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for emergency
contraception

Efficacy of emergency contraception and body weight

Current understanding and recommendations

November 2015

Summary

- **In 2014, regulatory changes raised the question of whether emergency contraceptive (EC) pills may be less effective for women with higher body weights.** Some data show that both levonorgestrel (LNG), sold in Europe as Escapelle®, NorLevo®, Postinor® or Vikela® among others brands, and ulipristal acetate (UPA) sold in Europe as ellaOne® and Dvella®, may be less effective for women at higher body weights, although LNG may lose effectiveness at a lower weight threshold than UPA.
- **There is significant disagreement about whether the data supporting these changes are definitive.** Whether, in fact, EC is less effective for heavier women is not proven; the precise weight at which EC may lose efficacy is not clear and could vary for individual women.
- **No woman should be refused or discouraged from using EC based on her weight.** UPA and LNG are the most accessible EC options in the majority of European countries. LNG EC is the most affordable option in most countries, and UPA is still not available in some. Women at higher bodyweights should be advised that LNG might be less effective for them, but each woman should make her own determination about whether or not to take LNG EC.
- **Regardless of body weight, the most effective form of EC is the copper IUD, followed by ulipristal acetate.** All women (but particularly women at higher weights) should be offered the copper IUD or UPA if these options are accessible and acceptable.

Background

Available data

In 2011, an article based on two clinical trials concluded that “the limit of efficacy was reached at a weight of 70 kg (154 lbs) for LNG compared with 88 kg (194 lbs) in women having taken UPA.”[1] These findings are potentially of great clinical significance, yet there are important limitations to the data. These trials were not specifically designed to study the relationship between efficacy and weight. Weight and height were not measured at one of the two study sites; they were self-reported by study participants, which may have introduced error into the results. The numbers of women in the “overweight” and “obese” categories were small (and the number of pregnancies in the highest weight category was extremely small).[2] A meta-analysis of three WHO studies, conducted primarily among populations of African and Asian women, found no trend toward reduced efficacy with increasing bodyweight.[3,4]

Regulatory decisions

The manufacturer of NorLevo (a 1.5 mg LNG EC) conducted additional analyses of their data, and requested that European regulatory authorities allow a change to the product label indicating that higher weight may reduce its effectiveness. In November 2013, European authorities granted a label change warning that “in clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more and levonorgestrel was not effective in women who weighed more than 80 kg.”[5] It should be noted that these different weight limits resulted from further analyses of the clinical trial data referenced above. Shortly thereafter, Health Canada (the Canadian regulatory authority) authorized the same label change for LNG EC.

In July 2014, the European Medicines Agency completed a review of all available data (including data from trials conducted by the World Health Organization) and found that “the data were too limited and not robust enough to conclude with certainty that contraceptive effect is reduced with increased bodyweight”, and that, therefore, reference to such statements should be removed from product labels and that “emergency contraceptive pills can continue to be used to prevent unintended pregnancy in women of any weight or body mass index.”[3]

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Significance
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According to data published in 2006 in the *Special Eurobarometer on Health and food*, the average reported weight of women from European Union countries was 65,8 kg. [6] Obesity affects 10-30% of the adult population [7], and the prevalence of overweight and obesity in men and women is rapidly increasing in this subregion, with the highest percentages of women with obesity found in Austria, the United Kingdom, and Germany.[8]

Therefore, an increasing proportion of women fall into the weight category in which LNG EC pills (and for a smaller subset of women, possibly UPA) may not work. It is of vital importance that the most effective forms of EC (the copper IUD and UPA) be made widely available. However, the copper IUD can only be obtained through a healthcare provider, while LNG and UPA EC pills are available without prescription in most European countries as of 2015. Many women purchase EC pills directly from stores and pharmacies without consulting a healthcare provider, and many providers may not routinely include counseling about EC in their patient interactions.

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Recommendations and conclusions

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Although the evidence is not clear, it is possible that there is some relationship between the efficacy of EC pills and the weight of the user, and there may be a weight at which EC pills, particularly LNG, are less effective at preventing pregnancy. However, it is likely that no new evidence will become available soon to clarify exactly what this relationship is or whether increasing the dose would improve efficacy. It is unclear whether reduced efficacy is related to biological processes, behavioral differences (such as repeated unprotected intercourse or taking EC too late to be effective), or a combination of the two. Therefore, women in need of EC and healthcare providers who serve women of reproductive age will most likely need to make decisions about EC without complete information about how (and whether) weight might impact efficacy.

Those who serve women seeking EC in a clinical setting are in an excellent position to counsel women on all of their options for EC. For all women, the copper IUD is the most effective EC method, followed by UPA and then LNG. For patients at higher bodyweights, special emphasis should be placed on the benefits of the copper IUD or UPA (although for very heavy women, the efficacy of UPA might be reduced as well). Providers should remind women choosing EC pills that they should be taken as soon as possible after sex.

However, most women do not obtain EC from a clinic; the majority of EC sales take place in pharmacies now that both LNG and UPA EC pills are available without prescription in most European countries. Advocates should work to spread information about all of the options for EC and encourage women with higher body weights in particular to consult a clinician if they are at risk of pregnancy after unprotected sex. Women should also be encouraged to acquire EC pills prior to needing them if possible. Women with higher body weights who are unable to access clinical care within 5 days of unprotected sex or who do not choose to use a copper IUD or UPA should still consider taking LNG EC pills. Health care providers and pharmacists should never deny access to LNG EC pills because of a woman's weight.

Options for Emergency Contraception in Europe

(in order of effectiveness)

- All EC should be used as soon as possible and within 5 days of unprotected sex.
- EC pills do not prevent pregnancy from future acts of intercourse; another contraceptive method must be used to reduce the risk of pregnancy following the use of EC pills.

Copper IUD

The most effective EC option, regardless of a woman's weight, is the copper IUD.

Benefits: The copper IUD is nearly 100% effective [9] in preventing pregnancy after sex and provides up to 12 years of excellent ongoing contraceptive protection. It is maintenance-free and does not contain any hormones.

Challenges: The IUD must be inserted by a clinician, so at least one office visit is required. Some women may find the insertion process uncomfortable or invasive, some may experience changes in menstrual bleeding patterns that are unacceptable, and not all women are interested in a long-acting method. Depending on the country's national insurance policies, the costs of the copper IUD may be covered; however, if women are expected to pay for the method and the insertion out-of-pocket, cost may pose a significant barrier.

Ulipristal acetate

UPA, sold in Europe as ellaOne® and Dvella®, is available without prescription from pharmacies in all European Union countries, except for Hungary and Malta, and is subject to medical prescription in all other European countries where it is available.

Benefits: UPA can work after the luteinizing hormone surge has begun, when LNG is not effective. The fact that it works closer to the time of ovulation makes it more effective than LNG.[10] It may be more effective than LNG for women of heavier body weights.

Challenges: In some European countries, UPA EC pills are still sold by prescription, so in these settings, women must obtain a prescription from their healthcare provider and find a pharmacy that stocks the product. Where UPA EC pills are available directly from pharmacies, the price is higher than LNG EC pills. Efficacy of UPA EC pills may also be reduced in heavier women (particularly those weighing more than 88 kilos).

Levonorgestrel

LNG EC pills are available without prescription in all European Union countries except for Hungary, Malta, and Poland. Outside of the European Union in Albania, Bosnia-Herzegovina, Kazakhstan, and the Russian Federation, LNG EC pills are a prescription-only drug.

Benefits: LNG EC pills are by far the most widely available and known EC option in Europe, and they are more affordable.

Challenges: LNG EC pills are less effective than other EC methods and may be less effective in particular for women of heavier body weights.

References

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This factsheet has been adapted from the statement *EFFICACY OF EMERGENCY CONTRACEPTION AND BODY WEIGHT: Current Understanding and Recommendations*, developed by the American Society for Emergency Contraception in January 2015.

The European Consortium for Emergency Contraception is a network of individuals and organizations that aim to increase **knowledge** and **access** to emergency contraception in Europe.

Visit our website to learn more and contact us to join our online community:

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