Clinical microbiological study of the removed intrauterine device

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Received: 06 March 2019
Accepted: 08 April 2019

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ABSTRACT

Background: Intrauterine contraceptive devices are one of the most efficient, cost effective long acting reversible contraceptives. But the worrying clinical symptoms, misconceptions and higher rates of genital tract infection have become a hurdle in its acceptance as the first choice of contraception. The objective of this study was to study the common reasons for removal of IUCD.

Methods: An observational study was done involving 430 women who reported to the OBG Outpatient of the hospitals attached to Bangalore Medical College, over a period of 2 years, for IUCD removal. Socio-demographic details, clinical symptoms compelling IUCD removal were elicited. The removed IUCD was subjected to culture and sensitivity. Initial descriptive analysis was used and statistical tests of significance like chi-square were used to know the relation between genital infections and IUCD. P value <0.05 was considered significant.

Results: Of the 430 women, 46.9% were between 21-25 years of age, 49.3% were primipara, and 71% used IUCD for 1-3 years. Most common reason for removal in the first 2 years was heavy menstrual bleed followed by pain abdomen. 15.3% culture reports showed growth of bacteria, with maximum cultures positive in <5 years of usage, the association was statistically significant.

Conclusions: Present study shows a lower risk of bacterial infections among IUCD users. Hence, effective counseling regarding the safety of IUCD over other spacing methods is essential to increase its acceptance.

Keywords: Genital infections, IUCD, Reasons for IUCD removal

INTRODUCTION

Intrauterine devices (IUDs) are long-term contraceptive methods with high effectiveness. It is estimated that more than 80 million women are using them for contraception in the world.1-3

The modern era of the IUD started in 1909 when Richard Richter in Germany used a ring from silkworm gut as an intrauterine device.4 This device was the first genuine IUD. Ernst Gräfenberg described in 1929 a device consisting of a core of silkworm gut encircled by an alloy of copper, nickel, and zinc that was highly effective in preventing pregnancy.5 The results of his experiments started a strong controversy on the problem of the induction of PID (pelvic inflammatory disease) and European practitioners rejected the idea. Fortunately, in Japan in 1934, Tenrey Otapresented the results of his studies on the use of elastic metallic rings as IUDs.6 The idea was accepted and the IUDs rapidly started to be used. After 1950, opinion about the IUD changed in Europe following the studies of Oppenheimer in Israel and Ishihama in Japan.7,8 These experiments and studies finally led to the first IUDs on the market in the 1960’s. However, the use of IUD seems to be associated with the increase in the risk of infection caused by other microorganisms, which might occur in the first 20 days after its insertion, or over time, especially in case of prolonged use.9-11
microorganisms is the ability to colonize these devices forming biofilms, which consists of layers of bacteria joining the epithelial cells hosts in an organized manner, thereby creating an environment of microbiome imbalance which might reach the upper genital tract.\(^2\) The prolonged use of IUD can also cause the imbalance in the vaginal bacterial flora, enabling the proliferation of anaerobic microorganisms as Gardnerella vaginalis, predisposing to the emergence of bacterial vaginosis.\(^12,13\)

Different studies were conducted to explore the IUD related diseases particularly those associated with infection. Some studies linked the infection related disease to the insertion method and technique.\(^14,16\) During reproductive age, women withhold large number of facultative bacteria, as streptococcus, staphylococcus and beta-hemolytic streptococcus, which may be transmitted to the neonate during child birth causing meningitis and other diseases.\(^17\)

The importance of studying the aerobic bacterial microorganism as E-Coli lies in fact that these organisms are opportunistic pathogens in the female genital tract and are involved in the pathogenesis of urinary tract infections. Furthermore, \textit{Staphylococcus aureus} has a role in toxic shock syndrome.\(^18,19\) Vaginal microflora are classified into two groups, the first is the predominant bacteria with \textit{Staphylococcus epidermidis} being an example, the other group is the potentially pathogenic, such as \textit{Staphylococcus aureus}, \textit{E. coli}, \textit{Streptococcus} group A.

Pelvic inflammatory disease Pelvic inflammatory disease (PID) is a broad term for any infection ascending from the cervix into the uterus, fallopian tubes, and ovaries.\(^20\) Several studies indicate that the risk of PID is highest in the first few months after insertion but decreases dramatically thereafter to become probably not greater than in women not using an IUD.\(^21\)

Thus our study aimed at knowing the genital infections prevalent among IUCD users and its association with duration of use.

**METHODS**

A hospital based observational study was designed to collect data for this research in Vani Vilas and Gosha hospital, BMCRI, Bangalore, India from May 2016 to May 2018. A total of 430 women who reported to the outpatient department of the hospitals attached to Bangalore Medical College, over a period of 2 years, for IUCD removal were taken for study.

**Inclusion criteria**

- Any women who came for IUCD removal
- Willing to participate in the study

**Exclusion criteria**

- Patients who refused to provide written informed consent.

Socio-demographic details, duration of use of IUCD, clinical symptoms compelling IUCD removal were elicited. The removed IUCD was subjected to culture and sensitivity.

**Statistical analysis**

The details were entered in Microsoft excel and SPSS software version 22 was used for data analysis. Initial descriptive statistics in the form of mean and frequency tables were used for socio-demographic details. Analytical statistics in the form of Chi-square test was done, odds ratio and p values were calculated to know the relation between duration of use of IUCD, the symptoms and the risk of genital infections. P value <0.05 was considered statistically significant.

**RESULTS**

Most women who approached for IUCD removal belonged to 21-25 years of age- corresponding to 46.9% of the study population. 90.9 % of the subjects were from urban areas. 55.5% of the subjects who approached belonged to Muslim community. 59.06% of the subjects had finished their schooling. 89.06% of the study group were home makers. 48.8% of the subjects belonged to lower middle class. 49.3% of subjects were primipara.

Majority of women used IUCD for 0-2 years- 57.2% followed by 3-4 years 23.2%.

Reasons for removal with duration of use:

- Pain abdomen
- Heavy menstrual bleed
- Need to change IUCD
- Failure of contraception
- White discharge per vagina
- Planning for conception
- Missing thread
- for sterilization.

Maximum women presented with pain abdomen between 0-2 years followed by 7-8 years. But the relation between pain abdomen and duration of IUCD was 3.09 times higher in 5-6 years of use which was statistically significant with p value<0.04. Maximum women presented with heavy menstrual bleed between 0-2 years followed by 7-8 years. But the relation between heavy bleed and duration of IUCD was 3.48 times and 4.04 times higher in 3-4 years and 5-6 years of use respectively, which was statistically significant with p value<0.05.
Table 1: Socio-demographic details of the study group.

| Demographic       | Categories  | Number | Percentage |
|-------------------|-------------|--------|------------|
| **Age in years**  | <20         | 8      | 1.8        |
|                   | 21-25       | 202    | 46.9       |
|                   | 26-30       | 139    | 32.3       |
|                   | 31-35       | 42     | 9.7        |
|                   | 36-40       | 20     | 4.6        |
|                   | >40         | 19     | 4.4        |
| **Region**        | Urban       | 391    | 90.9       |
|                   | Rural       | 39     | 9.1        |
| **Religion**      | Hindu       | 181    | 42.09      |
|                   | Muslim      | 239    | 55.58      |
|                   | Christian   | 10     | 2.32       |
| **Education**     | Up to metric| 254    | 59.06      |
|                   | Pre university | 133 | 30.93      |
|                   | Graduation and above | 43 | 10          |
| **Occupation**    | Manual worker | 2     | 0.46       |
|                   | Home maker  | 383    | 89.06      |
|                   | White collar| 45     | 10.46      |
| **Socio economic class** | Upper middle | 25 | 5.8        |
|                    | Lower middle | 210 | 48.83      |
|                    | Upper lower | 115    | 26.7       |
|                    | Lower       | 80     | 18.6       |
| **Parity**        | Para 1      | 212    | 49.3       |
|                   | Para 2      | 145    | 33.7       |
|                   | Para 3      | 73     | 16.9       |

Table 2: Timing of insertion of IUCD.

| Timing          | Number | Percentage |
|-----------------|--------|------------|
| Post placental  | 365    | 84.8       |
| Interval        | 65     | 15.2       |

84.8% in the study group had got post-placental IUCD insertion.

Table 3: Type of IUCD used among study group.

| Type  | Number | Percentage |
|-------|--------|------------|
| 375   | 148    | 34.4       |
| 380 A | 282    | 65.6       |

65.6% subjects had 380 A type of IUCD.

Table 4: Duration of use of IUCD among study group.

| Duration in years | Number | Percentage |
|-------------------|--------|------------|
| 0-2               | 246    | 57.2       |
| 3-4               | 100    | 23.2       |
| 5-6               | 40     | 9.3        |
| 7-8               | 12     | 2.79       |
| 9-10              | 12     | 2.79       |
| 11-12             | 5      | 1.16       |
| 13-14             | 4      | 0.93       |
| 15-16             | 10     | 2.32       |
| 17-18             | 0      | 0          |
| 19-20             | 1      | 0.23       |

Maximum women used IUCD for a period of 2 years.
Table 5: Reasons for removal with duration of use

| Duration | 1     | 2     | 3     | 4     | 5     | 6     | 7     | 8     | Total |
|----------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| 0-2      | 63 (25.6%) | 84 (34.1%) | 1     | 1     | 9     | 47    | 24    | 17    | 246   |
| 3-4      | 21    | 17    | 0     | 0     | 4     | 30 (30%) | 22    | 6     | 100   |
| 5-6      | 4     | 6     | 8     | 0     | 1     | 16 (40%) | 0     | 5     | 40    |
| 7-8      | 3 (25%) | 5 (41.66%) | 0     | 0     | 2     | 0     | 0     | 2     | 12    |
| 9-10     | 0     | 0     | 12    | 0     | 0     | 0     | 0     | 0     | 12    |
| 11-12    | 1     | 0     | 0     | 0     | 0     | 0     | 0     | 4     | 5     |
| 13-14    | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 4     | 4     |
| 15-16    | 0     | 5 (50%) | 5     | 0     | 0     | 0     | 0     | 0     | 10    |
| 17-18    | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     |
| 19-20    | 1     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 1     |
| Total    | 93    | 117   | 26    | 16    | 93    | 50    | 34    | 430   |

1-Pain abdomen, 2-HMB, 3-Need to change IUCD, 4-Failure of contraception, 5-WDPV, 6-Planning for conception, 7-Missing thread, 8-For sterilization.

Table 6: Relation of pain abdomen with duration of use of IUCD.

| Duration | Subjects with pain abdomen | Odds ratio | P value |
|----------|-----------------------------|------------|---------|
| 0-2      | 63                          | 1          | 1       |
| 3-4      | 21                          | 1.29       | 0.4     |
| 5-6      | 4                           | 3.09       | 0.04    |
| 7-8      | 3                           | 1.3        | 1       |
| 9-10     | 0                           | 0          | 0       |
| 11-12    | 1                           | 2.9        | 0.3     |
| 13-14    | 0                           | 0          | 0       |
| 15-16    | 0                           | 0          | 0       |
| 17-18    | 0                           | 0          | 0       |
| 19-20    | 1                           | 0          | 0       |

Table 7: Relation of heavy menstrual bleed with duration of use of IUCD.

| Duration | Subjects with heavy menstrual bleed | Odds ratio | P value |
|----------|-------------------------------------|------------|---------|
| 0-2      | 84 (34.1)                           | 1.377      | 0.4     |
| 3-4      | 17                                  | 3.48       | 0.05    |
| 5-6      | 6                                   | 4.04       | 0.09    |
| 7-8      | 5 (41.66)                           | 1          | 1       |
| 9-10     | 0                                   | 0          | 0       |
| 11-12    | 0                                   | 0          | 0       |
| 13-14    | 0                                   | 0          | 0       |
| 15-16    | 5 (50)                              | 0.7        | 1       |
| 17-18    | 0                                   | 0          | 0       |
| 19-20    | 0                                   | 0          | 0       |

The complaints of pain abdomen and heavy menstrual bleed was statistically significant among women who used IUCD for a period of 3-4 years.

Table 8: Alternate method used after IUCD removal.

| Alternate method | Number | Percentage |
|------------------|--------|------------|
| Tubectomy        | 64     | 20.88      |
| OCP              | 38     | 12.84      |
| DMPA             | 148    | 48.42      |
| Reinsertion      | 19     | 6.42       |
| No method        | 32     | 11.44      |

48.4% shifted to injectable methods after the removal of IUCD.
Table 9: Culture report of IUCD.

| Culture      | Number | Percentage |
|--------------|--------|------------|
| Normal       | 312    | 77.4       |
| Inflammatory | 52     | 12.09      |
| Gram positive| 43     | 10.0       |
| Gram negative| 23     | 5.34       |

77.4% had essentially normal culture.

Table 10: Culture reports with duration of IUCD.

| Duration | Normal | Inflammatory | Gram positive | Gram negative |
|----------|--------|--------------|---------------|---------------|
| 0-2      | 214    | 21           | 10            | 1             |
| 3-4      | 78     | 13           | 7             | 2             |
| 5-6      | 15     | 11           | 10            | 4             |
| 7-8      | 2      | 0            | 5             | 5             |
| 9-10     | 3      | 1            | 4             | 4             |
| 11-12    | 0      | 1            | 2             | 2             |
| 13-14    | 0      | 1            | 2             | 1             |
| 15-16    | 0      | 3            | 3             | 4             |
| 17-18    | 0      | 0            | 0             | 0             |
| 19-20    | 0      | 1            | 0             | 0             |

Maximum culture positives were found between 7-8 years of use. But this was not statistically significant.

Table 11: Relation of gram positive culture with duration of use of IUCD.

| Duration | Gram positive | Percentage | Odds ratio | P value |
|----------|---------------|------------|------------|---------|
| 0-2      | 10            | 4.06       | 16.8       | 0.002   |
| 3-4      | 7             | 7          | 9.48       | 0.003   |
| 5-6      | 10            | 25         | 2.14       | 0.29    |
| 7-8      | 5             | 41.66      | 1          | 1       |
| 9-10     | 4             | 33.3       | 1.4        | 1       |
| 11-12    | 2             | 40         | 1          | 1       |
| 13-14    | 2             | 50         | 0.7        | 1       |
| 15-16    | 3             | 30         | 1.66       | 0.6     |
| 17-18    | 0             | 0          | 0          | 0       |
| 19-20    | 0             | 0          | 0          | 0       |

Though more number of gram positive infections were found between 7-8 years of use. Statistically significant association was found up to 4 years of usage all the more in first 2 years.

Table 12: Relation of gram negative culture with duration of use of IUCD.

| Duration | Gram negative | Per centage | Odds ratio | P value |
|----------|---------------|-------------|------------|---------|
| 0-2      | 1             | 0.4         | 38.5       | 0.004   |
| 3-4      | 2             | 2           | 23.09      | 0.002   |
| 5-6      | 4             | 10          | 6.42       | 0.02    |
| 7-8      | 5             | 41.66       | 1          | 1       |
| 9-10     | 4             | 33.33       | 1.4        | 0.7     |
| 11-12    | 2             | 40          | 1          | 1       |
| 13-14    | 1             | 25          | 2.14       | 1       |
| 15-16    | 4             | 40          | 1.07       | 1       |
| 17-18    | 0             | 0           | 0          | 0       |
| 19-20    | 0             | 0           | 0          | 0       |

Though more number of gram negative infections were found between 7-8 years of use. Statistically significant association was found up to 4 years of usage all the more in first 2 years.
Table 13: Most prevalent genital infections.

| Gram positive     | Number | Percentage |
|-------------------|--------|------------|
| Lactobacillus     | 19     | 28.7       |
| Citrobacter       | 7      | 10.6       |
| Group B Streptococcus | 7   | 10.6       |
| Mssa              | 6      | 9          |
| Mrsa              | 4      | 6          |
| Total             | 43     | 65.2%      |
| Gram negative     | Number |            |
| E. coli           | 14     | 21.2       |
| Klebsiella        | 5      | 7          |
| Pseudomonas       | 4      | 6          |
| Total             | 23     | 34.8%      |

Most common Gram Positive organism isolated was Lactobacilli. Most common Gram Negative organism isolated was Escherichia coli which are essentially normal commensals.

DISCUSSION

Most women who approached for IUCD removal belonged to 21-25 years of age- 46.9% which correlates with study by Samar et al., where Most of IUD users were in the age group 20-30, and 30-40 years (35% and 28% of the study sample). 59.06% of the subjects had finished their high school. This was similar to study by Samar et al. where More than 50% of the sample had good education (39.5% had secondary education, and 12.5% had college education). Most of women in Samar et al. study were housewives (85.5%) which is similar to ours 89.06 % of the study group were home makers.19

In our study, 90.9% of the subjects were from urban areas, similar to study by Wang et al., where 40.8% were urban women. 55.5% of the subjects belonged to Muslim community. 48.8% of the subjects belonged to lower middle class. 49.3% of subjects were primipara, this was similar to study by Wang et al., where 57% were primipara. 85.1% subjects had no comorbidities.20 84.8% had got postplacental IUCD insertion. Of them, 65.6% subjects had 380 A Type of IUCD. This was similar to study by Samar et al, where more infection was seen with 380 A.19 This was probably because of longer duration of use. Majority of women used IUCD for 0-2 years - 57.2%. Followed by 3-4 years 23.2%.

Maximum women presented with pain abdomen between 0-2 years followed by 7-8 years. But the relation between pain abdomen and duration of IUCD was 3.09 times higher in 5-6 years of use which was statistically significant with p value<0.05. These were the most common complaints in other studies too. 48.4% shifted to injectable methods after IUCD removal. 77.4% of the IUCDs subjected to culture were found to be essentially normal.

In Samar’s study, Regarding the duration of IUD use, there is a significant increase of potentially pathogenic bacteria among IUD users during the first year of use, although the overall relationship between infection and duration of IUD use was not statistically significant. This was similar to our study where maximum culture positives were found between 7-8 years of use. But this was not statistically significant.19

Though more number of gram positive infections were found between 7-8 years of use. Statistically significant association was found up to 4 years of usage all the more in first 2 years. Likewise more number of gram negative infections was found between 7-8 years of use. Statistically significant association was found up to 4 years of usage all the more in first 2 years. This was similar to Samar’s study where during the first year, more than 70% of users had positive culture (41.3% potentially pathogenic and 31.7% predominant bacteria).19 The negative culture (no growth results) reached up to 31.3% among the IUD users, most of them (about 40%) were during the first year of use. The percent of potentially pathogenic swabs decrease with increasing duration of use (41.3-16.7%), while the percentage of predominant bacteria increases (31.7-44.4%). Although there was significant relationship between growth and duration for each period.

Most common gram positive organism isolated was Lactobacilli- 28.7%. Most common gram negative organism isolated was Escherichia coli - 21.2% which are essentially normal commensals. These results were correlating with study by Samar et al, 128 (64%) of all cultured swabs were positive, while 72 (36%) had no growth.19 Of the positive results, 25% were Beta-
Prospects of the study was easy access to sample and can be done on OPD basis. Gives a good knowledge of the prevalent genital infections.

Limitations of this study was that patients could not be followed up for treatment.

CONCLUSION

Our study showed that 84.6% of the women in study group using IUCD had no association with infections. Most common complaints compelling IUCD removal was Heavy menstrual bleed followed by pain abdomen more with 5-6 years of use, which was statistically significant. More number of culture positives was found between 7-8 years of use. Statistically significant association was found up to 4 years of usage all the more in first 2 years. Most common organisms isolated from the cultures were the commensals-like Lactobacilli as isolated by Escherichia coli. Thus, effective counselling regarding the long-term safety of IUCD over other spacing methods is essential to increase its acceptance.

ACKNOWLEDGMENTS

Thanks to Dr. Savitha C., Dr. Kala Yadav, professor and head, Department of Microbiology, without whom this work would be incomplete.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Kanakannavar SS, Ashwini RS. Clinico-microbiological study of the removed intrauterine device. Int J Reprod Contracept Obstet Gynecol 2019;8:2011-8.