

THE ROLE OF COLPOSCOPY IN THE DIAGNOSIS OF CERVICAL PATHOLOGY

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ABSTRACT:

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Background: Colposcopy-directed biopsy is considered the definitive test for diagnosing cervical cancer (CC) as it reveals the architectural arrangements of abnormal cells. The majority of females developing cervical cancer have reported not being screened for 5 years at least.

Aim: To investigate the role of Colposcopy in early detection and diagnosis of pre-cancerous lesions with or without viral infection compared with Pap smear.

Patients and methods: The current study was designed as cross-sectional study that included 90 females who attended the Early Detection of Cancer Unit of Al-Zahra'a University Hospital between the start of March 2020 and the end of December 2021. Colposcopy and Pap smears were performed upon the detection of abnormally stained areas after the cervix has been stained with acetic acid (VIA) and lugol's iodine (VILI), multiple cervical biopsies were obtained from the suspicious areas.

Results: Our study revealed that Abnormal Colposcopy is 99.6% sensitive and 33.3% specific with positive predictive values 42.8% and negative predictive values of 1.2.

Conclusions: Colposcopy has high accuracy in detecting cervical pre-malignant lesions than Pap smear. The use of colposcopy directed biopsy is recommended in screening for malignant and premalignant lesions of the cervix.

Key word : cervical cancer, CIN, pap smear. Colposcope, punch biopsy.

INTRODUCTION:

Cervical cancer is one of the greatest threats to women's health. It is estimated that a woman dies of cervical cancer every two minutes⁽¹⁾. Cervical cancer is also reported as her fourth most common malignancy in women worldwide. Moreover, this cancer kills hundreds of thousands of women in developing countries each year⁽²⁾. An estimated 500,000 new cases of cervical cancer and 311,000 deaths are reported each year⁽³⁾.

Cervical cancer is more common in women in developing countries. In other

words, these countries account for 84% of the global cervical cancer burden and 80% of mortality due to lack of adequate screening protocols. The world's poorest countries are even more severely affected, with an incidence rate of over 35 per 100,000 women compared to 3 per 100,000 women or less in Europe and North America⁽⁴⁾.

The disease progresses slowly and can take years, approximately 1.4 million women worldwide live with her CC, and two to five times as many, up to 7 million, need treatment. You may have the necessary pre-cancerous conditions. as early as possible⁽⁵⁾.

Papanicolaou (Pap) smear is an essential tool for the prevention of invasive cervical cancer. However, this is limited by inadequate specimens when the specimen lacks an endocervical component⁽⁶⁾. If the swab does not contain endocervical cells, the cytopathologist must request a resample, which is unsatisfactory for the patient and their healthcare provider and increases healthcare costs. This swab inadequacy may be due to poor sampling technique or the use of inefficient sampling equipment⁽⁷⁾.

Colposcopy is a test used to evaluate patients who have an abnormal cervical cytology swab (VIA or VILI) and an abnormal cervical appearance. This involves examining the cervix for acetic acid using a field microscope and using Lugol's iodine to temporarily stain the cervix⁽⁸⁾.

AIM OF THE WORK:

To study the diagnostic role of Colposcopy versus Pap smear in early detection of precancerous lesion with or without viral infection.

PATIENTS AND METHODS:

A cross-sectional study was performed on 90 females who attended the Early Detection of Cancer Unit of Al-Zahra's University Hospital in the period from the start of March 2020 to the end of December 2021.

Inclusion criteria:

All subjects meeting the following criteria

Patient aged from 20 to 70 years with intact uterus

Exclusion criteria:

Patient diagnosed as cervical, uterine, or ovarian cancer, any patient with cervical surgery or pregnant patient

Sample Size: 90

This number of cases was adopted by using Medcalc 19 program, by setting alpha error of 5%, 95% confidence level and 80% power sample. The sample size for this study calculated from prevalence of positive and negative cases (20, 80 respectively) by Colposcopy according to Sørbye et al (2017).

Sample size calculation:

Sample size is calculated according to the following formula:

The sample size was calculated by the following formula:

Positive cases:

$$N_+ = \frac{(z_\alpha \sqrt{V(\theta_0)} + z_\beta \sqrt{V(\theta_1)})^2}{(\theta_1 - \theta_0)^2}$$

(Machin D et al.; 2009)

Ethical statements:

1- Approval of ethical committee No (2021121137) was obtained from Quality Education Assurance Unit, Al-Azhar University Faculty of Medicine, Egypt.

2- All participating females underwent a detailed patient interview in which thorough history was obtained (i.e., personal menstrual, past and family history) in addition to a thorough general and abdominal examination. Local examination of the vulva vagina and cervix was also performed to determine any associated pathology.

3- Colposcopy: Preparation of the patient by treatment of any associated infection and instruction was given to the patient to avoid vaginal washing and intercourse 48hrs before Colposcopy.

The patient lied in the lithotomy position, good inspection for the vulva and perineum and detection of any abnormal areas. Cusco speculum was applied to explore the vagina and cervix. The cervix was washed with saline to remove the mucous, a general look was done to check for any growth pathology, Pap smear was done then the acetic acid 3%

was used to stain the cervix, then it was stained with lugol's iodine.

In participants with abnormal Colposcopic findings like acetowhite changes, coarse punctation, and mosaic or atypical vessels, directed biopsy was obtained; 2–3 biopsies from the observed acetowhite lesions were obtained, fixed using 10% neutral buffered formalin. Then, biopsies were taken to the pathology lab for histological examination. Histologically, cervical lesions were categorized as: normal, CIN1, CIN2, CIN3, and cervical carcinoma.

The Pap smear slides were checked by an experienced pathologist for the presence of cervical cells, and the results of this check were then reported via the 2014 Bethesda System. The final histopathological diagnoses were made based on the highest grade of the lesion observed in biopsy or in the Pap smear results.

Statistical analysis: after data collection, the collected data was coded and inserted into the Statistical Package for Social Science (IBM SPSS) v.20 mean, standard deviations and ranges were used to express quantitative data when their distribution found parametric, while median with inter-quartile range (IQR) were used when the distribution was found non-parametric. In addition, qualitative variables were expressed as numbers and percentage.

Chi-square test was conducted to compare groups regarding qualitative data.

Spearman correlation coefficients were used for assessing the relation between two quantitative parameters within the same group. The confidence interval (CI) value was preset to 95% and the accepted margin of error (MOE) was set to 5%. thus, p-value was considered significant as follow:

P-value>0.05: Non-significant (NS)

P-value<0.05: Significant (S)

P-value<0.01: Highly significant (HS)

Mean= is the calculated average (central) of a set of values: for calculating the mean: divide the sum of all values by the number of values you have.

Standard deviation= represents how spread-out values are. Its symbol is σ (the Greek letter sigma). It is calculated by obtaining the square root of the Variance.

Correlation coefficient= the degree to which change in the value of one variable predicts change in another variable's value. In variables that are positively correlated, the increase or decrease of values occurs in tandem.

The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of Pap smear and colposcopy were calculated according to each smear's pathology report. Receiver-operating characteristics (ROC) curve was plotted and areas under the curves (AUC) were estimated.

RESULTS:

A cross-sectional study was conducted on 90 female participants who attended the Early Detection of Cancer Unit of Al-Zahra's University Hospital in the time between the start of March 2020 to the end of December 2021. Pap smear and cervical biopsies results were assessed, in totally 90 women 60 patients (66.6%) demonstrated normal findings (normal Pap smear) and 30 patients (33.3%) showed atypical results (abnormal Pap smear).

After Pap smear and cervical biopsies results this patient was subdivided into 2 groups:

Patient group (no= 30) (with abnormal Pap smear results)

Control group (no= 60) (with normal Pap smear results)

Table (1): Demographic data of the studied groups

	Patient Group (I) (n=30)	Control Group (II) (n=60)	Paired t-test.		
	Mean ± SD	Mean ± SD	T	P-value	Sig
Age (yr)	42.55±7.384	42.65±7.487	0.747	0.491	NS
Age of marriage (yr)	20.45±3.504	20.43±3.501	0.198	0.844	NS
Duration of marriage (yr)	21.65±8.147	20.16±8.134	0.862	0.553	NS
Parity	4.21±2.382	4.23±2.382	- 0.941	0.357	NS

N=non-significant, S=significant, HS=highly significant

According to table (1) there is no significant difference between the two studied groups as regard to demographic data (i.e., age, age of marriage, duration of marriage and parity).

Table (2): Comparison between both groups as regard to contraception

Contraception	Patient Group (I) (n=30)		Control Group (II) (n=60)		Paired t test.		
	N	%	N	%	t	P value	Sig
O.C. P	3	10%	6	12%	0.918	0.862	NS
Injectable	2	6.6%	6	12%	0.662	0.436	NS
IUD	4	13.4%	6	12%	- 0.231	0.357	NS
No	21	70%	42	64%	4.437	0.000	HS

This table shows the comparison between both studied groups and contraception which reveals highly statistically significance difference between both groups as regard to negative use of contraception.

Table (3): Distribution of Patient group I as regard method of contraception and the Pap results

Contraception	The pap						Total	
	CINI		CINII		LGSIL			
	N	%	N	%	N	%	N	%
Injection	1	3.3%	1	3.3%	2	6.6%	4	13.3%
O.C. P	1	3.3%	0	0.00%	4	13.3%	5	16.6%
IUD	1	3.3%	0	0.00%	3	10%	4	13.3%
No	2	6.6%	1	3.3%	14	46.6%	17	56.7%
Total	5	16.7%	2	6.6%	23	76.7%	30	100%

13.3% of our patients group using injectable contraception and 16.6% using oral Contraceptive pills while 56.7% of our patient group not using any method of contraception.

Table (4): Comparison between both groups as regard to complaints

Parameter	Patient Group (I) (n=30)		Control Group (II) (n=60)		Paired t test.		
	N	%	N	%	T	P value	Sig
Complain							
Contact Bleeding	26	80%	49	81.7%	4.797	0.000	HS
Recurrent Infection	4	20 %	9	15 %	0.198	0.844	NS
Infection +bleeding	-	-	2	3.3%	1	-	NS

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This table states the highly statistically significance difference between both groups as regard to contact bleeding. 80% of our patients group complain from contact bleeding while 20% of patients group complain of recurrent infection.

Table (5): Correlation coefficient "r" between complaints and the Pap smear results in patient group I

Parameter	The pap						"r"	P
	CINI		CINII		LGSIL			
Complaint	N	%	N	%	N	%	0.213	> 0.05
Contact Bleeding	2	6.6%	2	6.6%	20	66.7%		
Recurrent infection	3	10%	0	0.0%	3	10%		
Total	5	16.6%	2	6.6%	23	76.6%		

The patient with past history of contact bleeding had an abnormal pathology result about 80%. While the patients with past history of recurrent infection have an abnormal pathology result in about 20%.

Table (6): Comparison between both groups as regard to positive koilocytosis and virus infection

Viral infection and Positive koilocytosis	Patient Group (I) (n=30)		Control Group (II) (n=60)		Paired t test.	
	N	%	N	%	P-value	Sig
Yes	25	83.3%	6	10%	0.000	HS
No	5	16.6%	54	90%	0.000	HS

This table shows 83.3% have positive koilocytosis and human papilloma virus infection in the patient group with abnormal cytology while only 10% in the control group has positive koilocytosis. Also, there is highly statistical significance between both studied groups in terms of positive koilocytosis and viral infection.

Table (7): Accuracy of Colposcopy steps

Colposcopic steps	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (PPV) (95% CI)	Negative predictive value (NPV) (95% CI)	Youden index
Aceto-white areas (VIA)	66.7% (64.0 -69.8 %)	76.7% (74.4 -79.3 %)	50% (48.5 -55.3 %)	80% (77.2 -83.8 %)	0.01
Positive Lugol's iodine areas (VILI)	99.3% (98.0 -100 %)	16.7% (13.6 -19.5 %)	75% (72.4 -78.3 %)	1.2% (1.0 -4.2 %)	0.01
Abnormal vessels	33.3% (30.6 -36.2 %)	91.2% (90.7 -94.5 %)	66.7% (63.4 -70.3 %)	73.4% (70.2 -77.5 %)	0.01
Punctuation	34.3% (32.6 -37.2 %)	92.6% (91.3 -96.3 %)	76.7% (73.4 -79.2 %)	75.2% (73.2 -78.8 %)	0.01
Mosaic	16.7% (12.2 -19.2 %)	95.2% (93.7 -98.1 %)	67.7% (64.3 -69.3 %)	68.7% (63.2 -72.3 %)	0.01

This table demonstrates that the aceto-white areas were 66.7% sensitive and 76.7% specific with PPV= 50% and NPV= 80%. Positive lugol's iodine areas have 99.3% sensitivity and 16.7% specificity with PPV= 75% and NPV= 1.2%.

66.7% and NPV=73.4%. Areas Punctuation of have 34.3% sensitivity and 92.6% specificity with PPV= 76.7% and NPV=75.2%. Mosaic areas have 16.7% sensitivity and 95.2% specificity with PPV= 68.7% and NPV= 80%.

Areas of abnormal vessels have 33.3% sensitivity and 91.2% specificity with PPV=

Table (8): Accuracy of abnormal Colposcopy

Parameter	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Youden index
Abnormal Colposcopy	99.6% (98.0 -100 %)	33.3% (31.4 -35.3 %)	42.8% (40.5 -44.2 %)	1.2% (1.0 -3.8 %)	0.06

Abnormal Colposcopy was found to be 99.6% sensitive and 33.3% specific with PPV= 42.8% and NPV= 1.2%.

Table (9): Accuracy of Pap smear

Pap smear	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Youden index
LGSIL	96.6% (92.4 -99.2 %)	1.3% (1.1 -3.3 %)	32.6% (31.4 -36.8 %)	98.4% (95.2 -99.8 %)	0.00
CINI	3.3% (2.4 -6.8 %)	1.2% (1.4 -45.3 %)	1.6% (1.0 -3.2 %)	68.4% (65.2 -70.8 %)	0.01

Pap smear has sensitivity 96.6% and 3.3% in LGSIL and CINI respectively and specificity 1.3% and 1.2% in LGSIL and CINI with positive predictive value 32.6% and 1.6% in LGSIL and CINI and negative predictive value 98.4% and 68.4% in LGSIL and CINI.

Table (10): Accuracy of Cervical biopsy

Parameter	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	Youden index
LGSIL	76.6% (72.6 -79.2 %)	1.3% (1.6 -4.2 %)	72.7% (24.4 -29.3 %)	78.9% (75.7 -80.8 %)	0.12
CINI	16.7% (14.4 -18.3 %)	2.3% (1.8 -5.3 %)	76.9% (73.2 -79.2 %)	70.9% (65.7 -74.3 %)	0.03
CIN II	6.7% (4.3 -8.7 %)	1.6% (1.24 -5.3 %)	32.2% (30.5 -36.2 %)	68.2% (64.2 -71.8 %)	0.02

Cervical biopsy has sensitivity 76.6%, 16.7 and 6.7% in LGSIL, CINI and CINII respectively and specificity 1.3%, 2.3% and 1.6% in LGSIL, CINI and CINII respectively with positive predictive value 72.7%, 76.9 and 32.2% in LGSIL, CINI and CINII respectively and negative predictive value 78.9%, 70.9% and 68.2% in LGSIL, CINI and CINII respectively.

DISCUSSION:

Among all types of cancer, cervical cancer is considered the most common type affecting women. It contributes to a high mortality rate of approximately 500 thousand women per year in the developing countries. It is also considered the leading cause of cancer-induced deaths among females in the developing world. Prevention and diagnosis of cervical cancer can be accomplished in its early stages if there is a routine, well-structured screening program of cervical cytology⁽⁹⁾.

Papanicolao (Pap) smear is still considered the easiest, most and cost-effective method in the diagnosing cervical pre-malignant and malignant lesions. When Pap smear is used, it allows for early

diagnosis of many cervical pre-malignant lesions such as inflammatory lesions and cervical dysplasia⁽¹⁰⁾.

Pap smear and cervical biopsy results were assessed, a total number of 90 women were examined; 60 patients (66.6%) demonstrated normal results (normal Pap smear) and 30 patients (33.3%) demonstrated atypical findings (abnormal Pap smear). Our patients were subdivided into 2 groups: **Patient group (no= 30)** (with abnormal Pap smear results).

Control group (no= 60) (with normal Pap smear results).

Our results revealed that the mean age (years) was (42.55±7.384) in patient group and (42.65±7.487) in control group, the mean age of marriage (years) was (20.45±3.504) in

patient group and (20.43±3.501) in control group, the mean duration of marriage (years) was (21.65±8.147 and 20.16±8.134) in patient and control group respectively and mean parity was (4.21±2.382 and 4.23±2.382) in patient and control group respectively. No statistical significance was found in the difference between both groups as regard to age, the age marriage, duration of marriage and parity. Table (1)

In correlation with our results Enechukwu et al. ⁽¹¹⁾; who found that the mean age of participants was 42.90 (11.27). most of them 84 (43.8%) were multiparous, 48(25.0%) were grand multipara. In a similar way most of the participating females, 157 (81.8%), were married while only 17(8.9%) were single.

On contrary, Hosseini et al. ⁽¹²⁾, demonstrated that the mean age of 54.47 ± 11.34 years, with participants ages ranging between 32 and 85 years, among these patients, 13.4% were ≤40 years of age, while 68.6% were ≥50 years. Singh et al. ⁽¹³⁾ documented that most of the females 299 (74.75%) who took part in their research were aged between 23 and 32 years. The median age of these patients was 28 while the mean age was 28.54±4.6 years.

In regarding to parity Kasamatsu et al. ⁽¹⁴⁾ revealed that the higher the number of pregnancies, the higher the risk of CIN+, they also reported a three-fold increased risk for females with more than four pregnancies in comparison with those with 0–1 pregnancy.

Also, Muwonge et al. ⁽¹⁵⁾; reported that high parity is closely associated with CIN2+ risk, especially in younger females, it is thought to be due to the prolonged exposure of the transformation zone to HPV and/or other factors in multiparous females.

The comparison between both studied groups and contraception in the current study revealed highly statistically significance difference between both groups as regard to negative use of contraception as shown in

table (2). Our results revealed that 13.3% of our patients group using injectable contraception and 16.6% using oral contraceptive pills while 46.6% of our patient group with LGSIL not using any method of contraception as shown in table (3).

This is coincided with International Collaboration of Epidemiological Studies of Cervical Cancer (2007) ⁽¹⁶⁾ in large collaborative epidemiological study on cervical cancer and hormonal contraceptives and reached a conclusion that the longer the duration of hormonal contraceptive use, the more the risk of cervical cancer.

Contact bleeding is one of the important signs of abnormality as shown in table (4) in the comparison between both studied groups and complaints and revealed highly statistically significance difference between both groups as regard to bleeding. 80% of our patients group complained from contact bleeding while 20% of patients group complained of recurrent infection as shown in table (5).

Our current study revealed infection by human papilloma virus and positive koilocytosis in 83.3% of patient group with abnormal cytology. It also revealed a significant difference between both studied groups as regard to human papilloma virus infection and positive koilocytosis. Table (6)

In the same line Roura et al. ⁽¹⁷⁾ reported that high estrogen and progesterone levels may be held responsible for the changes in the transformation zone as they may weaken the immune response to HPV infections and thus increase the risk for a progression or persistence of the infection. In another study.

However, Vaccarella et al. ⁽¹⁸⁾ reported that HPV prevalence is not linked to the number of pregnancies or the prolonged use of hormonally contraceptives. However, they reported that these two factors may result in the transition from HPV infection to neoplastic cervical lesions.

The accuracy of Colposcopy steps in our study revealed that: Firstly, the aceto-white areas was 66.7% sensitive and 76.7% specific with PPV=50% and NPV=80%. Positive lugol's iodine areas had 99.3% sensitivity and 16.7% specificity with PPV=75% and NPV=1.2%. Areas of abnormal vessels had 33.3% sensitivity and 91.2% specificity with PPV=66.7% and NPV=73.4%. Areas Punctuation of had 34.3% sensitivity and 92.6% specificity with PPV= 76.7% and NPV=75.2%. Mosaic areas had 16.7% sensitivity and 95.2% specificity with PPV=68.7% and NPV=80% as shown in table (7). Abnormal Colposcopy was 99.6% sensitive and 33.3% specific with PPV= 42.8% and NPV= 1.2% as shown in table (8).

In agreement with our work Savitha and Sapna. ⁽¹⁹⁾ observed that colposcopy is more sensitive but less specific in comparison with Pap smear in Indian population. In their research, colposcopy revealed a sensitivity of 85% and a specificity of 83.5% in comparison with the findings of our study that reported sensitivity and specificity of 99.8% and 96.19%, respectively.

Our results revealed that Pap smear has sensitivity 96.6% and 3.3% in LGSIL and CINI respectively and specificity 1.3% and 1.2% in LGSIL and CINI with positive predictive value 32.6% and 1.6% in LGSIL and CINI and negative predictive value 98.4% and 68.4% in LGSIL and CINI as shown in table (9).

Cervical biopsy in our results has sensitivity 76.6%, 16.7 and 6.7% in LGSIL, CINI and CINII respectively and specificity 1.3%, 2.3% and 1.6% in LGSIL, CINI and CINII respectively with positive predictive value 72.7%, 76.9 and 32.2% in LGSIL, CINI and CINII respectively and negative predictive value 78.9%, 70.9% and 68.2% in LGSIL, CINI and CINII respectively as shown in table (10).

Karimi and colleagues (2013), reported that repeated Pap smears for ASCUS was

found to have a sensitivity of 15% and specificity of 93%, while the use of colposcopy to diagnose CC was found 80% sensitive and 80% specific ⁽²⁰⁾.

Also, Fatemeh et al. (10) documented that colposcopy was found to be 64.72% sensitive and 52.74% specific. Similarly, the PPV and NPV of the colposcopy were estimated to be 76.32% and 95.41%, respectively.

Conclusion: Colposcopy has a higher diagnostic accuracy when it comes to the detection of cervical pre-malignant lesions in comparison with Pap smear. Thus, it is recommended to use colposcopy directed biopsy when screening for cervical malignant and pre-malignant lesions.

Conflict of interest:

No conflict of interests was declared by authors.

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دور منظار عنق الرحم في تشخيص امراض عنق الرحم

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المقدمة : ان سرطان عنق الرحم من اهم انواع الامراض التي تصيب عنق الرحم ويعد احد اهم المخاطر التي تؤثر على صحة المرأة. كما يعد الفحص الدوري ومسحات الانسجة لعنق الرحم احد اهم العناصر للتشخيص المبكر للمرض. حيث يساعد منظار عنق الرحم عن طريق التكبير وتحديد الاماكن المصابة لاخذ العينات الخلوية في التشخيص المبكر لسرطان عنق الرحم . وبالتالي فان منظار عنق الرحم يساعد على اخذ العينات من الانسجة المحتمل اصابتها في المراحل الاولى من سرطان عنق الرحم وتشخيصه في مراحل متقدمة .

الهدف من الدراسة : لذا كان الهدف من هذا البحث هو دراسة دور المنظار الرحمي في تشخيص حالات امراض عنق الرحم

النتائج: اشتملت هذه الدراسة على 90 سيدة من المترددات على وحدة التشخيص الميكروبيولوجي بمستشفى الزهراء الجامعي حيث تم اخذ التاريخ المرضي للمريضات كما تم عمل منظار عنق الرحم (الكليوسكوب) ومسحة البابس مير ثم تحديد الاماكن المحتمل للاختلال بعنق الرحم عن طريق استخدام مادة الاستيك اسيد والوجلز ايودين كما تم اخذ عينات خلوية من الاماكن المحتمل اصابتها بسرطان عنق الرحم وذلك في خلال الفترة من مارس 2020 الى ديسمبر 2021.

الاستنتاجات : قد وجدنا ان منظار عنق الرحم له القدرة على تشخيص 99.6% لحالات ما قبل سرطان عنق الرحم .

التوصيات : يوصى باستخدام منظار عنق الرحم في التشخيص المبكر لحالات ما قبل سرطان عنق الرحم.