

AN INTERVENTIONAL STUDY TO ASSESS THE CYTOLOGICAL AND COLPOSCOPIC CHANGES AFTER INTRAUTERINE CONTRACEPTIVE DEVICES INSERTION IN THE DEPARTMENT OF OBSTETRICS GYNAECOLOGY, SMS MEDICAL COLLEGE, JAIPUR

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Abstract

Background: Cytology examines exfoliated cells, while colposcopy examines the changes that occur in the vascular structure of the cervix⁵. Patients with an abnormal pap smear result or patients with a suspicious-looking cervix even if they had a negative pap smear, should be evaluated by colposcopy and colposcopy directed biopsy.

Methods: Interventional Prospective study conducted at Department of Obstetrics and Gynaecology, SMS Medical College & associated Hospitals, Jaipur.

Results: In this study, among 15 IUCD users, 5 (33.33%) had bacterial vaginosis, 2 (13.33%) had trichomonas vaginalis and 1 (6.66%) were found candidal infection, 1 (6.66%) polymicrobial infection.

Conclusion: The present study indicates that there is definite changes in the cervical architecture in IUCD users and the change is also dependent on the duration of use. A simple technique like cytology and colposcopy is highly useful in diagnosing these changes and combating them by early interference whenever necessary. The present study does not reveal any increased risk of cervicitis and dysplasia in IUCD users. We further recommend that a long term follow-up is required to rule out the possibility of any increased risk of dysplasia or carcinoma in-situ.

Keywords: IUCD, Colposcopy, Dysplasia.

Introduction

Worldwide, intrauterine devices are the most commonly used form of reversible contraception with 160 million women currently relying on this method.¹ Highest rates of utilization are found in China, South East Asia and Middle East.²

The copper intrauterine contraceptive devices (IUCDs) are the most commonly used type of IUCD over 106 million women worldwide use them.³ The CuT 380A has been found to be the most effective copper IUCD.⁴

The introduction of the CuT 380A was delayed for 3 yrs after its FDA approval in 1985, until 1988 because of extremely unfavourable medico legal environment for IUCDs at the time.⁵

Cytology and colposcopy are the most advantageous techniques used in the diagnosis of cervical cancer and pre-invasive lesions⁴. It is a screening method that should be performed with others for further examination. Cytology examines exfoliated cells, while colposcopy examines the changes that occur in the vascular structure of the cervix⁵. Patients with an abnormal pap smear result or patients with a suspicious-looking cervix even if they had a negative pap

smear, should be evaluated by colposcopy and colposcopy directed biopsy⁶.

Material & Methods

Study Type: Interventional study

Study Design: Prospective study

Place of Study: Department of Obstetrics and Gynaecology, SMS Medical College & associated Hospitals, Jaipur.

Duration of Study: May 2019 to November 2020.

Study Universe: Women those are using IUCDs attending the Department of Obstetrics & Gynaecology, SMS Medical College, Jaipur.

Sample size

Sample size was calculated at 95% confidence level assuming infection in 20% of subjects using intrauterine contraceptive devices as per result of seed article (Singh S, Chandra M and Solanki V. To study colposcopic and cytological changes in cervix in women using intrauterine

contraceptive device. International Journal of Biomedical Research. 2014; 4(12) : 679-681.)

At the precision (absolutely allowable error) of 10% minimum 62 IUCD users were required as sample in the present study which was enhanced and rounded off to 70 users as final sample size.

The formula used for sample size calculation is: -

$$n = \frac{z^2 p(1-p)}{d^2}$$

wherein; Z=1.96 (the approximate value of the 97.5 percentile point of the normal distribution for significance level of 0.05 or 5%), p is the prevalence, d is the precision level (5% or 0.05, also known as acceptable margin of error).

Inclusion criteria

- Never on any hormonal contraceptive method
- Active monogamous sexual life
- Written informed consent

Exclusion criteria

- Active sexually transmitted diseases or any infection of the lower genital tract.
- Uterine abnormalities, eg., bicornuate or septate uterus or uterine myomas Subjects with missing IUCD.

Methodology

The subjects were explained about the study. Detailed history including any complaints, menstrual history and obstetric history was obtained. Each subject underwent general physical, systemic and abdominal examination.

Informed & written consent of the patient was taken prior to the study.

Institute Review Board & Ethical Committee approval was taken.

The Study Group included 62 monogamous patients willing to use IUCD as the contraceptive method. Then, Pap smear from ectocervix and endocervix with the help of Ayres Spatula and cytobrush was taken. All cases were underwent a colposcopic examination. After this, IUCD was inserted under all asepsis after taking written and informed consent. The Pap smear and colposcopic examination was repeated during follow up visits at 6th and 12th months by the same gynecologist with the same colposcopic device (optical with built in light source and conversion objective lenses attached with a support appliance, focal length – 300%, low power - 2 x 6, medium power – 8 x 15, high power – 15 x 24). Smear test results and colposcopic examination findings at the start of the study was compared with the findings at 6th and 12th month.

Statistical analysis

Statistical analysis of the results were performed using EPI Info software. Chi-square test was employed for comparing the classified variables of the groups, and t test was used in independent samples to compare the continuous variables. Alternatively, Mann-Whitney U test was performed in the case of a different variations or a low number of subjects. p<0.05 was considered statistically significant. Classified variables were presented as number (n) and percentage (%) in the table.

Results

The study population included 62 subjects using intrauterine contraceptive device for period of 12 months attending the family planning OPD SMS Hospital, Jaipur. All the 62 subjects were using Cu-T 380A.

Table 1: Characteristics of Women

Age	28.16 ± 5.80 yrs
Age at Marriage	20.37 ± 3.50 yrs
No. of Children(1:2:3:>3)	21:24:8:9

Mean age of the IUCD use as spacing method in this study was found to be 28.16±5.80 yrs. Mean age of marriage was about 20.37 ± 3.50 yrs. 24 (38.71%) women had 2 children at time of IUCD recruitment, 21 (33.87%) had 1 child, 8 (12.90%) women had 3 children and 9 (14.52%) women had more than 3 children.

Table 2: Distribution of Cases According to Chief Complaints

Chief Complaints	No.	%
Backache	12	19.35
Lower abdominal pain	23	37.10
Menorrhagia	9	14.51
Vaginal discharge	15	24.19
Expulsion of IUCD	0	0.00

The above table shows the distribution of cases according to chief complaints in women. In this study results shows that the most common complaint was lower abdominal pain 23 (37.10%), followed by vaginal discharge 15 (24.19%), backache 12 (19.35%) and menorrhagia 9 (14.51%).

Table 3: Distribution of Cases According to Cervical Cytology at 6 & 12 Months

Cytologic Change	On Recruitment		6 Months		12 Months	
Normal	62	100.00	27	43.55	15	24.29
Inflammatory	0	0.00	35	56.45	47	75.81
Total	62	100.00	62	100.00	62	100.00

The above table shows the distribution of cases according to cervical cytology at 6 and 12 months. The incidence of inflammatory changes of 35 (56.45%) at 6 months, 47 (75.81%) at 12 months of Cu-T placement.

Table 4: Distribution of Cases According to Overall Impression of Colposcopy at 6 & 12 Months

Colposcopy Changes	On Recruitment		6 Months		12 Months	
Normal	62	100.00	62	100.00	62	100.00
Inflammatory	0	0.00	0	0.00	0	0.00
Total	62	100.00	62	100.00	62	100.00

The above table shows the distribution of cases according to overall impression of colposcopy at 6 and 12 months. The study shows no significant changes found in cervical and vaginal epithelium.

Table 5: Distribution of Cases According to Cervico-vaginal Swab (Total 15 women who complained of vaginal discharge)

Cervico-vaginal Swab	No.	%
Normal Flora	6	40.02
Trichomonas Vaginalis	2	13.33
Candidal Infection	1	6.66
Bacterial Vaginosis	5	33.33
Polymicrobial Infection (Bacterial vaginosis and candidal infection)	1	6.66
Total	15	100.00

The above table shows the distribution of cases according to cervico-vaginal swab. In this study, among 15 IUCD users, 5 (33.33%) had bacterial vaginosis, 2 (13.33%) had trichomonas vaginalis and 1 (6.66%) were found candidal infection, 1 (6.66%) polymicrobial infection.

Discussion

Intrauterine contraceptive devices (IUCDs) are one of the most efficient and the simplest contraception method used in patients selected very carefully. A number of reports suggested that copper devices are effective and safe but the effect of copper on cervical epithelium with regards to dysplasia has not been specifically reported. IUCD usage by a large number of women has caused concern about its safety specially regarding carcinogenicity.

The aim of this study was to report clinical, cytological and colposcopic findings among women using IUCDs. A total of 62 women using IUCD for 12 months of interval failed to reveal any cases of malignancy or dysplasia. Most of the subjects 23 (37.10%) with IUCDs presented with lower abdominal pain which was not specific and relieved by

NSAIDS. Out of total IUCD users, 15 (24.19%) presented with vaginal discharge. Their cervicovaginal swab were taken and results revealed that they were positive for bacterial vaginosis, trichomonas vaginalis and candidal infections. All subjects were treated for these infections. Non-specific backache was present in 12 women (19.35%) which was relieved by NSAIDS. Heavy menses was present in 9 women which was relieved by antifibrinolytic drugs (Tranexamic Acid) given for one cycle only. These patients never reported again in OPD with similar complaints. Similar results were found in study done by Nayak SR et al in 2007⁸. The most common complaint was backache 44%, followed by menorrhagia 38%, vaginal discharge 23%, ASCUS and CIN I were not seen in study. The incidence of ASCUS & CIN I increased when the duration of insertion was more than 3 yrs.

In the present study all the cases were subjected to PAP smear at 6 months and 12 months after IUCD placement. At 6 months of PAP smear 35 (56.45%) of the IUCD users had inflammatory changes in the cytology while 27 (43.55%) showed normal cytology. At 12 months of cytological study

47 (75.81%) had inflammatory changes. At 6 months and 12 months of colposcopic study, there were no significant cervical and vaginal epithelial changes.

Famhy K et al (1990)⁹ conducted a study of cervical pathology in IUCD users, including one hundred lippees loop users and 100 Cu-T-200 users and 200 control non IUCD users for >1 year. They were examined clinically, cytologically and for associated cervical pathological lesions. They found significant increase in non-specific inflammatory changes, in the IUCD users than the non-users ($p < 0.05$).

Ashwani R et al (1988)¹⁰ reported an incidence of inflammatory changes of 57% at 6 wks, 72.6% at 6 months of Cu-T insertion.

Agarwal K et al (2004)¹¹ conducted a study of microbiological and cytopathological changes in IUCD users. They found increased incidence of inflammatory changes in the IUCD users compared to non-users ($p = 0.52$).

Patankar A et al (2015)¹² found non-significantly increased incidence of inflammatory smear in IUCD group compared to control group (75.2% v/s 68.4%).

In our study 15 (24%) subjects complained of vaginal discharge. Their cervicovaginal swab were taken and results revealed that 5 (33.33%) were positive for bacterial vaginosis, 2 (13.33%) for trichomonas vaginalis and 1 (6.66%) for candidial infection. Possible explanation for an association between IUCD use and microbial infection may be because of the presence of string in the vagina as a foreign body in the uterus and increased volume and duration of menstrual flow in IUCD user.

In the present study, we found that the incidence of bacterial vaginosis in IUCD user was 33.33% which was similar to that of study by Shobeiri F et al (2014)¹³ which showed that 30.1% cases had bacterial vaginosis. We found from the present study that 6.66% of cases showed candidial infection which was similar to that of the study by Haltas H et al (2012)¹⁴ which showed that 4.74% of cases were infected by candida species.

Conclusion

The present study indicates that there is definite changes in the cervical architecture in IUCD users and the change is also dependent on the duration of use. A simple technique like cytology and colposcopy is highly useful in diagnosing these changes and combating them by early interference whenever necessary. The present study does not reveal any increased risk of cervicitis and dysplasia in IUCD users. We further recommend that a long term follow-up is required to

rule out the possibility of any increased risk of dysplasia or carcinoma in-situ.

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