

**CLINICAL EXPERIENCE WITH LEVONORGESTREL INTRAUTERINE SYSTEM AT A
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ABSTRACT

Background: Mirena, a long acting reversible hormonal intrauterine contraceptive device is one of the most effective contraceptive methods with a lot of non-contraceptive benefits. Despite these benefits, the users still discontinue its use due to various reasons. **Objective:** To determine the prevalence rate, side effects, discontinuation rate and indications for discontinuation of Levonorgestrel intrauterine device (LNG IUD) at Rivers State University Teaching Hospital (RSUTH), Port Harcourt. **Methods:** A retrospective study of 874 clients attending family planning clinic at the RSUTH from 1st January, 2015 – 31st December, 2019 was conducted. Their records were retrieved from the clinic and reviewed. Data was extracted, coded and analyzed using the statistical package for social sciences (SPSS) IBM version 25.0 (Armonk, NY). **Result:** Seventeen women used mirena out of 874 acceptors of contraceptives within the study period giving an uptake rate of 1.95%. The mean age was 33.47±5.20 years. Most age group was 30-34 years accounting for 52.9%. Age range was 27-45 years and most (64.7%) were multiparous. All were Christians and married and only one client (5.9%) had no formal education. No client discontinued the use although one (5.8%) had amenorrhoea and two each (11.8%) had irregular vaginal bleeding, lower abdominal pain and vaginal discharge respectively. There was no unintended pregnancy. **Conclusion:** Mirena is safe and effective. Irregular vaginal bleeding, vaginal discharge and lower abdominal pain were the commonest side effects which were not serious enough to cause discontinuation.

KEYWORDS: Mirena, uptake rate, side effects, discontinuation rate, RSUTH.**INTRODUCTION**

Millions of women worldwide have used mirena for contraception. It has both hormonal and intrauterine contraception.^[1] Among the several long-acting contraceptive methods, the intrauterine device (IUD) is the most popular and overall, it is second most popular contraceptive method worldwide after sterilization.^[2] Mirena was first marketed in Finland in 1990, but not approved by the United States Food and Drug Administration (USFDA) until 2000.^[1] Access to the use of mirena has been limited mainly due to the high cost of production.^[3,4] In 2016, Marie Stopes International Organization Nigeria (MSION) expanded LNS IUS provision through training and support in 17 States of Nigeria.^[5] As part of the global family planning 2020 initiative launched in 2012, Nigerian government has committed to reducing unmet need for family planning and increasing modern contraceptive prevalence to 27% among all women by 2020, compared with a prevalence of 15% in 2013.^[6]

According to the 2013 Nigeria Demographic and Health Survey, the copper intrauterine device comprised a small

portion (5%) of Nigeria's overall contraceptive method mix and use of the LNG IUS product was too low to be included as a separate method in National surveys.^[6] Mirena is available in Nigeria on a limited scale in the commercial sector at a high cost of at least N25,000.00. Other products of LNG IUS introduced in Nigeria are Emily (HLL life care ltd), Eloira (Pregna international ltd) and AVIBELA (Medicines 360).^[5]

The LNG-IUS reduces menstrual loss and is more popular in developed countries.^[7] It is not used for emergency contraception unlike Copper T380A which is a very effective form of emergency contraception. Contraceptive efficacy is high with 5 year failure rate of 0.5-1.1/100 users.^[8] Mirena consists of a T-shaped polyethylene frame (T-body) with a steroid reservoir around the vertical stem consisting of 52mg levonorgestrel released at a rate of 20mcg/day. The rate reduces progressively to half this value after 5 years.^[9-12] The IUCDs stimulate marked inflammatory reaction in the uterus and fallopian tubes. The concentration of the macrophages, leucocytes, prostaglandins and various enzymes in both uterus and tubal fluid interfere with the

transport of spermatozoa and ova. They also prevent implantation should a healthy fertilized ovum reach the endometrial cavity.^[13,14] Hormonal actions are due to the levonorgestrel component accounting for most of the non contraceptive benefits like reduction of menorrhagia, dysmenorrhoea, premenstrual syndrome, fibroids, adenomyosis, endometriosis and protection of the endometrium during hormone replacement therapy.^[1,9,15,16]

Common side effects associated with mirena which could probably lead to its discontinuation include menstrual changes, lower abdominal pain, back ache, breast tenderness, headache, vaginal discharge, weight gain and acne. Others are displacement, expulsion from the uterus, perforation of the uterus, accidental and ectopic pregnancies.^[9,17,18] It is on this background that this study aims at determining the acceptance rate, effectiveness, side effects, discontinuation rate and the reasons for discontinuation of mirena. The outcome of which will aid to improve the provider services and lead to a reduction in discontinuation rate among the acceptors.

MATERIALS AND METHODS

This retrospective study was carried out at the family planning clinic of the Rivers State University Teaching Hospital (RSUTH) Port Harcourt, southern Nigeria. The clinic gets its clients from within and outside the hospital. It has its own records section different from the hospital records and this makes it easy to retrieve the clients' case notes. The clinic is headed by a consultant Gynaecologist with the support of trained family planning nurses. Resident doctors, medical students and student nurses rotate through the clinic in batches. The clinic opens for eight hours daily from Monday to Friday. It is important to state here that the clients who used mirena got them from the drug company at an expensive amount, then bring them to the family planning clinic of RSUTH for expert insertion and follow up. Mirena is not supplied to the clinic by the health ministry like other methods of contraception because of the high cost of purchase.

At presentation, the clients were welcomed by trained family planning nurses and physicians who also counseled them. The clients were allowed to make informed choice based on their needs and available contraceptives suitable for them. Thereafter medical history and clinical examination were done. Urine analysis and pregnancy test were also done for the clients and informed consent obtained before insertion. Other contraindications to mirena insertion are huge uterine fibroids, postpartum endometritis, septic abortion in the past 3 months, acute pelvic inflammatory disease (P.I.D), uterine or cervical neoplasia, uterine bleeding of unknown aetiology, acute liver disease or tumour and breast cancer. Insertion was done during the first 7 days of menstrual cycle. Before and during insertion, the mirena acceptors were counseled on the side effects and

the need to continue with this method of contraception considering the numerous benefits from the use. They were also given oral analgesics to reduce the pain from cramping following insertion.

In the absence of complications, post insertion visits are at 1 month, 3 monthly and then yearly. The clients were advised to report any side effects and complications. These complaints were well documented and managed appropriately. At each follow up visit, detailed history and examination including breast examination are done. Clients were considered lost to follow up if they default 2 or more consecutive visits.

The record cards of all the clients that accepted and used mirena between 1st January, 2015 and 31st December, 2019 were retrieved and studied. The information extracted from the cards included the socio-demographic characteristics of the clients, previous contraceptive methods used and their sources, side effects and complications of the current contraceptive, discontinuation and the reasons for discontinuation. The data was analyzed with the statistical package for social sciences (SPSS) IBM version 25.0 (Armonk, NY) using frequency counts and percentages.

RESULTS

Seventeen women used mirena out of 874 contraceptive acceptors during the study period giving an uptake rate of 1.95%. It was the least accepted contraceptive method during the study period. The age range was 27-45 years and the mean age was 33.47 ± 5.20 years. Most age group was 30-34 years accounting for 9 (52.9%). No teenager used the mirena during the study period. Majority of the clients, 11 (64.7%) were multiparous, and all were married 17 (100%) and Christians 17 (100%). The parity range was 1 to 9 and modal parity was para 4. Five (29.4%) grandmultipara and one (5.9%) primipara used mirena. Sixteen (94.1%) clients had formal education out of which 5 (29.4%) had tertiary level of education while 10 (58.8%) and 1 (5.9%) had secondary and primary levels of education respectively. One (5.9%) client had no formal education. The socio-demographic characteristics of mirena acceptors are shown in table 1.

The sources of previous contraceptives used by the clients are shown in figure 1. Eleven (64.7%) clients got their previous contraceptives from government owned hospitals and 6 (35.3%) got theirs from private hospitals. Most of the clients 9 (52.9%) previously used intrauterine contraceptive device (IUCD), 7 (41.2%) used implants and 1 (5.9%) used injectables. This is shown in table 2. Thirteen clients (76.5%) got the knowledge about mirena from clinic personnel and remaining 4 (23.5%) knew about it from friends. The sources of information is shown in figure 2.

Side effects associated with the use of mirena during the study period are shown in table 3. Ten (58.8%) clients

did not have any complaints during the use of mirena. Two clients each (11.8%) complained of irregular vaginal bleeding, lower abdominal pains and vaginal discharge respectively while one (5.8%) client had amenorrhoea. No client desired to get pregnant and there was no unintended pregnancy. Also despite the side

effects complained by the clients, none of them discontinued its use. The reasons indicated by the clients for discontinuation of the previous contraceptives were irregular vaginal bleeding and menorrhagia in 1 (5.9%) and 16 (94.1%) clients respectively. This is shown in figure 3.

Table 1: Socio-demographic characteristics of the clients.

| Variable | No. | Percentage (%) |
|---------------------------|-----|----------------|
| AGE | | |
| 25-29 | 3 | 17.6 |
| 30-34 | 9 | 52.9 |
| 35-39 | 2 | 11.8 |
| 40-44 | 2 | 11.8 |
| 45-49 | 1 | 5.9 |
| EDUCATIONAL STATUS | | |
| No formal education | 1 | 5.9 |
| Primary | 1 | 5.9 |
| Secondary | 10 | 58.8 |
| Tertiary | 5 | 29.4 |
| RELIGION | | |
| Christianity | 17 | 100 |
| PARITY | | |
| Primipara | 1 | 5.9 |
| Multipara | 11 | 64.7 |
| Grand multipara | 5 | 29.4 |
| MARITAL STATUS | | |
| married | 17 | 100 |

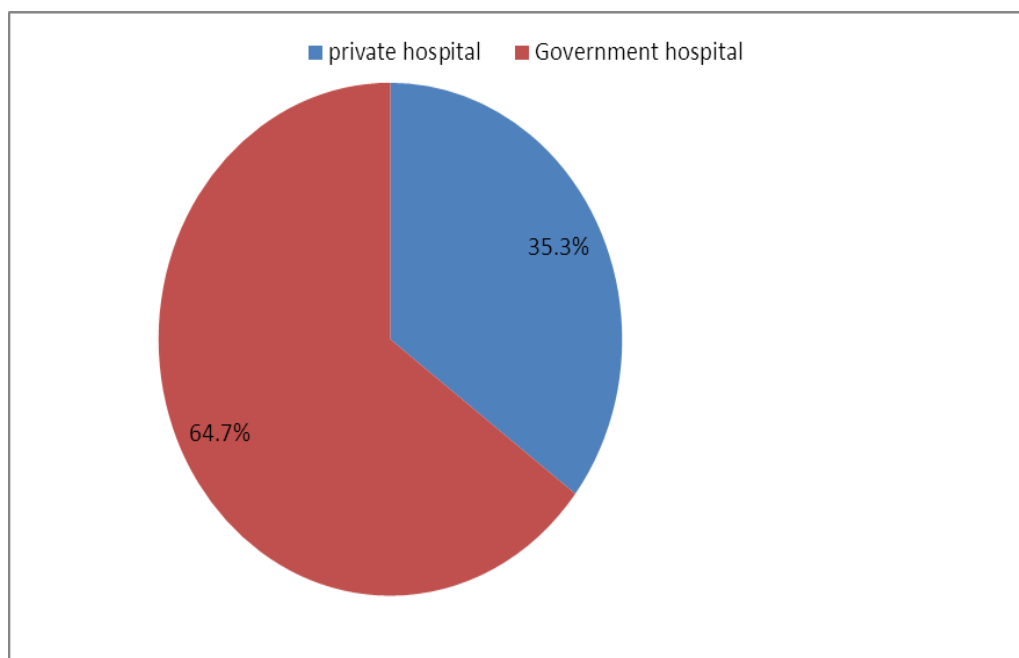


Figure 1: Sources of previous contraceptives used by clients.

Table 2: Previously used contraceptives by the clients.

| Methods | Frequency | Percentage |
|------------|-----------|------------|
| Injectable | 1 | 5.9 |
| Implant | 7 | 41.2 |
| IUCD | 9 | 52.9 |

IUCD: Intrauterine contraceptive device

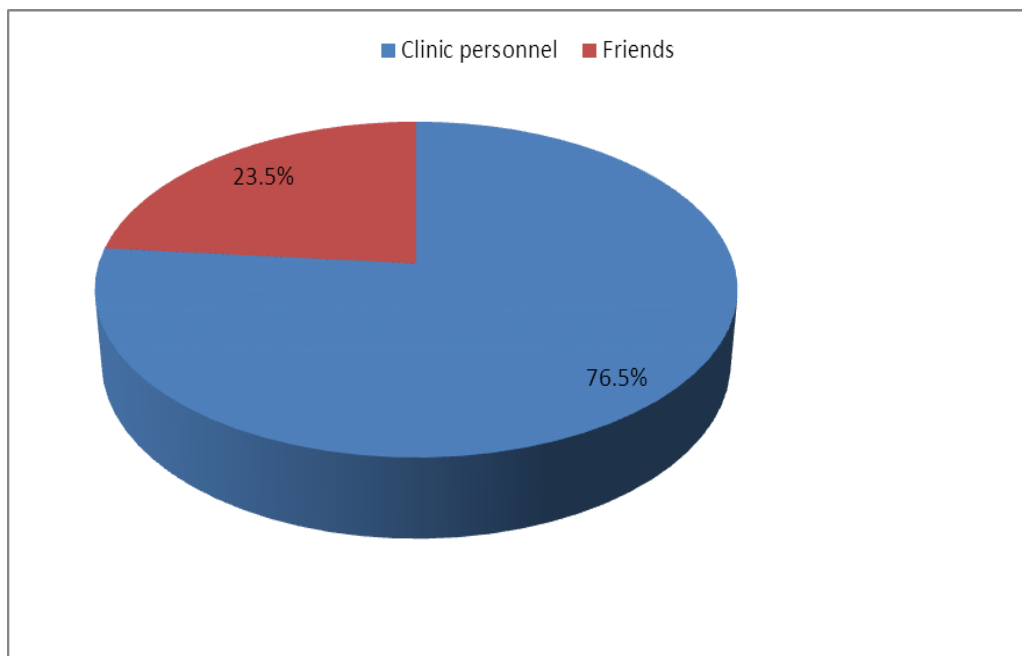


Figure 2: Sources of information.

Table 3: Side effects of mirena (n=7)

| Side effects | Frequency | Percentage |
|----------------------------|-----------|------------|
| Amenorrhoea | 1 | 14.2 |
| Lower abdominal pain | 2 | 28.6 |
| Irregular vaginal bleeding | 2 | 28.6 |
| Vaginal discharge | 2 | 28.6 |

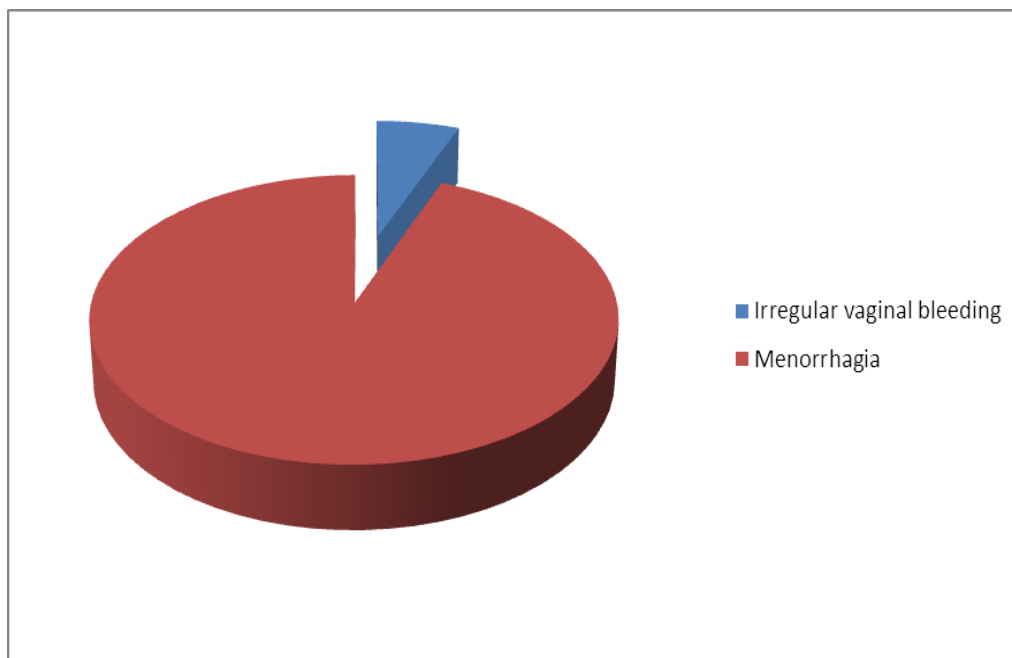


Figure 3: Reasons for discontinuation of previous contraceptives.

DISCUSSION

Few studies on Levonorgestrel intrauterine system mirena have been done in Nigeria. In fact the authors found only one similar study on this mirena done in Nigeria. Levonorgestrel intrauterine device is expensive and not readily available in the family planning clinics of

Government hospitals. The 17 women who used the LNG IUS, mirena (Bayer Whippany, New Jersey) during the study period bought them from the drug companies and came with them to be inserted by our trained family planning nurses. Therefore the poor cannot have access to LNG IUS which is not good enough for poor resource

countries like Nigeria which is the most populous country in Africa. This accounts for the paucity in its studies in developing countries as majority of the populace cannot afford it. The uptake rate of 1.95% was the least during the study period. In fact according to the 2013 Nigeria Demographic and Health Survey, mirena is available on a limited scale in the commercial sector at a very high cost and its use is too low to be included as a separate method in national surveys.^[6]

The uptake rate of 1.95% is far too small compared to the uptake rate of 25.5% for Copper T380A^[19] which has almost equaled 2020 Nigeria contraceptive prevalence target of 27%.^[6] Also the rate of 1.95% is higher than 0.4% reported in another study in Nigeria.^[5]

The average age of the acceptors was 33.47 years. This is similar to 34 years from a previous study^[5] and lower than 43 years in another study.^[12] Most of the clients 9 (52.9%) were within the age range of 30 and 34 years which is not in keeping with findings from other study where 47.2% of the acceptors were at least 35 years.^[5] There was no adolescent that used LNG IUS during the study period as was seen in other studies.^[5,12] Studies have shown increased risk of expulsion of IUCDs and Pelvic Inflammatory Disease (PID) among teenagers and nulliparous women. They are also unlikely to be married and would benefit from abstinence or barrier methods to prevent sexually transmitted infections (STIs) as well as the contraception effects. Hence IUCD is not advisable to be the first choice of contraceptive in this age group of clients.^[20] Levonorgestrel IUS is recommended for women who have had at least one child.^[17]

Multiparous women had the highest acceptance rate of 64.7% in this study as they are the most group who seek for contraception to limit the family size and space the childbirths.^[21] This finding is in keeping with other similar studies.^[5,12] Five (29.4%) grandmultiparous women used LNG IUS instead of sterilization which is not readily accepted by our women due to cultural reasons. Therefore IUCD whose pregnancy rates have been shown to be consistently less than 1% and whose effectiveness rivals that of surgical sterilization would be an excellent contraceptive option for these group of women.^[21]

All the acceptors were married and most acceptors, 97.1% and 93.8% respectively in similar studies were married too.^[5,12] This shows that this method of contraception is particularly for those women who are in stable relationship as in marriage.^[21] Most of acceptors in this study are educated with most of them having secondary education. The study done by Eva *et al* showed that 69.5% of the acceptors have completed at least secondary education.^[5] Experts have noted that educated couples are more likely to accept modern methods of contraception than the uneducated ones.^[21] All the clients are Christians because majority of the population in southern Nigeria are Christians. Most

clients heard of LNG IUS from health care personnel. This is similar to findings from Eva G *et al.*^[5]

More than 58% had no complaints indicating how safe this contraceptive method is. Menstrual disorders were the commonest complications of the IUD accounting for 42.8% of the side effects. This is in keeping with results of other studies.^[5,12] Though none of the women discontinued the use of the IUD, World Health Organization (WHO) has reported that side effects are the commonest reasons for its discontinuation.^[22] Discontinuation due to adverse effects occurred in 12.3% of users.^[23] Also a retrospective observational study showed that 21% of mirena users experienced progestogenic adverse effects.^[24] Ninety four percent of the acceptors discontinued the use of previous contraceptives used due to menorrhagia. The aim of discontinuing the previous contraceptive methods must have been achieved because none of the acceptors complained of heavy menstrual bleeding while on mirena. Two (28.6%) women had recurrent vaginal discharge. Studies have shown that the risk of vaginal discharge came from the insertion therefore the process of insertion has to be aseptic and done in an aseptic environment.^[20]

Since LNG IUS has side effects that can lead to discontinuation of the drug, it is important that health care providers should counsel the clients adequately on the side effects and numerous benefits before and during use to reduce the discontinuation rate caused by the side effects. There was no accidental pregnancy while the women were on the contraceptive, indicating how effective this method of contraception is.

CONCLUSION

The uptake rate of levonorgestrel intrauterine device is still low in our setting despite the increase in its use worldwide, especially because of non-contraceptive benefits. Efforts have to be made by both the drug companies and the government to reduce the price of this very effective drug so that it becomes affordable and easily accessed by our women. This is needed for this contraceptive to reach its full potential in Nigeria and other developing countries.

ETHICAL APPROVAL

The Hospital's Ethics committee gave the ethical approval.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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