At the time of the procedure it was noted that the IUS device was sited within the correct part of the uterus. The vertical stem was missing. Horizontal arms are rarely dislodged, either migrating up the device and getting stuck covering the arms or becoming detached, either migrating down the device and getting stuck covering the arms or becoming detached altogether. Clinicians should always check IUS devices after removal. They should also be aware that after a difficult removal the device can migrate up the device and get stuck over the horizontal arms and require removal to take them out.

The whole of the IUS device is radio-opaque and can be located with either X-ray or ultrasound. Transvaginal ultrasound is the first-line investigation as this provides the best images 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. 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. In 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.

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 intradetrusor device (IUD), which was identified as the likely source of infection. The IUDs had been in situ for 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 ureteric 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 infection control care, two of the women probably have died.

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

Reference


Reply

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

We acknowledge the 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 Pharmacovigilance 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 cylinder dislocating 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 2008 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 not have resulted from the long-term presence of her IUD. Pelvic actinomyces infection normally begins as subacute or chronic disease, months or years before presentation. IUDs made of copper 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 years, it 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 if the LMP is under the age of 50 years. These recommendations are based on current clinical 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. 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 smear results is in a linear fashion with the duration of use of devices. ALOs are more common with certain types of IUD and uncommon with the levonorgestrel-releasing intrauterine system. Pelvic actinomyces is an uncommon and poorly understood condition, but has been recognised to commence after the IUD is inserted. Awareness of this could usefully be increased among general practitioners and gynaecologists. We recommend that current guidelines be revised to include some recommendation to patients about the importance of IUD removal when no longer required. Women should be made aware that long-term retention may rarely result in serious complications with pelvic actinomyces infection and/or actinomyces infection. There should be more emphasis on timely removal of an IUD early in the menopause. This is not included in existing professional guidance and patient information leaflets.

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References

Intrauterine ContraceptionNov07.pdf [Accessed 10 August 2008].

Reply
With regard to the four cases of serious pelvic infection described by Pillai et al., the Clinical Effectiveness Unit (CEU) and the Faculty of Sexual and Reproductive Healthcare (FSRH) would like to comment.

Intrauterine ContraceptionNov07.pdf [Accessed 10 August 2008]

The patient, a 39-year-old woman, was fortunate not to have had a headache until the events reported here. In early 2007, the patient started to complain of severe menorrhagia. Her periods were heavy and had lasted for 14 days, and necessitated the use of 15–20 sanitary pads a day. Tranexamic acid 1000 mg qds was tried initially for 8 weeks but the heavy bleeding continued. Neutrophil counts in the leucocyte profile were low. A therapeutic trial of 5 tids was tried for many months resulting in a mild improvement. In desparation, the patient was referred to a gynaecologist who felt that the next step was to try to induce a menstrual and therefore a levonorgestrel-releasing IUS. This was duly done. Within 6 hours of inserting the IUS the patient’s attacks started. The patient’s attacks (averaging 5–7 attacks/day) were more severe. She was left alone and returned later. An attack started with pain to the side of the left eye that the patient described as unbearable, like the worst toothache ever. Associated with the pain was paraesthesia in the left side of his face, although the pain was so bad the patient also cried with her right eye. Her paralabral fissure narrowed, her nose ran and her eye became pink. Her face felt strange and numb though painful. Touching her face, or brushing her hair or her teeth, did not trigger an attack. The attacks continued daily for 4 weeks until the patient came to see us.

As she entered the room, an attack started. Following the attack I removed the patient’s IUS very easily and gave her a zolmitriptan nasal spray. In case I had been led astray I had been holding the patient for 7 days, at which time she appeared to be a completely different person. She had suffered one further attack some 6 hours after the IUS was removed and later had a zolmitriptan nasal spray. After this her attacks had totally stopped. At that clinic visit, in order to help her menorrhagia, which still raged, I started the patient on norethisterone again. Eighteen months later she is still totally free of attacks, and although her bleeding is still very heavy, she is not prepared to even consider allowing me to reinset an intrauterine device/system, with or without hormones. She says the pain was the worst pain she could ever imagine and as a result she would never, even for the purposes of research, have an IUS inserted again.

This woman appeared to develop a TAC, which approximated most closely to a cluster headache, and the IUS was rapidly curing 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 approximately 1 in 2000 women at fitting. 4 Risk factors for perforation include previous caesarean section and postpartum insertion up to 6 months after delivery. 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

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