

MICROBIAL AND CLINICOCYTOLOGICAL STUDY IN COPPER-T (CU-T) USERSAlka Patankar¹, Rajendra Wakankar²**HOW TO CITE THIS ARTICLE:**

Alka Patankar, Rajendra Wakankar. "Microbial and Clinicocytological Study in Copper-T (CU-T) Users". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 47, June 11; Page: 8143-8152, DOI: 10.14260/jemds/2015/1180

ABSTRACT: AIMS AND OBJECTIVE: To study clinical, microbial and cytopathological changes in Cu-T users in tertiary care hospital and to ascertain the safety of Cu-T with reference to cervical intraepithelial neoplasia. **METHODOLOGY:** We carried out a 2 month prospective analysis during a period of 02/06/2008 to 02/08/2008 in Tertiary care hospital and medical college in department of Obstetrics and Gynaecology. We included Study subjects as all Cu-T users irrespective of duration of use and Control subjects as all women other than contraceptive users. Sample size was estimated. The detailed history was obtained. Each subject underwent per speculum examination to look for thread, or expulsion of Cu-T, condition of vagina and cervix and discharge. Vaginal discharge was collected and sent for PH testing, wet mount, KOH mount, Gram staining and culture on Mac Conkey and blood agar. Cervical scraping was taken and subjected to Papanicolaou staining. Reporting was done by cytologist according to Bethesda classification. Data was analysed by using appropriate software. **RESULTS:** Maximum study subjects were in the age group of 21-25 years (58%). 75% of subjects were para1. Majority of women had excessive vaginal discharge (41%) and pain in lower abdomen (33%) as chief complaints, followed by backache (18%) and itching (15%). 27% women had menorrhagia which accounts for about 1/5th of removal of Cu-bearing IUDs. Cervical erosions were significantly higher in Cu-T users (P=0.038). Cytological findings were predominantly inflammatory and comparable in both groups. There was insignificant increase in Trichomonas and fungal infection but significant increase in bacterial infection. Benign reactive and reparative changes were seen with their increased incidence in longer duration of use. However the results were comparable to that in general population (P=0.917). Microbial findings showed insignificant qualitative alteration in vaginal flora with increase in Trichomonas and fungal infections among both groups. Gram staining revealed significant quantitative alteration in vaginal flora associated with nearly significant decrease in Doderlein bacilli along with significant increase in gram positive cocci and pus cells. However results of vaginal discharge culture depicts insignificant increase in growth of infectious organisms in Cu-T users. **CONCLUSION:** There is insignificant increase in infection and cervical cytopathology, and no case of cervical intraepithelial neoplasia (CIN). Hence we agree that Cu-T 380A is an excellent contraceptive choice for most women.

KEYWORDS: Vaginitis, dysplasia, neoplasia.

INTRODUCTION: Intrauterine contraceptive device (IUCD) is commonly used method of family planning.¹ About 106 million women throughout the world are using Intrauterine contraceptive device (IUCD).¹ Additional benefit of IUCD include rapid return to fertility after the device is removed, very few systemic and metabolic side effects and need for only single motivation for long term use. Despite these advantages less than 1% of women aged between 15-50 uses IUCD in the USA compared to 15-30% in most European countries and Canada.²

ORIGINAL ARTICLE

Currently only the Cu-T 380A and Levonorgestrel releasing IUD are available for use in US. In Europe the Multiload models 250 and 375 are also available. The Cu-T 380A is a non-hormonal contraceptive device composed of polyethelene frame with vertical length of 36mm and horizontal length of 32mm. The exposed surface area of copper is 380mm² and is approved for 10 years of use. In the first year of use Cu-IUD has 0.5% pregnancy rate and approximate 6% expulsion rate and 15% rate of removal for medical reason (Bleeding and pain).²

At present Cu-T 380A is widely used IUCD in India. It is reliable, reversible and economic method for regulation of population.

IUDs are extremely effective in preventing pregnancy, and they are safe for right women. They are easy to use because there is nothing to remember and they don't change the normal cyclic hormonal pattern. However unlike some methods of birth control, IUDs offer no protection from STDs. The device can also cause cramping, pain and extra bleeding when inserted.

IUCDs generally have shown to be safe and effective but tend to have some side effects.³

Microbial, clinical and cytopathological monitoring of women using these devices are important ascertaining- their side effects, risk of genital tract infection and detection of cervical intraepithelial neoplasia (CIN).

This study has evaluated- gynaecological problems, lower genital tract infection, pattern of cytopathology and risk of cervical intraepithelial neoplasia (CIN) in Cu-T users at tertiary care hospital.

AIMS AND OBJECTIVES:

1. To study clinical, microbial and cytopathological changes in Cu-T users in tertiary care hospital.
2. To ascertain the safety of Cu-T with reference to cervical intraepithelial neoplasia.

MATERIALS AND METHODS:

Study Design: Prospective analysis.

Study Setting: Department of Obstetrics and Gynaecology, Govt. Medical College and Hospital Nagpur.

Study Duration: Two months from 02/06/2008 to 02/08/2008.

Inclusion Criteria:

1. Study subjects: All Cu-T users were included irrespective of duration of use.
2. Control subjects: All women other than contraceptive users were included.

Exclusion Criteria: Unsatisfactory smear were excluded.

Sample Size:

1. Study subjects: Women visiting family planning clinic for follow-up (Cu-T users, N=100).
2. Control subjects: Women coming for Cu-T insertion/Non-Cu-T users (control, N=80).

ORIGINAL ARTICLE

METHODOLOGY:

- The subjects were explained about the study and informed consent was taken.
- The detailed history was obtained. Each subject underwent per speculum examination to look for thread, or expulsion of Cu-T, condition of vagina and cervix and discharge.
- Vaginal discharge was collected from posterior fornix by using cotton swab stick and brought to microbiology lab for PH testing, wet mount, KOH mount, Gram staining and culture on Mac Conkey and blood agar.
- Cervical scraping was taken by using Ayre's spatula and fix by standard method of fixation and subjected to Papanicolaou staining. Reporting was done by cytologist according to Bethesda classification.
- The women were counselled a week later using gathered information. Depending upon the diagnosis and patient's convenience, subsequent follow-up were made.

STATISTICAL ANALYSIS: All collected data were analysed by using statistical software STATA version 10.

Chi square test, Proportional test and Fisher exact test were used.

P value <0.05 was considered significant.

RESULTS:

Parameters	Study(N=100)	Control(N=80)
Average age	26.13±3.24	26.69±1.58
Mean parity	1.25±0.18	1.58±0.19

TABLE NO. 1: DEMOGRAPHIC PARAMETERS

Table no.1 shows that average age of study group was 26.13±3.24 and control group was 26.69±1.58. Maximum number of study subjects (58%) belonged to age group 21-25 years, followed by 30% in age group 26-30 years. Control cases were matched according to age of study subjects. The mean parity in study group was 1.25±0.18 and in control group was 1.58±0.19. Maximum number of study subjects were para1 (75%) and para 2(22%) whereas in control subjects maximum frequency of para 2(55%) and para 1(40%) were considered simultaneously.

COMPLAINTS	STUDY SUBJECTS (%) N=100
Vaginal discharge	41(41%)
Pain in lower abdomen	33(33%)
Menorrhagia	27(27%)
Backache	18(18%)
Oligomenorrhea	18(18%)
Itching	15(15%)
Polymenorrhea	08(08%)
Dysmenorrhea	07(07%)
Expulsion	01(01%)
No complaints	27(27%)

TABLE NO. 2: CHIEF COMPLAINTS OF Cu-T USERS

ORIGINAL ARTICLE

Table no.2 shows that in study subjects, majority of patients presented with excessive vaginal discharge (41%) as chief complaints followed by pain in lower abdomen (33%), menorrhagia (27%) and backache (18%). Other complaints were oligomenorrhea (18%), itching (15%), polymenorrhea (8%), Dysmenorrhea (7%), expulsion (1%) while 20% of study cases were having no complaints. All control subjects were asymptomatic by above defined criteria.

CHARECTORESTICS	STUDY, N=100	CONTROL, N=80	P-value
Healthy vagina	51(51%)	55(68.75%)	0.016
Vaginitis	43(43%)	25(31.25%)	0.104
Cervical erosions	08(08%)	01(1.25%)	0.038

TABLE NO. 3: PER SPECULUM EXAMINATION

Table no. 3 depicts that frequency of healthy vagina was significantly higher in control subjects (68.75%) than study subjects (51%) in per speculum examination. Significant proportion of women had cervical erosions in study subjects (8%) as compared to control subjects (1.25%). There was no significant difference in vaginitis (white discharge) among study subjects (43%) and control subjects (31.25%).

CHARECTORISTICS	STUDY, N=97	CONTROL, N=76	P-value
Normal	6(6.18%)	16(21%)	0.003
Inflammation	73(75.2%)	52(68.4%)	0.319
• Endocervicitis	16(16.49%)	09(11.8%)	0.395
• Nonspecific	57(58.76%)	43(56.5%)	0.769
Infection			
• Fungal(candida)	6(6.18%)	06(7.89%)	0.673
• Bacterial vaginosis	5(5.15%)	00(00%)	0.044
• Trichomonas vaginalis	9(9.27%)	03(3.94%)	0.165
Repair	6(6.18%)	05(6.57%)	0.917
ASCUS/LSIL/HSIL	NIL	NIL	

TABLE NO.4: CYTOLOGICAL FINDINGS

NOTE: ASCUS: Atypical squamous cells of undetermined significance.

LSIL and HSIL: low grade squamous intraepithelial lesion and high grade squamous intraepithelial lesion.

Table no.4 depicts that normal cytology was seen in 6(6.18%) Vs 16(21%) study subjects and control subjects respectively, significant higher in control group. Endocervicitis occurred in 16(16.49%) of study group Vs 9(11.8%) of control group. Nonspecific inflammation was seen in 57(58.76%) cases in study group as compared to 43(56.5%) cases in control group. Fungal infection occurred in 6(6.18%) study subjects Vs 6(7.89%) control subjects while 9(9.27%) of study subjects had Trichomonas vaginalis infection as compared to 3(3.94%) of control subjects.

The incidence of inflammation and fungal and Trichomonas vaginalis infections was not statistically significant in study and control group. Cytologist reported that plenty of clue cells were

ORIGINAL ARTICLE

suggestive of bacterial vaginosis. In cervical cytology, bacterial vaginosis was significantly found in study group 5(5.15%) as compared to control group 0(0%). No cases of Actinomycosis infection was detected in either group. No case of precancerous lesion was seen.

Cytological finding	Upto month (N=13)	Upto 1 year (N=13)	Upto 2 year (N=26)	Upto 3 year (N=6)	≥4 years (N=11)
Normal	01(7.69%)	1(2.4%)	1(3.8%)	1(16.6%)	2(18%)
Inflammation	09(69.2%)	33(80%)	19(78%)	4(66.6%)	8(72%)
Infection					
1.fungal	00(00%)	2(4.8%)	3(11.5%)	00(00%)	1(9%)
2.Bacterial vaginosis	1(7.69%)	2(4.8%)	2(7.69%)	00(00%)	00(00%)
3.trichomonas vaginalis	2(15.3%)	3(7.3%)	2(7.69%)	1(16.6%)	1(9%)
Repair	-	2(4.8%)	-	1(16.6%)	3(27.2%)

TABLE NO. 5: CERVICAL CYTOLOGY IN RELATION TO DURATION OF USE OF Cu-T (N=97)

Table no. 5 depicts decrease in incidence of normal cytology smear for up to 2 years of duration of use of Cu-T followed by slight increase thereafter. There was predominantly increased incidence of inflammatory cytological smear in initial 2 years which was then set into a relatively constant level. During the initial 2 years of use of Cu-T, there was increase in incidence of fungal (up to 11.5%) and bacterial vaginosis infection (up to 7.69%). The incidence decline thereafter while Trichomonas vaginalis infection showed progressive increased incidence of occurrence with increase in duration of use of Cu-T reaching a maximum or 16.6% up to 3 years.

Test	Study(N=100)	Control(N=80)	P-value
Wet mount (Trichomonas vaginalis)	09(9%)	3(3.75%)	0.166
KOH mount(fungal hyphae)	08(8%)	5(6.25%)	0.643

TABLE NO. 6: MICROBIAL FINDING

Table no. 6 shows that wet mount preparation for Trichomonas vaginalis positive in 9% of study subjects compared 3.75% in study subjects. KOH mount revealed 8% Vs 6.25% fungal hyphae in study group and control group respectively. None of these finding were significant.

Finding	Study(N=100)	Control(N=80)	P-value
Doderlein bacilli	44	48	0.052
Gram positive cocci	12	03	0.044
Gram negative cocci	01	01	0.872
Gram positive Gram negative coccobacilli	03	02	0.855
Yeast cells	10	09	0.784
Pus cells	75	44	0.004
Clue cells	26	15	0.245
Gram negative rods	37	25	0.421

TABLE NO. 7: GRAM STAINING FINDING

Table no.7 shows that there was nearly significant decrease in doderlein bacilli ($p=0.052$) and significant increase in gram positive cocci ($p=0.044$) and pus cells ($p=0.004$) in study subjects than

ORIGINAL ARTICLE

control subjects. Growth of anaerobic organisms and yeast cells showed comparable results in both groups which were insignificant.

Culture Findings	Study (N=100)	Control (N=80)	P-value
E.coli	33(33%)	24(30%)	0.664
Kleibseilla	03(03%)	04(5%)	0.484
Staphylococcus	10(10%)	07(8.7%)	0.778
Micrococci	07(07%)	09(11.25%)	0.316
Gram positive bacilli	08(08%)	04(5%)	0.416
Gram negative rods	04(04%)	01(1.25%)	0.272
Candida	08(08%)	05(6.25%)	0.643
Enterococci	02(02%)	02(2.5%)	0.838
Gram negative cocci	01(01%)	00(0%)	0.367
Sterile	24(24%)	24(30%)	0.367

TABLE NO. 8: VAGINAL DISCHARGE CULTURE

Table no.8 depicts that there was insignificant growth of aerobic and anaerobic organism in vaginal discharge culture in study subjects compared to control subjects.

DISCUSSION: In SR Nayak et al (2007)⁴ study maximum number of subjects (39.8%) were from 21-25 years age group. Similarly in present study 58% of subjects belong to 21-25 years of age. In present study 75% of study subjects belong to para1 which is comparable to study carried out by SR Nayak et al (2007)⁴ i.e.73.1% with para1. Present study found that majority of patients had excessive vaginal discharge (41%) as their chief complaints followed by pain in lower abdomen (33%) which is comparable to study carried out by Agrawal K et al (2004)⁵ i.e, vaginal discharge (46%) pain in lower abdomen (34%). Candida albicans, yeast fungus, normally grows in harmless quantities in vagina. It was assumed that in Cu-T users, yeast like organisms may grow profusely and cause thick white discharge. Also, increased incidence in Cu-T users was considered of being responsible for excessive white discharge. But researchers have found insignificant increase in both fungal infection and vaginitis in the users and thus little association between the complication due to the use of Cu-T contraceptive devices and excessive white discharge.

Foreign body response or constant irritation by Cu-T thread may be responsible for excessive discharge. Study by Agrawal K et al (2004)⁵ and SR Nayak et al (2007)⁴ found backache as the major complaints among IUCD users with its incidence of occurrence as 54% and 44% respectively. But present study showed only 18% cases of backache while National family health survey II (2000)⁶ reported 5.5% of the same. We conclude that backache is not medically related with the use of Cu-T but can be the outcome of frequent anaemia in some cases who are prone to increased bleeding associated with use of Cu-T IUD. Nearly all medical reasons accounting for removal of Cu-T IUDs involve one or more type of abnormal bleeding, either heavy or prolonged menses or intermenstrual bleeding. In Bangladesh, 40% of 3678 users surveyed had either their IUD removed with about 1/5th or removals due to menstrual problems.⁷ Menorrhagia occurred in a significant proportion of women in Agrawal K et al (2004)⁵ study as (18%), SR Nayak et al (2007)⁴ study as (38.2%) and in present study as 27%. The reason for this Cu-T IUD disturbs the blood vessels or alters the normal clotting mechanism in the endometrium. Excessive bleeding in the first few months should be treated with

ORIGINAL ARTICLE

reassurance to women that these side effects are normal and usually diminish over time. Treatment with oral iron as well as systemic administration of Prostaglandin synthetase inhibitors during menses is often prescribed. It is not medically necessary to remove the IUD unless the women also complains of fever, abdominal tenderness or unusual vaginal discharge (Signs of PID) or severe pain (That last longer than 12-24 hours and not responding to NSAIDs) or signs of uterine perforation. In present study, we found itching in 15% of study subjects.

Infection or vaginal discharge may be responsible for this. Expulsion is uncommon, during the first year of use, between 5-20% of IUD users experience spontaneous expulsion of device². This is most likely to happen in the first 3 months following insertion usually during menstruation. SR Nayak et al (2007)⁴ study reported 1.4% cases of expulsion while present study found only 1% incidence of expulsion within 1 month of use of Cu-T. Palpation of Cu-T strings after menses will reduce the risk of unnoticed expulsion and subsequent exposure to pregnancy. Above discussion brought us to the conclusion that regular counselling of women about the side effects and their proper management should be done to deal with the gynaecological problems associated with the use of Cu-T IUDs. Per speculum examination of study subjects and control subjects was compared. Agrawal K et al (2004)⁵ found rate of healthy vagina 78% Vs 100% in study and control subjects which was significantly higher in control subjects compared to study subjects (P=0.000). Erosions was significantly higher in IUCD users compared to none in controls (20% Vs none, P=0.17).

Present study is in accordance with the above mentioned study vagina is significantly healthy in control subjects as compared to study subjects (P=0.016), also erosions are seen in 8% study subjects Vs 1.25% control subjects (P=0.038) which is again significantly higher finding. Vaginitis present in 48% Vs 31.25% (P=0.104) doesn't reveal a significant association with the use of Cu-T. It is possible that the strings irritate the cervix and predispose the users to the cervical erosions. Prinz W et al (1981)⁸ reported that rate of inflammatory cytologic specimen was higher in study group than control group. Agrawal K et al (2004)⁵ study revealed only slightly increased incidence of inflammatory smear in study group compared to control group (P=0.52, statistically insignificant).

The present study revived these observations and found only slightly increased incidence of inflammatory smear in study group compared to control group (75.2% Vs 68.4%) which is statistically not significant (P=0.319). Agrawal K et al (2004)⁵ study shows insignificant increase in both fungal infection and bacterial vaginosis (P=0.93, P=0.77 respectively). In present study found insignificant increase in fungal infections (P=0.673) but significant increase in bacterial vaginosis (P=0.044). No cases of Actinomyces infection was found in either group. ASCUS was seen in 1.4% of the subjects as compared to 2% of the control in study conducted by SR Nayak et al (2007)⁴ while in present study we didn't find any case of ASCUS. LSIL (1% study subjects Vs 0% control subjects, P=1.00) and HSIL (2% study subject Vs 0% control subject, P=0.55) were found in Agrawal K et al (2004)⁵ study in women using IUCD for 15 and 25 years following forgotten insertion.

Only LSIL (1.4% study subjects Vs 2% control subjects) was seen in SR Nayak et al (2007)⁴ study in women having Cu-T in situ for >3 years (for 12 and 8 years with intermittent insertion). However incidence of dysplasia was comparable to that in general population. While none of either lesion is found in present study (major limitation in our study was none of the study subject had used Cu-T for prolonged duration). Study carried out by SR Nayak et al (2007)⁴ found 26.9% Vs 25% reactive and reparative changes among study group and control group respectively while present study found 6.18% Vs 6.57% reactive and reparative changes among study group and control group respectively which is statistically insignificant (P=0.917). None of the cases revealed malignant

ORIGINAL ARTICLE

cytological changes. Study carried out by SR Nayak et al(2007)⁴ reveals that as the duration of use of Cu-T increases the chances of infection increase maximum incidence of 35.4% with duration of Cu-T up to 3 years. Similar in present study we found increase in incidence of infection for up to 2 years of use of Cu-T. This finding is more consistent with *Trichomonas vaginalis* infection, incidence of which progressively increased up to 16.6% with increase in duration for up to 3 years.

However increase in infection cannot be attributed only to contraception, other factors such as hygiene, life style etc. might also responsible for these infections. SR Nayak et al (2007)⁴ study also showed no association between increase in incidence of reactive and reparative changes with increase in duration of use of Cu-T. In present study, we found between increase in incidence of benign changes of squamous metaplasia (Reactive and reparative changes) with increase in duration of use of Cu-T. There is possibility that these changes may lead to dysplasia with increase in duration of use of Cu-T. However more in depth and well developed studies are needed for confirmation. NRIFC (1999)⁹ study showed significant increase in fungal infection (21.8%) in study group than in (13.1%) control group While *Trichomonas vaginalis* infections were comparable in both groups. Agrawal K et al (2004)⁵ study found (12% Vs 4%, P=0.14) *Trichomonas* infection and (18% Vs12%, P=0.5) fungal hyphae.

Present study is comparable to study carried out by Agrawal K et al (2004)⁵ and points that though there is increased frequency of *Trichomonas* and fungal infections in study subjects than controls, but none of them is significant. Hence qualitative alteration in vaginal flora is not significantly seen. Gram stain findings in present study reveal that there is significant increase in gram positive cocci and pus cells. It may be due to increase in *Trichomonas* infection, bacterial vaginosis and inflammation due to increase in secondary infections (Growth of staphylococcus and anaerobic organisms).

Study carried out by Agrawal K et al (2004)⁵ found insignificant decrease in *dederlein* bacilli in study subjects compared to control subjects (P=0.75) while in present study we found nearly significant decrease in *dederlein* bacilli in study subjects than in control subjects (P=0.052) which suggestive of quantitative alteration in the vaginal flora. Results for vaginal discharge culture are more reliable which shows comparable results in two groups. In present study incidence of *E coli* (P=0.664), Gram positive bacilli (P=0.778) and Gram negative rods (P=0.272) is statistically not significant which is comparable to study carried out by Agrawal K et al (2004)⁵ where incidence of *E coli* (P=0.76), Gram positive bacilli (P=0.93) and Gram negative rods (P=0.73).

CONCLUSION: A significant proportion of women had gynaecological problems associated with the use of Cu-T. Symptoms like menorrhagia should be dealt properly to cope with the development of anaemia in users. However it is not unusual to experience these symptoms and not considered as serious side effects but makes proper counselling and scheduled follow up of women imperative.

Although cervical erosions, bacterial vaginosis and increases in incidence of *Trichomonas vaginalis* infection with increase in duration of use, were significantly seen but there was insignificant increase in vaginitis.

After re-examining the microbial findings of gram stain and vaginal discharge culture we conclude that there is insignificant occurrence of increase in infections among Cu-T users. Other factors, such as life style and hygiene may play a crucial role in development of complications among women using a Cu-T intrauterine device.

ORIGINAL ARTICLE

Cervical cytology did not reveal any case of cervical intraepithelial neoplasia (CIN), although there is no general consensus on this finding, based on our statistical analysis we conclude that women using copper containing IUD are not subjected to increased risk of cervical malignancy. But still we feel that future researches should go beyond the present incidence rate to find out if there is any relationship between the use of Cu-T and CIN.

Finally we agree that Cu-T 380A is an excellent contraceptive of choice for most women. And there is need to create awareness on the safety and effectiveness of this device to make it more acceptable.

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ORIGINAL ARTICLE

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