women tended to be more educated and 70% had a high school diploma). The women were recruited from four different geographical regions and included large Hispanic and black populations. Some selection bias is also likely because of the 3:1 ratio of medical to surgical treatment (women with a strong preference for surgical treatment would not have agreed to be randomised). Urban populations in the UK are far more diverse and the educational level varies significantly depending upon the area a particular hospital serves. This could have a greater impact on the women's understanding of treatment choices and subsequent side effects likely to occur, thus affecting QOL.

Conclusions
This study aims to inform us about the focus of counselling prior to patients undergoing the procedure and helps women to better understand the differences in experiences, expected adverse effects, and efficacy between the two methods as well as the similarities in recovery and QOL measures. It is unlikely to change the actual points we use when counselling women about different treatment options for EPF, but gives the clinician more confidence in assuring women about changes in QOL following their treatment choice.

Reviewed by **Neelima Deshpande**, MRCOG, DFSRH
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Crocus sativus L. (saffron) in the treatment of pre-menstrual syndrome: a double blind, randomised and placebo controlled trial. Agha-Hosseini M, Kashani L, Aleyaseen A, Ghoreishi A, Rahmanpour H, Zarrinara AR, *et al*. *Br J Obstet Gynaecol* 2008; **115**: 515–519

Saffron is the world's most expensive spice, which has been traditionally advocated for stomach, digestive problems and mood disorders. Iran produces 81% of the world's supply so it is not surprising that the first trial of saffron in premenstrual syndrome should come from the University of Tehran, Iran. This group have previously published on the use of saffron in depression.

The paper reports a double-blind placebo controlled study to investigate whether saffron could relieve symptoms of premenstrual syndrome. I would suggest that it is probably a pilot study since only 50 women were recruited of whom 47 completed. This should not detract from the study, which appears to have been very well designed and performed.

The authors are to be congratulated in that they recruited 78 women of whom 50 enrolled for a 4-month trial that had only three dropouts in a 12-month period. UK researchers may be envious of the speed of recruitment; but most participants were recruited after advertisement.

This was a 4-month study: the first 2 months acted as the control period in which women kept a daily symptom report of 17 premenstrual symptoms, attended for screening by a psychiatrist, and completed the Hamilton Depression Rating scale at the end of the second month. After being randomly allocated to saffron or placebo, the participant returned in cycles 3 and 4 to complete the Hamilton Depression Rating scale with a psychiatrist. The analysis appears appropriate and the study showed that there was a significant difference between saffron and placebo.

As the authors admit, participant numbers were not large and this study needs to be repeated. I would suggest that both larger numbers and different populations are used in future studies. This study has attracted a lot of interest on the Internet and some women's groups are already citing it to encourage women to increase saffron in the diet; which as well as not being evidence-based is costly to the woman concerned (saffron currently retails at £25–£35 per ounce).

Reviewed by **Gillian Robinson**, FRCOG, FFSRH
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Safety and efficacy of a testosterone metered-dose transdermal spray for treating decreased sexual satisfaction in premenopausal women: a randomized trial. Davis S, Papali M, Norman RJ, O'Neill S, Redelman M, Williamson M, *et al*. *Ann Intern Med* 2008; **148**: 569–577

Background
Considerable interest has been created by the publication of a few articles (and many commentaries) suggesting that correcting low testosterone levels in women may increase their sexual satisfaction.

Methods
This was a double-blind trial with 261 premenopausal women randomised into four almost equal groups. Women were recruited by means of press and radio advertisements. From the initial 480 women, 219 were excluded mainly because they did not meet the inclusion criteria (e.g. anyone with medical or psychiatric illnesses was excluded.) Those selected completed a 4-week pre-treatment diary. At completion of the 16 weeks of the trial, dropout rates (between 11 and 16) were similar for each group. Each group received one of three strengths of testosterone, or placebo, and completed a record of sexually satisfying sexual encounters (SSE) as the primary outcome measurement. One of the secondary outcomes measured was the Sabbatsberg Sexual Self-rating Scale score (included in article as an Appendix).

Results
All groups reported an increase in SSE. Compared with placebo, the increase only reached significance for the middle strength of testosterone. The increase was 0.8 SSE per month. No correlation between measured free testosterone and outcome was found. The total scores for the Sexual Satisfaction Scale, although slightly higher in the active treatment groups, did not differ statistically from the placebo group. The safety data showed few side effects at this low dose, mainly excess hair at the spray site and a slight increase in acne in the treated groups.

Relevance to current practice
Measurement of testosterone and free testosterone was developed mainly to investigate levels in men and identify high levels in women with conditions such as hirsutism. It is still unclear how identifying low levels in women can be used in sexual medicine, especially, as shown again in this article, correlation between testosterone levels and sexual satisfaction is poor or non-existent. A large number of articles have appeared discussing the reliability of measuring free testosterone levels, and although this trial used a sensitive method, doubts remain about the usefulness of such tests in clinical practice.[1,2] The Endocrine Society guidelines stated: "We recommend against making a diagnosis of androgen deficiency in women at present because of the lack of a well-defined clinical syndrome and normative data on total or free testosterone levels across the lifespan that can be used to define the disorder".[3]

The lack of correlation between hormone levels and sexual satisfaction confirms other work suggesting that the situation is more complex than just a low testosterone level. The (cited) large Australian community-based, cross-sectional study of 1423 women aged 18–75 years, who were randomly recruited via the electoral roll in Victoria, Australia, from April 2002 to August 2003, showed no correlation.[4]

It seems unlikely that most women would want to use a testosterone spray to their abdomen once a day to correct their (possibly) low testosterone levels in order to perhaps achieve less than one extra SSE a month.

Reviewed by **Gill Wakley**, MD, FFSRH
Advisory Editor, Journal of Family Planning and Reproductive Health Care

References

1 Sacks SS. Are routine testosterone assays good enough? *Clin Biochem* 2005; **26**: 43–45.
2 Rosner W, Auchus RJ, Azziz R, Sluss PM, Raff H. Utility, limitations, and pitfalls in measuring testosterone: an Endocrine Society Position Statement. *J Clin Endocrinol Metab* 2007; **92**: 405–413.
3 Wierman ME, Basson R, Davis SR, Khosla S, Miller KK, Rosner W, *et al.* Androgen therapy in women: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2006; **91**: 3697–3710.
4 Davis SR, Davison SL, Donath S, Bell RJ. Circulating androgen levels and self-reported sexual function in women. *JAMA* 2005; **294**: 91–96.

IMPLANON® – RECOMMENDATION FOR INSERTION SITE

Organon, a part of the Schering-Plough Corporation, wish to advise healthcare professionals responsible for inserting Implanon® that the recommended insertion site has recently changed and it is advised that implants are now inserted 8–10 cm above the medial epicondyle of the humerus. Enclosed with this issue of the Journal is a leaflet that describes the recommended insertion site and also includes a number of Q&As about Implanon insertion.

A revised Summary of Product Characteristics (SmPC) for Implanon has also been published. The instructions contained in the revised SmPC should be followed for all future insertions and removals of Implanon. The SmPC can be found at www.emc.medicines.org.uk.

For more information about Implanon, or to obtain further copies of the leaflet, interested individuals should contact Schering-Plough Medical Information Department. Tel: +44 (0) 1707 363636/363425.

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