LETTERS

Evidence-based reproductive medicine

Madam

I look forward to the arrival of the Journal. It is always a good read, full of relevant and practical information – much more ‘user-friendly’ than most journals I receive these days. July’s edition contains particularly interesting with a number of interesting articles.

However, my interest was quickly replaced by irritation. There is a lot to be said for evidence-based medicine (EBM) but it is always a good idea to have a review of the current evidence available in order to provide women with accurate information when discussing contraception. However, it is not sufficient just to provide the ‘evidence’. EBM must consider that clinicians need practical guidance with decision making.

The Clinical Effectiveness Unit (CEU) recommends that the desogestrel-only pill is different from other POPs in terms of efficacy, and that it is similar to combined oral contraception (COC) in this respect.1 The recommendation is based on insufficient evidence to support lower failure rates with the desogestrel-only pill. This is despite another study showing that the desogestrel-only pill was sufficient to inhibit ovulation in 97% of cycles and that this is its primary mode of action.2 The evidence and data provided by the manufacturers may not be credible raises an additional concern. In the same edition an excellent article on evidence-based reproductive health by Dr Dora Varandas quotes a Chinese proverb: ‘Be careful what you wish for: it may come true’.3 The author adds that pharmaceutical industry-funded trials tend to report more favourable findings than those funded by other means, noting that one of the trial authors for the desogestrel-only pill studies is affiliated to the company that manufactures the pill. If this is an issue, then we must ask ourselves whether it is more important to continue undertaking the desogestrel-only pill review have any relevant associations with the manufacturers of other progesteron-only pills (POPs), who are unlikely to be independent and impartial. I am not denying the need for more unbiased clinical trial evidence; I am just despairing at our sudden inability to put the information to practical action. I am afraid that we are still the rabbit in the headlights and we are just supposed to tell women that a POP that inhibits ovulation in 97% of cycles is no more effective than currently available POPs.

One final point refers to the FPFRHC Guidance on Contraceptive Choices for Women with Inflammatory Bowel Disease which includes the repeated comment that WHO 3 implies cannot use, e.g., ‘Women with primary sclerosing cholangitis should not use the POP (WHO Category 3 – risks outweigh the benefits)’. I am concerned that the CEU is perpetuating this misinterpretation of the WHO 3 category that does not absolutely contraindicate use, although other methods should be the first choice.

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References


CEU New Product Review of the desogestrel-only pill

Madam

The Clinical Effectiveness Unit (CEU)’s product review of the desogestrel-only pill’ and the recent article ‘Is Cerazette the minipill of choice?’ in the Drug and Therapeutics Bulletin (DTB)4 are both good reviews with useful data. But in my opinion they are marred by their surprisingly negative conclusions.

What do we do when we evidence from clinical trials and epidemiology is not as complete as we would all like, but we have clients sitting in front of us wanting our help in choosing from the available options? It is then not sufficient just to provide the ‘evidence’ from an ivory tower. A decision has to be made, at the present time. Pending more data, evidence-based medicine (EBM) must be subjected to informed clinical judgement, based on all the available evidence (including the reported pharmacology of the product) and – dare I say it? – clinical common sense.

The statement of the DTB is not inaccurate when it says: ‘it cannot be said that the desogestrel-only pill is the contraceptive of choice’ (the CEU?) ‘There is insufficient evidence on whether it (Cerazette) is a more effective contraceptive than other POPs in terms of efficacy’. The evidence and data provided by the manufacturers may not be credible raises an additional concern. In the same edition an excellent article on evidence-based reproductive health by Dr Dora Varandas quotes a Chinese proverb: ‘Be careful what you wish for: it may come true’. The author adds that pharmaceutical industry-funded trials tend to report more favourable findings than those funded by other means, noting that one of the trial authors for the desogestrel-only pill studies is affiliated to the company that manufactures the pill. If this is an issue, then we must ask ourselves whether it is more important to continue undertaking the desogestrel-only pill review have any relevant associations with the manufacturers of other progesteron-only pills (POPs), who are unlikely to be independent and impartial. I am not denying the need for more unbiased clinical trial evidence; I am just despairing at our sudden inability to put the information to practical action. I am afraid that we are still the rabbit in the headlights and we are just supposed to tell women that a POP that inhibits ovulation in 97% of cycles is no more effective than currently available POPs.

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References


Reply

Madam

On behalf of the FPFRHC Clinical Effectiveness Unit (CEU), I thank you for the opportunity to respond to the letter from Anne MacGregor concerning two articles in the July 2003 issue of the Journal relating to the desogestrel-only pill. I am sorry that your correspondent found the New Product Review from our Unit irritating, rather than clinically useful.

We also welcome the opportunity to respond to the letter from John Guillebaud on the same theme.

In my view, our New Product Review provides an utterly objective summary of currently available evidence concerning the desogestrel pill. I stand by our statements that ‘on theoretical grounds and on the basis of the evidence and data provided by the manufacturers the desogestrel-only pill to be more effective than existing progesteron-only pills ... but we do not have trial evidence to support this’. The evidence-based reproductive health paper by Foy et al2 is recommended by your first correspondent but reaches the same conclusion as our New Product Review: ‘You cannot tell if the DSG pill is superior to, inferior to or similar to the other POPs’.

Dr MacGregor mentions ‘the suggestion that the data provided by the manufacturers may not be credible’. Nowhere in our New Product Review is an argument or suggestion made relative to claims or data provided by the manufacturers. She goes on to seek assurance ‘that none of those undertaking the desogestrel-only pill review have any relevant associations with manufacturers of other progesteron-only pills’.

The New Product Review from the CEU does not include an explicit statement of interests. However, to assist the Journal in ascertaining whether the New Product Review was prepared in an impartial manner, and be based on available research evidence, and ‘CEU staff should not accept any honoraria or consultancy payments from pharmaceutical companies – either for their personal accounts or for CEU funds’.

Dr MacGregor also comments on the ‘established. This eight-point code of practice includes the following statements: ’In all aspects of the work of the CEU, staff will be required to apprise the relative benefits of individual contraceptives and products. Such appraisals will always be conducted in an impartial manner, and be based on available research evidence.’

References


John Guillebaud, FRCS, FRCOG
Emeritus Professor of Family Planning and Reproductive Health, University College London, London, UK

J Fam Plann Reprod Health Care: first published as 10.1783/147118904322702072 on 1 January 2004. Downloaded from http://jfprhc.bmj.com/ on October 25, 2022 by guest. Protected by copyright.
I trust that your readers can be reassured that the CEU is committed to providing objective summaries of available evidence as a service to Faculty members. Our documented code of practice precludes any relationship with pharmaceutical companies that might represent competing interests in our product reviews. In line with established principles of evidence-based medicine, we do not make clinical practice recommendations based on assumptions, personal beliefs or inappropriate extrapolations from research data. On this basis, we stand by our published conclusions and recommendations regarding the desogestrel pill.

Gillian Pennis

Honorary Director, Clinical Effectiveness Unit, Faculty of Family Planning and Reproductive Care, Aberdeen Maternity Hospital, Cornhill Road, Aberdeen AB25 2ZD, UK

References

New GyneFix® introducer

Madam

We wish to share our experience with the new GyneFix® introducer.

The Abacus Centre in Liverpool was the first service to offer the frameless intrauterine device, GyneFix in the UK, when it was introduced in 1997. To date we have fitted 1750 of these devices. Our audit of the first 100 insertions showed we had 11 failed insertions (of the 1000). Since the introduction of the new GyneFix introducer in our service in early 2001, our local report of failed insertion by all doctors carrying out insertions in our service. Initially we considered this to be part of the learning curve with the introduction of the new device. However, when the failed insertions continued, we undertook an audit of failed GyneFix insertions from January 2003 to August 2003. During this period there were 50 attempted GyneFix insertions of which 38 were successful and 12 failed to anchor the device. In 7/8 successful insertions, there was more than one attempt to implant the GyneFix. We wasted 18 devices during the 50 attempted insertions. There was no indication that doctors with prior experience in GyneFix fitting had fewer failed insertions compared to those who had fitted fewer devices. This has raised difficulties in our counselling of women for GyneFix insertions as well as in our ability to continue to offer it as part of our contraceptive menu. We have reported these failed insertions to the manufacturer. We have heard from them that they have decreased the thickness of the inserter to try and reduce this problem. However, this modification is only in the GyneFix 200, which only has four beads and for which there are few published long-term data.

We will be very interested to hear from other services as to whether they are experiencing similar problems with the new GyneFix introducer.

Andrea Brockmeyer, MRCoG, DFFP
Subspecialty Trainee; State Exam Med Tubingen/Germany, Abacus Clinics for Contraception and Reproductive Health Care, Liverpool, UK

Changes to cervical cytology screening

Liquid-based cytology will now be the preferred method of examination. In this method of screening the sample is collected from the cervix in the same way, but using a special plastic broom-like device which is swept over the transitional zone five times to collect cellular material. The broom is rinsed or broken off in a vial of preservative. The vial is mixed in the laboratory and treated to remove unwanted material by an automated process. The remaining suspension of cells can be stained and the prepared slide looks much clearer for examination. The number of unsatisfactory (inadequate) slides is reduced and fewer women will be made anxious by being recalled.

The frequency of screening will also be changed to a more equitable system. All women, wherever they live, are to be screened every 3 years from the age of 25–49 years and then every 5 years until the age of 64 years. Further information is available at www.medfash.org.uk.

Changes to menstrual cycle

Suggested that it is healthier to avoid menstrual bleeding at least once a month. Four periods a year will expand women's contraceptive options and increase convenience for some. This advance should not be undermining, however, by over-promising and over-promotion of the benefits of reduced menstrual loss. A statement that cannot be backed by evidence to present. Making Seasonale available will expand women's contraceptive options and increase convenience for some. This advance should not be undermined, however, by over-promising and over-promotion of the benefits of reduced menstrual loss. More information is available from www.womenshealthnetwork.org.

Review by Gill Wakeley, MD, MFFP
Visiting Professor in Primary Care Development, Staffordshire University and freelance General Practitioner and Writer, Abergavenny, UK

Four periods a year

Seasonale® has been approved by the Food and Drug Administration in the USA. It contains levonorgestrel and ethinyl oestradiol and is taken consecutively for 84 days, followed by seven pill-free days to produce a withdrawal bleed. Trials showed a similar effectiveness to conventional combined oral contraceptives. Some of the comment surrounding this alternative has suggested that it is healthier to avoid menstrual loss, a statement that cannot be backed by evidence to present. Making Seasonale available will expand women’s contraceptive options and increase convenience for some. This advance should not be undermined, however, by over-promising and over-promotion of the benefits of reduced menstrual loss. More information is available from www.womenshealthnetwork.org.

Reviewed by Gill Wakeley, MD, MFFP
Visiting Professor in Primary Care Development, Staffordshire University and freelance General Practitioner and Writer, Abergavenny, UK

New national standards for HIV and AIDS care

Funded by the Department of Health, these standards were drawn up in line with the National Strategy for Sexual Health and HIV. The Medical Foundation for AIDS and Sexual Health (MedFASH), a charity sponsored by the British Medical Association, is publishing the standards. They cover all aspects of HIV care from prevention and diagnosis to palliative care. Each of the 12 standards is accompanied by the evidence base and lists the key interventions. They include the implications for service planning, guidelines for administrative and clinical practice, as well as suggestions of how to audit what is provided. The main challenge will be how to implement these excellent standards. Primary care organisations may find the standards difficult to fund and implement because of competition with other areas, better funded, or more socially acceptable such as coronary heart disease. The standards can be downloaded from www.medfash.org.uk.

References

Dieting and breakthrough bleeding on COCs

Madam

When dealing with the Margaret Pyke postbag, I was interested to receive a couple of queries requesting advice on the development of breakthrough bleeding (BTB) on combined oral contraceptives (COCs) in women who had a regular bleeding pattern until they went on diets and lost a lot of weight quite quickly. In one case, the Atkins diet (high protein, low carbohydrate) had been followed; in another, the woman was using Lighter Life® meal replacements. All other causes of BTB had been excluded.

I would be interested to know if other readers have come across this phenomenon and if so, should add a question about dieting and weight loss to my list for women who present with BTB.

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Letters / News Roundup

NEWS ROUNDUP

A new IT solution for sexual health? Information technology (IT) has been promoted as a panacea for all ills and sexual health is no exception. The technological boom is here to lend a helping hand to deal with the current sexual health issues facing the country? The IT revolution could provide a solution. Appareo, aims to provide an effective, national, specialist, sexual health performance management system based around a data warehousing approach. The two critical elements are personal client data and clinical data and application.

The director assures us that the system will cater to the requirements of the national IT strategy and health care clinicians. Other benefits proposed are reduction in waiting times, improved patient access and an annual savings of £9 million.

The infrastructure needs to be clarified, in terms of the staff, resources and training. Should the responsibility for its smooth functioning rest with the already burdened clinicians or with new staff (with an added cost implication)? These issues warrant exhaustive thought before the adoption of such a system. For more details contact beyondpr@blueyonder.co.uk.

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