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RESEARCH ARTICLE
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TO COMPARE THE NEW SMART & HANDY DEVICE DEVELOPED WITH STANDARD COLPOSCOPY FOR PRECANCEROUS &CANCER CERVIX SCREENING

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Abstract

Introduction: It is estimated that cervical cancer will occur in approximately 1 in 53 Indian women during their lifetime. Several screening options are available. Patients with abnormal screening tests are evaluated by colposcopy. The existing Colposcope instrument for cancer cervix has an LED light source and it requires a power supply to display images captured and requires a separate monitor. It is may not portable in most centers. This needs to have a working distance of 300 mm. The New Smart and Handy device found to be easy to handle for cancer cervix screening and also cost-effective. The USB camera in the device of the present invention captures pictures and video from a distance of 3cm to 4cm with good quality and clarity.

Aim objectives of the research project: To compare the images of a standard Colposcope with those of images of a Smart and handy device to detect precancerous and cancer cervix.

Objectives of the research project:

1.To determine whether smart and handy device can be utilized in low-resource centers to detect cancer cervix
2.To determine whether the quality of images captured is comparable with standard Colposcope
3.To determine the sensitivity & specificity of the smart and handy device diagnosis with that of standard Colposcope

Methodology & Research design: After informed, after ethical clearance 154 Women attending the Gynaec outpatient department were screened for detection of precancerous and cancerous lesions of the cervix using a standard Colposcope and with a Smart& Handy device. Inclusion criteria were women for routine cancer cervix screening, women with abnormal Pap test, women with white discharge, and women with postcoital bleeding and exclusion criteria were women with cervical growth.

Results: Focus of the image at 91%, Sharpness of the image at 92% and zoom at 94% with a Smart & handy instrument and by colposcope Focus -at 94%, sharpness at 98% and Zoom at 100% In Smart & hand device evaluation done with Swede score without vessels Based on Aceto-white uptake, Margins, Lesion size, and Iodine uptake. Each was given two. score. Among -0 -3 score - 53.3%, 4-5 score -33.3%, 5-8 score - 13.3% In Colposcopy evaluation done with Swede score based on Aceto-white uptake, Margins, Lesion size, Iodine uptake,5. Vessels, Among 0-3 score -60% 4-7 score-

26.6 %.8-10score -13.4% Biopsy reports results in SMART AND HANDY DEVICE when score 0 -3 -Normal -72%, Score of 4-5 – LSIL - 15.8%, Score of 5-8- - HSIL-6.2% COLPOSCOPY biopsy results when score of 0-4 –Normal-78%, Score of 5-7 – LSIL- 14.8%, Score of 8-10-HSIL - 7.2%. The sensitivity, Specificity, Positive likelihood Ratio, and Negative Likelihood Ratio of Smart and hand Device are as follows 93.10%,90.32%,9.62, 0.08.
The sensitivity, Specificity, Positive likelihood Ratio, and Negative Likelihood Ratio of colposcopy are as follows 96.55 % 93.33%, 14.48, 0.04
Conclusion: SMART AND HANDY DEVICE gives high-quality images and video and an efficient method to store data. This can be incorporated into cervical screening methods in low-setting resources.

Keywords: Cancer cervical Screening, Low resources settings, Smart and handy devices, colposcopy

Need for the research: Need for the research:
In low-resource settings, where colposcopic facilities are not available at the community level, a simple low-cost, handy instrument is required
The existing **Colposcope** instrument for cancer cervix has LED light source and it requires a power supply to display images captured and requires a separate monitor. It is may not portable in most centers. This need to have a working distance of 300 mm.
Though various methods/devices are available in the state of art for detecting cervical abnormalities, still there is a need for a more accurate and affordable device for detecting and screening abnormalities in the cervix (6).
Smart and Handy device found to be easy to handle for cancer cervix screening and also cost-effective. The USB camera in the device of the present invention captures pictures from a distance of **3cm to 4cm with good quality and clarity**. Moreover, the **device is portable**, **provides good visualization of the cervix and is also user-friendly It can be used by paramedics, and images and video captured can be sent to specialists to give appropriate diagnosis and treatment.**

Components of the New instrument
1. **Cusco's speculum**
2. **USB LED camera –one end can be held near Cusco's**
3. **Other end of USB camera which can be attached to android phone**
4. **USB camera can capture an object 4 cm away, that is cervix with as much or even more clarity equal to a colposcopy**
5. **M Scope application can be downloaded from the play store of Android phone**
6. **M Scope Application - which records the image and video on the Mobile phone.**

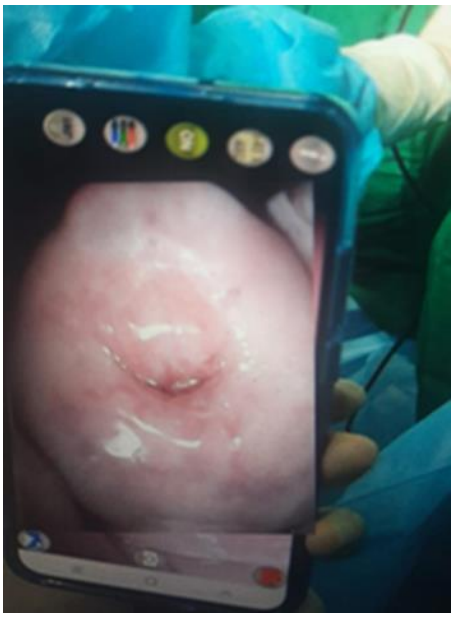

Fig -**Visualization of cervix with Smart & handy device**

Aim objectives of the research project: To compare the images of standard Colposcope with that of images of a Smart and handy device to detect precancerous and cancer cervix

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Methodology & Research design: After informed, after ethical clearance 154 Women attending the Gynaec outpatient department were screened for detection of precancerous and cancerous lesions of the cervix using a standard Colposcope and with a Smart& Handy device. After taking a detailed history and physical and Gynaec examination, a Pap smear was taken. VIA & VILL test was performed and images and video were captured both with the smart and handy device and with standard Colposcope. Findings will be documented Cervical Biopsy will be taken from the abnormal areas. Diagnostic accuracy of the Smart & Handy device and Colposcope will be calculated with Swede Scoring and agreement was compared between the two modalities. Findings will be documented. Cervical Biopsy will be taken from the abnormal areas. Image quality is assessed by the following criteria 1. Sharpness, 2 Focus on the cervix, 3. Zoom. The sensitivity and Specificity of the Smart & Handy device and Colposcope were calculated

Inclusion criteria: As Routine cancer cervix screening
Women with abnormal Pap Test
Women with white discharge
Women with postcoital bleeding

Exclusion criteria: Women with cervical growth

Sample size:

154 with a 95% confidence level and with margin error of 5%

$N+ Z^2 xp(1-p)/ e^2$

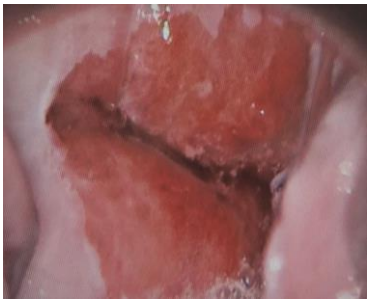
Sampling technique: Convenience Sampling
and statistical analyses –IBM **SPSS** software The sensitivity and specificity of Smart &Handy device and standard colposcopy will be calculated

Patients were recruited as per Inclusion Criteria

CERVIX GROSSLY INSPECTED

IMAGE CAPTURED WITH STANDARD COLPOSCOPE

IMAGE CAPTURED WITH SMART &HANDY DEVICE



VIA

IMAGE CAPTURED WITH STANDARD COLPOSCOPE

IMAGE CAPTURED WITH SMART & Handy Device

LUGOL'S IODINE APPLIED

IMAGE CAPTURED WITH STANDARD COLPOSCOPE

IMAGE CAPTURED WITH SMART & Handy Device

Results:
Table1 Shows - Focus of the image 91%, Sharpness of the image 92% and zoom at 94% with a Smart & handy instrument and by colposcope Focus -at 94%, sharpness at 98% and Zoom at 100%

Pie Diagram 1 - shows the comparison of the Swede Score
In Smart & hand device evaluation done with Swede score without vessels
1. Aceto-white uptake,2. Margins,3. Lesion size,4. Iodine uptake. Each was given 2 score

Among 0 -3 score - 53.3%, 4-5 score -33.3%, 5-8 score - 13.3%

In Colposcopy evaluation done with Swede score
1.. Aceto-white uptake,2. Margins,3. Lesion size,4. Iodine uptake,5. Vessels
Among 0-3 score -60% 4-7 score- 26.6 %.8-10score -13.4%
Pie Diagram 2 Shows a Comparison of the Biopsy Report

SMART AND HANDY DEVICE
When the score of 0 -3 -Normal -72%,
Score of 4-5 – LSIL - 15.8%,
Score of 5-8- - HSIL-6.2%

COLPOSCOPY
When the score of 0-4 –Normal-78%,
Score of 5-7 – LSIL- 14.8%
Score of 8-10-HSIL -7.2%

Table 5 Shows the Sensitivity, Specificity, Positive likelihood Ratio, and Negative Likelihood Ratio of Smart and hand Device as follows 93.10%,90.32%,9.62, 0.08

Table 6 shows the Sensitivity, Specificity, Positive likelihood Ratio, and Negative Likelihood Ratio of colposcopy as follows 96.55 % 93.33%, 14.48, 0.04

Limitations of the study: belong to a small group and will require a larger group of study

Discussion:
- Rashmi Bagga et al study(7) -The overall image clarity was either good or excellent at 82% .In the study, Overall focus is 91%, Sharpness 92%,zoom94%
- Meta-analysis by Emma R. Allanson et al (8)-Accuracy of Smartphone Images in 93% of cases to be appropriate quality photos with diagnostic utility. In the study sharpness 92% and zoom 94%
- Onsite digital images with a smartphone had a sensitivity of 66.7% (95%CI: 30.0-90.3) and a specificity of 85.7% in the Rosa Catarino study(9), In the study sensitivity and specificity were 93.10%,90.32%
- Systematic study conducted by Denise Champin et al (10) In five first studies, the sensitivity ranged between 66.7% (95% confidence interval (CI); 30.0–90.3%) and 94.1% (95% CI; 81.6–98.3%), and the specificity ranged between 24.0% (95% CI; 9.0–45.0%) and 85.7% (95% CI; 76.7–91.6%) In the study sensitivity and specificity were 93.10%,90.32%

Conclusion: This smart handy device for screening for cancer cervix can be utilized easily by paramedical staff in Primary health centers where more number patients will be benefitted. An easier method to save data. This application gives high-quality images and video and an efficient method to store data. This can be incorporated into cervical screening methods in low-setting resources

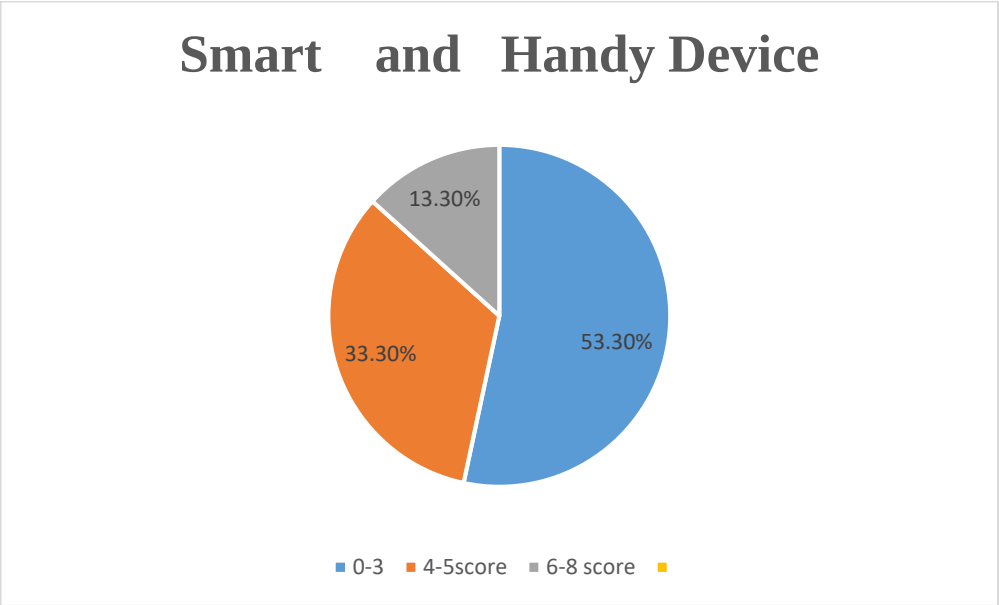
Future Works: Images & videos can be compared in the cloud with AI to improve diagnostic accuracy and reporting

Results:

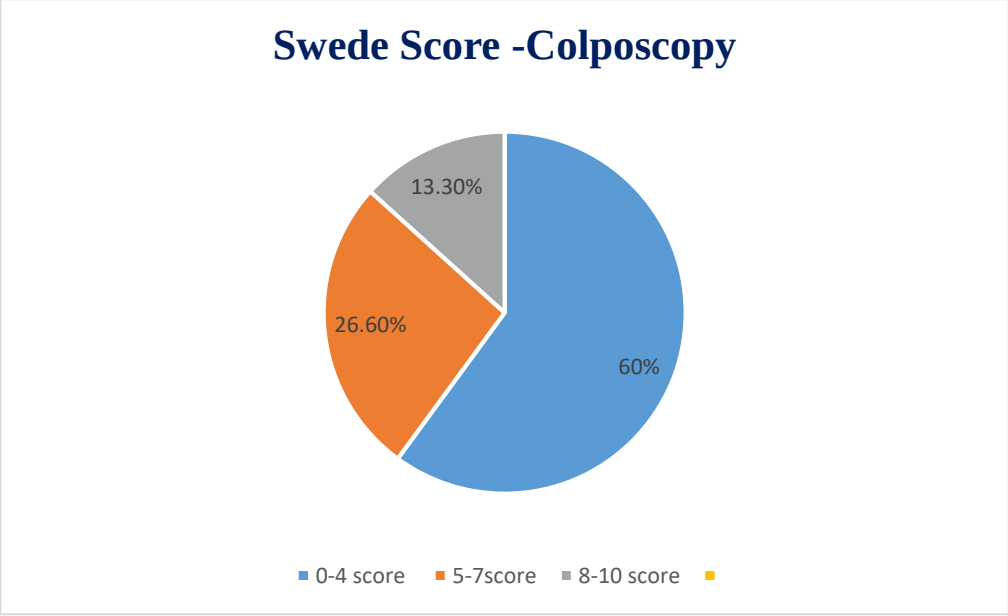
Table1. Analysis of Image

Standard colposcope	CRITERIA	Smart and handy device
94%	FOCUS	91%
98%	SHARPNESS	92%
100%	ZOOM	94%

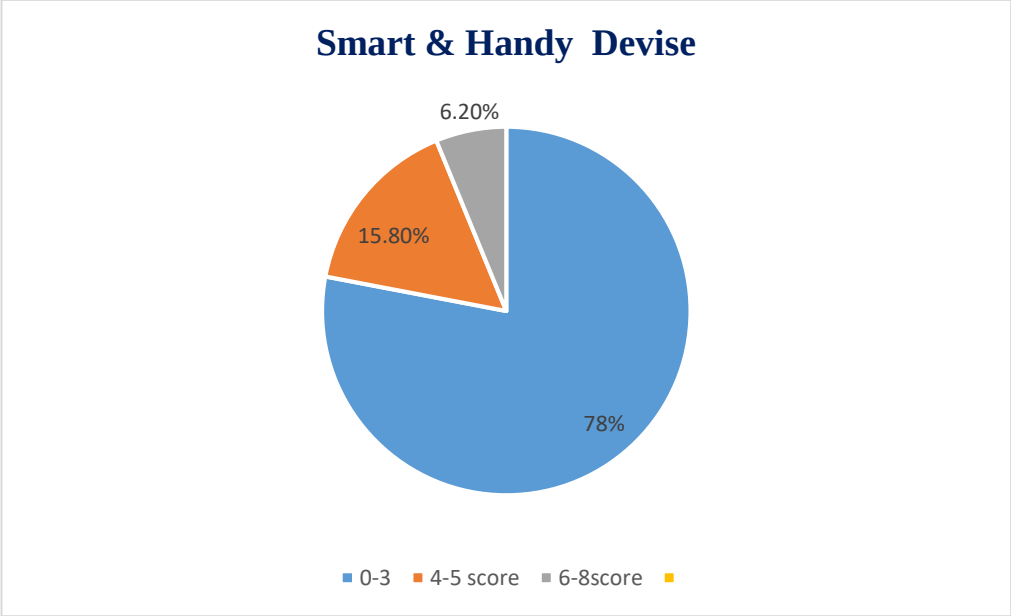
PIE diagram - Swede Score – Smart & Handy Device



PIE-diagram Swede Score-Colposcopy



PIE diagram – Biopsy report by Smart & Handy device based on Swede score



PIE diagram – Biopsy report by Colposcopy based on Swede score

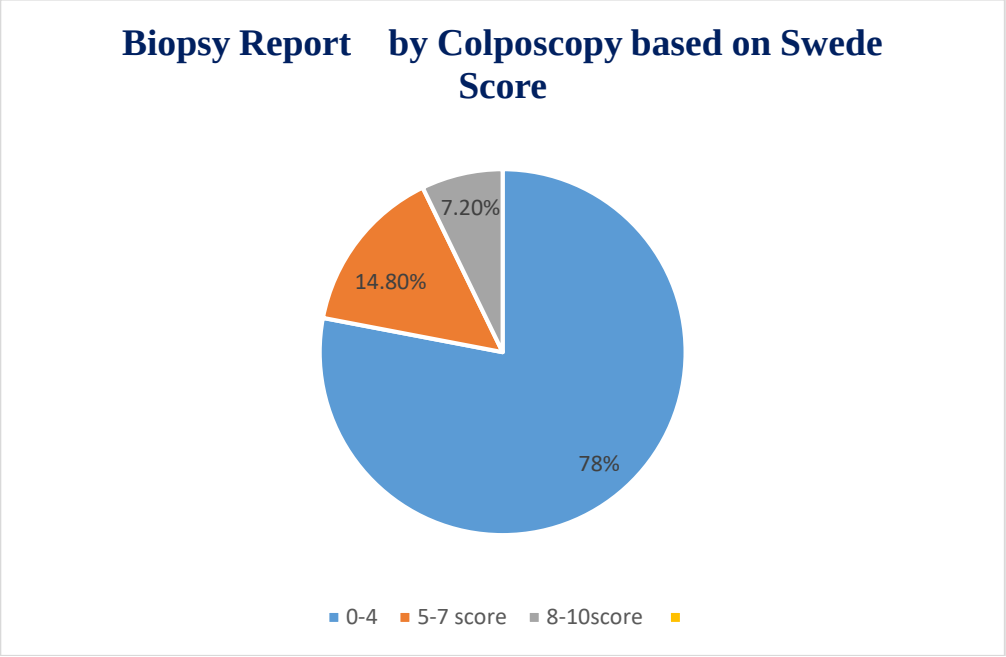


Table Shows Sensitivity & Specificity of Smart & hand device

Sensitivity	**93.10%**
Specificity	90.32%
Positive Likelihood Ratio	9.62
Negative Likelihood Ratio	0.08

Table Shows Sensitivity & Specificity of Colposcopy

Sensitivity	**96.55%**
Specificity	93.33%
Positive Likelihood Ratio	14.48
Negative Likelihood Ratio	0.04

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