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Title: Demonstration of Darkroom Technique: A novel approach

Ethical approvals: IEC: SMHRC/IEC/2023/04-60, CTRI/2024/01/061297
Regulatory approval: Received CDSCO test licence SW/MD/MD-13/2024/00000326





Introduction:

In order to eradicate cervical cancer by 2030, the WHO established a worldwide strategy. Achieving this goal requires effective cervical cancer screening modalities. In women with abnormal initial screening test results, a colposcopy examination is a crucial first step in diagnosis and treatment of pre-invasive lesions. For effective screen, triage, and treat approach, point-of-care techniques are imperative. We developed a portable smart-phone aided point of care colposcope (patented) with darkroom and modified technique of colposcopy (copyrighted) to enhance digital aided VIA and cancer screening programs.





Currently there are 2 methods of colposcopy

- Conventional method with standard colposcopy where images are captured at distance of 15-30 cm from the cusco speculum.
- Invasive method where a camera mounted on vaginal probe is used for capturing images at a distance of 2-3 cm.

We introduce a novel "Darkroom Technique of Colposcopy®", that utilises a specially created darkroom environment for performing colposcopy. To perform colposcopy a locally made hand held, smartphone-based software enabled point of care patented technology with a portable darkroom and inbuilt light source is used. Patient demographics, UID, complaints are entered in software enabled on smart phone, mounted on device, device is kept in close proximity of Cusco speculum and inbuilt light source is switched on and images of cervix captured as per routine colposcopy protocol.



Aim:

This study aims to demonstrate darkroom technique of colposcopy by newly developed portable colposcope and compare cervical images captured with conventional colposcope.

Objectives:

1. To compare image clarity and visibility of cervix by both methods. 2. To compare procedure time by both methods

Method:

A **low-cost portable indigenous digital colposcope** was designed and a prototype was developed. 148 women between 25 and 65 years, fulfilling the inclusion criteria who voluntarily consent enrolled for the study. Colposcopy was performed using a conventional colposcope and low-cost Portable Colposcope. 740 images (5 from each patient) were analysed subjectively by blinded observer. A subjective score was used on scale of 0 to 10 to compare images in terms of clarity of images, exposure / visibility of cervix, and white glare on cervix. Time required to perform procedure was also noted.

Results:

Image clarity	Score in group A (out of 10) (Indigenous portable colposcope)	Score in group B (out of 10) (Conventional colposcope)	
Minimum	8	6	
Maximum	10	9	
Mean	9.84	7.01	
Median	10.0	7.0	
Standard deviation	0.416	0.820	

Low-cost indigenous digital portable colposcope showed better image clarity than conventional colposcope with mean scores of 9.48 ± 0.416 and 7.01 ± 0.820 respectively.

Visibility of cervix	Score in group A (out of 10) (Indigenous portable colposcope)	Score in group B (out of 10)) (Conventional colposcope)	
Minimum	9.0	6	
Maximum	10	9	
Mean	9.14	7.66	
Median	9.0	8.0	
Standard deviation	0.66	0.96	

Low-cost indigenous digital portable colposcope ensured better visibility of the cervix than the conventional colposcope with a mean score of 9.14 ± 0.66 as compared to 7.66 ± 0.96 of the conventional colposcope.

	N	Mean	SD	Std. Error Mean
Procedure time: Group A (Indigenous portable colposcope)	148	6.00	1.16	0.10
Procedure time: Group B (Conventional colposcope)	148	9.04	1.03	0.08

Conclusion:

With these findings we conclude that our newly developed low-cost indigenous digital portable colposcope and modified darkroom technique of colposcopy is comparable with conventional colposcopes and has a potential to replace conventional colposcopes also enhance digital aided VIA / VILI in low resource settings to overcome burden of delayed disease diagnosis.

Validation Process :

ICMR approved validation studies initiated at Amrutha institute Kochi and Dr. Moopen's medical college Waynad

Objective Image Analysis:

Objective analysis of 8000 images is currently ongoing where we are using PSNR (Peak Signal-to-Noise Ratio) metric to measure the quality of an image by comparing it to a reference image. For this a special code was written and application developed.

Reference

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- Gallay C, Girardet A, Viviano M, Catarino R, Benski AC, Tran PL, et al. Cervical cancer screening in low-resource settings: a smartphone image application as an alternative to colposcopy. Int J Womens Health. 2017 Jun 22;