SMU
Sikkim Manipal University
Manipal
INSPIRED BY LIFE
SMU Medical Journal
ISSN : 2349 – 1604 (Volume – 1, No. 2, July 2014) Review Article

Emergency Contraception - A last Chance to Prevent Unintended Pregnancy: What Everyone should know and what Sikkimese knows

Hafizur Rahman
Department of Obstetrics and Gynecology, Sikkim Manipal Institute of Medical Sciences, Gangtok, India. E-mail- hafizezzy@gmail.com Tel +913592-231137/232041 (128) (O). Fax:+91-3592-231496

Manuscript received : 11.05.2014
Manuscript accepted: 11.06.2014

Abstract

Unintended pregnancy and unsafe abortions possess a major global problem. Unsafe and illegal abortions are among the top five leading causes of maternal mortality in developing countries. World Health Organization estimated that in developing countries every eight minutes one woman dies due to unsafe abortions. Unintended pregnancies result from unprotected sex or contraceptive non-use, misuse and method failure. A recent survey showed that India tops the list in unprotected sex. Most of the pregnancies in India are unplanned. Use of effective contraception will surely decrease unwanted pregnancies and abortion rates. However, no family planning method is hundred percent effective and people do not always use the methods correctly. Emergency contraceptives (EC) are the methods of contraception used for preventing a pregnancy after an unplanned or unprotected sexual intercourse or when a regular contraceptive method fails. There are three types of Emergency Contraceptive Pills (ECPs)-combined ECPs containing both estrogen and progestin, progestin-only ECPs, and ECPs containing an

antiprogestin (mifepristone). Under the National Reproductive and Child Health Programme, the Drug Controller of India has only approved Levonorgestrel (LNG) 0.75mg tablets for use as ECP. The emergency contraceptive pills must be preferably taken or given within 72 hours of an unprotected act of intercourse. ECPs are Safe and effective, easy to use and widely available. They can be taken at any time during the monthly cycle. They are highest efficacious when they are taken soon after unprotected coitus. ECPs can be provided safely and effectively by any well informed health care providers. Adequate knowledge of EC is essential among health care providers so that they can propagate information among general population.

Key words: Emergency Contraception, knowledge, reproductive women, unintended pregnancy.

Introduction

Worldwide more than 75 million women experience an unwanted pregnancy each year.[1] Two-thirds of these women opt for induced abortions. The reported worldwide abortion rate is around 35 per 1000 women aged 15-45 years. Of these procedures 20 million are deemed unsafe.[2] Fifty five thousand unsafe abortions take place every day with half of all the illegal abortions are conducted in Asia, 25% in Africa, 20% in Latin America, and the remaining 5% in Eastern Europe.[3]

Unsafe and illegal abortions are among the top five leading causes of maternal mortality in developing countries. World Health Organization (WHO) estimated that in developing countries every eight minutes one woman dies due to unsafe abortions.[4]

Every second a baby is born in India. Most of the pregnancies (78%) in India are unplanned and at least 25% are unwanted. Many of these unplanned and unwanted pregnancies end in induced abortions. It is estimated that every year 11 million abortions take place in India; half of which are performed in unsafe conditions and associated with a high morbidity and mortality. Twenty thousand women die every year due to abortion related complications in India.[5]

Unintended pregnancies result from unprotected sex or contraceptive non-use, misuse and method failure.[6] An international survey conducted in 29 countries in April-May 2012, reported Indians rank top in unprotected sex. As many as 72 percent of sexually active young people across India have had sex with new partner without any protection.[7] Use of effective

contraception will surely decrease unwanted pregnancies and abortion rates. However no family planning method is hundred percent effective and people do not always use the methods correctly.[8]

What is emergency Contraception?

Emergency contraceptives (EC) are the methods of contraception used for preventing a pregnancy after an unplanned or unprotected sexual intercourse or when a regular contraceptive method fails. Promotion and use of EC at an appropriate time will definitely reduce unwanted pregnancies and in turn will reduce incidence of induced abortions and maternal mortality.[9]

Emergency Contraception can be used after voluntary sexual act without contraceptive protection, incorrect or inconsistent use of regular contraceptive methods includes failure to take oral contraceptives for more than 3 days, being late for contraceptive injection, in case of contraceptive failure or mishaps: miscalculation of infertile period, failed coitus interruptus, expulsion of an intrauterine device and, or in case of slippage/leakage/breakage of condom and in the event of sexual assault.[10]

The various methods of emergency contraceptives include all the hormonal oral contraceptive pills (combined as well as single) in varying doses which are known as emergency contraceptive pills (ECPs) and the Copper T intrauterine contraceptive (IUDs).[10]

Emergency contraceptive pills (ECPs)

There are three types of ECPs: combined ECPs containing both estrogen and progestin, progestin-only ECPs, and ECPs containing an antiprogestin (mifepristone). Progestin-only ECPs have now largely replaced the older combined ECPs because they are more effective and cause fewer side effects. Although this therapy is commonly known as the morning-after pill, the term is misleading; ECPs may be initiated sooner than the morning after—immediately after unprotected intercourse—or later—for at least 120 hours after unprotected intercourse.[11]

Combined ECPs contain the hormones estrogen and progestin. The hormones that have been studied extensively in clinical trials of ECPs are the estrogen ethinyl estradiol and the progestin

levonorgestrel or norgestrel. One combined, dedicated (meaning it was specially packaged for use as EC) EC product (Preven) was approved by the FDA in 1998 but withdrawn from the market in 2004. This combination of active ingredients used in this way is also sometimes called the Yuzpe method, after the Canadian physician who first described the regimen. When dedicated ECPs are not available, certain ordinary birth control pills can be used in specified combinations as emergency contraception. In either case, the regimen is one dose followed by a second dose 12 hours later, where each dose consists of 1, 2, 4, or 5 pills, depending on brand.[11] Research has demonstrated the safety and efficacy of an alternative regimen containing ethinyl estradiol and the progestin norethindrone.[12] This result suggests that oral contraceptive pills containing progestins other than levonorgestrel may also be used for emergency contraception.

Progestin-only ECPs contain no estrogen. Only the progestin levonorgestrel has been studied for freestanding use as an emergency contraceptive. The original treatment schedule was one 0.75 mg dose within 72 hours after unprotected intercourse, and a second 0.75 mg dose 12 hours after the first dose. However, studies have shown that a single dose of 1.5 mg is as effective as two 0.75 mg doses 12 hours apart.[13,14] One of these studies showed no difference in side effects between the two regimens,[13] while the other found greater levels of headache and breast tenderness (but not other side effects) among study participants taking 1.5 mg of levonorgestrel at once.[15] Increasingly, levonorgestrel is marketed internationally in a one-dose formulation (one 1.5 mg pill) rather than the two-dose formulation (two 0.75 mg tablets, taken 12 hours apart). [15]

The second-generation antiprogestin, ulipristal acetate (30 mg in a single dose), has been studied for use as emergency contraception and has been found to be highly effective and well tolerated. [16, 17, 18] It has been marketed for use as emergency contraception in Europe since October 2009; it was approved by the FDA in August 2010 and is available for sale by prescription only, marketed under the brand name *ella*.

The antiprogestin mifepristone has also been extensively studied for use as an emergency contraceptive pill. Mifepristone is a first-generation progesterone receptor modulator that is approved for use in many countries for early first-trimester medication abortion. Mifepristone has been shown to be highly effective for use as emergency contraception, with few side effects.

However, the use of mifepristone as an abortion pill may limit its widespread acceptability for use for emergency contraception, and it is currently available only in Armenia, China, Russia, and Vietnam.[19]

Under the National Reproductive and Child Health Programme, the Drug Controller of India has only approved Levonorgestrel (LNG) 0.75mg tablets for use as ECP. LNG is the 'dedicated product' for emergency contraception and is specially packaged at the correct dosage for use as ECP. The emergency contraceptive pills must be preferably taken or given within 72 hours of an unprotected act of intercourse either voluntarily or in cases of sexual assault/rape, if misses more than three consecutive active OCPs, if condom breaks, slips or leaks. Earlier the tablets are taken, the better it is. Best if taken as soon as possible after the unprotected act and as a single dose of 1 tablet of 1.5mg or 2 tablets of 0.75mg each. There is an option of taking 2 doses of 1 tablet 0.75mg each, 12 hours apart too.[10]

Copper-bearing IUDs as emergency contraceptives

Implantation occurs 6-12 days following ovulation.[20] Therefore, copper IUDs can be inserted up to 5 days after ovulation to prevent pregnancy. Thus, if a woman had unprotected intercourse three days before ovulation occurred in that cycle, the IUD could prevent pregnancy if inserted up to 8 days after intercourse. Because of the difficulty in determining the day of ovulation, however, many protocols recommend insertion up to only 5 days after unprotected intercourse. The latest WHO guidelines allow IUDs to be inserted up to day 12 of the cycle with no restrictions and at any other time in the cycle if it is reasonably certain that she is not pregnant.[21] A copper IUD can also be left in place to provide effective ongoing contraception for up to 12 years. But IUDs are not ideal for all women. Women with active sexually transmitted infections (STIs) are not good candidates for IUDs; insertion of the IUD in these women can lead to pelvic infection, which can cause infertility if untreated. Women not exposed to STIs have little risk of pelvic infection following IUD insertion, [22] and use of a copper IUD is not associated with an increased risk of tubal infertility among nulligravid women. [23]

Mechanism of action of EC

The precise mechanism of action of ECPs in an individual case depends on the time of the menstrual cycle when the intercourse has occurred and when the ECP is taken. To summarize, ECPs interfere with ovulation/fertilization/implantation depending on the phase of the menstrual cycle of the woman.[10] Additional possible mechanisms include interference with corpus luteum function; thickening of the cervical mucus resulting in trapping of sperm; alterations in the tubal transport of sperm, egg, or embryo. [24]

Benefits of ECPs

ECPs are Safe and effective, easy to use and widely available. They can be taken at any time during the monthly cycle. A physical examination is not required to obtain EC. It is available without a prescription from registered medical practitioner and can be given to any women for whom use of hormonal contraceptive pills are contraindicated. No serious medical complications have been reported as short exposure and relatively small doses of hormone does not have any metabolic effects. If inadvertently pregnancy occurs after use of ECPs, they are not associated with fetal malformations/congenital defects nor do they increase the risk of ectopic pregnancy.[10]

Effectiveness of ECPs

It is important to recognize that not every woman will become pregnant after an unprotected intercourse even if she does not take any emergency contraceptive pills. It is also impossible to predict correctly who would become pregnant after an unprotected intercourse. The probability of conception after single act of intercourse is approximately 8%. Use of ECPs within time can reduce the chance of pregnancy to less than 2%. [10] Twelve studies of the levonorgestrel regimen concluded that this regimen reduced a woman's chance of pregnancy after a single sex act of coitus by between 52% and 100%. Several studies have found that both the efficacy and the side effects of the levonorgestrel regimen are equivalent whether the hormone is taken as a single 1.5 mg dose or as 2 doses of 0.75 mg either 12 or 24 hours apart.[13] The efficacy of the levonorgestrel regimen and other ECPs decreases with time since coitus. So they having highest efficacy if they are taken sooner after unprotected coitus. [25]

Side effects of ECPs

Side effects include nausea and vomiting, abdominal pain, breast tenderness, headache, dizziness, and fatigue. These usually do not occur for more than a few days after treatment, and they generally resolve within 24 hours. About 50% of women who take combined ECPs experience nausea and 20% vomit. The levonorgestrel regimen has a significantly lower incidence of nausea and vomiting than the combined regimen; according to a randomized controlled trial conducted by WHO, progestin-only ECPs are associated with an incidence of nausea 50% lower and an incidence of vomiting 70% lower than that for combined ECPs.[26]

- If vomiting occurs within two hours of taking the dose of ECPs, repeat the full dose.
- Women with irregular bleeding and spotting after taking with ECPs should be counseled that this is normal. They should be assured that there is nothing to worry about, also that it should not be confused with menses. Clients should be told that ECPs do not necessarily bring on menses immediately (a common misconception among users of ECPs); most women will have their menstrual bleeding on time or slightly early or 2-3 days later than the expected date
- If menstruation is delayed beyond one week from scheduled date, tests should be conducted to exclude the possibility of pregnancy.
- In about 10-15% of women, emergency contraceptive pills change the amount, duration, and timing of the next menstrual period. These effects are usually minor and do not need any treatment.
- Side effects such as breast tenderness, headache, dizziness, and fatigue are not common and do not generally last more than 24 hours. Paracetamol or Aspirin or Ibuprofen tablets can be safely recommended for breast tenderness and headache.[10]

Role of Service Providers in Provision of ECPs

ECPs can be provided safely and effectively by any well informed health care providers (clinical, nursing and paraclinical) such as doctors, nurses, midwives, pharmacists, paramedics, family welfare assistants, health assistants and community based health workers. Service providers

should routinely inform all women in their reproductive age group and their partners about the availability of ECPs during regular family planning consultations. Service providers should also provide women with a supply of emergency contraceptive pills in advance as a back-up method for contraceptive mishaps. Providers should also inform and explain regarding correct dosage, mode of action, failure rate, effectiveness, possible side effects and their management and when to come back for a follow-up visit, if required.[10]

What Sikkimese knows about ECs?

A study conducted by Hafizur et al.[27] assessed knowledge of, attitudes toward, and barriers to the practice of EC among 1474 reproductive women of Sikkim. Most of the women who were interviewed were married between 21 and 30 years of age. Of those who agreed to participate, 40.6% had ever heard of EC, and EC awareness was particularly low (6.4%) among illiterate women. The most common sources of EC information were electronic media (77.1%), friends and relatives (33.8%), and health personnel (30.4%). Overall, 71.9% of the participants who had heard of EC did not know the timeframe when it should be used. Only 19.6% of the women who had ever heard of EC had adequate knowledge of it, and only 15.1% of these (or 6.1% of the total sample) had ever used EC. The most common barriers to using EC were inadequate knowledge of it, its perceived non-availability, considering it an abortifacient, and religious beliefs. The authors concluded that knowledge and practice of EC was low among the women in Sikkim.

Another study[28] by same author evaluated the knowledge, attitude and practice of EC amongst the nursing staff working in two tertiary hospitals of Sikkim namely Central Referral Hospital and Sir Thutob Namgyal Memorial Hospital, both located at the heart of Gangtok city. Sixty six percent of participant nursing staff were between the age of 21 and 30 years and 30% were between 31 and 40 years. Fourteen percent nursing staff had never heard of EC. Those who heard of EC the most common source (80%) of knowledge regarding EC was from doctors and health personal followed by electronic media (42%) and print media (19%). When asked about potential methods of EC, 26% responded OCP, 11% mifepristone; only 4% felt progesterone only pills (levonorgestrel) and 6% identified IUD as one of the methods of EC. A very high

percentage (61%) of participants responded that condom could be used for EC! The authors concluded that only 38.5% of the participants nursing staff had actual knowledge of it. Attitudes among nursing staff were also not favourable. Although 61% were willing to use contraceptives but only 40% percent felt EC are beneficial and would encourage their friends and relatives to use EC. The authors were in view that knowledge of EC was inadequate among the nursing staff. The author felt that all health-care providers should know not only about contraception but also about EC and include it in routine consultations. Since nursing staff and all doctors' are important parts of health care system, the author explored in depth knowledge on EC of doctors and their professional experience with clients (article under consideration for publication). A total of 220 doctors working in different areas were invited to participate including trainee doctors irrespective of their area of specialization. Doctors working in the specialty of Gynaecology were excluded as they were expected to be aware of EC. Three quarter of the participant was below 40 years. Ninety five percent participant ever heard of EC (5% never heard of EC!), the most common source of knowledge were from medical text books. Overall, 27.4% of the participants who had heard of EC did not know the correct timeframe when it should be used. Correct dosage of levonorgestrel (LNG) regime of EC was aware by 71%, while Yuzpee regime was aware only by 15.4%. Forty percent doctors were not aware that a doctor's prescription is not required to obtain EC. About 44% percent doctor recommended or prescribed EC at least once in their life time. Surprisingly, although 74% participant doctor support wide publicity of EC, but at the same time they had a concern that EC might encourage contraceptive risk-taking behavior or increase sexual promiscuity. One third of the participant felt that they were reluctant to prescribe/recommend EC because of their inadequate knowledge about EC.

Conclusion

Emergency contraception provides women with a last chance to prevent pregnancy after unprotected sex. Women deserve that last chance, and barriers to availability should be eliminated. But it is unlikely that expanding access will have a major impact on reducing the rate of unintended pregnancy, primarily because the incidence of unprotected intercourse is so high, ECPs are only moderately effective, ECPs are not used often enough and awareness of EC is

low. There is an urgent need for information on the airwaves and in print, and for education at health centers and local health posts on modern methods of contraception, including EC. Targeted government programs in India and other low-income countries would lower the rates of unintended pregnancy, induced abortion, and maternal mortality. Focusing on EC at health centers and health posts would be especially important, as it would educate women on the costs and health consequences of unwanted pregnancies and induced abortion

References

1. UNFPA. "The state of World Population 1997: The Right to Choose: Reproductive Rights and Reproductive Health". http://www.unfpa.org/public/cache/offonce/home/publications/pid/3460;jsessionid=59D8D3B45CBF3B960579D7D9EF4F44E2. Published 1997, Accessed 30th May 2012.

2. WHO, Division of Reproductive Health. Unsafe Abortion: Global and Regional estimates of incidence and mortality due to unsafe abortion with listing of available country data. http://www.who.int/reproductive-health/publications/MSM_97_16/MSM_97_16_table_of_contents_en.html. Published 1998. Accessed 18th December 2012.

3. World Health organization. Unsafe Abortion: a worldwide Problem. Safe Motherhood, World Health Organization, 2000; 28(1):1.

4. World Health Organization. Unsafe Abortion; Global and regional estimates of the incidence of unsafe abortion and associated mortality in 2003. http://209.61.208.233/LinkFiles/Publications_Unsafe_Abortion.pdf . Published 2003. Accessed 18th December 2012.

5. National Family Health Survey. Ministry of Family Welfare and Health, Government of India, 1988.

6. Williams SP. Factors associated with unintended pregnancy. J. Society Advance. Contraception 1997; 13(4):385-458.

7. Bayer Healthcare. "The clueless or clued up: Your right to be informed about contraception". http://post.jagran.com/Indians-rank-top-in-unprotected-sex-Survey-1317568155. Published 2011. Accessed 27th May 2012.

8. Family Health International. Contraceptive Methods for Young Adults: Emergency

Contraception. Network Spring 1997; 17 (3): 16-17.

9. Grimes DA, Benson J, Singh S, Romero M, Ganatra B, Okonofua FE, Shah IH. Unsafe abortion: the preventable pandemic. Lancet 2006; 368(9550):1908-19.

10. Ministry of Health and Family Welfare Government of India. Guidelines for Administration of Emergency Contraceptive Pills by Health Care Providers. Government of India, New Delhi 2008: 1-20

11. Trussell J, Koenig J, Ellertson C, Stewart F. Preventing unintended pregnancy: the costeffectiveness of three methods of emergency contraception. Am J Public Health. 1997;87:932-7.

12. Ellertson C, Webb A, Blanchard K, Bigrigg A, Haskell S, Shochet T, Trussell J. Modifying the Yuzpe regimen of emergency contraception: a multicenter randomized, controlled trial. Obstet Gynecol. 2003;101:1160-7.

13. von Hertzen H, Piaggio G, Ding J, Chen J, Song S, Bártfai G, Ng E, Gemzell-Danielsson K, Oyunbileg A, Wu S, Cheng W, Lüdicke F, Pretnar-Darovec A, Kirkman R, Mittal S, Khomassuridze A, Apter D, Peregoudov A. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet. 2002;360:1803-10.

14. Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. Contraception. 2002;66:269-73.

15. Ngai SW, Fan S, Li S, Cheng L, Ding J, Jing X, Ng EHY, Ho PC. A randomized trial to compare 24h versus 12h double dose regimen of levonorgestrel for emergency contraception. Hum Reprod. 2004;20:307-11.

16. Creinin MD, Schlaff W, Archer DF, Wan L, Frezieres R, Thomas M, Rosenberg M, Higgins J. Progesterone receptor modulator for emergency contraception: a randomized controlled trial. Obstet Gynecol. 2006;108:1089-97.

17. Fine P, Mathé H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48-120 hours after intercourse for emergency contraception. Obstet Gynecol. 2010;115:257-63.

18. Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-

analysis. Lancet. 2010;375:555-62.

19. Cheng L, Che Y, Gülmezoglu AM. Interventions for emergency contraception. Cochrane Database Sys Rev. 2012, Issue 8.

20. Wilcox AJ, Baird DD, Weinberg CR. Time of implantation of the conceptus and loss of pregnancy. N Engl J Med. 1999;340:1796-9.

21. Selected practice recommendations for contraceptive use. Second Edition. Geneva: World Health Organization, 2004.

22. Farley TMM, Rosenberg MJ, Rowe PJ, Chen J-H, Meirik O. Intrauterine devices and pelvic inflammatory disease: an international perspective. Lancet. 1992;339:785-8.

23. Hubacher D, Lara-Ricalde R, Taylor DJ, Guerra-Infante F, Guzmán-Rodríguez R. Use of copper intrauterine devices and the risk of tubal infertility among nulligravid women. N Engl J Med. 2001;345:561-7.

24. Croxatto HB, Devoto L, Durand M, Ezcurra E, Larrea F, Nagle C et al. Mechanism of action of hormonal preparations used for emergency contraception: a review of the literature. Contraception. 2001;63:111-21.

25. Piaggio G, von Hertzen H, Grimes DA, Van Look PF. Timing of emergency contraception with levonorgestrel or the Yuzpe regimen. Task Force on Postovulatory Methods of Fertility Regulation. Lancet 1999;353:721.

26. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. Lancet. 1998;352:428-33.

27. Hafizur R, Khalda E, Kar S, Kharka L, Bhutia GP. Knowledge of, attitudes toward and barriers to Practice of emergency contraception among women in Sikkim, India. Int. J Gynaecol Obstet 2013; 122(2):99-103

28. Hafizur R, Renjhen P, Kumar A. A study on emergency contraceptives among nursing staff in Sikkim, India: A cross-sectional study. AMJ 2010; 3 (10): 667-671. Doi 10.4066/AMJ.2010.362

Authors Column

Dr. Hafizur Rahman is an Associate professor of Obstetrics and Gynaecology at the Sikkim Manipal Institute of Medical Sciences, Gangtok. His main areas of interest in research include Adolescent Gynaecology & contraception and Labour and delivery complications.

Dr. Rahman has more than a dozen publications in international journals including International Journal of Gynaecology and Obstetrics, Journal of Obstetrics and Gynaecology of Canada, AMJ, Nigerian Medical Journal etc and in several Indian journals. He is a peer reviewer of several international journals including Journal of Women's Health issues and care, Nigerian Journal of Clinical Practice, Kuwait Journal of Health & Medical Sciences, Journal of Healthcare Engineering Essex and Khyber University Medical Journal.

Dr. Rahman is also an editorial board member of Journal of Obstetrics and Gynaecology Barpeta.

SMU Medical Journal, Volume – 1, No. – 2, July, 2014, PP. 139 - 151, 2014