

LETTERS

Size does matter and Homeopathic treatment of premenstrual symptoms

Madam

I am somewhat concerned that in the same issue of the Journal as the statistical paper entitled 'Size does matter'¹ there was an Overview on 'Homeopathy treatments for premenstrual symptoms'² which may be considered to have depended on evidence that contradicted the statistical paper. I would be grateful for your opinion as to the reliability of the one clinical trial by Yakir et al.³, which was cited as evidence in favour of homeopathy. I would like to make clear that my motivation is not to discredit homeopathy.

1. The Overview refers to the 'recent' trial by Yakir et al. It was actually carried out in 1992–1994 and not published until 2001.
2. The Overview refers to there being 20 women in the study but actually only 19 completed the study.
3. The Yakir et al. study claims 90% of the homeopathy group had improvement – actually it was 91%, i.e. even more favourable to homeopathy than was claimed.
4. Yakir et al. set an arbitrary improvement level of 30% of the menstrual distress questionnaire to determine effectiveness of therapy resulting in three of the placebo group improving. However, Figure 2 shows that five of the placebo group had improved.
5. While claiming homeopathy effective they admit under Outcomes that, 'the between group difference ... fell just short of statistical significance'.
6. The study certainly suggests the possibility that homeopathy is effective so why no larger-scale trial 9 years later?

My main concern is that our Journal has given credibility to the effectiveness of homeopathy in the management of premenstrual syndrome on the basis of inadequate evidence. What do you think?

Michael Cox, Member of the Editorial Advisory Board, Journal of Family Planning and Reproductive Health Care and Consultant Obstetrician and Gynaecologist (Retired), Nuneaton, UK

References

1. Mollison J, Simpson JA, Hannaford PC. Size does matter. *J Fam Plann Reprod Health Care* 2003; **29**(1): 9–11.
2. Jones A. Homeopathic treatment for premenstrual symptoms. *J Fam Plann Reprod Health Care* 2003; **29**(1): 25–28.
3. Yakir M, Kreidler S, Brzezinski, et al. Effects of homeopathic treatment in women with premenstrual syndrome: a pilot study. *Br Homeopath J* 2001; **90**: 148–153.

Reply

Thank you for your letter regarding the above mentioned papers. I agree that the fourth key message point in the Jones article 'A randomised, controlled double-blind trial published in 2001 has confirmed the positive outcome of the previous anecdotal experience' is not substantiated. The findings of one, very small, randomised controlled trial are not enough to support such a statement. The text of the Jones article refers to the Yakir et al. study as a pilot. Although, technically, the Yakir et al. study was not a pilot, this terminology should have alerted our readers to the fact that the results of a single, very small study cannot, on its own, confirm the effectiveness of homeopathic treatment.

I agree with the points you have raised; some are minor but they do highlight errors in the Jones paper. In the Yakir et al. trial the characteristics of the two groups are not presented in a way that easily allows differences between the groups to

be assessed. Randomisation of 23 patients will not ensure comparable groups, albeit any difference will have occurred purely by chance. There is still the potential for differences in the characteristics of the women in the two groups to have had an impact on the between group comparisons. The final sentence in the Results section of the Yakir et al. paper states, 'No secondary or demographic characteristics affected response to the treatment'. This is very likely to be due to a lack of power rather than no effect, although this cannot be assessed as no data are provided.

In summary, I agree with you that the 'evidence' behind the fourth key message point in the Jones paper is not of sufficient quality or size to justify this statement.

Jill Mollison, Statistical Advisor, Journal of Family Planning and Reproductive Health Care and Biostatistician Research Fellow, Department of Public Health, Medical School, University of Aberdeen, Aberdeen, UK

More on how to remove a Chinese IUD

Madam

Stillwell's letter¹ in the April issue of the Journal prompted me to write to you with my findings and experience.

Of the 156 million intrauterine device (IUD) users worldwide, 106 million are in China where the IUD is used by 45% of married women and sterilisation used by 38%.²

The stainless steel ring (Shanghai ring) was first produced in Shanghai in 1970.³ The ring is 1 inch in diameter, flexible, springy and thread-free and designed not to be removed easily due to China's 'one child per family' policy. It was used for immediate post-placental insertion.

A meta-analysis by Li Yong et al. of 22 published and unpublished studies compared the efficacy of the steel ring IUD to the copper-bearing IUD⁴ and found failure rates of 19% compared to 5.9% with copper IUDs and an expulsion rate of 16.5% versus 5.8%. The State Family Planning Commission advised against its manufacture in 1993.

Information obtained by e-mail from China, via a Chinese patient, included pictures and instructions on insertion and removal of steel rings. The rings are fitted using a 'fitting fork' or 'fitting pliers', which carry the ring in the uterus. Removal is performed using a hook.

If the ring is stuck in the uterus and cervix then it is cut in half between two haemostat forceps before taking it out. This is preceded by cervical dilation.

A literature search revealed no relevant information about removal of these devices in the existing Faculty of Family Planning and Reproductive Health Care (FFPRHC) and Royal College of Obstetricians and Gynaecologists (RCOG) Guidance documents, the National Guidelines Clearing House or World Health Organization (WHO) publication, *Improving Access to Quality Care in Family Planning - Selected Practice Recommendations for Contraceptive Use, 2002*.

The Clinical Effectiveness Unit (CEU) of the FFPRHC helped by conducting a MEDLINE and EMBASE search for the period 1996–2002. They found one paper recommending the use of three-dimensional ultrasound imaging to locate and detect the type of IUD and successful removal in 26/28 cases by hysteroscopy, laparoscopy or laparotomy⁵.

When faced with a thread-free device, there are two instruments available: the rigid uterine hook similar to the one used by the author of the reference paper and the flexible Rocket IUD-removing forceps.⁶ In my experience I have found the forceps superior to the uterine hook, allowing more control and therefore giving more confidence. They also have the advantage that any part of the IUD can be grasped and brought down.

I hope others will try the technique for themselves. The most successful instrument will be the one with which the operator is most familiar with and confident to use.

I would like to thank the CEU for their literature search and my patient for providing the information and pictures via e-mail. For more information about forceps, please contact the author.

Noreen S Khan, Head of Community Gynaecology and Reproductive Health Care, The Palatine Centre, 63–65 Palatine Road, Manchester M20 3LJ, UK

References

1. Stillwell S. How to remove a Chinese IUD. *J Fam Plann Reprod Health Care* 2003; **29**(2): 60.
2. UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Training in Human Reproduction. HRP. The intrauterine device (IUD) – worth singing about. *Prog Reprod Health Res* 2002; **60**: 1–4.
3. Bradley J. Obgyn.net, ultrasound section. 'Chinese ring'. www.obgyn.net [access date August 1998]
4. Li Yong P, Bourne KL, Rowe PJ, et al. The demographic impact of conversion from steel to copper IUDs in China. *Int Fam Plann Perspect* 1994; **20**: 124–130.
5. Xia E, Duan H, Huang X, et al. Hysteroscopic removal of foreign bodies and its methods of monitoring. *Chin Med J* 2003; **116**: 125–128.
6. Johnson N, Dalton ME, Bramham DR, et al. A randomised crossover trial comparing thread retrievers with IUD removing forceps. *Br J Fam Plann* 1990; **16**: 71–73.

Vasectomy techniques

Madam

There are a few points that we would like to make regarding the paper comparing scalpel and the electrocautery no-scalpel vasectomy (ENSV) techniques.¹

We believe that the phrase 'no-scalpel vasectomy' is a misnomer because, although it implies that no scalpel is used to incise the skin, a special dissecting clamp² or, as in this case, electrocautery is used to breach the skin and subcutaneous tissues to gain access to the vas. Whichever method is used the incision in the skin has to be at least twice the diameter of the vas that is being exteriorised.

We use two Allis' forceps or a single Allis forceps and a skin hook to deliver a loop of vas through an incision made by a Number 11 blade. We assessed some of the parameters described in the paper with the following results:

- (1) Using a visual analogue scale (0–10) to measure pain during the operation it was found that the average score for pain during surgery was 2.52 (range 0–9). The duration of analgesic use after vasectomy was for a mean of 3.6 days (range 0–1.4 days).
- (2) Patients returned to work on average 4.89 days after surgery (range 1.17) although, as in the Black and Francome paper, not all the time off work was related to the operation.
- (3) On average 13.9% of patients visited their general practitioners after surgery; this was for infection in 2.8% and antibiotics were prescribed to 5.6% of patients.

In a survey of patient satisfaction 68% graded the service as excellent and 26% as good, while in a service assessment these figures were 53% and 43%,³ respectively.

We have used this technique a few thousand times and believe that the single incision mini-vasectomy is as good as the ENSV procedure.

N K Menon, General Practitioner, The Ongar Surgery, High Street, Ongar CM5 9AA, Essex, UK
J Kelly, Practice Nurse, Keats House Surgery, Harlow, Essex, UK
J Norton, Practice Nurse, Keats House Surgery, Harlow, Essex, UK

References

1. Black T, Francome C. Comparison of Marie Stopes scalpel and electrocautery no-scalpel vasectomy techniques. *J Fam Plann Reprod Health Care* 2003; **29**(1): 32–34.
2. Li SQ, Goldstein M, Zhu J, Huber D. The no-scalpel vasectomy. *J Urol* 1991; **145**: 341–344.
3. Menon NK. Patient satisfaction with a direct access vasectomy service. *Br J Fam Plann* 1998; **24**: 105–106.