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References

Missing IUS arms?
We want to describe a couple of cases that serve to demonstrate that the hormone capsule of the Mirena® intrauterine system (IUS) can dislocate during removal thus changing its appearance. As a result, careful examination of the device is required to prevent further unnecessary investigations.

A 58-year-old woman presented to her general practitioner for removal of a Mirena IUS as it was no longer required. It had been inserted at the practice 7 years previously to provide the progesterone component of her hormone replacement therapy.

At the time of removal the cervix and the IUS were found to be suboptimal. More traction than usual was required on the threads to remove the device. On inspection it appeared that the horizontal arms had become detached as they were no longer evident at the vertical end of the IUS had been removed with the hormone release capsule attached. The patient was asymptomatic and was allowed home.

A 50-year-old woman presented to the colposcopy clinic with moderate dyskaryotic smear. She had undergone two previous LLETZ procedures with removal and reinserion of the Mirena IUS for completeness of the IUS has been ascertained.

At the time of the procedure it was noted that the IUS threads were visible and the internal cervix was clearly more tractable than usual was required on the threads to remove the device. On inspection it was thought that the arms had become detached; the long stem of the device was seen extending beyond the release capsule present which was attached to the threads. A saline hysteroscopy was therefore performed to locate the IUS arms. Good views of the entire cavity failed to demonstrate the presence of IUS pieces or perforation. The LLETZ procedure was performed and a new IUS inserted. The patient underwent an uneventful post-operative recovery.

Replies
We would like to take the opportunity to respond to Dr Torbé et al.’s letter.1

One extremely rare, isolated case reports of hormone cylinder dislocations in the Mirena® intrauterine system (IUS) similar to the ones described by the authors have been received by the company’s Pharmaceuticals, Vigilance and Quality Assurance Unit. The company’s investigations have shown that these cases could not be attributed to a quality defect of the product. Difficult removal has been found as the underlying cause, and no further adverse effect in the Mirena user are mentioned in the majority of cases.

To make physicians aware of this extremely rare situation, and to avoid unnecessary interventions in search of ‘missing’ Mirena arms, the company has recently introduced the following statement into the Core Safety Information for Mirena: “After removal of Mirena®, the system should be checked to be intact. During difficult removals, single cases have been reported of the hormone capsule sliding over the horizontal arms and hiding them together inside the cylinder. This situation does not require further intervention once completeness of the cylinder has been ascertained. The knobs of the horizontal arms usually prevent complete detachment of the cylinder from the T-body.”

Implementation of this statement into the local product information is currently ongoing in all countries where Mirena is marketed, and it was submitted at the beginning of December 2008 to the Medicines and Healthcare products Regulatory Agency (MHRA) to be implemented in the UK.

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Reference

Serious morbidity with long-term IUD retention
We have recently encountered four patients with serious intraperitoneal sepsis over an 18-month interval (2007/2008). Each was associated with long-term retention of a copper intrauterine device (IUD), which was identified as the likely source of infection. The IUDs had been in situ for 8, 15, 18 and 20 years, respectively. Three women were several years within their menopause. All four women presented as systemically unwell with a complex pelvic mass. One had uterine obstruction at the site of the abscess, simulating gynaecological malignancy. In all cases laparotomy was technically difficult owing to the inflammatory pelvic mass adhering to bowel. Intermediate or prolonged hospitalisation resulted and, without IUD excision care, two of the women would probably have died.

Pelvic actinomycosis was reported in the two patients’ histology. Cultures of frank pus grew Actinomyces israelii in a treated. Actinomyces-like organisms (ALOs) had been reported in the cervical smear of the fourth woman. In 2004 she had undergone appendectomy, which showed
severe suberosal inflammation without mucosal inflammation leading to the conclusion that the source was elsewhere within the abdomen or pelvis. It is speculative that this episode 4 years earlier may have resulted from the long-term presence of her IUD. Pelvic actinomyces is normally benign as subacute or chronic disease, months or years before presentation.

Intrauterine devices marketed in the UK have licensed durations of 5, 8 or 10 years. In women aged under 40 years it is recommended they are changed according to licence. If inserted after age 40, an IUD may remain in situ until 1 year after the menopause if the last period (LMP) is over the age of 50 years, or 2 years after the LMP is under the age of 50 years.2

These recommendations are based on expert opinion and acknowledge that insertion-related risks are minimised by reducing the frequency of IUD changes. National guidance places strong emphasis on timely removal of an IUD early in the series of these women develops morbidity with long-term IUD retention.2

We cannot provide any denominator data for the number of women in the UK with a long-term IUD, but the occurrence of a cluster of cases of serious intraperitoneal sepsis in a single hospital in a relatively short space of time is unusual. It is likely that single cases are not reported, or the association with the copper IUD overlooked, by surgeons and not fed back to those providing contraception services. When a pelvic mass or abscess, fever and other signs of infection are found in patients with a long-term IUD, pelvic actinomyces should be considered. Awareness of this could usefully be increased among general surgeons and gynaecologists. We recommend that current guidelines be revised to include some emphasis on the importance of timely removal of an IUD, once its contraceptive properties are no longer required. Women should be made aware that long-term retention may rarely result in serious complications such as pelvic actinomyces and/or actinomycosis. There should be more emphasis on timely removal of an IUD early in the menopause. This is not included in existing professional guidance2 and patient information leaflets.

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References

IntrauterineContraceptionNov07.pdf [Accessed 10 August 2008].


Reply
With regard to the four cases of serious pelvic infection described by Pillai et al.,3 the Clinical Effectiveness Unit (CEU) acknowledges that long-term retention of an intrauterine device (IUD) is associated with infection and that the risk of actinomycesic pelvic abscesses increases with duration of use. For this reason, Faculty of Sexual and Reproductive Healthcare (FSRH) Guidance recommends that an IUD is removed at the end of its licensed duration or when no longer required.2 In women having an IUD inserted between the age of 40 years and the menopause, FSRH Guidance recommends that, based on expert opinion, the risk of infection in the 20 days following replacement of an IUD outweighs the risk of extending use until the menopause. In this situation, the IUS should be continued until 1 year after the last menstrual period (LMP), or 2 years after the menopause if the LMP occurs under the age of 50 years.2

Intrauterine devices.2

It is not clear how many IUD users retain their IUD after the menopause and what proportion of these women develops complications. However, the cases described by Pillai et al.3 highlight the potential for life-threatening infection and a lack of awareness of the need for IUD removal among some IUD users and health professionals. Current FSRH Guidance recommends that health professionals need to advise patients about the importance of IUD removal when no longer required and about the potential risks of long-term IUD retention. We are grateful to Dr Pillai and colleagues for highlighting this to our attention and we shall ensure that a recommendation to this effect is included in future updates of the Guidance on ‘Intrauterine Contraception’.

Case reports are a useful source of evidence where no other evidence exists. We would encourage others to report complications that are particularly rare, serious or associated with prolonged contraceptive use.

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Informed consent for IUD fitting
Perforation of the uterus is a rare complication of intrauterine device (IUD) fitting. It is quoted as occurring in up to 2 in 1000 insertions.1 Risk factors for perforation include previous caesarean section2 and postpartum insertion up to 6 months after delivery.2

Perforation may occur during the sounding of the uterus or the device itself may perforate the uterus. This can lead to the device being free in...