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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 visible. 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 not evident and the vertical main stem of the IUS had been removed with the hormone release capsule attached.

The patient was asymptomatic and was allowed home. A transvaginal ultrasound scan was performed on an outpatient basis. The scan demonstrated echogenic specks at either end of the endometrium in longitudinal section, and in coronal section some did not visualise within the lateral walls of the uterus. It was queried whether these represented the arms of the IUS. The patient was then referred to the gynaecology department, for consideration for operative hysteroscopy to remove the retained arms.

A 50-year-old woman presented to the colposcopy clinic with moderate dyskaryotic smear. She had undergone two previous large loop excision of the transformation zone (LLETZ) procedures for cervical intraepithelial neoplasia (CIN) with complete excision at each. On this occasion colposcopy examination was limited because of unsatisfactory views of the squamo-columnar junction. It was decided the patient would have a further LLETZ treatment with removal and reinsertion of the Mirena IUS under general anaesthesia.

At the time of the procedure it was noted that the IUS threads were visible and the internal cervix was os seen in situ. Again more traction 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 with the hormone release capsule present 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.

In both cases, when the removed IUS was re-examined, it became apparent that the entire device had been removed from the uterine cavity.

The arms were still attached to the main stem of the IUS. The hormone release capsule, usually situated at the base of the vertical stem, had migrated up the shaft, trapping the arms and bringing them together in the midline, making it appear as if they had been detached (Figure 1).

The majority of IUS are removed without difficulty. There are no published cases of IUS arms becoming detached. However, an intrauterine-retained hormone release capsule following IUS removal has been documented.2

The common theme in the two patients described above and Forrest et al.’s patient1 is difficult retrieval of the device requiring more traction on the threads than normal. This presumably led to the hormone capsule being dislodged, either migrating up the device and getting stuck covering the arms or becoming detached altogether. Clinicians should always check IUS devices for retention. They should also be aware that after a difficult removal the capsule can migrate and obscure the arms but the device remains complete. Knowledge of this possibility will prevent patients being subjected to unnecessary investigations and interventions to find ‘missing’ IUS arms and for appropriate investigations and interventions when the capsule has detached.

The whole of the IUS device is radio-opaque and can be located with either X-ray or ultrasound.2 Transvaginal ultrasound is the first-line investigation because it provides the best image to help determine whether or not the IUS is correctly sited within the uterus. The vertical stem of the IUS is visualised in the sagittal plane with multiple reflective parallel planes and in the axial plane as a single echogenic focus.3 However, in the cases reported here the vertical stem was missing. Horizontal arms are rarely seen in the uterus unless it is possible to obtain a coronal view.3 In view of this difficulty abdominal X-ray would confirm whether or not the horizontal arms of the IUS were within the pelvis. This would be useful, especially prior to embarking on hysteroscopic investigation.

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Figure 1 The intrauterine system (IUS) shown in the upper part of the photograph has been removed entirely but its appearance is atypical. The IUS in the lower part of the photograph has a normal appearance

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 into their menopause. All four women presented as systemically unwell with a complex pelvic mass. One had pericolic 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 appropriate care, two of the women would probably have died.

Pelvic actinomycosis was reported in the two patients’ histology. Cultures of frank pus grew Actinomyces sp. in the infected. Actinomyces-like organisms (ALOs) had been reported on a smear of the fourth woman. In 2004 she had undergone appendicectomy, which showed


caption: Figure 1 The intrauterine system (IUS) shown in the upper part of the photograph has been removed entirely but its appearance is atypical. The IUS in the lower part of the photograph has a normal appearance.

Reply

We would like to take the opportunity to respond to Dr Torbe et al.’s letter.1 This 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 Pharmaceutical 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. Difficulty removed 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 product 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 IUS 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 2007 to the Medicines and Healthcare products Regulatory Agency (MHRA) to be implemented in the UK.

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Reference
severe subserosal 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 might have resulted from the long-term presence of her IUD. Pelvic actinomyces normally begins 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 the age of 40, however, they 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 when removal is safe from a contraceptive point of view.3 There is no clear mention of the need for removal once the contraceptive action is no longer required, or of the risks of failing to do so. The frequency with which ALOs are reported in routine smears rises in a linear fashion with the duration of use of devices.4 ALOs are more common with certain types of IUD (e.g. Multiload®) and uncommon with the levonorgestrel intrauterine system.5 Pelvic actinomyces is an uncommon and poorly understood condition, but has been recognised to complicate IUD use since the first report in 1973.6 However, *Actinomyces* also normally reside in the female genital tract.7

We cannot provide any denominator data for the number of women in the catchment population 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 infection with pelvic actinomyces and/or actinomyces. There should be more emphasis on timely removal of an IUD early in the menopause. This is not included in existing professional guidance8 and patient information leaflets.9

In summary, on the face of it this would appear to be a simple case of a woman having an IUS inserted and developing a TAC, which was rapidly cured by removing the device. I would be delighted to discover if any of the Journal’s readers have observed a similar case.

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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 women in up to 2.5 in 10,000 IUD fittings.1 Risk factors for perforation include previous caesarean section2 and postpartum insertion up to 6 months after delivery.1

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 the abdomen.
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