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Clinical Audits in Colposcopy at Al-Azhar University Hospital

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ABSTRACT
Background: Cervical cancer is 2nd prevalent cancer between females in developed countries. Colposcopy is a simple diagnostic process used to look at cervix, vagina and vulva with illumination and magnification of the view,
Aim and objectives: This study aimed to investigate the role of colposcopy performance according to the standard guidelines in enhancing patient care and outcomes according to National Health Service Cervical screening program.
Subjects & methods: This cross-sectional observational research was carried out on 100 studied cases who came to the Outpatient Colposcopy Unit of Al-Azhar University Hospital (Assiut).
Result: As regards excisional form of biopsy, recording ectocervix when substituted with high-grade abnormality and when low grade coloposcopic variation was related to high grade dyskaryosis or worse, there were significant different from guidelines (p=0.214 & 0.003 respectively),
Conclusion: In selected studied cases, colposcopy is critical to "see-and-treat" method of treating great-grade cervical cytologic abnormalities,
Keywords: National health service, Cervical screening program.

INTRODUCTION

Colposcopy, first step in management of women with abnormal Pap smear outcomes, is visual method that is prone to observe distinction, implying need for extensive apprenticeship, continuous training, & quality assurance measures. Level of responsibility for organising subjects, geographic coverage, scope, model, & type of actions vary among colposcopy QA programmes. Programmes addressing clinical standards of colposcopy are more limited in space & less long-term than those focusing on service provision [(1)]. Key step in management of females with abnormal Pap smear outcomes is colposcopy, which is visual test of uterine cervix & vagina using lighted field microscope after application of diluted solution of acetic acid & Lugol's iodine solution as staining agents. Colposcopy is used to identify macroscopic variations in tissue characteristics like colour & morphology. Clinician can characterise lesions & recognise abnormal areas that may need to be biopsied for recognizing precancerous or cancerous lesions by comparing these features to established patterns of disease [(2)].

Colposcopy's role in identifying studied cases with important lesions becomes even more critical [(3)]. Colposcopy allows identification & treatment of underlying significant lesions as early as possible. This primary benefit is especially important in areas with great incidence of cervical cancer, like Chiang Mai as underlying invasive lesions are notably great across all grades of cervical smear abnormalities [(4)]. Colposcopy service requires periodic auditing to confirm that quality of colposcopy services meets or exceeds minimum requirements, based on desire for quality assurance & continuous improvement of clinical practice [(5)].

NHS Cervical Screening program aims to decrease incidence & mortality from cervical cancer by providing eligible females with systematic, quality-assured population-based screening programme. As result, screening programme has reduced number of cervical cancer cases by half, saving approximately 4.500 lives per year in Netherland [(6)].

PATIENTS & METHODS

Cross-sectional observational research that was carried out on 100 patients referred for colposcopic examination at the Colposcopic Unit in the Department of Obstetrics & Gynaecology, Al-Azhar University Hospital (Assuit) Egypt through the period from January 2021 till the completion of this study.

All the participants were subjected for:

Full detailed history: Last menstrual period and current contraception, past obstetric history, past gynaecology history and menstrual history. Patient information leaflet was recorded, and pelvic examination was carried out and findings.

General and systemic examination: Including pulse, blood pressure, temperature, complexion, cardiovascular disease, central nervous system disorders, respiratory system, GIT system, urinary system, lymphatic system and endocrine diseases.

Local examination: vulval inspection (look for anatomical appearance e.g. juvenile external genitalia

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and large labia minora). Dermatological complications e.g. lichen sclerosis, lichen planus, eczema, and psoriasis. Sexually transmitted infections, e.g. genital ulceration and warts. Suspicious of benign & malignant lesions and Scar tissue.

Colposcopy procedure: colposcopy is performed by specialist known as colposcopist. This may be doctor or trained nurse.

During procedure: studied case should undress from waist down & sit in chair with padded leg supports. Speculum is inserted into vagina & gently opened, similar to cervical screening examination. Light-emitting microscope is used to examine cervix, which is kept outside vagina. Liquids are applied to cervix to highlight any abnormal areas. The patient may experience mild tingling or burning as result of this. Small sample of tissue may be deleted for further test in laboratory that should not be painful, but she may experience slight pinching or stinging sensation. If it is clear that she has abnormal cells in her cervix, she may be offered immediate therapy to eliminate cells. Alternatively, she will have to wait for biopsy results.

After colposcopy: She will be able to return home as soon as she is ready, which is usually immediately. She can return to her normal activities, such as work & driving, immediately, but she may prefer to rest until next day. Following biopsy, she may experience brownish vaginal discharge or light bleeding. This is normal & should resolve within three to five days. Before having gender or using tampons, menstrual cups, vaginal medicines, lubricants, or creams, wait until any bleeding has stopped. Nurse or doctor may be able to tell her right away what they've discovered. If she had biopsy, it would be tested in laboratory & she would have to wait few weeks for results.

Ethical Approval: This research was approved by Ethics Board of Al-Azhar University Assiut, & each participant in research provided informed written consent. This work was done in accordance with World Medical Association's Code of Ethics for human researches.

Statistical analysis

Data were collected, coded, & entered into spread sheet using Microsoft Excel 2016 for Windows, part of Microsoft Office bundle (Microsoft Corporation, USA). IBM Statistical Package for Social Sciences software was used to analyse data. Kolmogorov-Smirnov exam was used to confirm distribution's normality. The level of significance was taken at **P value <*0.05*** is significant, otherwise is non-significant. The p-value is a statistical measure for the probability that the results observed in a study could have occurred by chance.

RESULTS

Table (1) showed that age of studied women ranged from 20 to 61 years with a mean of 34.70 ± 9.00 years. As regards residence, it was found that 67 (67%) women were from rural areas and 33 (33%) women were from urban areas. 57 (57%) women were not educated and only 15 (15%) were occupied. The parity ranged from nulliparous to para 8 with mean of 3.51 ± 1.899. The mean duration of marriage was 13.28 ± 8.97 years.

Table (1): Demographic features of studied women

		Studied cases (n=100)	
		No.	**%**
Age (years)	Mean ± SD	34.70 ± 9.00	
	Median	35.0	
	Range	20.0 – 61.0	
Residence	Rural	67	67%
	Urban	33	33%
Education	Educated	43	43.0%
	Not educated	57	57.0%
Occupation	Occupied	15	15%
	Not occupied	85	85.0%
Parity	Mean ± SD	3.51 ± 1.899	
	Median	3.0	
	Range	0.0 – 8.0	
Duration of marriage (years)	Mean ± SD	13.28 ± 8.97	
	Median	12.0	
	Range	1.0 – 44.0	

Bacterial vaginosis was found in 80% cases while post subtotal hysterectomy was done for 20% cases. Clinical features in studied cases were shown in table (2). 75 % cases had AUB. Ectropion was found in 20 cases, Nabothian follicles in 5 cases, leukoplakia in 15 cases, polyp in 4 cases, bleeding in 55 cases and discharge in 20 cases.

Table (2): Clinical features in studied cases

		Studied cases (n=100)	
		No.	%
Colposcopic Finding	**Normal**	43	43.0%
	Cervical Ectopy	22	22.0%
	Ch. Non-specific cervicitis	18	18.0%
	CIN II	1	1.0%
	Others as: hypertrophy	16	16.0%
cause of hysterectomy	**Adenomyosis**	1	1.0%
	AUB	15	15.0%
	multiple fibromatosis	1	1.0%
	postpartum hemorrhage	3	3.0%
Ectropion	**Negative**	80	80.0%
	Positive	20	20.0%
Nabothian follicles	**Negative**	95	95.0%
	Positive	5	5.0%
Leukoplakia	**Negative**	85	85.0%
	Positive	15	15.0%
Polyp	**Negative**	96	96.0%
	Positive	4	4.0%
Bleeding	**Negative**	45	45.0%
	Positive	55	55.0%
Discharge	**Negative**	80	80.0%
	Positive	20	20.0%
Bleeding	**Milky**	35	35.0%
	opaque white	15	15.0%
	Shady	45	45.0%
	Transparent	5	5.0%
Margin	**Diffuse**	65	65.0%
	Irregular	5	5.0%
	Sharp	30	30.0%
Vessels	**Absent**	60	60.0%
	Coarse	15	15.0%
	Fine	20	20.0%
	Regular	5	5.0%
lesion size	**>15 mm**	5	5.0%
	2 quadrants	30	30.0%
	3 quadrants	50	50.0%
	4 quadrants	15	15.0%
Iodine staining	**distinct yellow**	55	55.0%
	Faintly	10	10.0%
	patchy yellow	35	35.0%

As illustrated in table (3), offering verbal information & sending written information before & after cervical screening & before colposcopy was not done in all cases with high significant differences with NHSCSP – 2016 guidelines ($p<0.001$). Also, **Previous PAP smear before colposcopy, precautions before colposcopy and** sending appropriately worded invitation with contact name, telephone number, & clinic times were not done in all cases with high significant differences with NHSCSP – 2016 guidelines ($p<0.001$). Meanwhile communication with the women within four weeks of their attendance about results of colposcopy and management were done for all cases that is consistent with guidelines.

Table (3): Audit of colposcopy performance using NHSCSP – 2016 guidelines

	Total cases (n)= 100				Guidelines vs. Al-Azhar university hospital (Assiut)
	Done		Not done		
	No	%	No	%	p- value
Women should be offered verbal information and be sent written information before and after cervical screening and before colposcopy	0	0.0%	100	100.0%	**<0.001**
Counseling must be available as an integral part of colposcopy.	100	100.0%	0	0.0%	-
Women must be sent an appropriately worded invitation with a contact name, telephone number, and clinic times	0	0.0%	100	100.0%	**<0.001**
Within 4 weeks of her attendance, female should be informed about visit & outcomes of colposcopy. All females were required to receive their outcomes within eight weeks.	100	100.0%	0	0.0%	
Within four weeks of females, outcomes & planning processes should be communicated to referring practitioner. Within 8 weeks, all referring practitioners should receive outcomes & planning processes.	One hundred	100.0%	0	0.0%	
Precautions before colposcopy	0	0.0%	100	100.0%	**<0.001**
Previous PAP smear before colposcopy	0	0.0%	100	100.0%	**<0.001**

As regards colposcopy examination, recording reason for referral, presence or absence of vaginal & endo cervical extension and colposcopic features of any lesion were done for all cases that is consistent with guidelines. On the other hand, recording grade of cytological abnormality, adequate examination to the entire cervix, colposcopic impression of lesion grade was done for all cases that is consistent with guidelines and type of transformation zone, ie 1, 2, 3 were not available with high significant difference with guidelines ($p<0.001$) (Table 4).

Table (4): Diagnostic standards for colposcopy

Colposcopy examination	Total cases (n)= 100				Guidelines vs. Al-Azhar university hospital (Assiut)
	Done		Not done		
	No	%	No	%	p- value
Reason for referral	100	100.0%	0	0.0%	
Grade of cytological abnormality	0	0.0%	100	100.0%	**<0.001**
To be thorough, entire cervix should be examined.	0	0.0%	100	100.0%	**<0.001**
Vaginal & endo cervical extension is present or absent.	100	100.0%	0	0.0%	
Colposcopic features of any lesion.	100	100.0%	0	0.0%	
Colposcopic impression of lesion grade.	0	0.0%	100	100.0%	**<0.001**
Type of transformation zone, i.e. 1, 2, 3	0	0.0%	100	100.0%	**<0.001**
Place of any colposcopic directed biopsies.	20	20.0%	0	0.0%	**<0.001**

DISCUSSION

Cervical cancer is 2nd common cancer in females in developed countries when it progresses to invasive stage, however it is deadliest of all women genital tract cancers. It is only cancer that can be prevented if detected early, & it is nearly one hundred percent curable with proper screening & early detection [7].

Regarding demographic characteristics of studied cases, years old of studied females ranged from 20 to 61 years with a mean of 34.70 ± 9.00 years. As regards residence, it was found that 67 (67%) women were from rural areas and 33 (33%) women were from urban areas. 57 (57%) women were not educated and only 15 (15%) were occupied; the parity ranged from nulliparous to para 8 with mean was 3.51 ± 1.899 and the mean duration of marriage was 13.28 ± 8.97 years. **Rahman *et al.*** [8] in research aimed to recognize cervical cancer & precancerous conditions between studied cases noted to VIA centre & Colposcopy clinic resulted in 3604 respondents, with mean years old of 35.9 years & highest proportion in years old category thirty one to forty years. Majority of respondents were housewives with low monthly incomes. 46.5% of respondents were from rural areas. Mean years old at marriage & years old at first coitus was showed to be 16.25 years, with 92.7% falling between ages of eleven & twenty.

According to the history taken from the studied cases, the present study showed that among 100 cases, bacterial vaginosis was found in 80 cases, CINII was found in one case, Ectropion was found in 20 cases, Nabothian follicles in 5 cases, leukoplakia in 15 cases, polyp in 4 cases, bleeding in 55 cases and discharge was in 20 cases. **Rahimi *et al.*** [9] reported that cytology revealed that twenty eight studied cases had low-grade dyskaryosis, twenty eight had high-grade dyskaryosis, eight had borderline squamous cells, & thirteen had borderline/suspicious high-grade squamous cells. Endocervical outcomes were normal in eleven studied cases & abnormal in sixty six. Endocervical biopsy revealed that thirteen studied cases had negative outcomes, fourteen had low-grade CIN, & fifty had high-grade CIN.

Pretorius *et al.* [10] reported that endocervical curettage is blind, painful procedure that is connected to excessive bleeding & great percentage of false-negative outcomes. Meanwhile, communication with the women within four weeks of their attendance about results of colposcopy and management were done for all cases that are consistent with guidelines. **Waxman *et al.*** [11] showed that, gold standard in diagnosis of cervical dysplasia is colposcopic test with biopsies for pathologic assessment. Prior to colposcopy researches reported sensitivity of only 53.6% - 69.9%. However, there has been increase in colposcopy literature regarding number of biopsies to acquire & role of random biopsies in colposcopy practice.

There was large difference in routine (>seventy five percent of time) biopsy practice between survey respondents in research. While most colposcopists said they would take more than one biopsy, total number of biopsies & practice of taking "random" biopsies varied. Intensity of referral cytology & colposcopy practice volume frequently affected decision to biopsy.

As regards colposcopy examination, recording reason for referral, presence or absence of vaginal & endo-cervical extension and colposcopic features of any lesion were done for all cases that are consistent with guidelines. On the other hand, recording grade of cytological abnormality, adequate examination to the entire cervix, colposcopic impression of lesion grade were done for all cases that are consistent with guidelines and type of transformation zone, i.e. 1,2,3 were not available with high significant difference with guidelines ($p<0.001$). **Bornstein *et al.*** [12] reported that proportion of studied cases with large-degree cytological abnormalities who underwent colposcopy within four weeks (32.9% of goal), transformation zone type (22.6% of goal), biopsy site (18% of goal), & lesion grade (31% of goal) all failed to meet international standards. Positive predictive value of colposcopy exceeded expectations (30% higher than expected). There were variations among clinical settings. **Thompson and Marin,** [13] reported that, histology outcomes of large loop excision of transformation zone were recorded in medical records for ninety seven percent of studied cases. Females whose LLETZ histology was unavailable (nine) & females (three percent) were diagnosed with cancer and were also excluded from analysis (four cervical & three endometrial). According to **Umar and Yakasai,** [14] biopsy revealed that eighteen studied cases had cervical intraepithelial neoplasia I. Only 2 of these had top grade lesions, while rest had low grade lesions (eighty one percent concordance). CIN II or CIN III was found in 19 females. On colposcopy, only 2 cases were identified as low grade lesions & 1 case as supposed invasive cervical cancer. Remaining studied cases all had large lesions (eighty five percent concordance). In eighty seven percent of cases, colposcopic impression agreed with histological diagnosis.

CONCLUSION

Colposcopy is essential first step in determining the cause of abnormal cervical cancer screening examination outcomes. It enables detection of invasive cervical cancers followed by definitive

treatment in most cases without need for excisional process. When precancer is detected, colposcopy provides information needed to personalise therapy by characterising lesion size, site, & severity. Colposcopy enables detection & monitoring of subset of females whose cervical disease can be monitored safely over time.

DECLARATIONS

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