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Review

Emergency Contraception: Can We Benefit from Lessons Learned?

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A B S T R A C T

The aim of the paper was to evaluate current emergency contraception (EC) methods and policies in order to implement lessons learned and maximize potential population impact while introducing dedicated EC pills in Croatia. Literature search for potential reasons for EC failing to show positive population impact and detecting actionable points to be implemented in national guidelines. Six potential reasons for ECs failure to show population impact were evaluated and four actionable points were detected: low use of EC compared to the numbers of risk events, low awarenes on EC in general populaton, differences in efficacy of EC methods and EC vailability. In order to ensure EC's population impact in Croatia it is of a critical relevance to establish continuous education programs for population of women at risk. When recommending an EC method, superior efficacy must be a key decison-making criteria therefore cooper IUD and ulipristal acetate should be our primary options. Counseling is a critical step to ensure maximal efficacy of the EC method, but also to encourage future use of regular contraceptives. Finally, national ECP dispension protocol is needed to close the loop from effective women screening, prompt yet appropriate ECP administration/dispensing towards structured follow up after EC pills intake.

Key words: *emergency contraception, population impact of emergency contraception, emergency contraception efficacy, providing emergency contraception pills*

Introduction

Emergency contraceptives are methods women can use after intercourse to prevent pregnancy[1]. Up to the very recent past, there was no dedicated emergency contraception pill (ECP) in Croatia: a single 1.500mcg levonorgestrel pill was introduced only in 2010, 10 years after its introduction in Europe[2]. It was shortly followed by a single 30mg ulipristal pill[3], quickly up on its registration in EU and US. Current ECP options in Croatia resembles US, however both products are prescription products in Croatia, while levonorgestrel pill (LNG) has »over the counter« status in US. In some other countries combined pills (containing ethinilestradiol and levonorgestrel or norgestrel), often called Yuzpe regimen, are also available.

Combined EC pills were withdrawn from the US market in 2004, due to the availability of safer and more effective emergency contraceptives[4]. Although in Croatia there was never a dedicated and registered Yuzpe pill, the method is most probably still in use (usingregular COCs available) due to the late introduction of levonorgestrel in the market. In China, Vietnam and Russia mifepristone is also available as ECP, but in the most EU markets it is used as an chemical abortificant only[4,5]. Similar to the case in US, mifepristone is unavailable in Croatia. In despite of wide availability of contraceptive methods, including ECPs, close to 50% of pregnancies are still unplanned, and 25%of those are artificially terminated[6,7].

Almost 2 decades ago an objective for EC has been set by Trussel et al., aiming for widespread use of ECPs to prevent half of all unintended pregnancies and abortions in the US each year[8]. Regrettably, none of the eleven published studies – 9 randomized trials and 1 cohort study enrolling altogether 11.830 women – has demonstrated that increasing access to ECPs reduces pregnancy or abortion rates at population levels[9,10]. One demonstration project (ECPs were given to 17.831 women)[11] and three clinical trials[12–14] were designed to address this issue.

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In despite of several flaws in studies, consistency in the findings can hardly be ignored: increased access to EC did not have any impact in terms of reducing non-intended pregnancy rates[9–14]. Since the number of legally introduced abortions in Croatia is high (10.616 in 2008), from Croatian national perspective it is important and practically relevant to evaluate current EC methods and policies in order to implement lessons learned and maximize potential population impact while still introducing dedicated ECPs in Croatia[15].

Methods

Literature search has been executed to establish population impacts of emergency contraception and further more to detect and evaluate potential reasons for method failing to show any substantial population benefits. Six potential reasons were further evaluated: flaws in studies addressing the topic, possible increased risk taking related to the availability of ECP, low ECP usage rates compared to risk event rates, low ECP awareness in general population, problems with ECPs efficacy, and ECP availability. Four actionable points were detected and recommendations for action were drawn based on the literature findings.

Results and Discussion

In searching for action points, several possible explanations for ECPs failing to show population impact were detected and evaluated.

Problems with the studies

Eleven studies were conducted in 4 countries during the period from 1998–2006. Yuzpe pills, levonorgestrel and mifepistrone (in China study only) were provided as emergency contraception method. Total of 11.830 women were enrolled in 9 comparative trials and one cohort study. Additional 17.831 women were given ECPs in advance as a part of demonstration project[11]. Women were followed up to one year, and pregnancy rates were compared between the two groups: group with increased access compared to the group with standard access. Consistently, no difference has been demonstrated between the groups, failing to demonstrate ECP's benefits at population level. Several problems with the studies could be highlighted: small size (ranging from 160–2.686 women), substantial loss to follow up (ranging from 1–62%), moderate intervention, sound access in the control group, lack of randomization, low baseline risk of pregnancy[9–14]. However, none of the studies had all flaws, and 3 studies and 1 project were designated particularly for the purpose. In this context, consistency in findings out wages each particular study flaws, therefore it seems hard to attribute lack of ECPs population impact to the flaws in study designs.

Increased risk taking related to the availability of ECP

Fifteen studies have demonstrated that making ECPs more widely available did not increase sexual risk taking[11–14,16–27]. In addition, four studies further demonstrated no impact of easier access of ECPs on rates of sexually transmitted diseases and incidence of STD[12,14,21,26]. One study has demonstrated that educating teens about ECPs did increase their knowledge about proper ECP administration; however it did not increase their level of sexual activity[28]. However, one reanalysis of the randomized trial suggested that easier access to ECPs may have increased the frequency of coital acts with the potential lead to pregnancy[29].

Women with increased access to ECPs in this study were more likely to report that they had used EC because they did not want to use another contraceptive method[30]. Therefore, though there are some conflicting findings, it is hard to attribute lack of ECPs population impact to the increased risk taking.

ECPs are used too rarely compared to the number of risk situations to result in a substantial population impact

The fraction of women aged 15–44 years who had ever used EPCs increased from 2% in 2022 to 10% in 2006–2008[31]. Still, one trial has demonstrated that even when provided in advance, 45% of the women who had an unprotected intercourse did not use ECP[14]. In another trial 33% of women in the advance provision group had at least one unprotected intercourse without using ECPs[32]. Furthermore, in the same trial increased access to ECPs increased its use the most within the group of the women who were at lower baseline risk of pregnancy[32]. Existing data suggests EC underuse and may partially explain the lack of measurable population effects from an increased access to ECPs. Also, this represents an actionable point that is highly related to the awareness about and availability of ECPs.

Low awareness on EC options among women

Due to the small size of the pharma companies initially distributing ECPs, those companies were not able to promote emergency contraception products at the same scale as most pharmaceuticals, particularly in terms of raising population education campaigns. Furthermore, even after levonorgestrel being acquired by major generic players, none of these companies made significant investments in direct to consumer advertising and education. Without commercial marketing and broad educational campaigns many women still do not know that emergency contraception is available, effective and safe. Many initiatives have been undertaken to improve awareness and use of emergency contraception. In despite of the lack of the precise population awareness data, this observation may partially explain why we still lack measurable population effects from an increased access to ECPs, and it represents an actionable point.

Problems with ECPs efficacy

The effectiveness of emergency contraception as a preventive therapy is measured by comparing the chance that the pregnancy will occur if the treatment is used to the chance that it will occur without any treatment. Unlike many other preventive treatments, in emergency contraception initial efficacy was demonstrated by non comparative observational studies as in this indication placebo controlled study design is considered non ethical. Therefore, ECPs efficacy estimations compare published data on the probability of pregnancy on each day of the menstrual cycle to the actual number of pregnancies observed after treatment in observational treatment trials. Emergency insertion of copper-releasing IUDs is more effective than emergency contraceptive pills (ECPs) reducing the risk of pregnancy following unprotected intercourse by more than 99%: more than 12.000 post-coital insertions of copper IUDs known resulted in 12 pregnancies only[33,34]. Although copper IUDs act primarily to prevent fertilization, such a high level of effectiveness implies that it must prevent some pregnancies after fertilization as well. Emergency contraceptive pills (ECPSs) prevent pregnancy primarily by delaying or inhibiting ovulation and inhibiting fertilization. The best available evidence indicates that ECPs prevent pregnancy by mechanisms that do not interfere with post-fertilization events[35–38]. ECPs do not cause abortion; neither have they harmed established pregnancy[39]. Their efficacy is calculated as a ratio between observed and expected number of pregnancies[40,41]. Obviously, emergency contracpetives effectiveness calculation model implies many assumptions that are hard to validate (including timing of the intercourse and cycle day/time of ovulation), but it is quite clear that that providing emergency contraception is better than doing nothing in preventing pregnancy after unprotected intercourse[42]. Ulipristal acetate, a progesteron receptor modulator is the most effective ECP option with reported

effectiveness ranging from 62% to 85%[43–45]. Two randomized trials compared the efficacy of levonorgestrel and ulipristal acetate, 72 and 120 hours after intercourse[43,44]. After these two studies were combined in a meta analysis, ulipristal acetate was found to have a pregnancy rate 42% lower than levnorogestrel up to 72h and 65% lower in the first 24 hours[43]. In the second randomized trial ulpiristal prevented significantly more pregnancies than levonorgestrel in the 72–120h subgroup[43]. Key reason for superior efficacy seems to be the fact that UPA is more effective than LNG in postponing imminent ovulation: LNG is no more effective than placebo in preventing ovulation when the leading follicle reaches 15–17 mm[46].

On the contrary, UPA delays ovulation for at least 5 days in 59% of cycles by the time follicle reaches 18–20 mm and when probability of conception without medication is more than 30%[37]. Levonorgestrel only regimen was studied in eleven studies[43,44,47–49,50–55] finding that this regimen reduced a woman's chance of getting pregnant by 52–100%. Studies have shown that a single dose of LNG is as effective as and causes no more side effects than taking two 750 mcg doses apart[48,50].

Two randomized trials compared efficacy of levonorgestrel *versus* Yuzpe regimen, demonstrating superior levonorgestrel efficacy[52,53]. A meta-analysis of eight studies of the combined regimen concluded that this regimen prevents 74% of expected pregnancies[56]. However, more recent analysis has established that this might be an overestimation, finding effectiveness of 53% and 47% in two of the largest trials of the combined regimen[57]. Furthermore, combined data from two randomized trials that directly compared levonorgestrel only to combined regimen showed relative risk of pregnancy of 0.51, indicating that the chance of pregnancy among women who received levonorgestrel only was about half of the chance among those who received combined regimen[42,52,53]. Obviously this estimate only implies relative efficacies of two regimens, while it does not assume the number of pregnancies that would have been observed in the absence of the treatment. Several studies demonstrated that both regimens are more effective the sooner after intercourse pills are taken[48,50,53,54,58–69], and the initial studies showed that these regimens are effective when used up to 72 hours after intercourse[53,61].

Later studies indicated that both regimens continue to be moderately effective within 120 hours[48,51,54,62,63] but local regulators clearly limit their use within 72 hours[2,3]. An interesting pilot study has demonstrated that adding a COX-2 inhibitors (meloxicam 15mg) to 1.500 mcg levonorgestrel has increased the proportion of cycles with no follicular rupture or with ovulatory dysfunction, and that COX-2 inhibitors can disturb the ovulation after the onset of the LH surge[64]. However, much more evidence is needed on this interesting matter to become promising. To ensure maximal EC efficacy, it seems relevant to underline that only proper counseling prior EC taking could secure women to understand that ECPs protect only from the previous unprotected intercourse, while IUD protects also from future intercourses.After evaluating efficacy data, it is clear that copper IUD is the most effective method that is seldom implemented in emergency contraception. The most effective ECP is ulipristal acetate, while progestin only regimen is more effective compared to the combined regimen. Introduction of the most effecitve ECP ulipristal acetate whenever possible and as soon as possible may improve total efficacy outcomes, and it also seems reasonable to recommend providing it to patients planned for EC IUD insertion as well[4]. From the safety side, there are no evidence that ECPs cause any long term adverse effects on woman's fertility. Levonorgestrel is substantially better tolerated when compared to combined ECPs[53]. When comparing local summaries of product characteristics (SMPCs) for levonorgestrel and ulipristal acetate, it becomes obvious that side effect profiles are comparable, mostly mild and moderate for both products. However, unlike clinical trials conclusions on the comparable tolerability of levonorgestrel and ulipristal acetate[43,44], SMPCs suggests that side effects in general occur more frequently (more than

10%) or lower with LNG (nausea, tiredness, lower abdominal pain, vaginal bleeding that is not a menstrual bleeding) [2]. Ulipristal causes the same side effects, but it seems that they occur in category frequently (more than 15 but less than 10%) or less[3]. Routine administration of the anti-nausea medication 1 hour before ECP may help reduce nausea and vomiting[65], but it is generally considered unnecessary with use of ulipristal acetate or levonorgestrel. It is not yet clear if it is necessary to repeat the ECP dose if the woman vomits within 2 hours after taking ECP as there are entirely opposite views on this without conclusive evidence. When considering potential ECPs' effects on inadvertently exposed pregnancies, it is important to note that in the case of the treatment failure, ECPs are taken long before organogenesis starts so they should not have teratogenic effect[66]. A number of studies have examined births to women who inadvertently continued to take COC without knowing they were pregnant and have found no increased risk of birth defects[67–69]. One study of 332 pregnant women who had used levonorgestrel only ECP in the conception cycle found no increased risk of birth defects[70]. Preclinical data and pregnancy register on ulipristal acetate suggests the same although the numbers are small. ECPs indeed should not be used in pregnancy but not because they are harmful but because they are ineffective[4].

Emergency contraception availability

Determining pregnancy risk is not always straightforward – the risk is low except 5 days before ovulation and on the day of ovulation. Regrettably, neither woman or clinician is likely to know on which day ovulation occurs. As it is established that only 30% of women ovulate within the fertile window[71], any women requesting emergency contraception after unprotected intercourse should be offered treatment within 120h of intercourse[48,51,62,63]. Until summer 2010 the lack of a product specifically packaged, labeled and marketed as an emergency contraceptive was a major obstacle to more widespread use of emergency contraception in Croatia. In mid 2010 levonorgestrel (Escapelle) was brought into market, and shortly afterwards in December 2010 ulipristal acetate (ellaOne) has been approved. Both products are prescription only products in Croatia, and both products are not reimbursed, therefore both are paid by the user. Both products fall into the same price range for the end user (25€ and 29€ respectively), both being significantly more expensive compared to combined contraceptives that were previously used off label for this indication.

While ulipristal acetate (due to its recent introduction in 2009) is prescription product, levonorgestrel has been available over the counter with or without restrictions in many countries. However in most countries it is still not available on the shelf but it is kept behind the pharmacy counter, and its use is limited by pharmacist's will to dispense EPC, but also by woman's embarrasses to ask for an ECP. OTC as a solution has another negative outcomes – loss of opportunities for physicians to counsel patients about use of more effective longer term contraceptive methods, but also an increase in price of levonorgestrel from 25$ to 45$ [4]. However, among women aged 15–44 who have ever had intercourse the fraction who had ever used ECPs increased from 2% in 2002 to 10% in 2006–2008 (31). Unfortunately, this increase in exposure has not resulted in positive population impact.Key question is how can Croatia benefit from global learning and secure population impact from the recent emergency contraceptives introduction.

Learning and recommendations on actionable points to secure positive EC population impact in Croatia

EC efficacy: Copper baring IUD is the most effective emergency contraception, yet it is not easy to secure product and expertise availability for insertion in emergency settings. If planning EC insertion of copper IUD, ECPs, preferably ulipristal acetate should be advised to women. The most effective ECP – ulipristal acetate – should be recommended to all women seeking EC in line with SMPC as it significantly reduces risk of unintended pregnancy compared to levonorgestrel. Levonorgestrel is the second most effective ECP option, as is significantly more effective and better tolerated compared to combined oral contraceptives. Combined contraceptives use in EC should be abandoned in Croatia for its lower efficacy and tolerability. EC availability: For EC to demonstrate its positive impacts, it is important to ensure minimal delay in EC use from the moment of the unprotected intercourse. However, potential »over the counter« availability of levonorgestrel needs to be weighted to the availability of more effective prescription treatment option. Structured and close collaboration of physicians and pharmacists is necessary for EC to demonstrate population impact, therefore a national ECP dispension protocol is needed to ensure effective women screening, appropriate ECP administration/dispensing and counseling, but also to ensure structured follow up after ECPs intake.

Conclusion

It would be relevant to establish current level of EC awareness / knowledge within general population, however we should plan our immediate actions assuming it is low. Continuous emergency contraception awareness campaign should be executed at level of school medicine and at gynecology care level. Pre-EC counseling should be provided for every women seeking EC, in order to advise on importance and possibilities for regular contraception, but also to clearly underline that ECPs protect only from previous intercourse, while IUD protects from future intercourses only.

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HITNA KONTRACEPCIJA: MOŽEMO LI ŠTO NAUČITI?

SAŽETAK

Cilj ovog rada je evaluirati dosadašnje metode hitne kontracepcije (HK) kako bi implementirali dosadašnje stečeno znanje i povećali udio korisnica HK u Hrvatskoj. Prikazali smo dosadašnja istraživanja o razlozima neuspjeha primjene HK s ciljem detekcije mjera u nacionalnim preporukama za korištenje HK. U radu je prikazano šest potencijalnih razloga neuspjeha HK u postizanju populacijskog učinka, te četiri moguće točke akcije. To su mala stopa korištenja HK u usporedbi s mogućim rizičnim događanjima, nizak stupanj znanja o HK u općoj populaciji, razlike u efikasnosti i dostupnosti pojedinih metoda HK. S ciljem postizanja većeg broja korisnica HK u Hrvatskoj nužno je započeti s kontinuiranim edukacijskim programima posebice za žene koje spadaju u rizičnu skupinu. Preporuke za korištenje HK se moraju temeljiti na boljoj djelotvornosti i sigurnosti preparata, pa se kao primarne opcija za HK preporuča primjena materničkog bakrenog uloška i ulipristal acetata. Savjetovanje je najvažniji korak u osiguranju maksimalne učinkovitosti metoda HK, kao i poticanju budućeg korištenja oralnih hormonskih kontraceptiva. Konačno, nacionalni algoritam za korištenje metoda HK trebao bi obuhvatiti učinkoviti probir žena, promptnu primjenu HK, te adekvatni »follow up« korisnica HK.