

True Mirena failure: Twin pregnancy with Mirena *in situ*

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ABSTRACT

Mirena levonorgestrel intrauterine system (LNG-IUS) is a very reliable method of contraception with the failure rate comparable to sterilization. We present a case of failure of the Mirena intrauterine device *in situ* in a woman with twin gestational sac with positive Beta Human Chorionic Gonadotropin (β HCG) within 2 years of insertion. Although LNG-IUS is one of the most effective methods of contraception, the risks of failure should always be kept in mind and the women be appropriately counseled before its use.

Key Words: Contraception, intrauterine device failure, levonorgestrel intrauterine system, Mirena, risk factors

INTRODUCTION

Mirena is a hormonal intrauterine contraceptive device which is inserted in the uterus for a fixed period of time. It is a long acting reversible contraceptive and is considered to be among the most effective of methods of contraception. The failure rates for the Mirena are comparable to tubal sterilization, but the effects are reversible.^[1,2] These failures cause unwanted pregnancies and subsequent induced abortions. Unfortunately, very few studies have tried to identify the risk factors for these failures.

CASE REPORT

A 36-year-old parous lady presented with complaints of severe epigastric pain for last 25 days, which was increasing in severity and worse after taking meals. She also gave a past history of acid peptic disease for which she used to take an antacid on and off. So, she consulted the gastroenterologist for epigastric pain and was advised to undergo few blood tests, Ultrasonography (USG) whole abdomen and pelvis and then accordingly planned to go for upper gastrointestinal (GI) endoscopy. Her blood test and upper abdomen scan was normal. Incidentally on the pelvic ultrasound two gestational sac corresponding to 6 weeks days and 6 weeks 3 days with Mirena in uterine cavity were detected. Sacs were irregular without fetal node and yolk sac. Urine for pregnancy test was positive. On retrospection, she gave a history of Mirena insertion

2 year back. Mirena was inserted 3 month following normal vaginal delivery without any problems. She always had irregular periods following the insertion of Mirena intrauterine device (IUD) lasting 2-3 days at an interval of 45-50 days. From past 2 month patient had amenorrhea, which she had been explained can occur with Mirena at the time of insertion. Before Mirena insertion she was having regular periods at an interval of 30-35 days lasting for 4-5 days. Speculum examination showed Mirena intrauterine system (IUS) threads in place, but no evidence of active bleeding. Bimanual examination revealed a gravid uterus enlarged to 10 weeks size.

She was taken up for suction and evacuation under USG guidance under sedation along with upper GI endoscopy. The Mirena IUD was removed at the same time. She was discharged home on the same day with a follow-up appointment to discuss various options for contraception.

DISCUSSION

The levonorgestrel intrauterine system (LNG-IUS) is a hormonal IUD which provides highly effective, long-term, safe, and reversible contraception, with a pearl index of 0.1.^[1] Compared to other reversible methods, the LNG-IUS

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is among the most effective with a failure rate of 0.1% in the 1st year, which is similar to or even better than female sterilization.^[2] LNG-IUS provides a highly effective form of reversible contraception that is not user-dependent.

A large retrospective study was conducted in 2004 and evaluated 17,360 Finnish women who used the LNG-IUS. Over 5 years all reported pregnancies were analyzed (giving a total exposure of 58,600 woman-years). Sixty four pregnancies occurred, which provided a cumulative pregnancy rate of 0.1% at 1 year and of 0.5% at 5 years.^[3] A randomized multicenter study that was conducted in 1991, in 2244 women, the cumulative pregnancy rate after 7 years of use was 1.1% for the levonorgestrel IUD as compared to 1.4% for the copper T380A device.^[4] Though a pregnancy rate of 1.1% at 7 years is low compared to other reversible contraceptive methods, this rate is still almost double compared to the pregnancy rate of 0.5% at 5 years. Hence, LNG-IUS is approved for 5 years of contraceptive use, but there is evidence that it can be effective for up to 7 years of continuous use. The ectopic pregnancy rate is 0.02/100 women-years.^[1] However, the absolute number of ectopic pregnancies is lower among IUD users as compared to non-contraceptors, because the overall pregnancy rate in IUD users is lower.^[5]

Although IUDs are one of the most effective methods of contraception, a substantial number of unintended pregnancies take place due to failures. Studies conducted to identify the risk factors for IUD failure indicate that the causes of failure of LNG-IUS are malplaced IUD, expulsion of IUD and pregnancy missed at the time of insertion of IUD. None of these was present in our case. In fact, our case is reported because of its rarity, since intensive Medline literature search did not reveal any case of failure of Mirena IUS *in situ* leading to twin gestational sac.

In a review of risk factors for IUD failure in 2001, it was analyzed that advancing age also increases IUD effectiveness, probably due to decreasing fertility with advancing age^[6] and displacement of the IUD decreases effectiveness.^[7] However, other studies indicate that women can enjoy same high contraceptive efficacy throughout their reproductive years with LNG-IUS irrespective of age^[8] as is seen in our case.

A retrospective case-control study carried out between 1999 and 2002, stated that there was a significant relationship between history of IUD expulsion and IUD failure risk while there was no relationship observed between the risk of IUD failure and gynecological background (fibroma, polyps and miscarriage) or any type of medicine taken by the women.^[6] IUD expulsion was more likely in the presence of unfavorable uterine conditions (slight malformation, small uterine size) due to abnormal

positioning of device in uterine cavity. In a prospective study of 195 women in 2003, where the prevalence of abnormally positioned IUD was as high as 4%, it was assessed that, the intrauterine position of the device was closely linked to its contraceptive effectiveness.^[9] Similarly, uterine perforation is a known cause of failure with IUD. Case reports of term pregnancies have been reported in patients using LNG-IUS and hence, the clinician is advised to do regular surveillance of these women. It is also prudent that the LNG-IUS position be established with ultrasound after insertion to minimize risk of expulsion or malpositioning. In addition to expulsion, the other common cause of failure was inadvertent insertion of the device while the patient was pregnant.

In a review of 33 cases of intrauterine pregnancy with LNG-IUS insertion over last 6 years in South Africa, 11 patients (33%) were pregnant before insertion as pregnancy was missed at the time of insertion. Mirena provides a favorable environment for implantation of an already fertilized ovum and unlike copper IUD, it is not a method of post-coital contraception. Only three patients (9%) had genuine Mirena failure with the Mirena IUS *in situ*, with an intrauterine pregnancy. These devices had been inserted before the pregnancy and were confirmed to be in the uterus before and during pregnancy.^[10]

It is well-documented that true Mirena failure is extremely rare, our patient being one of them. She is 36 years old, LNG-IUS was placed 2 years before the pregnancy and after failure IUD was found to be present in intrauterine position ultrasonographically. This case highlights certain issues with the LNG-IUS. This patient continued to have cyclical bleeding despite a normally placed device in her post-partum period. The amenorrhea that followed was because of the pregnancy and not because of the Mirena. It is difficult to say whether Mirena was effective at all in this patient or not. Although ovulation is not affected in patients using this device, the endometrium is severely retarded after 2 years of use. It is therefore difficult to comprehend how a pregnancy took place in this condition. Needless to say however, that the pregnancy could not continue in our patient as well as (ended up in a missed abortion) because of a hostile environment locally.

This case cautions clinicians to strictly monitor patients in whom the device has been inserted for contraception because true failures can take place and cause problems for the patient who does not desire a pregnancy.

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