LETTERS

Letters to the Editor

Full-term pregnancy with Implanon® in situ

An 18-year-old nulliparous woman who had had no bleeding since the insertion of an etonogestrel subdermal contraceptive implant (Implanon®) 4 months earlier had a positive pregnancy test. The implant was easily palpable and correctly sited. An ultrasound scan showed the gestation was 27.2 weeks.

Review of the patient’s general practitioner (GP) records indicated that the Implanon had been inadvertently inserted when she was already pregnant. She had not regained regular menstruation since stopping depot medroxyprogesterone acetate contraceptive injections (Depo-Provera®) 6 months previously and switching to condoms. At the time of fitting she denied any sexual intercourse since splitting up with her boyfriend 6 weeks previously and was therefore seemed to be an option. Her GP was referred her to a specialist contraception clinic for removal of the implant, which she attended 3 weeks after the pregnancy diagnosis (now 30 weeks’ gestation). The patient said she was always happy with the implant and would wish to use it again after delivery, and she asked if it could be removed.

The doctor in the clinic (H.C.) informed the patient of the pregnancy but mentioned that the lack of evidence about the correct course of action, and explained that progestogens in pregnancy have not been linked with fetal abnormality. In addition, it was unlikely that the rate of progestogen release from the implant would be altered in pregnancy and there was no reason to expect ultrasound scans of the gestation to interfere with labour or delivery. Use of Implanon during lactation is standard (although the patient planned on keeping the implant in place therefore seemed to be an option).

The GP informed the manufacturers of Implanon (Organon), who of course recommended removal. A few days later a letter was received, stating that the implant was no longer considered to be suitable for use in pregnancy. This was reasonable for the implant to be left in place, giving the patient the opportunity to return if she changed her mind and decided she wanted it removed. Informational discussion with a few colleagues indicated the majority would advise removal but could not give any clear reason.

The patient had a spontaneous labour and normal delivery of a healthy baby girl weighing 3.3 kg at 40+2 weeks’ gestation. At routine follow-up 2 weeks later the baby was being bottle-fed and showed no signs of abnormality. The mother was healthy and the implant still had not been removed. The implant was easily palpable and correctly sited.

One positive chlamydia result was less than the figure expected from local and national prevalence figures of 3–12%. Risk of infection can be discussed in the consultation to exclude those who are asymptomatic for pelvic inflammatory disease or at high risk of acquiring an STI. We believe pre-implant counselling helps clients most at risk of chlamydial infection to choose not to have an IUD fitted, even if the patient withholds relevant information (the informed user being a sensible user). A prospective study of all clients considering a postcoital IUD would be valuable to explore this impression further.

Our study supports research findings that prophylactic antibiotics are not cost-effective.

Wendy Morris, MFFP

Staff Grade in Family Planning and Reproductive Health Care, Sheffield Contraception and Sexual Health, Central Health Clinic, 1 Mulberry Street, Sheffield S1 2PJ, UK.

E-mail: wendy.morris@sheffield.ac.uk

Salmon Omokanye, FRCOG, MFFP

Consultant in Family Planning and Reproductive Health Care Central Health Clinic, 1 Mulberry Street, Sheffield S1 2PJ, UK.

E-mail: salmon.omokanye@sheffield.ac.uk

References

Mirena® IUS and ovarian function

“Accurate, up-to-date information is essential to enable users to make an informed and voluntary choice of contraceptive method”, declared the National Institute for Health and Clinical Excellence (NICE) guidelines, which also stated that “User satisfaction and successful use of contraception depend on adequate knowledge and accurate perceptions of the method”. At present there is strong evidence that the frequency of functional ovarian cysts is increased in the presence of the levonorgestrel-releasing intracervical system (Mirena®). Some of the studies showed that as many as 30% of women identified ovarian cysts 3 months after LNG-IUS insertion. According to the NICE guidelines, “The incomplete suppression of ovarian activity in LNG-IUS users is a recipe not only for erratic bleeding, but also for the development of ovarian follicular cysts”. As stated in the Summary of Product Characteristics for the Mirena® IUS, functional ovarian cysts have been diagnosed in 10–12% of patients. In most cases they are small and asymptomatic, and disappear spontaneously.

The FPRHC Guidance published in April 2004 stated that: “Women may be reassured that although ovarian cysts occur in LNG-IUS users, there is no significant increased risk compared to IUD users”. The NICE guidelines published in October 2005 stated that: “Development of ovarian follicular cysts ... occurs in 20% of women using the LNG-IUS”. But according to these NICE guidelines there is no evidence that LNG-IUS cause any harm to pregnant patients about this risk prior to IUS insertion.

“The LNG-IUS is a suitable option for most women who need contraception and/or treatment for menorrhagia” stated the FPRHC Guidance. According to the NICE guidelines, the IUS is becoming one of the most cost effective, close to an ideal contraceptive device with high efficacy, ease of use and almost no absolute contraindications (except current malignancies or genital/pelvic infection). “The IUS may be used contraceptively in postmenopausal women who need contraception and/or treatment for menorrhagia”. But according to the NICE guidelines it is important that IUS users are made to have no menstrual or pelvic pain problems prior to IUS insertion and they are highly likely to develop them later, which will have a negative effect on the IUS discontinuation rate and the overall cost effectiveness. At present, up to 60% of women will stop using the IUS within 5 years. The most common reason for discontinuation is unacceptable vaginal bleeding and pain.

Cost effectiveness and utility for the patient are also heavily affected by the way IUS-induced ovarian cysts are investigated. Functional ovarian cysts are infrequent in women not using hormonal contraception or in women on combined oral contraception. Currently, the typical IUS user is over 30 years old. Westhoff and Clark found that women aged 30–34 years had the highest rate of ovarian cysts, 50% for functional cysts; 142/100 000 woman-years.

While there are Royal College of Obstetricians and Gynaecologists (RCOG) guidelines for the management of ovarian cysts in postmenopausal women, there is currently no nationally agreed algorithm for the management of ovarian cysts in premenopausal women. There is also no absolute opinion on the place of routine ultrasound investigations for LNG-IUS users, some studies recommend it and some do not, as ovarian cysts have a high rate of spontaneous resolution. It is, for example, unclear how long one should be monitoring the cyst, when the scan should be performed and how frequently it is to be repeated. This was not an issue in the past when IUS use was infrequent. The new generation of IUS users may not be prepared to cope with functional ovarian cysts. The likelihood of increased IUS use will make the development of algorithms for the management of functional ovarian cysts and/or pelvic pain a high priority. As Sturridge and Guillebaud declared in 1996, “the unique unwanted non-contraceptive effects of the system, including possible development of functional ovarian cysts, and the relationship between menstrual irregularity and ovarian function, also require better understanding, in order to offer appropriate patient counselling and maximum acceptability and continuation of use of the method”. Although this statement was originally made in 1996, it is even more appropriate for 2006.

Elena Valarche, MFFP

Staff Grade in Family Planning and Sexual Health Service, Endfield PCT, West End Health, 3 Easton Road, Endfield, London EN1 1NJ, UK.

E-mail: elenavalarche@aol.com

References


Faculty of Family Planning and Reproductive Health Care Clinical Effectiveness Unit. FFPRHC Clinical Effectiveness Unit, University of Aberdeen, UK. E-mail: ffprhc@abdn.ac.uk

References

Emergency contraception and the LNG-IUS

The Faculty Guidance document on the CEU on ‘Emergency contraception’ (April 2006 issue) is comprehensive, and does provide sound practical guidance on the subject. It is surprising that no mention is made that the levonorgestrel-releasing intrauterine system (LNG-IUS) is not suitable and not licensed for emergency contraception. It would have been appropriate to emphasise that there is no research evidence available on the effectiveness of the LNG-IUS for use for emergency contraception.

R K Bhathena, M.D. FRCOG Consultant, Petit Parsee General and Masina Hospitals, B Petit Road, Camballa Hill, Bombay 36, India. E-mail: rkbhathena@hotmail.com

References

Reply
Thank you for the opportunity to respond to the letter from Dr Elena Valarche on ovarian cysts and the levonorgestrel-releasing intrauterine system (LNG-IUS) (Mirena). Based on the evidence, the Faculty of Family Planning and Reproductive Health Care Guidance (April 2004) stated that ‘...women may be reassured that although ovarian cysts occur in levonorgestrel-releasing intrauterine system (LNG-IUS) users, there is no significant increased risk compared to copper-bearing intrauterine device users (Grade A)’. A systematic review did not identify an increased risk of ovarian cyst formation in LNG-IUS users, and the CEU Guidance in this way. Dr Bhathena points out that our letter from Dr Bhathena regarding the CEU Guidance on emergency contraception was our first choice, particularly if the woman intends to continue the IUD as contraception”. I imagine this advice was taken from the recent National Institute for Clinical Excellence (NICE) report on ‘Emergency contraception’ which would satisfy these criteria from the IUDs available in the UK today. The ‘CEU Guidance’ series has been established itself as the final arbiter in ‘small print’ contraceptive advice in the UK today.

In ‘EBM’ Box 7 you state that ‘IUDs with banded copper on the arms and containing at least 380 mm² of copper have the lowest failure rates and should be the first choice, particularly if the woman intends to continue the IUD as contraception’. I find the recent summary on emergency contraception so both timely and comprehensive.

However, there are three points I would like to take issue with, two of which have considerable bearing on the LNG-IUS. In ‘EBM’ Box 7 you state that ‘IUDs with banded copper on the arms and containing at least 380 mm² of copper have the lowest failure rates and should be the first choice, particularly if the woman intends to continue the IUD as contraception’. I imagine this advice was taken from the recent National Institute for Clinical Excellence (NICE) report on long-acting reversible contraception. Many of us find it hard enough to promote the use of IUDs to young teenagers and nullips in these circumstances and do not welcome the suggestion that to use a Nova-T 380 would be suboptimal treatment.

The third point is one of omission. Reference 5 in your article refers to PRODIGY Guidance – Contraception emergency. [Accessed 7 February 2006]. The PRODIGY list of indications for emergency contraception includes discussion about the contraceptive patch, which surely for completeness should be included in your ‘EBM’ Box 7.

My final reservation concerns ‘off-licence use’. In several of your ‘Good Practice Point boxes’ you make the commendation that the LNG-IUS is ‘outside the product licence’ in the 2003 Guidance2 use ‘more than once in a cycle’ was listed in this category and in the current advice this is no longer mentioned. Had the product licence been changed in this respect?

Terry McCarthy, M.D. FRCOG Consultant, Directorate of Sexual and Reproductive Health, Gwent Healthcare NHS Trust, Llanyravon House, Cwmbran, Torfaen NP44 4YN, UK. E-mail: terry.mccarthy@gwent.wales.nhs.uk

References

Letter to the Editor

Thank you for the opportunity to respond to the letter from Dr Terry McCarthy regarding the CEU Guidance on emergency contraception. Dr McCarthy has studied the recommendations in detail and given careful consideration to their implications for his own practice. He is very rewarding to the CEU team to know that clinicians are using the Guidance in this way.