

**COMPARE THE RISK OF GENITAL TRACT INFECTION IN INTRAUTERINE CONTRACEPTIVE USERS AND NON USERS**Jayshree Vaman<sup>1</sup>, Deavikrishna<sup>2</sup>, Ajitha Raveendran<sup>3</sup>**HOW TO CITE THIS ARTICLE:**

Jayshree Vaman, Deavikrishna, Ajitha Raveendran. "Compare the Risk of Genital Tract Infection in Intrauterine Contraceptive Users and Non Users". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 22, March 16; Page: 3792-3803, DOI: 10.14260/jemds/2015/547

**ABSTRACT: INTRODUCTION:** Despite many advantages of intrauterine contraceptive devices (IUCD) as a method of family planning, it generally suffers from unpopularity worldwide. The scenario in India is the same, with less than 2% of women adopting IUCD as a method of contraception. One amongst the reasons is the fear of infection. **AIMS AND OBJECTIVE:** To compare the risk of genital tract infection in copper T users whose pre-insertional screening for genital tract infection is negative and non IUCD users whose screening for genital tract infection is negative at onset of study. **MATERIALS AND METHODS:** Women attending family welfare department of medical college Trivandrum, Kerala, for IUCD insertion and group of non-users meeting the requirements of inclusion and exclusion criteria whose screening for genital tract infection were negative were included in the study group. All patients in whom the screen test was negative for Candidiasis Bacterial vaginosis Gonorrhoea and Chlamydia were selected for Cu T380 A IUCD insertion. 80 non users whose screening tests for genital tract infection were negative were included in the study. The test was repeated after one and six months in IUCD users and non-users. **RESULTS AND OBSERVATION:** In this study Bacterial vaginosis was present in 8.75% of IUCD users and 5% of non-users. Candidiasis was present in 11.3% of IUCD users and 12.5% of non-users. Chlamydia infection was present in 3.8% users and 2.5% non-users. 5% of IUCD users and 3.75% non-users developed infection after one month. Risk after one month is 1.3. After six months 14 IUCD users (17.5%) were infected and 14 non users (17.5%) were infected. The risk of infection after six months is 1. In total 18 IUCD users (22.5%) were infected and 17 non users (21.25%) were infected. **CONCLUSION:** No significant difference in occurrence of genital tract infection in IUCD users and non-users. Risk of genital tract infection in IUCD users is same as that of non-users by this study. **KEYWORDS:** GENITAL TRACT INFECTION and IUCD.

**INTRODUCTION:** Intrauterine Contraceptive Device (IUCD) is one of the most commonly used reversible methods of contraception among married women of reproductive age worldwide. Fears about side effects, concerns about infection and infertility, lack of technical training for providers, and the time and costs involved in providing services combine to discourage use of IUCDs. Studies show the Copper T IUCD is nearly as effective as male or female sterilization, the IUCD is often ignored or overlooked. Despite the fact that the government offers IUCD services free of cost, it still remains largely underutilized.<sup>(1)</sup>

**RATIONALE OF THE STUDY:** Despite the many advantages of the IUCD as a method of family planning, it generally suffers from unpopularity worldwide. The scenario in India is the same, with less than two percent of currently women adopting IUCD as a method of contraception. There has been a decline in the number of IUCD acceptors in SAT Hospital over the years. One amongst the

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reasons is due to fear of infections. This study aims to prove that there is negligible risk of reproductive tract infections after IUCD insertion if it is inserted under strict aseptic precautions. This type of study has not been done in SAT Hospital previously. Among IUCD acceptors, the morbidity is mostly related to lack of appropriate screening prior to insertion and inadequate aseptic precaution during insertion resulting in opportunistic infections in lower reproductive tract presenting in the post insertion period.

### AIMS AND OBJECTIVE:

1. To study the risk of genital tract infections in Copper T users, pre-insertional screening for reproductive infection is negative, in a tertiary care centre.
2. To study the risk of genital tract infections in non-user s who's screening for reproductive infection is negative.
3. To compare the risk in both the groups.

**REVIEW OF LITERATURE:** The intrauterine contraceptive device (IUCD), a flexible frame that fits inside a woman's uterus, provides very effective, safe, and long term quickly reversible-protection from pregnancy.

Insertion of the IUCD may introduce bacteria into the uterus. The insertion process carries an increased risk of pelvic inflammatory disease in the first 20 days following insertion,<sup>(2)</sup> but the risk is still low, and is attributable to preexisting gonorrhoea or chlamydia infection present in the cervix at the time of insertion, and not to the IUCD itself. Antibiotics should be given before insertion to women at high risk for endocarditis (infection of the valves within the heart), but should not be used routinely.<sup>(3)</sup>

Although IUCD users are more likely to develop PID than nonusers, it is still an uncommon complication. A WHO study of multiparous women, mostly in developing countries, who were using copper IUCDs reported a cumulative rate of removal for PID of less than one per 100 women after six years of use.<sup>(4)</sup>

Providers can minimize the risk of infection just after IUCD insertion by carefully following infection-prevention procedures during IUCD insertion.

It remains unclear whether the IUCD increases the risk of developing PID in a woman with gonorrhoea or chlamydia, however, beyond the usual risk just from having these STIs. The ideal study that would answer this question definitively cannot be conducted because it would require randomly assigning women with current gonorrhoea or chlamydia either to a group having an IUCD inserted or a group receiving no contraception at all.

Overall levels of PID in IUCD users are low. In large studies mostly in developing countries, rates of acute PID among IUCD users have been between 0.6 and 1.6 per 1,000 woman-years of use. Long-term WHO multicentric studies report 4 to 11 IUCD removals for diagnosed PID per 1,000 women over a 10- to 12-year period of use.<sup>(5)</sup>

Greatest PID risk is in the first few weeks after IUCD insertion. Analysis of data from 13 WHO clinical trials conducted in Africa, the Americas, Asia, and Europe found that the risk of developing PID was 6.3 times greater during the first 20 days after IUCD insertion than at any later time. After the first 20 days from insertion, the number of new PID cases occurring each year remained at a fairly constant low level-around 1.4 per 1,000 woman-years-throughout eight years of use. This low level is similar to or even lower than that among women in developed countries who do not use IUCDs.<sup>(6)</sup>

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**MATERIALS AND METHODS:**

**STUDY DESIGN:** Prospective cohort study.

**STUDY SETTING:** Family Welfare outpatient department. Department of Obstetrics and Gynaecology. Sree Avittom Thirunal Hospital (SATH). Medical College, Thiruvananthapuram.

**DURATION OF STUDY:** One Year.

**INCLUSION CRITERIA:** Consenting women aged 18yrs and over attending family welfare outpatient department, Sree Avittom Thirunal Hospital for IUCD insertion and non-users whose pre insertional screening for genital tract infections is negative is to be included in study group.

**EXCLUSION CRITERIA:**

- Women with history of menorrhagia.
- Immunosuppressant drug use in the past.
- Not giving consent.
- Those who have recently taken antibiotics (both local and systemic) for the past 2 weeks.
- Postpartum puerperal sepsis.
- Immediately after a septic abortion.
- Unexplained vaginal bleeding.
- Malignant gestational trophoblastic disease.
- Cervical cancer (awaiting treatment).
- Distortions of the uterine cavity by uterine fibroids or anatomical abnormalities.
- Current pelvic inflammatory disease.
- Current purulent cervicitis, chlamydial infection or gonorrhoeal STIs.
- Known pelvic tuberculosis.

**SAMPLE SIZE:** Considering the exclusion and inclusion criteria and with an error of 6%, the samples size required for the present study was calculated as 88 per group which was rounded off to 90 individuals each in IUCD user and non-user group totaling to 180 subjects in entire study population. After six month follow up study, only 80 patients per group was obtained after dropouts, which was taken for further statistical analysis.

**STATISTICAL ANALYSIS:** Data were analyzed using computer software, Statistical Package for Social Sciences (SPSS) version 10. Data are expressed in its frequency and percentage as well as mean and standard deviation. To elucidate the associations and comparisons between different parameters, Chi square ( $\chi^2$ ) test was used as nonparametric test. Multivariate logistic regression analysis was performed to assess the risk factors of different factors for each group. For all statistical evaluations, a two-tailed probability of value,  $p < 0.05$  was considered significant.

**METHODOLOGY:** Women attending family welfare outpatient department for IUCD insertion and a group of non-users meeting the requirements of inclusion and exclusion criteria whose screening tests for genital tract infections were negative were included in the study group. All details were collected using a standardized questionnaire after getting their consent. Demographic, socioeconomic, menstrual history and sexual health history were noted.

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All patients in whom the screening tests were negative were selected for Cu T380 A IUCD insertion. 80 non users whose screening tests for genital tract infections were negative were also included in the study group. The tests were repeated after one and 6 months in IUCD users and non-users. All patients had to undergo the tests. The tests were done in Dept of Micro Biology, Medical College, and Trivandrum.

Candidiasis was detected clinically by the presence of thick curdy white discharge, trichomoniasis by greenish frothy discharge, and Bacterial vaginosis by the presence of homogenous white discharge. A wet mount preparation was obtained by diluting the vaginal discharge with one or two drops of normal saline and place it on a clean slide and cover it with cover slip. Then it was examined under low power and high power objective to detect motile trophozoite forms of *Trichomonas vaginalis* and fungal hyphae.

Candidiasis was detected in the laboratory by gram stain from a swab taken from posterior fornix and culture by sabouraud s agar. Colonies formed were cream coloured, and smooth both at 25°C and 37°C.

From the double swab taken from the upper vagina, one was used for gram staining to observe the number of pus cells, gram reactions and to assess the Nugent's score – to score Bacterial vaginosis.

<b>Bacterial morphotypes</b>	<b>0-3 (normal)</b>	<b>4-6 (Intermediate)</b>	<b>7-10 (BV)</b>
Lactobacillus	4+ to 3+	2+ to 1+	0
G. vaginalis/ Bacteroides	0 to 1+	2+ to 3+	≥4+
Mobiluncus (curved rods)	Nil	Nil	1+ to 4+
Clue cells	Nil	Nil	Present
Average no. of morphotypes seen per oil immersion field 0 = nil, 1+ = <1, 2+ = 1-4, 3+ = 5-30, 4+ = >30			

The criterion for Bacterial vaginosis is a total score of 7 or higher, score of 4-6 is considered intermediate and score 0-3 is considered normal.

The presence of Gonorrhoea was tested by direct inoculation of the swab taken in to Thayer martin medium.

Screening for Chlamydia was done by using The SD Bioline Chlamydia, solid phase immunochromatographic assay for the rapid, qualitative detection of Chlamydia antigen directly from endocervical swab and cytology brush specimens. The specimens were processed immediately after collection. Interpretation of the test.

**NEGATIVE RESULT:** The presence of only one purple colour band within the result window indicates a negative result.

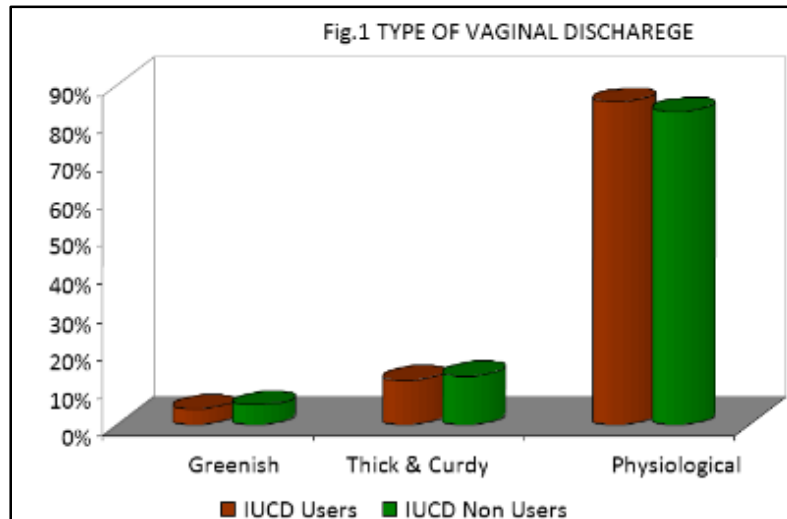
**POSITIVE RESULT:** The presence of two colour bands within the result window indicates a positive result.

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**INVALID RESULT:** If purple colour band is not visible within the result window after performing the test, the result is considered invalid.

Chlamydia trachomatis IgM antibody detection test was done in follow up visits at one and six months. Chlamydia trachomatis IgM ELISA kit –Calbiotech was used to detect IgM Chlamydia antibodies.

### RESULTS AND OBSERVATION:



As the table shows greenish discharge was present in 3.8% IUCD users and 5% non-users. Thick curdy white discharge was present in 11.3% IUCD users and 12.5% non-users. As p value >0.05 no significant association.

**TABLE 1:** Distribution of bacterial vaginosis based on nugent scoring after one month in iucd users and non-users whose screening results were negative.

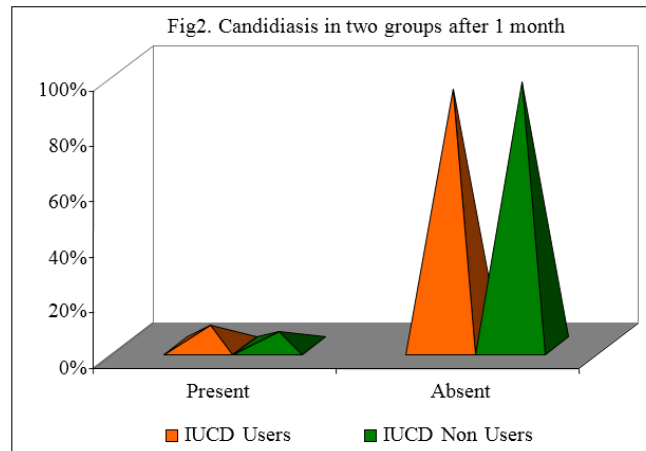
Bacterial Vaginosis	Group		Total
	IUCD Users	IUCD Non Users	
Present	-	-	-
Absent	80	80	160
	100.00%	100.00%	100.00%
<b>Total</b>	<b>80</b>	<b>80</b>	<b>160</b>
Chi Square: 0.000; P > 0.05			
<b>TABLE 1</b>			

No cases of by were detected in both groups.

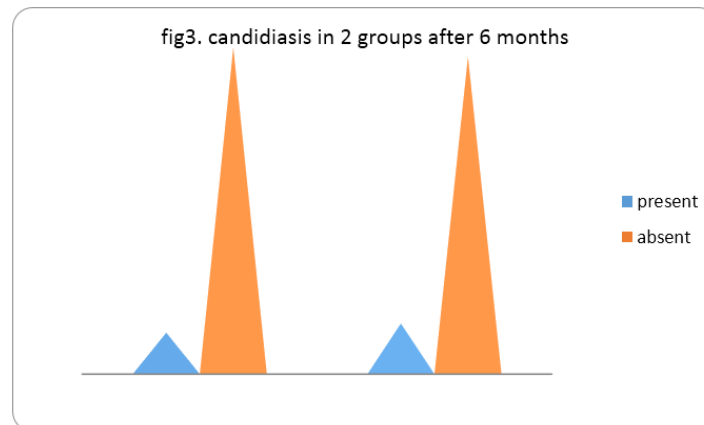
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**TABLE 2:** Distribution of bacterial vaginosis based on nugen scoring after six months in iucd users and non-users.

Bacterial Vaginosis	Group		Total
	IUCD Users	IUCD Non Users	
Present	6	5	11
	7.50%	6.25%	6.9%
normal	74	75	149
	92.50%	93.75%	93.1%
<b>Total</b>	<b>80</b>	<b>80</b>	<b>160</b>
Chi Square: 0.386; P > 0.05; RR 1.2			
<b>TABLE 2</b>			



As shown in the table 4 IUCD users (5%) and 3 non users (3.75%) developed candidiasis after one month. As p value >0.05 no significant association.



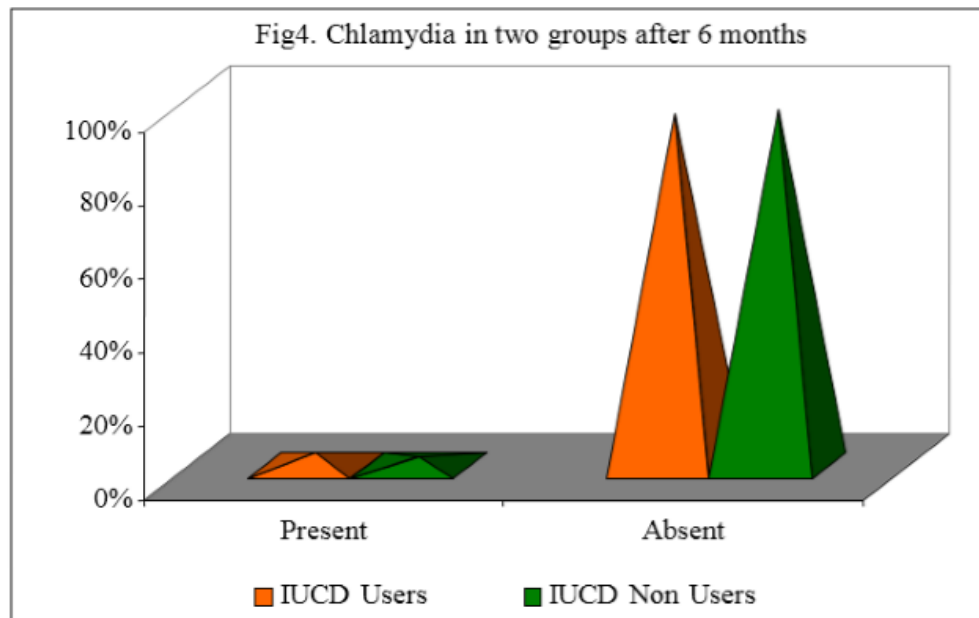
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9 IUCD users (11.25%) and 11 non users (13.75%) developed candidiasis at the end of 6 months by culture on sabouraud s agar swab. As p value >0.05 no significant association.

**TABLE 3:** Distribution of igm chlamydia antibody by elisa after one month in iucd users and non-users whose screening results were negative.

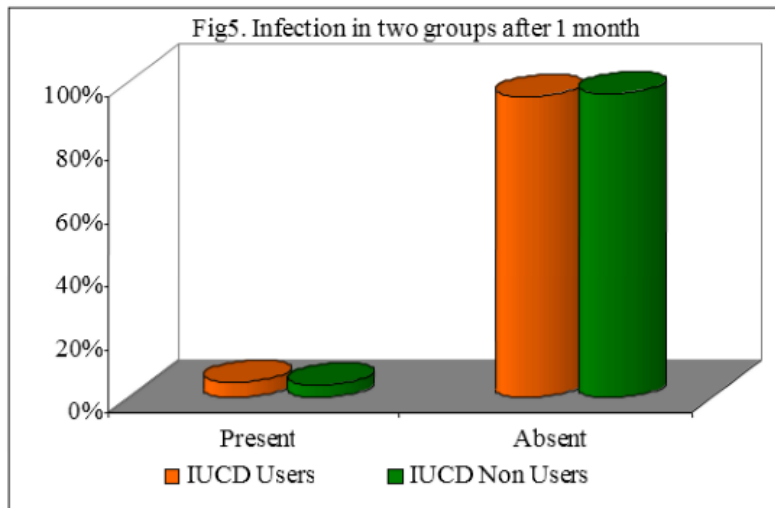
Chlamydia IgM antibody	Group		Total
	IUCD Users	IUCD Non Users	
Present	-	-	-
Absent	80	80	160
	100.00%	100.00%	100.00%
Total	80	80	160
Chi Square: 0.000; P > 0.05;			
<b>TABLE 3</b>			

No cases were detected by ELISA after one month.

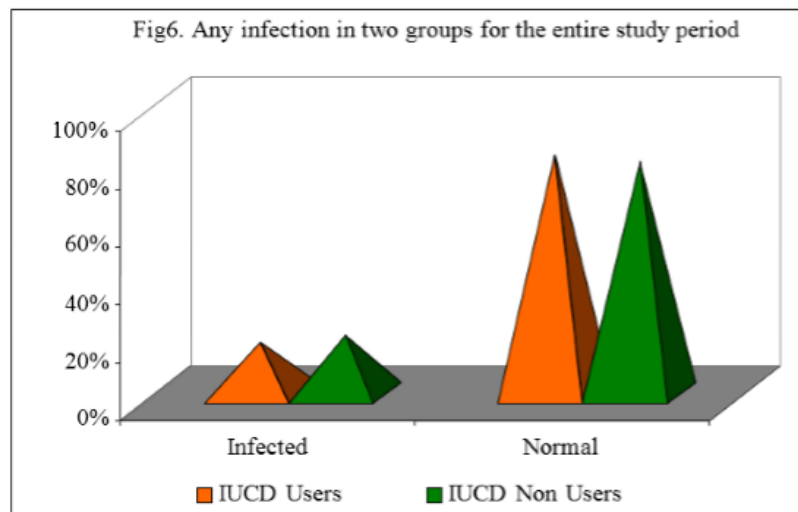


As the table shows 3 IUCD users (3.75%) and 2 non users (2.5%) had Chlamydia infection after 6 months on ELISA testing. As p value >0.05 no significant association.

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As shown in the table 4 IUCD users (5%) and 3 non users (3.75%) developed infections after one month. As p value >0.05 no significant association.



As shown in the table in total 18 IUCD users (22.5%) and 17 non users (21.25%) were infected. As p value >0.05 no significant association.

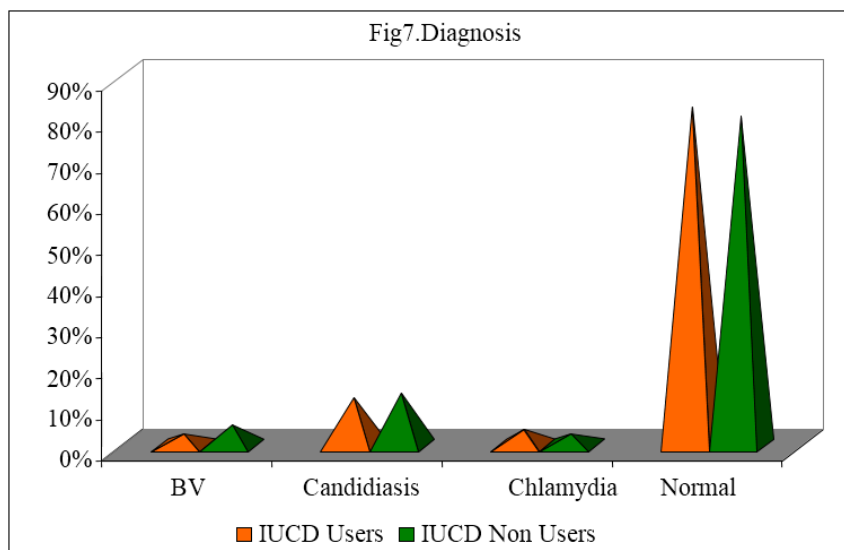
**TABLE 4:** Distribution of genital tract infections with micro biological diagnosis after six months in iucd users and non-users.

Diagnosis	Group		Total
	IUCD Users	IUCD Non Users	
BV	6	5	11
	7.50%	6.25%	6.80%



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Candidiasis	9	10	19
	11.25%	12.50%	11.90%
Chlamydia	3	2	5
	3.75%	2.50%	3.10%
Normal	62	63	125
	77.50%	78.75%	78.1%
<b>Total</b>	<b>80</b>	<b>80</b>	<b>160</b>
Chi Square: 0.951; P > 0.05			
<b>TABLE 4</b>			



**DISCUSSION:** In this study women between 18 to 35 years who attended the family welfare outpatient department of Sree Avittom Thirunal Hospital were selected and were given a standardized questionnaire that elicits socioeconomic, reproductive, sexual health history and menstrual history, satisfying the inclusion and exclusion criteria till the proposed sample size was met. Sample collection was completed in 12 months. All women underwent a speculum examination – to visualize the vaginal mucosa to look for any abnormal vaginal discharge. High vaginal swab were taken and the tests were done. These swabs were examined for Bacterial vaginosis, Candida albicans, Group B streptococcus, Trichomonas vaginalis, N. Gonorrhoea and Chlamydia trachomatis. Hence the microbiological diagnosis was established. All patients in whom the screening tests were found to be negative were selected for Cu T380. A IUCD insertion. A group of non-users in whom the screening tests was negative were also selected. The patients were followed up after one and six months and screening tests were repeated in these patients to find the risk of genital tract infections.

Greenish discharge was present in 3.8% iucd users and 5% non-users. Thick curdy white discharge was present in 11.3% iucd users and 12.5% non-users.

In this study, 6 IUCD users (7.5%) and 5(6.25%) non users had bacterial vaginosis infection on grams staining and nugents scoring after 6 months. Relative risk was detected to be 1.2. Hence this study doesn't show any significant difference in the risk of bacterial vaginosis infection in both the

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groups. The incidence of BV in this study was lower than that described in other populations. But in another study T Ferraz do Lago et al. followed 223 women over a period of six months after IUCD insertion, found BV to be the most common vaginal infection.<sup>(7)</sup> In this study 4 IUCD users (5%) and 3 non users (3.75%) developed candidiasis after one month. 9 iucd users (11.25%) and 10 non users (13.75%) developed candidiasis at the end of 6 months by culture on sabourauds agar swab. Risk after one month was 1.3 and after 6 months it is 0.7. There is no significant difference in the incidence of candidiasis in the two groups. A study by Ferraz do Lago R et al which aimed to study incidence of complications among new users of IUCD, 1 and 6 months after its insertion, in the City of Campinas, Brazil in which a total of 223 women who had a TCu-380A IUCD inserted, found not associated with IUCD complications.<sup>(8)</sup> Another study by Okonkwo N. Stella-Maris et al has shown that: IUCD-related vaginitis is reported to be four times more common in IUCD users than in non IUCD users.<sup>(9)</sup> Cases detected to have candidiasis were treated with Fluconazole 150 mg one tablet in single dose and clotrimazole 100 mg vagina tablet at night before sleep for 7 days.

In the present study infection with group B streptococci, trichomonas and n. gonorrhoea could not be detected. 3 IUCD users had Chlamydia infection after 6 months (3.75%) and 2 non users (2.5%) had the infection on IgM Chlamydia antibody ELISA testing after six months. A study by Nasir et al has shown that the use of copper IUCD for a long period causes growth of Tv on the genital mucosa so special attention should be paid to women who have prolonged copper-IUCD for the possible presence of Tv.<sup>(10)</sup> But Farley et al. (1992) also suggest that the reason why IUCDs that have been in place for a long time are associated with more PID is that aseptic practices during insertion have significantly improved over the years, so that more recently inserted devices are less likely to be infected during the procedure.<sup>(11)</sup>

In this study bacterial vaginosis infection was present in 8.75% iucd users and 5% non-users. Candidiasis was present in 11.3% iucd users and 12.5% non-users chlamydia infection was present in 3.8% users and 2.5% non-users. 4 IUCD users (5%) and 3 non users (3.75%) developed infections after one month. Risk of infection after one month is 1.3. 14 IUCD users (17.5%) were infected and 14 non IUCD users (17.5%) were infected. Risk of infection after 6 month is 1. In total 18 IUCD users (22.5%) were infected and 17 non IUCD users (21.25%) were infected. Risk of infection in IUCD users was found to be same as that of non-users. This study supports the fact there is no significant difference in the risk of genital tract infections in IUCD users and non-users i.e., IUCD as such does not increase the risk of infections if inserted under strict aseptic precautions.

### SUMMARY:

- 80 IUCD users and 80 non users were prospectively followed up over 6 months during my one year study period.
- IUCD users and non-users in whom the screening tests were negative were selected. The patients were followed up after one and six months and tests were repeated in these patients to find the risk of genital tract infection.
- Vaginal discharge was present in 15 % IUCD users when compared to 17.5% non-users.
- Greenish discharge was present in 3.8% IUCD users and 5 % non-users. Thick curdy white discharge was present in 11.3% IUCD users and 12.5% non-users.
- No cases of BV were detected after one month.

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- 6 IUCD users (7.5%) and 5 non users (6.25%) had bacterial vaginosis infection after 6 months on grams staining and nugent s scoring after six months. Relative risk of BV is 1.2.
- 4 IUCD users (5%) and 3 non users (3.75%) developed candidiasis after one month. Relative risk after one month is 1.3.
- 9 IUCD users (11.25%) and 11 non users (13.75%) developed candidiasis after 6 months by culture on sabourauds agar swab. Relative risk is 0.71.
- No cases of Chlamydia were detected by ELISA after one month.
- 3 IUCD users (3.75%) and 2 non users (2.5%) had Chlamydia infection after 6 months on ELISA testing. Relative risk is 1.5.
- 4 IUCD users (5%) and 3 non users (3.75%) developed infections after one month. Relative risk is 1.3.
- 18 IUCD users (22.5%) and 17 non users (21.25%) had infection at the end of six month. Relative risk is 1.05.

### CONCLUSIONS:

- Risk of genital tract infections found more prevalent among 20 to 24yrs.
- No significant difference in the occurrence of genital tract infections in IUCD users and non-users.
- Risk of genital tract infections in IUCD users is same as that of non-users by this study.

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