areas, poor fixation, air drying artifacts, contaminants that prevent the interpretation of 50-70% of epithelial cells;
- No endocervical or transitional cells.

☞ **Inadequate specimen if one of the following criteria is applied**

This criterion indicates that the sample is not suitable for the detection of cervical epithelial abnormalities. It is therefore inadequate under the following conditions :

- No patient information and demand;
- Blade technically unacceptable, broken non repairable, poorly preserved material
- Poor material;
- Hemorrhagic and / or inflammatory smear, thick, poorly fixed, drying artifacts, prevent interpretation of 75% or more of epithelial cells.

RESULTS AND DISCUSSION

The balance sheet reported 508 CVS retained for the study and 08 excluded (02 missing records and 06 missing slides).

Result 1: Validity of the samples

We noted some inconformities in each criterion of validity. Table I groups these results (n = 508).

Table I : Main inconformities of validity criteria

Criteria of validity	Number (%)
No clinical information	246 (48.83)
Thick spreading	224 (44.09)
Poor visualization of squamous cells	147 (28,74)
Presence of inflammatory elements	93 (17.91)
Poor preservation of squamous cells	71 (13,98)
Bad quality of fixation	68 (13.39)
Presence of hemorrhagic elements	49 (9.65)
Absence of endocervical and / or metaplastic cells	47 (9.25)
Low squamous cellularity (number <10%)	31 (6,10)
Absent Contact	29 (5.71)
Age unspecified	5 (0.97)

Several reasons can explain the inconformities found in the criteria of validity

- ☞ Inadequate clinical information may result from insufficient awareness among practitioners of any clinical information the absence of which could compromise the interpretation of CVS, or a lack of vigilance by practitioners when collecting information. There was a significant link with the quality of the samples ($P < 0.01$).
- ☞ The poor quality of the spreading, could be explained by a bad technical skill at the time of the spreading of the cells on the blades, which causes a poor quality of the spreading with more than 75% of the squamous cells superimposed the to each other. The square KHI test showed a significant distribution with the quality of the sample ($P < 0.01$). At GOPEHD, one slide is used for three sampling zones (Vagina, Exocol and Endocol), which could considerably reduce the spreading field especially when the Ayre spatula brings back a material rich in cell. The technique advocated by Wied and Bahr (1959) to spread the vaginal, exocervical and endocervical samples on the same slide would allow a rapid microscopic reading but would require great dexterity at the time of spreading and fixation [10].
- ☞ The poor preservation of the cells can be explained by a defect of fixation because the purpose of fixation is to preserve the morphological state of the cells. As a result, a statistically significant association ($P < 0.05$) was observed with poor preservation.
- ☞ As for the poor visualization of the cells, it can be explained by the presence on the CVS, of an inflammatory and / or hemorrhagic context which obscured near 70% of the cells, the statistical test of

the square KHI showed a significant difference between poor visualization and each of these elements ($P < 0,01$ with inflammation).

- ☞ The low squamous cellularity can be explained on the one hand by a poor spreading technique that leaves cells on the spatula, which therefore again involves the technical ability of the sampler at the time of spreading, and on the other hand, the fact that some women may have a neck that is difficult to access.
- ☞ The absence of the endocervical and / or metaplastic component also highlights the technical ability of the sampler and his control of the anatomy of the cervix. The absence of both devalues the smear because according to the Bethesda system, the presence of endocervical cells without the metaplastic cells does not always mean that the sample did not interest the junction zone.
- ☞ The presence of inflammatory elements can be explained by common infections of the female genital tract, particularly parasitic, mycotic, bacterial and viral infections [10]. On the other hand, the cases of hemorrhagic CVS can be explained by the non-respect of the sampling conditions in particular the non-respect of the date of last rule with respect to the date of sampling, which calls once more the vigilance of the sampler. . In some cases of hemorrhagic CVS, bleeding was not always related to a date of last rules not taken into account before the beginning of the sampling but to a pathology.
- ☞ The poor quality of the fixation could be related to a poor or outdated fixator and to a long fixation time (3 minutes or more).

Result 2: Quality of sampling

147 samples were satisfactory for the evaluation, 220 satisfactory but limited by the absence of at least one of the Bethesda criteria, and 141 were inadequate, respectively 28.94%, 43.31% and 27.76% (Table II).

Table II : Quality of sampling

Sampling	Quantity	%
Satisfactory but limited by...	220	43,31
Satisfactory for the evaluation	147	28,94
Inadequate samples	141	27,76
Total	508	100

Sampling satisfactory for the evaluation

We obtained 28.94% of satisfactory samples for evaluation. This result is not far from that found by Chosia [11] who obtained 36.9% satisfactory samples for evaluation at the Department of Pathomorphology of the Pomeranian University of Medicine in Szczecin, Poland. This result was obtained by applying the Bethesda System Evaluation Criteria (1988 version). The result obtained in our study can be explained by the fact that our analyzes were based on specimens made in clinical practice and also by the fact that GOPEHD has a much lower volume of cytocyclusal-vaginal cytology (monthly volume of nearly 34 CVS in 2016), compared to the Chosia study where analyzes were based on screening campaigns with a sample of 202,345 CVS.

Sampling satisfactory by limited by...

The rate of satisfactory but limited sampling in our study was high (43.31%). This result can be compared to that found by Chosia [11] who had obtained 59.9% in 2001 and 44.2% in 2002 after informing practitioners about the quality of CVS. The difference in outcome is probably related to variations in technique, risk factors of the patient and the laboratory application of the criteria. Davey in the United States [12], estimated that 50% of quality-controlled cervico-vaginal cytology laboratories had satisfactory CVS levels but were limited by ... between 0.7% and 21.4% and this rate could be increased in laboratories with a larger cytology case volume; This may suggest that the amount of CVS achieved has an impact on the quality of the sample.

Sampling inadequate

In the analysis of Chosia [11] and Davey [12], the rate of inadequate smears was not high, respectively 3.25% and 0.7-2%. This is not the case in our study (27.76%). It is therefore likely that our criteria are quite rigorous.

Result 3: Reasons for the devaluation of smears

Table III present the main reasons for the devaluation of CVS in our study.

Table III : Main reasons for the devaluation of smears

Satisfactory but limited by	Yes	No	Total
Coverage of 50 to 70% of the cells	191	29	220
No clinical information	156	64	220
No endocervical and / or metaplastic cells	24	196	220
Inadequate levies due to	Yes	No	Total
Total			
Recovery of over 75% of cells	138	03	141
Poor preservation of squamous cells	70	79	141
Low squamous cellularity	29	112	141

Sampling satisfactory by limited by...

Most of the samples were satisfactory but limited by obscuration of 50 to 70% of the cells (86.94%) followed by the absence of clinical information (70.72%). The absence of the endocervical and / or metaplastic component (10.81%) was poorly represented. These two associated reasons limited the quality of CVS to 55.41% (122).

These results are comparable to those of Davey [12], who found as main reasons the partial obscuration by inflammation and haemorrhage and others; and the endocervical / metaplastic component null / weak. It is the same as the reasons found by Chosia.

Sampling inadequate

As before, Chosia and Davey had identified two main reasons that made the specimens inadequate, including the darkening of cells by inflammation and blood, and low squamous cellularity. In our case, the criteria in favor of this category are mainly obscuration of more than 75% of the cells not troublesome elements (97.87%) followed by poor preservation of squamous cells (43.97%) and finally

an insufficient number of squamous cells (20.57%); results similar to those found by Davey [12] and Chosia [11]. These reasons in this study were most often associated with at least 02 to make the samples inadequate. However, other criteria such as Technical Quality, patient information and also clinical information also had their participation.

Result 4: Devaluing elements of CVS

We evaluated the participation rate of each element of the common criterion to satisfactory but limited samples and to inadequate sampling, namely inflammation, haemorrhage, quality of fixation and quality of spreading. Table IV presents these results.

Table IV : Common criteria in the devaluation of smears

Quality criteria	Criteria of validity	Participation rate (%)
Satisfactory but limited by...	Thick spreading	73,18
	Inflammation	47,73
	Bleeding	22,72
Inadequate specimens due to	Poor quality of fixation	17,27
	Thick spreading	48,94
	Poor quality of fixation	46,10
	Inflammation	44,68
	Bleeding	26,24

From this table, it appears that the thick sprawl was always at the top of the ranking. This result can be explained by the fact that the CVS of the study were of conventional type, especially when we know the CVS in liquid medium offers a better quality of the spreading. In addition, the poor technical skill at the moment of spreading seen above can also be associated with this result. In fact, this result puts back into question the conventional technique still widely practiced in our country.

Result 5: Quality of sampling and reporting

The quality of the levy did not appear in 330 reports (64.96%).

The analysis showed that 64.96% of the reports had no information on the quality of the sample. This result clearly shows the absence of quality control of CVS in pathology anatomy laboratories and can be explained by the fact that the sampling examiner does not find it interesting to specify this information on the quality of the sample taken. However, according to the Polish analysis [11], detailed information concerning the quality of the smears must be included in the cytological report. This could then trigger a dialogue between the person performing the smear and the person examining it to improve the quality of smears.

Finally, the analysis of the relationship between the validity criteria and the quality criteria of the samples using the square KHI test revealed a statistically significant association with a P value of less than 0.05. So the quality of the sampling depends on these criteria as specified in the Bethesda system.

CONCLUSION

Based on these results, we can say that the GOPEHD CVS partially comply with the quality requirements of the Bethesda system. In addition, the quality control is almost absent. As a result, ACP professionals must truly engage in quality improvement in the practice of CVS. It would be desirable to consider the introduction of liquid technology.

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