The Emergency Contraceptive Pill

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"It is undesirable to believe a proposition when there is no ground whatever for supposing it true" – Bertrand Russell.

This editorial will confine itself to levonorgestrel (LNG) emergency contraception (ECP, "morning after pill"), which the World Health Organization (WHO) defines as "methods of contraception that can be used to prevent pregnancy in the first 5 days after sexual intercourse. ECP is intended for use following unprotected intercourse, contraceptive failure or misuse (such as forgotten pills, or breakage or slippage of condoms), rape or coerced unprotected sex".[1] Furthermore, this editorial will confine itself to ECP which utilizes (synthetic) sex hormones, namely LNG.

Briefly, there are three types of ECPs: combined ECPs containing both estrogen and progestin, progestin-only ECPs, and ECPs containing an antiprogestin (mifepristone or ulipristal). Progestin-only ECPs have now replaced the older combined ECPs as they are more effective with fewer side effects. The primary mechanism of ECP is the prevention of fertilization by the inhibition of ovulation. To date, the best available evidence is that these LNG ECPs do not have any post-fertilization effects – such as the prevention of implantation – when used as defined above.[2] The most recent scientific evidence shows that LNG ECP delays ovulation and does not prevent implantation nor does ECP cause the loss of implanted embryos.[3] Indeed, Germany's Catholic bishops have ruled that levonorgestrel (progestin) ECP is acceptable for the prevention of pregnancy in the setting of rape, a significant change in the usually conservative Catholic posture. This pronouncement cites the total lack of evidence to the effect that levonorgestrel ECP is abortifacient since there is no evidence whatsoever that it prevents implantation.[4]

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The possibility of the introduction of ECP in Malta has been raised – and greeted by storm. This ignores the facts that there are local equivalents that can and are being used as emergency contraception and that ECP can be delivered by fast courier to our doors. The additional fact that a form of ECP is centrally licensed within the European Union (EU) and can be imported under current local legislation is also being ignored.

The ECP issue, once raised was locally naturally instantly riven with tension. However, the scientific truth of the matter is that extant medical knowledge, up to the time of writing, has never demonstrated that LNG ECP prevents the implantation of a fertilized ovum (a conception followed by implantation). ECP therefore cannot, in any way be considered abortifacient. Hence, the matter has become needlessly fraught, with individuals and authorities sounding off on the subject with gross inaccuracies, clearly without reading the relevant scientific literature and the latest research. Indeed, WHO has stated that

> all women and girls at risk of an unintended pregnancy have a right to access emergency contraception and these methods should be routinely included within all national family planning programmes. Moreover, emergency contraception should be integrated into health care services for populations most at risk of exposure to unprotected sex, including post-rape care and services for women and girls living in emergency and humanitarian settings … As part of this core obligation, states should ensure that the commodities listed in national formularies are based on the WHO model list of essential medicines … including emergency contraception, is included in the core list of essential medicines.[1]

In the same publication, WHO also points out that "in some countries emergency contraception is not available on the false grounds that it causes

abortion".[1]

This is an editorial in the *Malta Medical Journal* and we are scientists who strive to adhere to the Baconian scientific method which comprises systematic observation, measurement, experimentation, and the formulation, testing, and modification of hypotheses. All of this is done within the Popperian scientific framework of falsifiable hypotheses. It is these precepts that lead us to practice evidence-based medicine. These dicta should serve "as a reminder of the need for bioethics to be based on current scientific literature as well as articles of faith and morals".[4] Blind statements that ECP can or possibly might cause implantation failure must be backed by evidence-based scientific literature – which (up to the time of writing) is nonexistent. Wild accusations simply will not suffice to sway anyone – scientific evidence must and should.

This article has deliberately steered clear of definitions of commencement of life and commencement of pregnancy since such definitions are moot to the tenet that LNG ECP does not prevent implantation. This article has also deliberately foregone forays into women's rights. Again, these arguments are moot since ECP does not prevent implantation and is therefore not abortifacient. This article has also deliberately avoided detours into the morality of sex and the risk of sexually transmitted diseases in unprotected sexual encounters since these are not germane to the issue. The central tenet is that ECP "does not prevent embryo implantation and therefore cannot be labeled as abortifacient".[5]

This is despite the fact that some of these product labels continue to state that one of the modes of action "may be" the (unwarranted claim that a mode of action includes) prevention of implantation. Indeed, back in 2008, the International Federation of Gynecology and Obstetrics (FIGO) issued a statement that with levonorgesterol ECP, "pregnancies occurred only in women who took ECPs on or after the day of ovulation, while no pregnancies occurred in the women who took ECPs before ovulation, providing evidence that ECPs were unable to prevent implantation".[6-7] Furthermore, FIGO noted that "studies show that LNG ECPs have no such [inhibitory] effect on the endometrium, indicating that they have no mechanism to prevent implantation".[8-9] Moreover, FIGO also noted that "levonorgestrel did not prevent the attachment of human embryos to a simulated (in vitro) endometrial environment".[10]

FIGO further clarified[6]

- "Emergency contraception is not the same as early medical abortion. EC is effective only in the first few days following intercourse before the ovum is released from the ovary and before the sperm fertilizes the ovum. Medical abortion is an option for women in the early stage of an established pregnancy, but requires a different drug from levonorgestrel.
- EC cannot interrupt an established pregnancy or harm a developing embryo".[11-12]

FIGO therefore recommended that "language on implantation should not be included in LNG ECP product labeling" since there was no evidence whatsoever that this was a mode of action.[6]

FIGO noted the corollary that "the fact that LNG ECPs have no demonstrated effect on implantation explains why they are not 100% effective in preventing pregnancy, and are less effective the later they are taken. Women should be given a clear message that ECPs are more effective the sooner they are taken", before ovulation occurs.[6]Inan updated statement in 2012, FIGO reiterated: "review of the evidence suggests that LNG [levonorgestreol] ECPs cannot prevent implantation of a fertilized egg. Language on implantation should not be included in LNG ECP product labeling".[13]

Clearly, citing a package insert which contains a myriad of biases that date back from 2006 and are thus based on data prior to 2005 is ludicrous given the plurality of robust studies published in peer reviewed journals since. This appears to be the stance blindly taken by several individuals and organisations in this country, who repeatedly cite an inaccurate package insert while ignoring abundant and unbiased scientific research, along with recommendations by reliable bodies such as WHO and FIGO.

The contention that this form of LNG ECP does not prevent implantation is supported by several studies, one of which dates back to 2001, clearly stating that ECP works by "disrupting the normal development and/or the hormonal activity of the growing follicle only when LNG is given preovulatory. In addition, peri- and post-ovulatory administration of LNG did not impair corpus

luteum function or endometrial morphology".[9]

Similarly "levonorgestrel, given as emergency contraceptive on the day of LH surge, does not disrupt either ovulation or progesterone production by the corpus luteum. The contraceptive mechanism of levonorgestrel at the time of LH surge does not include changes in the progesterone receptors or the endometrial receptivity biomarkers".[14] Likewise, "neither the magnitude nor the nature or direction of the changes [found in this study] endorses the hypothesis that LNG interferes with endometrial receptivity".[15] And finally, "levonorgestrel caused either only minor or no alterations in markers of endometrial receptivity".[16]

Withdrawal bleeding after ECP has also been cited as indicating that these medications are potentially abortifacient. Indeed, transient menstrual disruptions are not uncommon with about half of women who used LNG ECPs experiencing withdrawal bleeding within seven days if taken prior to ovulation.[17] However, if taken after ovulation, ECP may actually increase the luteal phase, delaying menstruation by a few days.[18]

All of these studies point to one indisputable fact: this form of ECP does not prevent implantation. Thus, "ECPs do not interrupt a pregnancy (by any definition of the beginning of pregnancy)",[6] not unsurprisingly since progesterone is the so-called pregnancy hormone. It is indispensable for pregnancy, a "pro-gestational" hormone, hence the name.

Yet another point that must be borne in mind is that while abortion, the deliberate termination of a human pregnancy (most often performed during the first 28 weeks of pregnancy) is unavailable and indeed illegal in Malta, this does not prevent Maltese from travelling abroad in order to secure termination of pregnancy in significant numbers.[19] The Malta National Statistics Office stated in 2010 that "the past 10 years saw an average number of 57 abortions per year being carried out on Maltese nationals in England and Wales" alone.[20] Furthermore, tourists are often unaware that ECP is not available in Malta and may have few qualms to carry out an abortion in their own country. It is for this reason that FIGO also stated the obvious: "ECPs can prevent abortions by reducing unwanted pregnancies".[6]

All discussions on this topic should therefore be informed by, nay, predicated by the following six points:

1. There is no extant proof that LNG ECP prevents implantation.
2. Locally available products can and are already being used as ECP.
3. There are websites that deliver the ECP door to door from overseas.
4. There is central European Union authorisation for a form of ECP –this ECPmay be imported under current legislation.
5. Even Catholic Bishops have acknowledged that ECP does not prevent implantation. Naturally the Church only approves the use of ECP for rape.
6. ECP may *prevent* abortion by preventing unwanted pregnancies.

In conclusion, this media furor has once again highlighted the local penchant for generating storms in teacups, wasting time, effort and resources on a non-issue. Reservations dependent on science should be settled by scientific evidence. This particular topic has needlessly vexed individuals and groups into dogmatic postures that are entirely without basis in fact – they are fighting a lost battle.

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