ABSTRACT

Background: In the past, the use of intrauterine contraceptive device (IUCD), in particular, Dalkon Shield was found to be associated with increased risk of pelvic infection. Recent literature illustrates that the risk of pelvic infection after insertion of an IUCD is low and that the risk peaks in the 1st month after insertion. We set out to determine the incidence of genital infection among IUCD users after the 1st and 3rd months of insertion compared to users of other contraceptive methods; to determine the risk of genital infections among IUCD users compared to users of other contraceptive methods and to determine the organisms associated with genital infection among the contraceptive users.

Materials and Methods: This was a cohort study involving new clients who chose various forms of contraceptives.

Results: The incidence of genital infection was 3 (8.5%) at 1 month and 4 (12.1%) at 3 months. The incidence in non-IUCD contraceptive users was 2 (5.9%) at 1 month and 3 (8.8%) at 3 months. The relative risk was 1.44 and 1.5 at 1 and 3 months, respectively. The observed difference in the rate of infection between IUCD users and other contraceptive users was not statistically significant. Bacteria vaginosis and *Trichomonas vaginalis* were commonly observed in the two groups.

Conclusion: The incidence of genital infection among IUCD users was relatively low compared to non-IUCD users. IUCDs do not significantly increase the rate of genital infection.

Key words: Contraceptives; genital; infection; intrauterine contraceptive device; Nigeria.

Introduction

The intrauterine contraceptive device (IUCD) is one of the most widely used long-acting contraceptive methods.\[1-3\] It offers effective protection from pregnancy and is effective for long-term use. The device can be inserted at anytime as long as pregnancy has been ruled out.\[4,5\] It is estimated that there are about 180 million users worldwide, with over 80% of these residing in Asia.\[6\] In Nigeria, the acceptance rate for IUCD ranges from 47% to 66% in different family planning centres.\[3,5,7\] Different studies have been conducted to explore the IUCD-related diseases particularly those associated with infection. Some studies linked the infection-related diseases to the insertion method and technique. This is because the postinsertion pelvic infection is generally low but appears to be highest in the first 3 weeks’ postplacement.\[8,9\] Despite the overall low risk documented in various places, it is prudent to determine the risk in the northwest subregion of Nigeria.

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We set out to determine the incidence of genital infection among IUCD users after the 1st and 3rd months of insertion compared to users of other contraceptive methods during the same period; to compare the incidence of common organisms isolated in the two groups and also to determine the risk of genital infections among IUCD users compared to users of other contraceptive methods.

Materials and Methods

Study area
The study was conducted at the two Family Planning clinics of the Usmanu Danfodiyo University Teaching Hospital, Sokoto.

Study design
This was a Cohort study.

Sample determination
The sample size of 35 in each group was obtained using the formula for group comparison and considering 10% attrition rate.

Study population
This includes women who presented to the family planning clinic for new method of contraception. Thirty-five new clients who chose IUCD and another 35 new clients who chose other forms of contraceptives and had no genital infection were recruited.

Sampling method
The patient who met the inclusion criteria were enrolled consecutively.

Inclusion criteria
Clients that chose IUCD for contraception and gave consent for the study were included as cohorts while those that chose other forms of contraceptives served as controls.

Exclusion criteria
Women with genital infections and contraindications to IUCD insertion such as gynecological cancers, pelvic inflammatory disease (PID), and pregnancy were excluded from the study. An endocervical specimen was collected for culture using a sterile cotton swab during vaginal examination to detect Neisseria gonorrhoeae, after inoculation into Thayer Martin and 5% blood agar. Thereafter, the endocervical swab was used to make smear to detect Chlamydia trachomatis inclusion body. Two different high vaginal swabs were taken to isolate for Trichomonas vaginalis, Candida species, Gardnerella vaginalis, and anaerobes. One of the high vaginal swabs was used to make wet mount and Gram staining, while the second swab was used for culture.

Three drops of physiological saline were added and mixed with the first high vaginal swab. A drop of the sample collected was transferred to a microscope slide, covered with a cover slide, labeled, and then delivered to the laboratory for immediate examination. A drop from the same sample was also transferred to another microscope slide and spread to make a thin smear. It was then allowed to air dry, labeled and transferred to the laboratory for Gram staining. The sample from the second swab was inoculated into MacConkey agar and 5% sheep blood agar. The cervix, vagina, and vulva were then cleaned with antiseptic solution. The IUCD was then inserted using “no touch technique” by the researcher. The same procedure was done for clients that chose other contraceptive methods. The endocervical and vaginal sampling were then repeated after 1 month and after 3 months by the investigators.

Specimen transport
The swab sticks had Amies medium which served as transport medium used for the transport of samples to the laboratory. Samples were also analyzed within 2 h of collection.

Study procedures
Wet saline preparation
This was carried out to detect T. vaginalis trophozoites, motile bacteria, Candida species, epithelial cells, and pus cells. The high vaginal swab was utilized to make the preparation. The preparation was examined using a microscope with the 10 × and 40 × magnification objectives. Trophozoites of T. vaginalis may measure about 10–20 µm, and they are round or oval and move by an aid of undulating membrane and four anterior flagella while the fifth flagellum forms an undulating membrane. These features were checked.

Direct Gram smear
The high vaginal swab was gently rolled onto a glass slide. The smear was allowed to air dry then fixed with methanol and stained by Gram’s technique. Using the 40 × and 100× (oil immersion) objectives, the smear was examined for pus cells and bacteria. Pus cells containing Gram-negative diplococci denote N. gonorrhoeae. Large Gram-positive yeast
cells and pseudohyphae could be Candida species. In bacterial vaginosis, epithelial cells with adhering Gram-negative short bacilli and Gram-variable cocobacilli (G. vaginalis, Mobiluncus, or Anaerobes) may be visualized. The margin of the epithelial cells is often obscured (clue cells) by the adhering bacteria.

Giemsa staining for chlamydial inclusion body
The endocervical swab was used to make a smear on a glass slide. The smear was allowed to air dry, fixed and then stained with Giemsa stain. Chlamydial infection was suspected when blue-mauve colored inclusion bodies were seen in epithelial cells.

Culture and colonial morphology
The high vaginal swab was inoculated on two plates of 5% Sheep Blood agar and one plate of MacConkey agar. The MacConkey agar plate was incubated aerobically at 37°C for 18–24 h. The first plate of 5% Sheep Blood agar was incubated aerobically at 37°C for 18–24 h for aerobes and facultative organisms. The second plate of 5% Sheep Blood agar was incubated anaerobically in an anaerobic jar looking for obligate anaerobes.

Staphylococcus aureus produces yellow-cream colored colonies that are 1–2 mm in diameter and they are beta hemolytic on 5% Sheep blood agar. On MacConkey agar, the Staphylococcus colonies appear pinkish signifying lactose fermentation. Streptococcus agalactiae produce grey mucoid colonies about 2 mm in diameter surrounded by a beta hemolytic zone on Blood agar. Escherichia coli produce 1–4 mm in diameter colonies that appear pinkish signifying lactose fermentation. They are slightly mucoid and beta hemolytic on 5% Sheep blood agar. Candida albicans produces pale, creamy colored, pasty colonies on blood agar with a distinctive yeasty smell. Actinomyces israeli produces small creamy white colonies with a rough nodular surface that glistens on 5% sheep blood agar following anaerobic incubation.

The endocervical swab was inoculated in Thayer Martins medium looking for N. gonorrhoeae. The Thayer Martins medium was incubated in a moist carbon dioxide enriched atmosphere at 35°C–37°C for 18–24 h. This was then examined for growth after overnight incubation. N. gonorrhoeae produces small raised, gray shiny colonies.

Motility testing
E. coli is motile by means of peritrichous flagella. The motility test was demonstrated by using a fresh culture of suspected colonies of E. coli grown on MaConkey agar plate after inoculation in normal saline then transferred to a hanging drop slide. This was viewed using the 10 × objective.

Biochemical test
Oxidase and Sugar fermentation test was performed on suspected N. gonorrhoeae colonies. N. gonorrhoeae colonies are oxidase positive and ferment glucose but not lactose, maltose, or sucrose.

Catalase and coagulase test was employed to differentiate between the Gram-positive cocci. S. aureus is catalase and coagulase positive while S. agalactiae is catalase negative.

Candida species was further confirmed to their specie level by the use of Germ tube test and sugar assimilation test. C. albicans is germ tube positive, while other species are negative.

Data analysis
The results obtained were analyzed using Statistical Package for Social Sciences (SPSS) version 21.0 (Armonk, NY, IBM Corp). Data were presented using tables and Figures. Categorical data such as occupation of respondents were summarized using frequencies and percentages. Chi-square test was used to compare associations. P <0.05 was considered statistically significant.

Ethical consideration
Ethical clearance was obtained from the Ethics and Research Committee of the University Teaching Hospital. Informed consent was also obtained from the respondents before data collection. Patients with infection were treated and their spouses and co-wives were referred to appropriate clinics.

Limitations
- The clients were followed-up for only 3 months; therefore, a long-term effect of IUCD could not be determined
- The effect of other copper-containing IUCDs other than copper T-380A could not be assessed as they are not commonly used in the study area.

Results
A total of 70 women were enrolled for this study. Sixty-eight clients returned for follow-up at 1 month and 67 were seen at the third contact, therefore, the response rate was 97% and 95% at 1 and 3 months, respectively. The mean age of the respondents with IUCD was 26.54 ± 2.1 years and that of the non-IUCD group was 26.30 ± 2.4 years. The age range was similar between the two groups which was 17–45 years. Eighteen (51.4%) of the respondents from each group were between 25 and 34 years of age.

The majority of the respondents were unemployed, 14 (40%) in the IUCD group and 25 (71.4%) in the control group were
Of the 35 respondents who used IUCD, 24 (34.29%) used Copper T 380A and 11 (15.71%) used levonorgestrel intrauterine system containing IUCD. Thirty-five women used other forms of contraceptives during the same period. Twenty-six (37.14%) women used subdermal implants, 5 (7.14%) used injectable contraceptives, and 4 (5.71%) used combined oral contraceptive pills [Figure 1].

Following insertion of IUCD, the incidence of genital infection was 3 (8.5%) at 1 and 4 (12.1%) at 3 months. The incidence in other contraceptive users was 2 (5.9%) at 1 month and 3 (8.8%) at 3 months [Figure 2].

At 1 month, 34 women from each group came for follow-up. Three (8.5%) respondents among IUCD users had genital infection while 2 (5.9%) had genital infection in the non-IUCD group. Although more IUCD users had genital infection, the differences between the IUCD users and non-IUCD users was not statistically significant ($\chi^2 = 0.654, P = 0.464$). At 3 months, 33 women among IUCD users came for follow-up while 34 of the non-IUCD users returned for follow-up. Among the IUCD users, 4 (12.1%) had genital infection while 3 (8.8%) had genital infection among non-IUCD users. The observed difference among the two groups was not statistically significant ($\chi^2 = 2.967, P = 0.085$) [Table 2].

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<tr>
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Table 1: Sociodemographic characteristics of respondents

Figure 1: Types of contraceptives used

Figure 2: Incidence of genital infection among intrauterine contraceptive device users compared to nonintrauterine contraceptive device users
The relative risk of IUCD causing genital infection was 1.44 at 1 month and 1.5 at 3 months while the attributable risk at 1 month was 26/1000 and 40/1000 at 3 months. However, the observed difference in the rate of infection between IUCD users and other contraceptive users was not statistically significant.

In the IUCD group, 2 (5.8) women had Bacteria vaginosis at 1 month and 2 (6%) had it at 3 months while 1 (2.9) had T. vaginalis at 1 month and 2 (6%) at 3 months. In the non-IUCD group, 1 (2.9%) woman had T. vaginalis, Bacteria vaginosis at 1 month while 1 (2.9%) woman had T. vaginalis, Bacteria vaginosis, and Candida albicans at 3 months. Only 1 (3%) of the clients in the IUCD group had N. gonorrhoeae and it was at 3 months, but none had C. trachomatis. In the non-IUCD group, no participant had N. gonorrhoeae or T. vaginalis [Table 3].

**Discussion**

The incidence of genital infection among IUCD users was 8.5% at 1 month and 12.1% at 3 months following insertion of the devices. In the non-IUCD users, the incidence of genital infection was 2.5% at 1 month and 3 (8.8%) at 3 months. The relative risk was 1.44 and 1.5 at 1 and 3 months, respectively, however, the difference was not significant.

Recent studies consistently revealed that relative risk of PID in IUCD users compared to women using no method to be 1.5–2.6. This increase is only for a few months after insertion. The relative risk from a study by Buchan et al. was 3.3 for copper IUCD and 1.8 for hormonal IUCDs when compared to noncontraceptive users. The difference between the three groups was not significant. Similarly, Beerthuizen also found a relative risk of 1.8 in clients with copper-containing IUCD compared to noncontraceptive users. The separation of copper and hormonal IUCDs may have influenced the overall result, more so the comparison in these two studies were with noncontraceptive users. The studies also assessed women with only upper genital tract infection and did not consider lower genital infection.

In the WHO IUCD clinical trial data to explore the incidence and pattern of PID risk with the use of IUCD, the overall rate of PID among 22,908 IUCD insertions and during 51,399 woman-years of follow-up was 1.6 cases/1000 woman-years of use. Unlike in our study where genital infections were considered generally, only PID (upper genital tract infection) was considered in the WHO study. In a cohort study conducted in England, the incidence of acute of PID was 1.51/1000 woman-years while that of chronic PID was 0.54 per 1000 woman-years. Like in the WHO study, only upper genital infection was considered. Rydén et al. found the incidence of gonorrhea among IUCD users to be 23.5% and 8.8% among hormonal contraceptive users and 15.1% in women using neither technique. There was no significant difference demonstrated. In the United States, the incidence of Bacteria vaginosis was 37% among IUCD users, and the incidence among oral contraceptive users was 19.3%. This was also a cohort study, but the clients were followed for 6 months. In addition, only Bacteria vaginosis was studied. Blum et al. found the incidence of C. trachomatis to be 16.7% in IUCD users, 38.6% among oral contraceptive users and 21.1% in other contraceptive users. Avonts et al. found the incidence of Chlamydia to be 0.8/100-woman years among IUCD users and 7/100-woman years for oral contraceptive users yielding a relative risk of 0.11. In the same study, the incidence of Bacteria vaginosis was 25/100-woman years among IUCD users and 9/100-woman years in oral contraceptive users with a relative risk of 2.8. Only Bacteria
vaginosis and chlamydia were considered in the study unlike the study conducted where some other organisms were considered.

T. vaginalis and G. vaginalis were the most common isolated organisms among IUCD users. They were also isolated in the non-IUCD group hence IUCD may not be responsible for higher incidence of T. vaginalis. A similar finding was made in Antakya, Turkey. In contrast, Candida species were the commonest isolated organisms in Benin, Sudan and Trabzon, Turkey. Bacteria vaginosis was the most prevalent genital infection among IUCD users in studies conducted in Brazil and Iran. However, in addition to T. vaginalis and Bacteria vaginosis, Candida was also common among IUCD users in Basra, Iraq. These studies were prevalence studies, the infection status of the clients were not known before commencement of the various methods. The different organisms isolated in these studies may be a reflection of the pattern of genital infections in the general population of the study areas. Although studies evaluating microbes in non-IUCD contraceptives as a group are few, some have studied different contraceptive methods. In the study by Shobeiri et al., Staph aureus was the most common organism among other contraceptive users. Avonts et al. found that C. trachomatis was the most common isolated microbe among users of oral pills. Sharief found G. vaginalis among users of oral pills.

The incidence of genital infection among IUCD users was relatively low. IUCDs do not significantly increase the rate genital infection when compared with other contraceptive methods. T. vaginalis and G. vaginalis were isolated in both groups.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References