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A COMPARATIVE STUDY ON THE ACCURACY OF PAPSMEAR,VISUAL INSPECTION WITH ACETIC ACID(VIA) AND VISUAL INSPECTION WITH LUGOL'S IODINE(VILI) VERSUS COLPOSCOPIC BIOPSY ALONE AND IN COMBINATION OF PAP SMEAR,VIA,VILI VERSUS COLPOSCOPIC BIOPSY IN DETECTING PREMALIGNANT AND MALIGNANT LESIONS OF CERVIX

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ABSTRACT

Background-. Cervical cancer is the fourth most frequent cancer in women worldwide.. Carcinoma Cervix is the most common cause of malignancy-related deaths among women in developing countries.[1,2]In 2022, GLOBACAN estimated 127,526 incident cases and 79,906 deaths[3] .Mortality due to cervical cancer is also an indicator of health inequalities, as 86% of all deaths due to cervical cancer are in developing, low- and middle-income countries. In developing countries like India, the burden of cervical cancer is still high. According to the World Cancer statistics, >80% of all the cervical cancer cases are found in developing and low-resource countries, because of a lack of awareness and difficulty in running cytology-based screening programs. Cervical cancer is a preventable disease due to the long preinvasive stage. Early detection and appropriate treatment are possible if robust screening is implemented.. **Objective-** 1. To assess the sensitivity and specificity of Pap smear versus colposcopic biopsy in detecting premalignant and malignant lesions of the cervix. 2. To compare the sensitivity and specificity of Visual Inspection with Acetic acid versus colposcopic biopsy in detecting premalignant and malignant lesions of the cervix. 3. To compare the sensitivity and specificity of Visual Inspection with Lugol's Iodine versus colposcopic biopsy in detecting premalignant and malignant lesions of the cervix. 4. To assess the sensitivity and specificity of a combination of Visual Inspection with Lugol's Iodine, Visual Inspection with Acetic acid, and Pap smear compared with colposcopic-guided biopsy. **Methods-** It is a cross sectional study conducted in Department of Obstetrics and Gynecology at Sri Siddhartha Medical College and Hospital, Tumkur.Total 400 cases (100 cases in each group)Cases fulfilling the inclusion criteria , the procedure was explained and written informed consent was taken and detailed history regarding the age, parity, occupation, socioeconomic status, duration of marriage, consanguinity of marriage, obstetric history, history of medical disorders, any history of malignancies in family were noted.Clinical examination and investigations like Per abdomen and per vaginal examination and per speculum examination were done. They were divided into 4 groups. Pap smear, Visual Inspection with Acetic acid and Lugo.l's iodine were done and colposcopy guided cervical biopsy was taken and screened at laboratory for the test results. **Pap Smear Test Collection :** Procedure was done according to standard protocol ,samples were taken and evaluated by Bethesda system. **Visual Inspection With Acetic Acid Sample Collection**: This procedure was done according to standard protocol. **Visual Inspection With Lugol's Iodine:** This procedure was also done according to standard protocol. All 3 combination of tests (PAP+VIA+VILI) were performed according to standard protocol, All the patients in the study were subjected to colposcopy , biopsy was taken based on Swede colposcopic index and sent for histopathological examination **Results-** There was a statistically significant increase in detecting cervical cancer with combined test when compared to individual test alone **Conclusion-** Cervical cancer is a preventable disease but there is no perfect screening test which has 100% sensitivity and good specificity.Quality Pap smear is good screening test as compared to VIA & VILI.However,VIA and VILI can replace Papsmear if there is nonavailability of cytology services and challenge to maintain good quality pap smear and also its reporting.The combination of all 3 tests can be used to improvise sensitivity and specificity,in those with suspected cervical pathology.

KEYWORDS

Pap smear, VIA, VILI

INTRODUCTION-

Cervical cancer is a major global health concern, ranking as the fourth most common cancer among women worldwide. According to the World Health Organization, nearly 90% of cervical cancer deaths occur in low- and middle-income countries, highlighting the disparity in access to effective screening and early intervention. Persistent infection with high-risk human papillomavirus (HPV) types is the primary cause of cervical cancer, making early detection of precancerous lesions critical for prevention. [1]

Screening for cervical cancer has significantly reduced its incidence and mortality in high-income countries, primarily due to the widespread implementation of effective screening programs. However, in resource-limited settings, the lack of infrastructure, trained personnel, and affordability often limits the availability of cytological methods such as the Pap smear. This underscores the need for alternative, cost-effective screening methods that can be easily integrated into healthcare systems. [2]

The Pap smear, developed by Dr. George Papanicolaou in the 1940s, has been the cornerstone of cervical cancer screening for decades. It involves the collection and cytological examination of exfoliated cervical cells to detect abnormalities. While it has proven effective in reducing cervical cancer rates in countries with well-established screening programs, its sensitivity can vary significantly, particularly in settings with limited resources and inconsistent follow-up care. [3]

In contrast, Visual Inspection with Acetic Acid (VIA) offers a simpler and more immediate method for detecting cervical abnormalities. Acetic acid, when applied to the cervix, highlights acetowhite changes in precancerous areas, allowing healthcare providers to identify suspicious lesions during the same visit. VIA is particularly advantageous in low-resource settings due to its low cost, non-reliance on laboratory infrastructure, and ability to provide immediate results. [4]

Visual Inspection with Lugol's Iodine (VILI) is another low-cost technique that involves applying iodine to the cervix. Healthy squamous epithelium absorbs iodine and appears dark brown, whereas abnormal areas do not absorb iodine and appear pale. VILI complements VIA and has been shown to have a high detection rate for cervical abnormalities, especially in conjunction with other screening methods. [5]

Colposcopy, a specialized diagnostic procedure, remains the gold standard for evaluating abnormal cervical findings. It involves magnified visualization of the cervix and targeted biopsy of suspicious areas. While highly accurate, colposcopy is resource-intensive and often inaccessible in many low- and middle-income countries. The comparison of simpler methods like VIA, VILI, and Pap smear with colposcopic biopsy can help determine their feasibility as alternatives or adjuncts in such settings. [6]

Combining multiple screening modalities, such as Pap smear, VIA, and VILI, has been proposed to increase the overall diagnostic accuracy of cervical cancer screening programs. Each method compensates for the limitations of others, potentially improving the sensitivity and specificity of screening efforts. Such combinations

could provide a cost-effective and practical approach to cervical cancer prevention, particularly in resource-limited regions. [7,8]

Several studies have explored the efficacy of individual screening methods, but comprehensive comparisons of their diagnostic accuracy—individually and in combination—are limited. Understanding the strengths and weaknesses of these methods is essential for optimizing screening strategies and allocating resources efficiently. [9] This study builds on existing knowledge by evaluating these screening techniques against colposcopic biopsy as the gold standard.

The burden of cervical cancer on healthcare systems, particularly in resource-limited regions, underscores the need for effective and accessible screening strategies. [10] By examining the diagnostic accuracy of VIA, VILI, and Pap smear, both individually and in combination, this research aims to identify practical solutions for early detection and prevention of cervical cancer. Such findings can inform healthcare policies and programs, contributing to the global effort to reduce cervical cancer incidence and mortality.

This study focuses on comparing the diagnostic accuracy of Visual Inspection with Acetic Acid (VIA), Visual Inspection with Lugol's Iodine (VILI), and Pap smear, both individually and in combination, against colposcopic biopsy. It aims to assess the sensitivity and specificity of these methods in detecting premalignant and malignant lesions of the cervix, offering valuable insights into their potential roles in cervical cancer screening programs.

MATERIALAND METHODS:

This cross-sectional study was conducted to evaluate and compare the diagnostic accuracy of Pap smear, VIA, and VILI in detecting premalignant and malignant cervical lesions. The research employed purposive sampling to select participants and focused on assessing these screening methods against the gold standard of colposcopic-guided biopsy. This design allowed a systematic evaluation of the methods, capturing data at a single point in time for each participant to ensure reliability and consistency in comparative outcomes.

The research was conducted over 12 months, from April 2023 to March 2024. This duration encompassed all phases of the study, including participant recruitment, clinical assessments, diagnostic procedures, laboratory analyses, and data collection. The extended timeline allowed for the inclusion of a sufficient number of participants to meet the calculated sample size and ensured robust data collection for meaningful statistical analysis. The sample size was determined using statistical calculations to ensure adequate power for detecting differences in diagnostic accuracy. A minimum of 400 participants (100 participants in each group) was included, based on the sensitivity rates of VIA, VILI, and Pap smear, with a 95% confidence level and 80% study power. This ensured statistically significant findings.

There Are 4 Groups (100 Participants In Each Group)

Group A: Comparision of pap smear versus colposcopic biopsy
Group B: Comparision of via versus colposcopic biopsy
Group C: Comparision of vili versus colposcopic biopsy
Group D: Comparision of pap smear +via+vili versus colposcopic biopsy

$$(P_1 - P_2)^2$$

$Z_{1-\alpha/2} = 1.96$ (Value of normal deviate at 95% level of confidence)

$Z_{1-\beta} = 0.842$ (Value of normal deviate at 80% power of study)

$P_1 = 94.7\%$ (Sensitivity of VIA + VILI)

$P_2 = 84.2\%$ (Sensitivity of PAP smear)

$P = \frac{P_1+P_2}{2}$

N=400

Objective-

1. To assess the sensitivity and specificity of Pap smear versus colposcopic biopsy in detecting premalignant and malignant lesions of the cervix.
2. To compare the sensitivity and specificity of Visual Inspection with Acetic acid versus colposcopic biopsy in detecting premalignant and malignant lesions of the cervix.
3. To compare the sensitivity and specificity of Visual Inspection with Lugol's Iodine versus colposcopic biopsy in detecting premalignant and malignant lesions of the cervix.
4. To assess the sensitivity and specificity of a combination of Visual Inspection with Lugol's Iodine, Visual Inspection with Acetic acid, and Pap smear compared with colposcopic-guided biopsy.

Inclusion Criteria's:

Women Aged 21–65 Years Presenting With:

- Postmenopausal bleeding
- Intermenstrual spotting
- Postcoital bleeding
- Persistent vaginal discharge
- Cervical erosion or ulceration
- Early sexual exposure or marriage
- Clinically unhealthy cervix
- Women who consented to participate.

Exclusion Criteria-

- Women with invasive cervical cancer.
- Pregnant women and those less than three months postpartum.
- Women who underwent hysterectomy.
- Patients with active vaginal bleeding or infection at the time of examination.
- Unmarried individuals.

RESULT-

1) Group A : Comparision Of Pap Smear Versus Colposcopic Biopsy:

A) Diagnostic Comparison – Pap Smear Versus Biopsy Findings

The table compares Pap smear results with colposcopic biopsy outcomes in 100 cases. Out of 41 biopsy-positive cases, Pap smear correctly identified 34 as positive while missing 7, suggesting a robust sensitivity in detecting cervical lesions. Conversely, among the 59 biopsy-negative cases, Pap smear resulted in 14 false positives and correctly identified 45 as negative. Overall, 48 cases were Pap smear positive and 52 negative, reflecting the method's moderate specificity. This data underlines the utility of Pap smear as an effective screening tool when compared to the biopsy gold standard, though the presence of false positives warrants consideration for supplemental diagnostic confirmation.

Table-1 Comparison Of PAP Smear And Biopsy Results

	Pap smear positive	Pap smear negative	Total
Biopsy positive	34	7	41
Biopsy Negative	14	45	59
Total	48	52	100

B) Diagnostic Performance Metrics – Pap Smear Diagnostic Accuracy

The diagnostic performance metrics for Pap smear indicate a robust screening tool. With a sensitivity of 82.93%, the Pap smear correctly identifies a significant majority of true positive cases, ensuring that most cases with cervical lesions are detected. Its specificity of 76.27% reflects a reliable ability to rule out non-disease, reducing false positives. The PPV of 70.83% and NPV of 86.54% further validate that positive and negative results are predictive of the true disease status. An overall accuracy of 79.00% underscores its effectiveness, while a p-value of 0.0000 confirms the strong statistical significance of its diagnostic correlation with biopsy results.

Table 2: Diagnostic Performance Metrics (PAP Smear)

Sensitivity (True Positive Rate)	**82.93%**
Specificity (True Negative Rate)	**76.27%**
Positive Predictive Value (PPV)	**70.83%**
Negative Predictive Value (NPV)	**86.54%**
Accuracy	**79.00%**
p-value (Chi-square test)	**0.0000**

2) Group B: Comparision Of Via Versus Colposcopic Biopsy

A) Diagnostic Comparison – Via Versus Biopsy Findings

The comparative data between VIA and colposcopic biopsy shows that of the 45 cases confirmed positive by biopsy, VIA detected 30 as positive and missed 15, categorizing them as negative. Among the 55 biopsy-negative cases, VIA incorrectly flagged 17 as positive while correctly identifying 38 as negative. Overall, there were 47 VIA-positive and 53 VIA-negative results out of 100 cases. This distribution highlights the moderate concordance between VIA and biopsy,

suggesting that while VIA detects a majority of true positives, its false-positive and false-negative rates indicate the potential benefit of employing additional diagnostic methods to enhance accuracy.

Table 3: Comparison Of Via And Biopsy Results

	VIA POSITIVE	VIA NEGATIVE	TOTAL
BIOPSY POSITIVE	30	15	45
BIOPSY NEGATIVE	17	38	55
TOTAL	47	53	100

B) Diagnostic Performance Metrics – Via Diagnostic Accuracy

The diagnostic performance metrics for VIA indicate that it has a sensitivity of 66.67%, meaning it correctly identified two-thirds of the true positive cases. Its specificity of 69.09% suggests a moderate ability to correctly recognize true negatives. The positive predictive value of 63.83% and negative predictive value of 71.70% reflect the probabilities that patients with positive and negative VIA results actually do or do not have the disease, respectively. An overall accuracy of 68.00% points to moderate diagnostic reliability. The p-value of 0.00077 from the Chi-square test confirms a statistically significant association between VIA findings and biopsy results.

Table 4: Diagnostic Performance Metrics

Sensitivity (True Positive Rate)	66.67%
Specificity (True Negative Rate)	69.09%
Positive Predictive Value (PPV)	63.83%
Negative Predictive Value (NPV)	71.70%
Accuracy	68.00%
p-value (Chi-square test)	0.00077

3) Group C: Comparision Of Vili Versus Colposcopic Biopsy

A) Diagnostic Comparison – Vili Versus Biopsy Findings

Among 44 biopsy-positive cases, VILI correctly identified 28 while missing 16, demonstrating moderate sensitivity. In the 56 biopsy-negative cases, VILI resulted in 24 false positives and correctly classified 32 as negative. Overall, VILI produced 52 positive and 48 negative results out of 100 cases. This distribution indicates that while VILI detects a substantial portion of true positives, its performance is constrained by both false positives and negatives. These findings highlight the necessity of supplementing VILI with additional diagnostic tests to enhance accuracy in detecting premalignant and malignant cervical lesions. Integrating VILI with adjunct modalities may reduce diagnostic errors.

Table 5: Comparison Of Vili And Biopsy Results

	VILI POSITIVE	VILI NEGATIVE	TOTAL
BIOPSY POSITIVE	28	16	44
BIOPSY NEGATIVE	24	32	56
TOTAL	52	48	100

B) Diagnostic Performance Metrics – Vili Diagnostic Accuracy

The diagnostic performance metrics for VILI indicate a moderate ability to identify and exclude disease. With a sensitivity of 63.64%, VILI correctly identifies nearly two-thirds of cases with cervical lesions, while a specificity of 57.14% shows a modest rate of correctly ruling out disease in negative cases. The positive predictive value of 53.85% means that slightly more than half of the positive test results are true positives, and the negative predictive value of 66.67% indicates that approximately two-thirds of negative results are accurate. Overall, an accuracy of 60.00% reflects moderate performance. The Chi-square test p-value of 0.0625 suggests that the association between VILI results and biopsy findings does not reach statistical significance.

Table 6: Diagnostic Performance Metrics

Sensitivity (True Positive Rate)	63.64%
Specificity (True Negative Rate)	57.14%
Positive Predictive Value (PPV)	53.85%
Negative Predictive Value (NPV)	66.67%
Accuracy	60.00%
p-value (Chi-square test)	0.0625

4) Group D: Comparision Of PAP Smear + VIA+VILI Versus Colposcopic Biopsy

A) Diagnostic Comparison – Combined PAP Smear, VIA, And Vili Versus Biopsy Findings

The combined screening approach of Pap smear, VIA, and VILI shows high concordance with colposcopic biopsy. Out of 50 biopsy-positive cases, 44 were correctly identified as positive by the combined test, resulting in an approximate sensitivity of 88%. In contrast, only 6 biopsy-positive cases were missed. Among the biopsy-negative group, 46 cases were correctly identified as negative, indicating a specificity of around 92%, with 4 false positives. Overall, the combined method achieves an accuracy close to 90%. These promising results underscore that integrating multiple screening modalities can significantly enhance the detection of premalignant and malignant cervical lesions.

Table 7: Combined Diagnostic Results (PAP Smear + VIA + VILI Versus Biopsy)

	(PAP SMEAR+VIA+ VILI) POSITIVE	(PAP SMEAR+ VIA+VILI) NEGATIVE	TOTAL
BIOPSY POSITIVE	44	6	50
BIOPSY NEGATIVE	4	46	50
TOTAL	48	52	100

B) Diagnostic Performance Metrics – Combined Screening Modalities (PAP SMEAR, VIA, VILI)

The combined screening approach, integrating Pap smear, VIA, and VILI, demonstrates impressive diagnostic performance. With a sensitivity of 88.00%, the combined test accurately identifies the majority of true positive cases, while its specificity of 92.00% confirms that most non-diseased cases are correctly excluded. The positive predictive value of 91.67% indicates a high probability that a positive result reflects actual disease, and the negative predictive value of 88.46% shows reliability in ruling out disease. Overall, the combined approach achieves an accuracy of 90.00%. The statistically significant p-value (0.0000) further supports the strong correlation between the combined test outcomes and biopsy results.

Table 8: Diagnostic Performance Metrics (COMBINED PAP SMEAR, VIA, VILI)

Sensitivity (True Positive Rate)	88.00%
Specificity (True Negative Rate)	92.00%
Positive Predictive Value (PPV)	91.67%
Negative Predictive Value (NPV)	88.46%
Accuracy	90.00%
p-value (Chi-square test)	0.0000

DISCUSSION-

The cytological evaluation via Pap smear yielded a sensitivity of 82.93%, specificity of 76.27%, PPV of 70.83%, NPV of 86.54%, and an overall accuracy of 79.00%, supported by a highly significant p-value of 0.0000. These strong performance metrics confirm the Pap smear's longstanding reputation as an effective screening tool in cervical cancer detection. However, earlier studies have reported variable performance. For instance, Dawood et al. (2015) [11] documented a sensitivity as low as 32% yet with an impressively high specificity of 98%, suggesting that while Pap smear can effectively exclude non-diseased cases, its sensitivity may be compromised in some settings due to factors like sample collection quality. HariPavithraReddy et al. (2015) [12] reinforced the reliability of Pap smear by noting high specificity (85%) and excellent negative predictive value. Bhattacharya et al. (2016) [13] observed a sensitivity of 86.66% and specificity of 75%, closely mirroring our findings, while Saleh et al. (2017) [14] reported a sensitivity of 78.57% and an outstanding specificity of 96.75%. Additionally, studies by Gandavaram et al. (2019) [15] and Najib et al. (2020) [16] have also shown that despite lower sensitivities, the high specificity of Pap smear remains a consistent strength. Our results, with high sensitivity and good specificity, underline the importance of Pap smear in early detection. Nonetheless, challenges remain in optimizing sensitivity to avoid false negatives, and these findings support integrating Pap smear with other modalities to achieve even higher diagnostic precision and improved clinical outcomes.

The Visual Inspection with Acetic Acid (VIA) screening results yielded a sensitivity of 66.67%, specificity of 69.09%, a positive predictive value (PPV) of 63.83%, a negative predictive value (NPV) of 71.70%, and an overall accuracy of 68.00%, with a highly significant p-value (0.00077). These findings indicate that while VIA can correctly identify a moderate number of true positive cases, its performance is hindered by relatively lower specificity, potentially

leading to false positives. Comparatively, Dawood et al. (2015) [11] reported a sensitivity of 89% and specificity of 95% for VIA under optimal conditions in a larger sample of 820 women, highlighting the significant impact of operator expertise and standardization protocols. Similarly, HariPavithraReddy et al. (2015) [12] found VIA sensitivity at 91%, further supporting the view that high performance is achievable with rigorous training. Bhattacharya et al. (2016) [13] documented an even higher sensitivity (96.15%) for VIA but observed a specificity of 62.5%, demonstrating that while detection rates can be high, ensuring correct exclusion of non-cases remains challenging. Saleh et al. (2017) [14] reported values of 91.3% sensitivity and 85.33% specificity, suggesting that improvements in technique could yield better results. In our study, the moderate metrics may be attributable to local factors such as differences in lesion prevalence or variations in technical execution. These results underscore the need for continued standardization and training to improve VIA performance, especially in low-resource settings where VIA remains a critical, cost-effective screening tool.

Visual Inspection with Lugol's Iodine (VILI) screening outcomes showed a sensitivity of 63.64%, specificity of 57.14%, PPV of 53.85%, NPV of 66.67%, and an overall accuracy of 60.00%, with a p-value of 0.0625. These moderate results indicate that VILI, as a standalone screening tool, may be less reliable, with its lower specificity particularly raising concerns about false-positive rates. In contrast, Dawood et al. (2015) [11] achieved a sensitivity and specificity of 95% each for VILI, suggesting that under highly controlled conditions, VILI can perform significantly better. HariPavithraReddy et al. (2015) [12] similarly noted that VILI's sensitivity is comparable to that of VIA, though our results indicate a potential gap in diagnostic performance. Bhattacharya et al. (2016) [13] observed a sensitivity of 89.65% for VILI, albeit with a low specificity of 40%, which aligns with the challenge of interpreting iodine uptake variations accurately. Furthermore, Saleh et al. (2017) [14] reported a sensitivity of 66.54% and a notably high specificity of 91.32%, highlighting that improved technique and training may yield more favorable outcomes than those observed in our study. The relatively lower sensitivity and specificity in our setting may reflect local operational challenges such as inconsistent iodine application, differences in interpretation, or subtle variations in lesion appearance. These findings suggest that while VILI is an attractive, low-cost screening option, its diagnostic accuracy may be enhanced through rigorous quality control measures and by considering its use in conjunction with other screening modalities rather than as a sole diagnostic tool.

The combined screening approach, achieved remarkable diagnostic performance with a sensitivity of 88.00%, specificity of 92.00%, PPV of 91.67%, NPV of 88.46%, and an overall accuracy of 90.00% ($p = 0.0000$). Such high values indicate that combining these screening tests leverages the unique strengths of each modality while counterbalancing their individual weaknesses. Pap smear's high specificity complements the high sensitivity of VIA and VILI, resulting in fewer false negatives and positives. Comparable findings have been reported by Bhattacharya et al. (2016) [13], who demonstrated that combining tests can substantially improve overall diagnostic accuracy. Saleh et al. (2017) [14] further corroborated these results by documenting enhanced detection rates when multiple screening methods were employed concurrently. Additionally, Christe et al. (2021) [18] noted that while VIA and VILI alone may yield high sensitivity, the inclusion of cytological evaluation significantly bolsters specificity. Lokhande et al. (2022) [19] also emphasized that a multi-modality approach not only improves accuracy but also reduces the need for subsequent confirmatory tests, thereby streamlining patient management. Mahezabeen et al. (2024) [20] provided further evidence, indicating that a combined approach can reach sensitivity and specificity close to 90%, making it highly effective in early detection programs. The superior performance of the combined screening method observed in our study suggests its potential for routine use, especially in low-resource settings where maximizing diagnostic accuracy is crucial. This multi-faceted strategy promises to enhance early detection, reduce overtreatment, and ultimately improve patient outcomes by ensuring timely and appropriate intervention.

CONCLUSION-

Cervical cancer is a preventable disease but there is no perfect screening test which has 100% sensitivity and good specificity.

Quality Pap smear is good screening test as compared to VIA & VILI.However,VIA and VILI can replace Papsmear if there is nonavailability of cytology services and challenge to maintain good quality pap smear and also its reporting.The combination of all 3 tests can be used to improvise sensitivity and specificity,in those with suspected cervical pathology.

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Conflicts Of Interest: None

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