Failure to Insert a Levonorgestrel-Releasing Intrauterine System: A Survey Based on Self-Reports by Israeli Gynecologists

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ABSTRACT: **Background:** The insertion of a levonorgestrel-releasing intrauterine system (LNG-IUS) requires experience and is associated with a low failure rate.

Objectives: To assess the reasons given by gynecologists why they failed to insert a LNG-IUS.

Methods: We obtained data from the sole distributor in Israel that prospectively recorded these cases when contacted by gynecologists following an insertion failure.

Results: The mean rate of failed insertions was 0.95% (range 0.77–1.03%) for the 5 year study period 2006–2010. The most common reasons reported by gynecologists for LNG-IUS insertion failure were loss of sterility of the device, inability to insert the device due to a stenotic cervical canal, accidental removal of the device following a successful insertion due to hasty removal of the inserter or the use of blunt scissors, and removal of the newly inserted LNG-IUS following ultrasound evidence that it was misplaced.

Conclusions: Gynecologists should be aware of the common pitfalls associated with insertion of an LNG-IUS. Several techniques that may aid in avoiding these mishaps are described.

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KEY WORDS: levonorgestrel-releasing intrauterine system (LNG-IUS), Mirena™, insertion failure, misplaced intrauterine device, long-acting contraception, stenotic cervical canal

The levonorgestrel-releasing intrauterine system is currently one of the most common forms of long-acting contraception used around the world [1,2]. It was launched in Israel over a decade ago and rapidly gained popularity. The rate of intrauterine device and LNG-IUS use in Israel is high, with about 14% of all fertile women using it as their contraceptive method (Pharmaquest survey of 1391 women aged 16–45, unpublished data, 2010). It is estimated that around 32% of the intrauterine devices inserted in Israel are LNG-IUS (Bayer-Israel, unpublished data, 2010).

LNG-IUS = levonorgestrel-releasing intrauterine system

It is well recognized that proper insertion of the LNG-IUS is the key to preventing complications such as perforations, expulsions and pain [1]. The LNG-IUS may be more difficult to insert than most copper IUDs due to its slightly wider diameter [2]. Data from post-marketing monitoring in New Zealand found that difficult insertion was reported almost three times more often with LNG-IUS compared to IUDs [3]. The bulkier frame is especially more likely to interfere with easy insertion in a small nulliparous uterus [4]. A recent study from Sweden reported a relatively high failure rate, 2.7%, among 224 nulliparous women attending family planning services for insertion of an LNG-IUS [5]. However, stratified analyses of the data from New Zealand suggested that the higher rate of difficult insertions was not explained by the presence of more nulliparous women in the LNG-IUS cohort or the non-contraceptive indications for use of LNG-IUS. Mechanical problems with the device were reported in about 1% of LNG-IUS insertions compared to 0.01% with the Multiload™ copper IUD (ML Cu 375) (Multilan AG, Ireland) insertions and this difference was statistically significant ($P < 0.001$) [3]. Adverse reactions to insertion, including pain and vaso-vagal reaction, were more frequent with LNG-IUS than with Multiload Cu 375 ($P < 0.001$) [3].

Failure to insert a LNG-IUS is not a common occurrence, but it can create an awkward situation for the woman and her doctor. On such rare events, gynecologists in Israel always approach the distributor of the LNG-IUS (Bayer, Israel), because for cases of failed insertion a replacement for the costly device is always provided.

The objective of the present study was to assess the reasons for insertion failure of LNG-IUS. Previous articles on the increased rate of failed insertions stress the technical difficulties, but little has been reported on common mistakes made by the gynecologist that could lead to insertion failure. Since the study was based on self-reports provided by gynecologists to the LNG-IUS distributor's representative after a failed attempt to insert a LNG-IUS, we had a unique opportunity to gather information on the mistakes made during the insertion process.

Table 1. Insertion failure rate of the levonorgestrel-releasing intrauterine system per year

Year	Failed insertion (%)
2006	0.99
2007	1.03
2008	0.97
2009	0.98
2010	0.77

PATIENTS AND METHODS

Over a period of 5 years, January 2006 to December 2010, Israeli gynecologists reporting an insertion failure of an LNG-IUS (Mirena™, Bayer, Berlin) to the local distributor (Bayer, Israel) were questioned regarding the events that led to the failed insertion before replacing the no longer usable device with a new one.

The distributor prospectively recorded the reasons given by the gynecologists for the LNG-IUS insertion failure: We were allowed to study this unique database to determine the reasons leading to the failure. Since the database was anonymous, we did not request approval from the ethics committee for human investigations (institutional review board).

RESULTS

The mean failure rate was 0.95% for the 5 year study period (range 0.77–1.03%). The failure rates for each year are given in Table 1. Absolute numbers are not provided due to marketing discretion by the distributor. The most common reasons for insertion failure as given by the gynecologists were:

- The device fell after the product package was opened and sterility was lost
- The package was opened, but the cervix was found to be closed and the device could not be inserted through the tightly closed cervix
- The device was inserted correctly, but upon removing the inserter the threads were entangled in the inserter and the device was incidentally pulled out as well
- The device was correctly placed, but when the threads were cut using dull scissors the device was pulled out together with the uncut threads
- An ultrasound after the insertion showed that the device was placed too low in the uterine cavity, and according to the common recommendations it was removed.

DISCUSSION

The LNG-IUS has a unique hand-held inserter that assists in its accurate placement and its diameter is slightly larger than that of most IUDs. Thus, its insertion may occasionally be more difficult and more dependent on the physician's experience. We found that the major causes of LNG-IUS insertion failure were largely due to technical problems that could have been avoided in many cases through more careful preparation, additional experience, and better adherence to the manufacturer's product instructions. Based on the information gathered we suggest a few simple guidelines that could help the physician minimize the chances of LNG-IUS insertion failure.

- When opening the LNG-IUS package, place the device on a flat solid surface, ensuring that its horizontal wings are parallel to the flat surface as they enter the inserter. This must be done on a sterile surface, and usually the most readily available option is to use the inner side of the device package

- The physician inserting the device should always consider passing a uterine sound to assess the patency of the cervical canal before opening the package of the device

- The LNG-IUS has very long threads that have a tendency to curl. One must first make sure that the threads are free to their full length and that there are no curls or knots. Once the device is inserted, the inserter should be pulled gently. Brisk movements should be avoided, as the threads can get entangled in the inserter and the device can be pulled out when trying to remove the inserter

- The use of blunt scissors can lead to insertion failure. Presuming that the threads are cut, the physician pulls on the scissors, which in turn extricates the device. Most gynecologists buy a pair of scissors and use that pair for years. One should take care to keep the scissors sharp

- We recommend performing a routine ultrasound after insertion of the LNG-IUS, if possible, to ensure that the device is correctly placed in the uterine cavity. As advised by the manufacturer, the device should be removed whenever it is misplaced. To avoid having to remove the costly IUS, the misplaced IUS can be repositioned. This possibility can be offered to the patient. We recently reported our experience using an alligator forceps to push the device back to its correct position [6]. The procedure was deemed successful in 17 (94.4%) of 18 cases. In 3 (17.6%) of the 17 successful procedures, the LNG-IUS was found again to be malpositioned within 2 months. No complications were noted and no post-procedural infection occurred [6].

Doctors do not always like to admit their failures. This study had the unique advantage of anonymously gathering data from physicians who failed the insertion process. From the informa-

tion obtained it seems that many gynecologists make the same mistakes repeatedly. The failure rate in our series remained steady over the years, around 1%, except for a small decline in 2010, which does not seem of significance. The failure rate appears small at first, but when calculating the absolute number of devices lost, it is not negligible. Due to the high cost of the device, and the fact that the distributor replaces all devices that were damaged during the insertion process, we are convinced that most failures were reported to the local distributor. The observation that the failure rate remained constant over 4 years may help sustain this conviction. We could expect the number of failures to decline with increasing physician experience. However, the finding that this does not happen may reflect the fact that every year fresh and inexperienced physicians are newly introduced to the IUS insertion procedure.

Insertion of the LNG-IUS is different from insertion of the copper IUD. Not only is the inserter different, but the insertion technique is not the same. Insertion failures occur with all physicians, experienced or not. A young physician is expected to follow the labeling instructions but may make mistakes due to lack of experience. Moreover, doctors with considerable experience inserting copper IUDs may feel over-confident and bypass the instructions for inserting the unique LNG-IUS.

Medication-induced cervical priming, namely prostaglandins, though not proven to reduce insertion pain, may facilitate insertion of the LNG-IUS and help avoid a difficult insertion, especially among nullipara or women known to have cervical stenosis [7]. However, pretreatment with misoprostol is currently not recommended as standard treatment before insertion of an IUD [8].

The reported mistakes were often not directly due to lack of training, but may have been associated with hastiness in the insertion process or unsharpened scissors. It is important that regardless of the physician's previous experience in inserting copper IUDs, he/she should undergo a training session on how to insert the LNG-IUS and how to avoid common pitfalls. With appropriate training and adherence to the simple guidelines described above, one can probably avoid most LNG-IUS insertion failures.

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Capsule

Crosstalk between neutrophils, B-1a cells and plasmacytoid dendritic cells initiates autoimmune diabetes

Type 1 diabetes develops over many years and is characterized ultimately by the destruction of insulin-producing pancreatic beta cells by autoreactive T cells. Nonetheless, the role of innate cells in the initiation of this disease remains poorly understood. Diana et al. show that in young female non-obese diabetic mice, physiological beta cell death induces the recruitment and activation of B-1a cells, neutrophils and plasmacytoid dendritic cells (pDCs) to the pancreas. Activated B-1a cells secrete IgGs specific for double-stranded DNA. IgGs activate neutrophils to release DNA-binding cathelicidin-related antimicrobial peptide (CRAMP), which binds self DNA. Then, self DNA, DNA-specific IgG and CRAMP peptide activate pDCs through the Toll-like receptor 9–myeloid differentiation factor 88 pathway, leading to interferon-alpha (IFNα) production in pancreatic islets. The authors further demonstrate through the use of depleting treatments that B-1a cells, neutrophils and IFNα-producing pDCs are required for the initiation of the diabetogenic T cell response and type 1 diabetes development. These findings reveal that an innate immune cell crosstalk takes place in the pancreas of young NOD mice and leads to the initiation of T1D.

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