Screening of suspicious cervix by Using Visual Inspection with Acetic acid (VIA) in Assiut Governorate: A Prospective Cohort Study

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Abstract: Objective: The objective of this study was to determine evaluate the sensitivity of the VIA test in early detection of cancer cervix & cervical punch biopsy and histopathology for suspicious cases and who guidelines for screening of suspicious cancer cervix. **Design** Prospective cohort study. **Setting:** Department of obstetrics and gynecology of Al-Azhar University Hospital (Assuit) Egypt. Patients and methods We performed a prospective cohort study on 500 women aged 20-65 years with different complaints including recurrent vaginal discharge, pelvic pain, contact bleeding, dyspareunia, back pain, vaginal spotting with no previous history of cervical cancer. **Main outcome.** VIA over other methods of screening include higher sensitivity, low costs, and immediate results. The availability of immediate results overcomes the problem of "loss to follow-up" that occurs in cytology-based programs. **Results:** VIA for 500 women were negative in 306 women (61.2%) and showed abnormal aceto-white appearance (positive) in 194 (38.8%) women. these positive via cases (the performance done on 150 cases that resulted no. of women with no malignant lesions: 90 & no. of women with different degrees of malignant lesions: 60). **Conclusions** the higher sensitivity of via in comparison to other methods of screening allows the detection of positive cases with decreased frequency of missed cases but, on the other hand, the false positive cases leads to increased the referral to histopathology in countries with low incidence of cancer cervix like our country, via is a good screening before the correct treatment can be instituted. It has a high sensitivity and specificity in detecting cervical neoplasia.

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Keywords: Screening of suspicious cervix, Visual Inspection with Acetic acid (VIA), punch biopsy, cervical histopathology.

1. Introduction

Cervical cancer is one of the leading causes of cancer-related deaths in developing countries worldwide, with incidence rates varying considerably from,528 000 new cases and more than with an about the reasons for this high incidence 250 000 deaths & are lack of valuable screening curriculums and poor organized resources [(1)], A lack of access to effective and affordable screening methods to detect and treat pre-invasive cervical intraepithelial neoplasia (CIN) contributes to higher invasive cancer rates in developing countries. [(2)] Cytology based programs have generally demonstrated acceptable sensitivity and specificity, but the infrastructure required to offer widespread screening and follow-up of abnormal smears is beyond the capability of many third-world countries cervical cancer is potentially preventable, and effective screening programs can lead to a significant reduction in the morbidity and mortality associated with this cancer in developing countries, are 80% of cervical cancers untreatable at the time of discovery due to non-effective screening done for early detection. [(3),] Presence of approach for effective screening programs is very important. [(4)], WHO guidelines in cancer cervixthis guideline provides recommendations for strategies for a screen-and-treatment programme of cancer cervix this guideline is intended primarily for choosing strategies for cervical cancer prevention, at country, regional and district levels. [(5)] the goal of these guidelines program is cancer and related mortality with relatively few adverse events the sequence of tests to reduce cervical cancer. common screening tests that are widely used include tests for human papillomavirus (HPV), cytology (pap test), and unaided visual inspection with acetic acid (VIA). the present study assessed the adequacy and predictive performance of visual inspection with acetic acid (VIA) and compared the specificity and sensitivity of via with that of the conventional cytology. cytology-based cervical cancer screening programs have not really worked well developing countries in reducing cervical cancer

incidence and mortality. [6]. The adequacy of VIA declined with age. However, the squamocolumnar junction was visible to the naked eye in the majority of women, indicating that they are good candidates for VIA [7].

Aim of the Work

The aim of this study is to evaluate the sensitivity of the VIA test in early detection of cancer cervix & Cervical punch biopsy and histopathology for suspicious cases and WHO guidelines for screening of suspicious cancer cervix.

2. Patients and methods

Patients

Design: prospective cohort study.

Setting: Department of obstetrics and gynecology of Al-Azhar University Hospital (Assuit) Egypt.

Study population. The study was conducted on 500 women within the age of 20-65 attending to outpatient clinic of Department of obstetrics and gynecology of Al-Azhar University Hospital (Assuit) Egypt. so the study was done on 500 women In the period from February 2018 - july 2018 the study is designed to evaluate the sensitivity of the VIA test in early detection of cancer cervix & cervical punch biopsy and histopathology for suspicious cases and who guidelines for screening of suspicious cancer cervix. The consent was taken from all patients.

Inclusion Criteria:

1-non-pregnant women aged 20-65 years. - intact uterus.

2- No past history of cervical neoplasm.

Calculation of the sample size is based on the prevalence of the disease or the number of the population at risk.

Exclusion criteria:

1- Pregnant women, women with active vaginal bleeding,

2- Anyone had undergone management for pre cancer or cancer of cervix. was taken after full information about the study and reassurance that the process was painless were given to all participant.

Methods:

All cases of study were subjected to:

1- Detailed history taking with emphasis on gynecological history

2- History of present condition of unfell inclusion and exclusion criteria

Medical history to fulfill inclusion and exclusion criteria

Full physical examination:

1. vital sign
2. General examination edemas kind is coloration
3. Local examination; by inserting an un lubricated bivalve vaginal speculum, with the help of side lamp (100 watt). pass the speculum comfortably and position it so that the cervix is fully visible in a plane perpendicular to the line of vision. followed by inspection of cervix by naked eye. Sterile piece of cotton with good emersion by aceto acetic acid 5% for 1 minutes and wait till detection of any color changes of suspected case VIA findings were recorded 1 minute after application of the acetic acid. After that, all women who with (abnormal smear, positive VIA & those with clinical indications) were examined by punchbiopsies were obtained from areas on the cervix that were assessed to be abnormal.

Results of VIA test application:

VIA-positive: mostly with one or more of the following features; A- Polyps. B- Ulcer. C- Aceto-white areas VIA-negative: mostly with one or more of the following features: A-Smooth, pink, uniform. B-Ectropion with no aceto-white change.

Statistical analysis Statistical analysis was performed by using Statistical analysis was performed using Statistical package for social science (SPSS) version 25,. Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

- Sensitivity: Probability that a test result will be positive when the disease is present (true positive rate).

- Specificity: Probability that a test result will be negative when the disease is not present (true negative rate).

3. Results

The clinical findings of the studied cases were summarized in table (1).

Age of examined women

20-30 years……182 (36.4%)

31-40 years…..213 (42.6%)

41-50 years….71 (14.2%)

> 50 years……34 (6.8%)

Number of parity of examined women:

0-3……105 (21%)

4-6……...346 (69.2%)

> 6……..49 (9.8%)

Duration of marriage in years of examined women:

< 10 years……...160 (32.0%)

11-20 years…….234 (46.6%)

20-30 years…..82 (16.4%)

> 30 years……24 (4.8%)

Occupation of examined women:

Unemployed…..424 (84.8%)
Employed…….76 (15.2%)
Education of examined women:
Illiterate……111 (22.2%)
Read and write….119 (23.8%) intermediate education…....221(44.2%)
Higher education…….49(9.8%)
Residence of examined women:
Rural…….364(72.8%)
Urban……136(27.2%)

In our study most of our patients were in age of 31-40 years…..213 (42.6%) of all cases, most of them with parity number 4-6……..346 (69.2%), the duration of marriage affect the result of our study, most of our pts. with in11-20 years…….234 (46.6%), unemployed…..424 (84.8%) intermediate education…....221(44.2%), rural…….364(72.8%).

Table (1): All parameters distribution of the study group.

	N (%)
Age Groups	**N (%)**
20-30 YEARS	182 (36.4)
31-40 YEARS	213 (42.6)
41-50 YEARS	71 (14.2)
> 50 YEARS	34 (6.8)
Parity	**N (%)**
0-3	105 (21)
4-6	346 (69.2)
> 6	49 (9.8)
Duration Of Marriage, Year	**N (%)**
< 10 YEARS	160 (32.0)
11-20 YEARS	234 (46.6)
20-30 YEARS	82 (16.4)
> 30 YEARS	24 (4.8)
Occupation	**N (%)**
Unemployed	424 (84.8)
Employed	76 (15.2)
Education	**N (%)**
Illiterate	111 (22.2)
Read And Write	119 (23.8)
Intermediate Education	221(44.2)
Higher Education	49(9.8)
Residence	**N (%)**
Rural	364(72.8)
Urban	136(27.2)

Data are expressed as mean ± standard deviation (SD) and frequency (%).

This table shows: patients characteristics of 500 examined pts. in our study most of our patients were in age of 31-40 years…..213 (42.6%) of all cases, most of them with parity number 4-6……..346 (69.2%), the duration of marriage affect the result of our study, most of our pts. with in11-20 years…….234 (46.6%), unemployed…..424 (84.8%) intermediate education…....221(44.2%), rural…….364(72.8%).

Table 2 Shows: The Percentage Of Positive & Negative Results Of Via Test In 500 Women That shows positive results in 194 women of all pts. & And Negative in 306 women.

Table (2): Results Of Via In 500 Women

Results	No. Of Cases	No. (%)
Negative	306	(61.2%)
Positive	194	(38.8%)
Total	500	500 (100%)

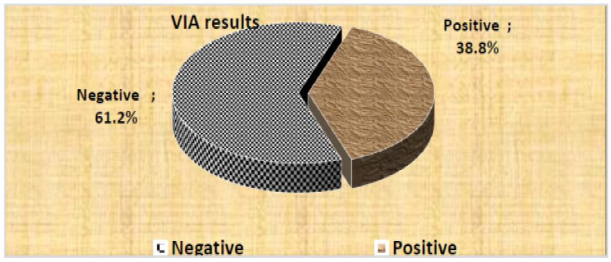

Figure (1): Results Of VIA In 500 Women

Table (9): Results Of Histopathological Examination In 150 Women

Histopathological Diagnosis	No.	(%)
Inflammation (Cervicitis)	90	(60%)
LSIL	36	28.5%)
HSIL	16	(5.5%)
Malignant	8	(6%)
TOTAL	150	(100%)

HSIL = high-grade squamous intraepithelial lesion. LSIL = low-grade squamous intraepithelial lesion.

Table shows: Results of histopathological examination in 150 women, cervicitis of 60% of cases & different degrees of cancer of 40 % of cases.

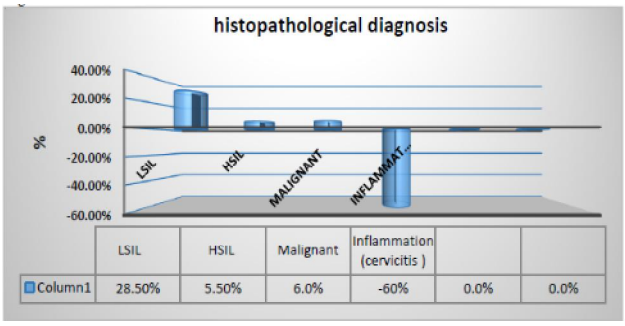

Figure (2): Results Of Histopathological Examination In 150 Women.

Diagnostic performance of VIA test

The VIA test is done 500 pt., positive results were 194 cases, only we can deal with 150 pts. of those of positive via for their cooperation till ending of histopathological examination: that resulted the following: 90 women with no malignant lesions & 60 women with different degrees of malignant lesions.

Table (3): diagnostic performance of VIA test

Performance Of VIA Test	No. In 150 Cases	NO. (%)
No. Of True Positive	51	(34%)
No. Of False Positive	8	(5.3%)
No. Of True Negative	82	(54.6%)
No. Of False Negative	9	(6%)
Sensitivity	95.3%	
Specificity	97.5%	
Positive Predictive Value	53%	
Negative Predictive Value	99.8%	
ACCURACY	97.5%	

Total no. of women: 150no. of women with no malignant lesions: 90.

No. of women with different degrees of malignant lesions: 60.

Table shows: the end results of performance of VIA test after examination of 150 positive VIA cases by histopathology as regards the sensitivity, PPV, NPV and accuracy of VIA test. test was statistically accuracy, 97.5%.

Table (4): Sensitivity and specificity of visual inspection with acetic acid in selected cross-sectional studies

Author, year of publication, country of study	No. of participant	Sensitivity %	Specificity %
Denny et al., 2000, South Africa	2944	67	84
Belinson et al., 2001, China	1997	71	74
Denny et al., 2002, South Africa	2754	70	79
El-Shalakany et al., 2004, Egypt	2049	85	96.8
Abd-Elhady et al., 2006, Egypt	5000	97	94
Our study 2019, Egypt	500	95.3%	97.5%

Table shows: the end results of different cross-sectional studies for comparison of sensitivity and specificity of visual inspection with acetic acid in different countries & cities that detected in our study with (sensitivity 95.3%, specificity 97.5%%, positive predictive value53%).

4. Discussion

Women with different complaints including recurrent vaginal discharge, pelvic pain, contact bleeding, dyspareunia, back pain, vaginal spotting were found to have an increased risk of cervical cancer. This study was conducted at the Department of Obstetrics and gynecology, Faculty of Medicine – Al-Azhar University, Assiut, Egypt, between from February 2018 till July 2018. During the study period the outflow of suspected cases at the department was 37%. All women with were asked to participate by me or my college when conducting the VIA test examination Thus, 500 women constituted the study group.

A power calculation was completed, presuming an incidence of positive VIA test. By Cervical visual inspection after acetic acid application (VIA) for all women in the study, In order to assess the validity of VIA as a screening test, statistical analysis of performance was done Results of VIA were negative in 306 women (61.2%) and showed abnormal aceto-white appearance (positive) in 194 (38.8%) women.

The performance of VIA test done after comparison of results of positive VIA to the results of Cervical histopathological analysis of these positive VIA cases (the performance done on 150 cases that resulted:

-Women with no malignant lesions 90 cases-Number of women with different degrees of

malignant lesions: 60 cases VIA detected premalignant lesions & different degrees of malignant lesions With (sensitivity 95.3%, specificity 97.5%, positive predictive value53%). Cervical cytological histopathological analysis in 150 women with positive VIA test identified 60 cases of different degrees of malignancy.

We compare our study to others to assess the effect of surrounding factors & geographical distribution effects on the end results of the efficacy of VIA test as the following:

Conducted a cross-sectional prospective pilot study enrolling 100 asymptomatic women, to assess the risk factors of cervical cancer and the feasibility and acceptability of a visual inspection with acetic acid (VIA) screening method in a primary health center in Khartoum, Sudan. Women with a positive test were referred for colposcopy and treatment. The authors concluded that women who have uterine cervix laceration, assisted vaginal delivery, female genital mutilation, or episiotomy are at an increased risk of cervical cancer. It also showed that VIA is a feasible and acceptable cervical cancer screening method in a primary health care setting that resulted in a sensitivity of 92.0% and a specificity of 79.9% [(8)].This study similar to our one but different number of examined women comparison to our study cases number.

This was a population-based sample of 5603 women were invited to participate in a study comparing Pap cytology, VIA, and HPV DNA screening for the detection of CIN3. Participation in primary screening and all subsequent follow-up visits was rigorously tracked. A 20% random sample of all women screened, in addition to all women with a positive screening test result underwent colposcopy with directed biopsy for final diagnosis. Sensitivity, specificity, positive and negative predictive values were adjusted for verification bias. HPV testing had a higher sensitivity (100%) and specificity (90.6%) compared to Pap cytology (sensitivity = 78.2%; specificity = 86.0%) and VIA (sensitivity = 31.6%; specificity = 87.5%). Since 58% of the sample refused involvement and another 28% refused Biopsy, we estimated that potentially 87.6% of the total underlying cases of CIN3 and cancer may have been missed due to program failures. [(9)]This study used Pap cytology, VIA, and HPV DNA screening for the detection of CIN3. so its different results and accuracy as our examined women used VIA only & and different examined number of cases & different geographical distribution of this study and its subspecialty in detection of CIN3 in comparison to our one as a general methods for detection of different degrees of cervical cancer.

Conducted a study in Mongolia to assess the test parameters of VIA as a screening method for cervical lesions in comparison to cervical cytology in which 2009 women were enrolled. Women with abnormal test results and 5% of women with normal results were recommended to have colposcopy. The sensitivity of VIA was 82.9 % versus 88.6% for Pap smear, VIA specificity was 88.6 % versus 98.5% for Pap smear, PPV for VIA was 12.2% versus 51.7% for Pap smear and NPV for VIA was 99.7% versus 99.8% for Pap smear. The authors concluded that VIA has an acceptable test parameters for population-based cervical screening in Mongolia [(10.)]This study used (VIA),), cytology (Pap smear) testing so its different results and accuracy as our examined women used VIA only & and different examined number of cases & different geographical distribution of this study in comparison to our one.

Conclusion

In developing countries like ours, adequate coverage of the entire female population by cytology-based screening programs is not at present feasible. also, women are often not compliant regarding follow-up visits. in such a situation, via is a suitable primary screening alternative for a large population. the advantages of via over other methods of screening include higher sensitivity, low costs, and immediate results. the availability of immediate results overcomes the problem of "loss to follow-up" that occurs in cytology-based programs. the higher sensitivity of VIA in comparison to other methods of screening allows the detection of positive cases with decreased frequency of missed cases but, on the other hand, the false positive cases leads to increase the referral to histopathology in countries with low incidence of cancer cervix like our country, via is a good screening before the correct treatment can be instituted. visual inspection by via has been suggested as a possible alternative method for cervical cancer control. it has a high sensitivity and specificity in detecting cervical neoplasia. also has the advantage of its low cost and ease of use, its immediate results.

Recommendations

First of all Cervical cancer is potentially preventable, and effective screening programs can lead to a significant reduction in the morbidity and mortality associated with this cancer in developing countries, are High percentage of cervical cancers untreatable at the time of discovery due to non-effective screening done for early detection prevention of cervical cancer through screening and treatment of precancerous lesions of the cervix is associated with

an overall reduction of morbidity and mortality due to cancer of cervix programs is very important Adopting a screening program for early detection of cancer cervix requires the following items:

(1) Give the people simplified knowledge about cancer cervix via personal or mass approach.

(2) Motivate the people to participate in community health services.

(3) Change faulty health believes into favorable ones.

(4) The screening test used for early detection should be rapid, harmless, non-invasive, inexpensive and can be after appropriate training courses. thus via is the ideal test for screening.

(5) Screening should begin at the level of MCH (medical center health) centers as large number of women attending them, with referral of positive cases to tertiary health care centers like university hospital for triage test as colposcopy with directed biopsy when indicated.

(6) The age group of special concern are women between 20-50 years, to pick up cases of CIN.

(7) Establishment of cancer early detection in Al-Azhar university hospital (Assuit) Egypt with team of gynecologists, pathologists and laboratory technicians with notification of the health authorities at Assuit governorate.

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