

LETTERS

Progestogen-only pills (POPs) and body weight

Madam

Vessey and Painter¹ cannot support the hypothesis that the failure rate in women of high body mass with current POPs may be higher than in those who are normal or underweight. Equally, however, their study has insufficient power to refute it. The numbers are small, yet comprise *all* the accidental conceptions in POP-takers, including those due to pill-taking errors. One could hardly expect an effect of body mass to emerge except among consistent-use failures.

A pointer to some real effect of body mass comes from a pilot study by Kovacs et al.² Investigating the possibility of using levonorgestrel (LNG) or norethisterone POPs as pre-coital pills, they studied cervical mucus penetration. In three women whose BMI was above 35 there was no significant change in mucus penetration, despite the same dose as 13 other women, all of whom had either complete inhibition of sperm-mucus penetration or marked reductions in progressive sperm motility. This would be compatible with the local concentration of the progestogen reaching the mucus being reduced by the dilution effect of a larger amount of total body fluid in bigger women. Indeed this is the biological basis of the concern about this issue.

Doses of the vast majority of drugs are unsurprisingly reduced when given to children or very small adults. Among oral drugs it is actually the combined pill that is exceptional, presumably because with its back-up contraceptive mechanisms its efficacy has too much 'margin' for any possible body size effects to be detectable.

Moreover, as the article points out,¹ failure rates are clearly related to body weight in women using related contraceptives, namely the high density polymer version of Norplant, and the levonorgestrel-releasing vaginal ring. These methods deliver very similar, low, systemic levels of levonorgestrel (LNG) to the LNG POPs - albeit by different, non-oral, routes.

Should this paper change practice, given that current practice is to use the FPA's leaflet on the progestogen-only pill which warns of the possibility of an increased failure rate in overweight women? I think not, pending more data. When asked, as one obviously is by such women, "so - what can be done about it?" I shall continue to recommend taking two progestogen-only pills daily (usually at the same time), above 70 kg. After all, we do know that the extra risk to health of taking two POPs rather than one daily is probably negligible, if not nil.

The trigger level of 70 kg is arbitrary and probably excessively cautious. It seems to have been chosen only because both the above-mentioned Norplant and vaginal ring studies reported a statistically significant increase in failure rate above that particular cut-off. Moreover, as this is an unlicensed use of a licensed product, the prescribing should be on a 'named patient' basis³ - and individualised. The anticipated risk of failure must be greater if body mass exceeds 100 kg. On the other hand I would not increase the dose at all in women expected to have reduced fertility (in particular, older women above 45 years of age or during lactation).

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- 3 Guillebaud J. Contraception Today. Martin Dunitz; 2000, 114-115.

Competing interests: The author has received ad hoc consultancy fees, lecture fees, research grants and related expenses from various manufacturers of contraceptive products.

Madam

I was interested in the article in this quarter's Journal about weight and the effectiveness of the COC and POP. It has been the practice in our locality when using DMPA to give double dose in the overweight patient. Extrapolating from this article, it would now seem to be unnecessary to continue this practice. I would be interested in what the contributor's opinion is, and whether there has been research done in this area. I do note in John Guillebaud's book - *Contraception, Your Questions Answered* - that he notes that injectable contraceptives are less effective in underweight patients.

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Author's reply

Madam

I agree with the point made by Guillebaud¹ that our study² has insufficient power to refute the postulated increase in the risk of accidental pregnancy in women of high body mass index taking POPs. Indeed, our conclusion makes this clear. We state 'the Oxford-FPA study offers no support to the hypothesis that the risk of accidental pregnancy is related to body weight in women..... using POPs. Nonetheless, the findings in users of Norplant and of levonorgestrel-releasing vaginal rings raise the possibility that such a relationship does exist, but that the available data are too few to detect it'. I also agree that the paper should not lead to a change in current practice; the policy outlined by Guillebaud seems reasonable in view of the continuing lack of conclusive data.

I was puzzled by the letter from Cooper.³ If injectable contraceptives are less effective in underweight patients, why give double dose DMPA to overweight patients? I followed up the reference to Guillebaud's book and found that he was quoting Sapire.⁴ In her book, Sapire quotes Fotherby as reporting that accidental pregnancies occur more frequently with norethisterone oenanthate in women of low body mass. She also says that 'the author has found that although accidental pregnancy is extremely rare on Depo Provera, it occurs more frequently in low weight than obese women'. This seems to be very slender evidence to me. Furthermore, in my search of the literature, I did not turn up any papers on failure of injectables and body weight. In the circumstances, it would be interesting to hear the reason why double dose DMPA for overweight patients was ever introduced in Cooper's district, since the weak evidence that is available points in the other direction.

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International readership

Madam

My subscription to *The Journal of Family Planning and Reproductive Health Care* is as a member of the Society for the Advancement of Reproductive Care. I have enjoyed reading the Journal and have learnt a great deal from it. It is especially gratifying to know that the UK has a cadre of specialists in family planning.

As the Journal's readership becomes international, I have a suggestion. It would be helpful for those of us who do not practice in the UK if attention were paid to avoid UK medical slang. In the July issue, I had to use my imagination to understand several terms. For instance, does 'triple swabs' on page 159 refer to tests for Chlamydia, gonorrhoea and cervical cytology? On page 171, how could I get more information from the 'fpa' if I needed it?

Please continue the excellent articles, but try to make them more understandable for readers outside of the UK.

Richard Grossman MD, MPH
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Further information and recommendations to prevent perforation with the frameless GyneFix IUD

Madam

I have read the case reports on perforation of the GyneFix IUD published in the last issue of the Journal. I am responding to one of the author's request for further information.

First, an ultrasound study conducted in 405 users of the frameless IUD followed-up for 5 years, concluded that the anchored IUD does not migrate over time.¹ This is in agreement with clinical experience which shows that the majority of cases of perforation have been detected during the first months following insertion, indicating that a partial perforation has occurred at the time of insertion. The likely mechanism is that the anchoring knot is placed on the serosal surface of the uterus after which the device is pulled in the abdominal cavity by bowel action. This likelihood is greater in case of hypoplastic uterus (i.e. long-term pill use, Depo Provera). As the GyneFix is frameless and flexible, it is unlikely that the device is forced through the uterine wall by uterine contractions, as is suspected with framed IUDs reported by Tatum (the inventor of the T-shaped IUD) and Connell.³ In their review article, published in 1989, they make the following comments about perforation: '*The incidence of this complication ranges from 0.0 to 8.7 per thousand insertions, and is directly proportional to the skill of the individual performing the insertion. One major reason for perforation is the failure to establish the size and orientation of the uterus by careful pelvic examination. This is particularly important where there is sharp ante- or retroflexion of the uterus, and where it is not straightened with traction using a tenaculum prior to insertion.*'

A further study supporting this conclusion looked radiographically at the effect of cervical traction on the uterocervical angle in 24 women undergoing diagnostic curettage. Cervical traction in a caudal direction (force 2 N) reduced the median uterocervical angle from 75° to 10° (p = 0.001). Moderate cervical traction straightens the uterus and the routine use of a

tenaculum theoretically makes insertion of an IUD safer.³

This study confirms my personal experience. Even though the GyneFix inserter tube is quite stiff, insertion up to the fundus is easy, as long as sufficient traction is exerted on the cervix. This is also the experience in retroverted uteri. A prerequisite, however, is that traction is applied all the way until fitting of the IUD is accomplished. Use of the lithotomy position to maximise access to the uterus is also recommended.

It may reassure the readers of this letter that once experience is obtained with the new anchoring technique, perforation rarely occurs, as post-marketing surveillance has shown. Furthermore, long-term experience in a major randomised comparative multicenter clinical trial, covering approximately 10 000 women-years of use, did not report one single case of uterine perforation with the frameless device.⁴

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Competing interest: Dirk Wildemeersch is a Belgian gynaecologist and Medical Director of *Contrel Research*, a company which was established to manage clinical research and to develop and study innovative drug delivery technologies. *Contrel* is the manufacturer of the GyneFix IUD.

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Neuropathy associated with Norplant

Madam

I read with interest the article by Nash and Staunton on focal brachial neuropathy associated with Norplant use.¹

In the upper half of the upper arm the medical cutaneous nerve of the forearm travels down, accompanying the brachial artery on its medial side. It then pierces the deep fascia of the arm with the basilic vein and travels downward with the latter. The point of penetration of the investing layer of deep fascia by the nerve and the vein is usually deeper than the sub-cutaneous plane in which Implanon and Norplant should be inserted.

It is vital that the original injection of local anaesthetic for the insertion for Implanon and Norplant be strictly done in the sub-cutaneous

plane. This can be assured by tenting the skin all along the line of deposition of local anaesthetic. The act of tenting draws the skin away from the basilic vein and, more importantly, the neurovascular bundle on the medial side of the forearm. Following injection of local anaesthetic the rods of Norplant or Implanon should be inserted immediately under the skin within the channels created by the local anaesthetic.

The description of this case raised the important question about the possibility that the rods may have been inserted deeper than normal. Herein lies the danger, and it is fortunate that only the medial cutaneous nerve of the forearm was damaged, as there could have been injury to the neurovascular bundle.

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Reference

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Blood pressure measurement – Does anyone do it right?: An assessment of reliability of equipment in use and the measurement techniques of clinicians.

Madam

James McVicker and colleague have highlighted important issues with regard to the elusive parameter of accurate blood pressure measurement.¹

The use of questionnaires to assess equipment is a useful audit tool as a first line of investigation, and it is alarming that there is no record of servicing for 88% of the devices in clinical use. However, there is no indication given in the paper with regard to the type of devices in the study (presumably a mixture of mercury sphygmomanometers and aneroid devices), and none of the equipment in this study was actually tested for accuracy.

With the advent of automated blood pressure measuring devices it has become apparent that there is a need for the formal validation of new devices according to accepted protocols.² What is less well known is that all manual devices, mercury or aneroid in design, are also prone to significant measurement error, and this can only be minimised by regular servicing and calibration. The authors provided no justification on the grounds of accuracy for their decision to change mercury devices for aneroid devices. Indeed, there have been many reports of aneroid device inaccuracy,³ and when we performed a similar study that included both site inspection and validation studies on all the devices within a

large maternity hospital, we found aneroid devices to be surprisingly inaccurate. Of 39 aneroid and 36 mercury sphygmomanometers, 31 (86%) of the mercury devices and 36 (92%) of the aneroid devices were in adequate working condition and suitable for analysis.⁴

In light of the finding of a poor service history and to minimise the risk of erroneous blood pressure recording, all blood pressure devices should be regularly checked for accuracy using dynamic calibration methods as recommended in validation protocols.

One cannot stress enough the need for consensus and training in the correct techniques for blood pressure measurement following guidelines such as those of the BHS. However, one of the advantages of automated blood pressure measurement devices is the elimination of many of these sources of observer and measurement error (though not all, as poor technique will still lead to mistakes). If consideration is to be given to replacing mercury devices, then validated automated devices might be a route towards more accurate blood pressure recording, particularly if at present the measurement is being performed by a variety of busy clinic staff lacking in formal training and assessment.

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