Volume 1 Issue 1 January, 2025

Maiden Edition

NIGERIAN JOURNAL OF ONCOLOGY

NJO

ARCON
Association of Radiation and Clinical Oncologists of Nigeria

w.w.w.ngjoncology.com

Printed by Ahmadu Bello University Press Ltd.,
P.M.B. 1094 Samaru, Zaria, Nigeria. Tel: 08065949711.
E-mail: abupress@abu.edu.ng, info@abupress.com.ng
Website: www.abupress.com.ng

A COMPARATIVE PILOT STUDY OF A FIVE BLADE SPECULUM (BOUQUET SPECULUM) AND TWO- BLADE TRADITIONAL VAGINAL SPECULUM: PATIENT COMFORTABILITY VERSUS CERVIX VISUALIZATION

Ayuba Hannatu U[1], Lawal Hanafi B[1], Mahmoud R.A[2], Akintola O.S[2], Fatona K.O[2], Aminu U[1]

1. Radiotherapy and Oncology Department, National Hospital Abuja, Nigeria
2. Obstetrics and Gynecology Department, National Hospital Abuja, Nigeria

Corresponding Author:
Dr. Ayuba, Hannatu Usman, Radiotherapy and Oncology Department, National Hospital Abuja, Nigeria, hannatuayuba@gmail.com. +2348097046624

Citation: Ayuba HU, Lawal BH, Mahmoud RA, Akintola AS, fatona KO, Aminu U. A Comparative Pilot Study of a Five Blade Speculum (Bouquet Speculum) and Two- Blade Traditional Vaginal Speculum: Patient Comfortability versus Cervix Visualization. *Niger J of Oncol* 2025;1(1):52-59

ABSTRACT

Introduction: The vaginal speculum is an important tool used in cervical cancer prevention and control. This study compared patients' comfort, cervical visualization and ease of using the bouquet speculum to the traditional bivalve vaginal speculum during the cervical cancer screening procedure at National Hospital Abuja. Due to the need to improve cervical cancer screening attendance, exploring the comfortability, cervical visualization and ease of use of other improved speculums like the 5-petaled speculum referred to as the bouquet vaginal speculum made by Viospex, a newly innovated FDA-cleared disposable speculum is important.

Methodology: This study was an observational cross-sectional study which received ethical clearance with number NHA/EC/015/2024. The study randomized 40 women into two groups of 20 women per group. Group B were screened using the bouquet speculum while group A were screened with the traditional bivalve plastic Cusco speculum used routinely in the Gynecology clinic by trained healthcare workers who are Gynecology and Oncology nurses. The inclusion criteria included females 18 years of age or older, healthy females presenting for cervical cancer screening and females who consented to participate in the study. Exclusion criteria included females who never had a pelvic exam with the traditional bivalve speculum and those who did not consent to the study.

Results: The bouquet speculum was found not inferior in comparison to the traditional bivalve speculum with respect to the client or patient's comfort, visualization of the cervix, vagina, lateral walls and fornices and ease of application. More women reported being more comfortable with the bouquet speculum which was significant for patients' preference despite the pain scores that were noted to be higher for the bouquet speculum group. Mean pain score for group A vs. group B was 2.89 ±1.97 vs. 3.83 ±2.73 (t=1.205; p=0.236). Interestingly, 52.5% of the women had never had a Pap smear test.

Conclusion: The bouquet speculum is not inferior to the bivalve speculum in ease of application.

KEYWORDS: Cervical cancer screening, bouquet speculum, cervix, bivalve Cusco speculum, plastic speculum, comfortability, cervix visualization, ease of application

INTRODUCTION

Globally, Cervical cancer is the fourth most common cancer, responsible for 604,127 (3.1%) new cancer cases and 341,831 (3.4%) deaths with the highest regional incidence and mortality seen in sub-Saharan Africa in 2020.[1] The African continent documented 117,316 new cases and 7,6745 deaths in 2020. It is estimated that at this rate, new cases will reach 135,000 and 83,000 deaths by 2030 in Africa.[2] Cervical cancer is the second most common malignancy in women and second leading cause of cancer mortality in women in Nigeria.[2] This disease is responsible for 12,075 newly diagnosed cases with 7,968 deaths in Nigeria.[3] The efforts to scale up cervical cancer screening in Nigeria will need the health systems strengthening approach from healthcare governance and policies to awareness creation, healthcare workers training, availability of the appropriate healthcare consumables to the women at the reproductive healthcare facility at the grassroots where the bottom billion reside. The vaginal speculum is an important tool used in cervical cancer prevention and control. In the prevention aspect, it is used to better visualize the cervix, vaginal walls, fornices and vagina during the process of cervical cancer screening and colposcopy for certain interventional procedures. Recently, different types of vaginal specula are used in the process ranging from the metallic Cusco or Graves specula, to plastic disposable equivalents of the Cusco and Graves.

The 5-petaled speculum referred to as the bouquet vaginal speculum made by Viospex is a newly innovated Food and Drug Administration (FDA)-cleared disposable speculum which radially opens the vagina, giving an unobstructed view of the cervix, with designed gaps between the petals which eliminates the risk of pinching discomfort felt by the patient during the process. [4-8] It is important to test its usability in our setting.

METHODOLOGY

This study was an observational cross-sectional study which utilized the simple random sampling method using the ballot system which determined the groups the patients were assigned to. The study received ethical approval from the National Hospital Research Ethics Committee with approval number: NHA/EC/015/2024.

All participants consented and signed consent forms based on Helsinki Declarations prior to the procedure. Inclusion criteria included females 18 years of age or older, healthy females presenting for cervical cancer screening and females who consented to participate in the study. Exclusion criteria included females for whom basic data could not be retrieved from the medical records, females who never had a pelvic exam with the traditional bivalve speculum and females who did not consent to the study. The population size was 40 women with 2 groups of 20 women per group. One group was screened using the bouquet speculum (Group B) while the plastic Cusco speculum used routinely in the Gynecology clinic was used for the other group (Group A).

Figure 1: Images of the bouquet speculum and the traditional bivalve speculum respectively

Figure 2: Images of the cervix in the same patient using the bouquet and bivalve speculums respectively

Self-administered questionnaires were answered by the women and the healthcare workers. The healthcare workers were trained Gynecology and Oncology nurses to maintain standards. Using the Lickert scale, questions on the level of comfort were answered by the patients while questions on ease of use, cervical and vaginal visualization and other colposcopy-related questions compared to the routine plastic cuscus were answered by the healthcare workers.

Forty women were recruited for the study from March 27 to July 27, 2024. Fisher's exact test was used to test for statistical significance.

RESULTS

Forty women were randomly sampled into 2 groups of 20 women per group, namely A and B and underwent cervical cancer screening using the bouquet speculum (B) and the other group (A) used the plastic bivalve cuscus speculum which is used routinely in the gynecology clinic.

Table 1: Patients' variables and some speculum application parameters

Indication	Group				Fisher's exact P
	A		B		
	N	%	N	%	
History of Pap smear done in the past					0.264
No	12	60.0	9	45.0	
Yes	8	40.0	11	55.0	
History of pelvic exam in the past					
No	7	35.0	8	40.0	
Yes	13	65.0	12	60.0	
Any history of vaginal birth?					0.500
No	5	25.0	6	30.0	
Yes	15	75.0	14	70.0	
Need to adjust the patients' body					0.106
No	11	55.0	15	78.9	
Yes	9	45.0	4	21.1	
Ease of visualizing the lateral wall of vagina					0.500
No	1	5.0	2	10.0	
Yes	19	95.0	18	90.0	
Was patient asked to move body to get A better view of cervix?					0.500
No	17	85.0	16	80.0	
Yes	3	15.0	4	20.0	
Was special maneuver performed for better visualization of cervix?					**0.028***
No	17	85.0	12	60.0	
Yes	3	15.0	8	40.0	
Need to use a different speculum					0.244
No	20	100.0	18	90.0	
Yes	0	0.0	2	10.0	
Was an application of condom necessary for visualization?					
No	20	100.0	20	100.0	-
Was there need to reinsert the speculum?					0.500
No	18	90.0	17	85.0	
Yes	2	10.0	3	15.0	

* P <0.05 was statistically significant

There was no record of Pap smear in the past in 21 (52.5%) of the women who consented to this study, but 40.0% in group A and 55.0% in group B had done a Pap smear in the past.

Table 2: Patients' comfort level during the cervical cancer screening procedure using the bouquet speculum (group B) compared with the traditional bivalve vaginal speculum (group A)

		Group		Total	U	P
		A (%)	B (%)			
Level of comfort	Nil	0 (0.0)	1 (5.0)	1 (2.5)		
	Less comfortable	6 (30.0)	2 (10.0)	8 (20.0)		
	Same level of comfort	8 (40.0)	8 (40.0)	16 (40.0)	161.000	0.301
	More comfortable	6 (30.0)	9 (45.0)	15 (37.5)		

U- Mann Whitney test, P- p-value

Equal number of patients (8) in both groups experienced the same level of comfort. However, patients in group B were more comfortable with their screening procedure 45.0% as against 30.0% in group A. But the differences were not statistically significant.

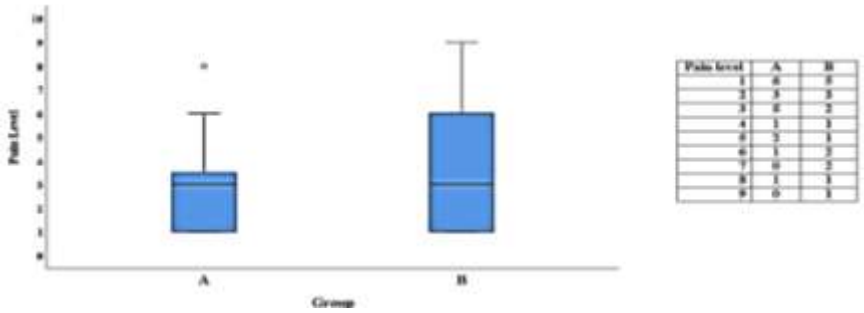

Figure 1: Box plot showing the pain level across Groups A and B

The mean pain score for group A versus group B was 2.89 ±1.97 versus 3.83 ±2.73 (t=1.205; *p*=0.236).

Median [interquartile range IQR] for group A vs. group B was 3.00 [1.00 – 3.50] vs. 3.00 [1.00 - 6.00] (U=142.500; *p*=0.377). Note that U is Mann Whitney test, P-value <0.05 is statistically significant.

Table 3: Estimated time speculum was inserted as perceived by the participants and health workers (feedback)

	Participants				Health workers				P	P
	Group A (n=20)		Group B (n=20)		Group A (n=20)		Group B (n=20)			
Estimated time speculum was inserted	N	%	N	%	N	%	N	%	0.535	0.444
0 – 30 s	1	5.0	1	5.0	1	5.0	0	0.0		
30- 60 s	10	50.0	9	45.0	15	75.0	15	75.0		
1 – 2 mins	5	25.0	3	15.0	2	10.0	1	5.0		
2 – 3 mins	3	15.0	5	25.0	2	10.0	3	15.0		
> 3 mins	1	5.0	2	10.0	0	0.0	1	5.0		

P=p value

The majority of patients and healthcare workers in both groups (A and B) reported an estimated time of 30 -60 seconds was used for the whole Pap smear procedure, p value was 0.444.

Bivariate analysis on the healthcare workers feedback on the differences in the extent of cervical visualization scale, extent of vaginal walls and fornices visualized and ease of speculum application were statistically not significant with the p- values of 0.9, 0.411 and 0.489 respectively.

DISCUSSION

Bivariate analysis of some predictors of patient comfort, visualization and ease of use feedback from the healthcare workers between the A and B groups namely the number of Pap smear exams in the past, number of births, pelvic exams in the past, estimated time the speculum examination lasted from the participant feedback, if patient was asked to move her body for a better view or a special manoeuvre for better visualization from healthcare worker feedback was done. Both groups' parameters differences were not statistically significant except for the healthcare worker feedback of a special manoeuvre was made for better visualization which p value was 0.028.

Further regression analysis of some predictors of patients' comfort against the B group namely the number of Pap smear exams in the past, number of births, pain scores, pelvic exams in the past, estimated time the speculum exam lasted from participant feedback, if patient was asked to move her body for a better view or a special manoeuvre for better visualization from healthcare worker feedback were not statistically significant except for the healthcare worker feedback which a special manoeuvre for better visualization of the cervix from the healthcare worker feedback. *P* values was 0.049 and pain level which was 0.042.

The mean pain score for group A vs. group B was 2.89 ±1.97 vs. 3.83 ±2.73 (t=1.205; *p*=0.236). the median pain score [IQR] for group A vs. group B was 3.00 [1.00 – 3.50] vs. 3.00 [1.00 -6.00] (U=142.500; *p*=0.377). The analysis revealed slightly higher pain scores for the bouquet speculum, despite some women expressing more comfortability, this may be explained by the fear of a pelvic exam, fear of trying something new and having only one size (large) being available as compared to the bivalve which had a medium and large size available. Some of the women had undergone prior external beam and brachytherapy procedures which could increase the chances of pain during the pelvic exam procedure.

Statistical significance is just one aspect of evaluating research findings. Other aspects like the clinical significance, sample size, measurement reliability and validity, confounding variables, patient preferences, effect size, practical significance and clinical judgments are equally important in determining the benefits and implications of a study's results.[9] The patients' preference for the new type of speculum, that is the bouquet speculum, expressing more comfort is significant despite the pain scores noted.

According to van Teijlingen and Hundley V (2001) as cited by Luker A et al amongst reasons for publishing a pilot study include providing objective data when developing or testing adequacy of research instruments[10]. Having the bouquet speculum in a pilot study in Nigeria is important in understanding the Nigerian client/ patient characteristics, further understanding of ways to improve the cervical cancer screening process in our context and adequacy of the instrument (the bouquet speculum) for our client/patient populations, healthcare worker capacity and climate conditions.

These objective findings will enable recommendations for manufacturing modifications, proper patient selection and refinement of subsequent studies using this research instrument.

Ethical consideration: The study received ethical approval from the National Hospital Research Ethics Committee with approval number: NHA/EC/015/2024. All participants consented and signed consent forms prior to the procedure.

Limitation of the study: The study didn't include variables for women who had undergone external beam radiotherapy and brachytherapy returning for cervical cancer screening or vault smear screening, most had varying degrees of vaginal stenosis with some having complications which translated to more pain scores recorded. The study did not include images for comparison on cervix visualization. There was a small sample size and thus lack of generalizability to the general population.

Recommendations: Modification of the bouquet speculum to have a retaining feature and a set of three sizes e.g. big, medium and small sizes. Multi-center studies to enable a wider population testing with more patient selection into homogenous groups and more healthcare worker training on the use of the speculum.

Conclusion: The bouquet speculum is not inferior to the bivalve speculum in the client or patient comfortability, visualization of the cervix, vagina and lateral walls and fornices, with ease of application. More women reported been more comfortable with the bouquet speculum, this patient preference is significant despite the pain scores which were noted higher for the bouquet speculum group.

This research opens up the possibility of further studies in our low-and-middle income country LMIC context of scaling up cervical cancer screening activities with the improved bouquet speculum coupled with image acquisition of the different cervical lesions to be used in correlation with histological diagnosis using machine learning algorithms and utilizing artificial intelligence in cervical cancer screening.

Acknowledgement: Gratitude to our fellow healthcare workers, research assistants and statisticians.

Funding support: In the course of this study, we received complimentary bouquet speculums and locally sourced bivalve speculums from Viospex due to shortage of funds encountered for purchasing additional speculums. This support was essential in completing the study.

Conflict of interest: The bouquet speculums were provided free of charge by the Viospex company after the research team experienced a funding shortfall. While the company had no influence in the design, data collection, analysis or interpretation of the study, this support is disclosed to maintain transparency.

REFERENCES

1. Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, et al. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. CA Cancer J Clin [Internet].

2021 May 1 [cited 2022 Jan 22]; 71(3):209–49. Available from: https://onlinelibrary.wiley.com/doi/full/10.3322/caac.21660

2. Treatment NIFCR and. National Strategic Plan for Prevention and Control of Cancer of the Cervix in Nigeria 2023 -2027. 2023.
3. ICO/IARC Information Center on HPV and Cancer. Nigeria HPV Fact sheet [Internet]. 2023.Availablefrom:chromeextension://efaidnbmnnnibpcajpcglclefindmkaj/https://hpvcentre.net/statistics/reports/NGA_FS.pdf
4. Kelly Wong VL. The Vaginal speculum: a review of the literature focusing on speculum redesigns and improvements to the pelvic exam.Columbia Undergrad Res J. 2021; 5:1–14.
5. Choudhury J. MBACMQ. A New Vaginal Speculum and an Inexpensive Kit to screen and Treat Dysplasia and Cancer of the Cervix. J Women's Heal Care. 2019; 8(4):470.
6. J.Roe;Hanley.K.Z C. Updates in Cervical Cytology: The 90 year- Long Journey from Battle Creek to Today. Pathol Clin. 2018; 11(3):589–99.
7. Viospex. The Bouquet Speculum: A paradigm shift in cervical examinations [Internet]. 2023. Available from: https://www.linkedin.com/pulse/bouquet-speculum-paradigm-shift-cervical-examinations-viospex/
8. Chi-Hong Tseng DS. Sample size planning for pilot studies. J Title XX sagej.cls [Internet]. 2020;(X):1–15. Available from: sagepub.co.uk/journalsPermission.nav
9. Kobiru Otebele. Common Misconceptions About Statistical Significance. AWA 20th May 2024 https://awa-digital.com/blog/common-misconceptions-about-statistical-significance
10. Ronald Martin; Austin L; Luker K; Editorial: Pilot studies: to publish or not? J Clin Nurs. 2006;