

This article was downloaded by:[CDL Journals Account]
On: 17 July 2008
Access Details: [subscription number 785022370]
Publisher: Informa Healthcare
Informa Ltd Registered in England and Wales Registered Number: 1072954
Registered office: Mortimer House, 37-41 Mortimer Street, London W1T 3JH, UK



Acta Obstetrica et Gynecologica Scandinavica

Publication details, including instructions for authors and subscription information:
<http://www.informaworld.com/smpp/title~content=t716100748>

Advance provision of emergency contraceptive pills reduces treatment delay: a randomised controlled trial among Swedish teenage girls

Maria Ekstrand ^a; Margareta Larsson ^a; Elisabeth Darj ^a; Tanja Tydén ^{ab}

^a Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden

^b Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden

Online Publication Date: 01 January 2008

To cite this Article: Ekstrand, Maria, Larsson, Margareta, Darj, Elisabeth and Tydén, Tanja (2008) 'Advance provision of emergency contraceptive pills reduces treatment delay: a randomised controlled trial among Swedish teenage girls', Acta Obstetrica et Gynecologica Scandinavica, 87:3, 354 — 359

To link to this article: DOI: 10.1080/00016340801936024
URL: <http://dx.doi.org/10.1080/00016340801936024>

PLEASE SCROLL DOWN FOR ARTICLE

Full terms and conditions of use: <http://www.informaworld.com/terms-and-conditions-of-access.pdf>

This article maybe used for research, teaching and private study purposes. Any substantial or systematic reproduction, re-distribution, re-selling, loan or sub-licensing, systematic supply or distribution in any form to anyone is expressly forbidden.

The publisher does not give any warranty express or implied or make any representation that the contents will be complete or accurate or up to date. The accuracy of any instructions, formulae and drug doses should be independently verified with primary sources. The publisher shall not be liable for any loss, actions, claims, proceedings, demand or costs or damages whatsoever or howsoever caused arising directly or indirectly in connection with or arising out of the use of this material.

ORIGINAL ARTICLE

Advance provision of emergency contraceptive pills reduces treatment delay: a randomised controlled trial among Swedish teenage girls

MARIA EKSTRAND¹, MARGARETA LARSSON¹, ELISABETH DARJ¹ & TANJA TYDÉN^{1,2}

¹Department of Women's and Children's Health, and ²Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden

Abstract

Objective. To evaluate an intervention involving advance provision of emergency contraceptive pills (ECP) to Swedish teenage girls. **Material and methods.** Some 420 girls aged 15–19, requesting ECP at a local youth clinic were randomly assigned to intervention group (IG) ($n=214$) or control group (CG) ($n=206$). Both groups received ECP on request. The IG received one extra dose of ECP, condoms and an information leaflet regarding ECP and condom use. Main outcome measures were differences between IG and CG regarding ECP use, time span between unprotected intercourse and ECP intake, contraceptive use, and sexual risk taking. Questionnaires were completed at the initial visit, and the girls were followed up by structured telephone interviews 3 and 6 months later. **Results.** At the 3-month follow-up, girls in the IG were almost twice as likely to have used ECP compared to girls in the CG (IG: 24.0%, CG: 13%, $p=0.02$), and they used it sooner after unprotected intercourse (mean time IG: 13.61 h, CG: 25.47 h, $p=0.007$). Significant differences persisted 6 months after the intervention (ECP use IG: 31%, CG: 19%, $p=0.01$; and mean time IG: 15.59 h, CG: 26.38 h, $p=0.006$). No significant differences were found in the use of regular hormonal contraceptives or condoms at either follow-up. About 40% of the girls in both groups had risked pregnancy during the follow-up period, but only half of these had used ECP. **Conclusions.** This intervention shortened the time interval from unprotected intercourse to pill intake without jeopardising contraceptive use and without increasing sexual risk taking.

Key words: Emergency contraception, teenage girls, RCT, Sweden

Abbreviations: ECP: emergency contraceptive pills, STI: sexually transmitted infection

Introduction

In Sweden, the emergency contraceptive pill (ECP) has been available on prescription since the mid-1990s, and the levonorgestrel-only method without prescription since 2001. ECP can also be obtained free of charge at family planning clinics, hospitals, and youth clinics. Nevertheless, Sweden has the highest abortion rate among the Nordic countries; between 1995 and 2006, the number of teenage abortions increased by 50% (from 16.9 to 25.4 abortions per 1,000 women aged 15–19) (1).

ECP can prevent pregnancy up to 120 h after coitus (2–4), but is recommended to be taken as soon as possible after unprotected intercourse, since its effect is estimated to decline gradually from 95 to

58% during the first 72 h (5). If used correctly, ECP is theoretically capable of preventing up to 95% of all unintended pregnancies (6). Thus, difficulties in accessing ECP on time have been reported as a great barrier to its use (7,8).

Need for ECP frequently arises on weekends (7), and Swedish clinicians have noted that many teenage girls turn to the youth clinics on Mondays in order to obtain ECP free of charge. At weekends, pharmacy-opening hours are limited and the youth clinics are closed, potentially causing a delay that may decrease the efficacy of the treatment.

ECP is still highly controversial in many countries, mainly due to fears of increased sexual risk taking followed by negative health consequences, especially

for teenagers. Studies among women aged 14–45 have shown that those who received ECP in advance used it more frequently than controls, and sooner after unprotected intercourse, without increasing their sexual risk taking or compromising the use of other contraceptive methods (9–11). Studies of ECP use specifically among teenagers found that adolescents did not behave any differently from adults nor did they take greater risks in response to improved access to ECP (12–14).

The aim of this study was to evaluate the effect of advance provision of ECP to teenage girls regarding ECP use, time span from unprotected intercourse to ECP intake, contraceptive habits, and sexual risk taking.

Material and methods

Design and setting

Between July 2005 and November 2006, we conducted a randomised controlled trial among 420 teenage girls requesting ECP. The study took place at a local youth clinic in a medium-sized university town in Sweden. This clinic sees approximately 7,000 visits annually, about 600 of which are due to requests for ECP.

Procedure

Swedish-speaking girls aged between 15 and 19 who visited the youth clinic to obtain ECP were consecutively asked to participate. Each eligible participant was given verbal and written information about the study by a midwife. Those willing to participate provided informed consent and contact information, and were thereafter randomly assigned to IG or CG.

Randomisation was organised in blocks of four. Envelopes were sequentially labelled with a study identification number, using a table of random digits, and handed out consecutively to each participant. The envelopes contained a baseline questionnaire which participants were asked to fill out by themselves, before receiving the requested ECP.

All participants received ECP on request (1.5 mg levonorgestrel taken as a single dose), and were scheduled for a re-visit for contraceptive counselling and a urine HCG pregnancy test 3 weeks later. Girls in the IG received one extra dose of ECP. In addition, the IG also received 10 condoms and a specially-designed leaflet containing information regarding ECP and condom use, since we were hesitant to distribute ECP in advance to young girls without giving them additional information and protection against both unwanted pregnancy and

STI. All participants, regardless of group assignment, received a wallet card with the research team's contact information in case they had any questions.

Participants were followed up by structured telephone interviews 3 and 6 months after enrolment; they were notified by e-mail or text message a few days prior to each interview. The interviews were conducted by specially trained research assistants. In order to maintain discretion, interviewers made sure each informant could talk undisturbed at the time of the interview. If necessary, several attempts were made to initiate contact for the first follow-up. Those who still could not be reached despite this were not excluded, but were contacted again for the second follow-up.

Instrument

The questions were partially based on previous studies (13,15). A pilot study was performed at the youth clinic for 2 months prior to the study, in order to test the baseline questionnaire and the recruitment procedure. A few questions were rephrased and clarified after comments from the pilot participants ($n=31$).

The baseline questionnaire included sociodemographic data, sexual health history, contraceptive use, sexual risk taking, and ECP use (Table I). The follow-up interviews used a 12-item questionnaire covering ECP use, time intervals for ECP intake, pregnancy history, contraceptive use, and sexual risk taking. To examine contraceptive use and sexual risk taking, we asked respondents to recall for the past 3 months their number of new sexual partners, contraceptive use at first intercourse with most recent partner, non-condom use with new partners, occasions of unprotected intercourse, and acquisition of STI; additionally, we asked about contraceptive use at most recent intercourse. The study was approved by the local Medical Research Committee in Uppsala.

Sample size

We conducted a power calculation based on previous results from Gold et al. (13). Assuming 15 and 8% ECP use (IG and CG, respectively) and a standard deviation of about 14 h from unprotected intercourse to ECP intake, 150 subjects per group would give approximately 80% power to detect a time difference of 11 h between groups at the 5% significance level. We assumed a drop-out rate of about 30%, and hence planned to recruit 210 subjects per group.

Table I. Baseline characteristics of girls in the intervention and control groups.

	Intervention group <i>n</i> = 214 (%)	Control group <i>n</i> = 206 (%)
Age	Mean 17; SD 1.3	Mean 17; SD 1.3
Ethnicity – Nordic origin	196 (91.6%)	191 (92.7%)
Ethnicity – non-Nordic origin	18 (8.4%)	15 (7.3%)
Immigrant parent(s)	56 (26.2%)	52 (25.2%)
Student	183 (86.7%)	172 (84.4%)
Working/other	28 (13.3%)	32 (15.7%)
Daily smoker	47 (22%)	58 (28.4%)
Mean age at coitarche	15.3; SD 1.3	15.3; SD 1.4
No. of sexual partners	Mean 4.35; median 3.00; range 1–26	Mean 4.57; median 3.00; range 1–38
Condom use at first intercourse	158 (73.8%)	144 (70.9%)
Previous ECP use-no. of times	Range: 1–15	Range: 1–7
Once	46 (56.8%)	42 (49.4%)
Twice or more	35 (43.2%)	43 (50.6%)
Previous history of STI	19 (8.9%)	16 (8.0%)
History of abortion	13 (6.1%)	21 (10.3%)

Data analysis

The Statistical Package for Social Sciences (SPSS) for Windows (14.0) was used when entering and analysing data. Differences between groups were tested at baseline and at follow-up using Student's *t*-test (mean time between unprotected intercourse and ECP intake) and Fischer's Exact Test/Pearson's χ^2 test for two independent samples on nominal data (contraception/ECP use, sexual risk taking, pregnancy outcome, and STI).

Results

A total of 667 girls requested ECP during the study period; 52 did not meet the inclusion criteria regarding age and/or language barriers, 108 declined to participate, and 31 were not invited due to lack of staff time. During the recruitment period, 56 girls visited for ECP on two or more occasions, but were only invited once. In total, 420 girls were finally enrolled and randomised to the study. Girls who declined participation were nearly five times more likely to have a non-Nordic background compared to participants (38 versus 8%, $p < 0.01$).

As shown in Table I, the baseline characteristics between IG ($n = 214$) and CG ($n = 206$) were almost identical. Since we did not exclude those who participated in only one follow-up interview, the response rates vary between the follow-ups. Some

78% of all participants were followed up at least once. Of all participants, 62.6% were reached both at the first and second follow-up, 72.6% at the first follow-up only, and 70% at the second follow-up only.

Girls who could not be contacted for either of the follow-ups were nearly twice as likely as those followed up to have a non-Nordic background (36.4 versus 19.6%, $p < 0.01$), and they were also more likely to be daily smokers (38.4 versus 20.5%, $p < 0.01$).

At the 3-month follow-up, girls in the IG were almost twice as likely as those in the CG to have used ECP, and they used it significantly sooner after unprotected intercourse. These differences remained significant at the second follow-up (Table II).

About 40% ($n = 128$) of all girls reported unprotected intercourse at least once between enrolment and the 6-month follow-up (IG: 43%, CG: 36%). Only half (49%, $n = 63$) of these had used ECP afterwards. However, more girls in the IG had used ECP compared to controls (IG: 58%, CG: 37%, $p = 0.02$). Only half (55%, $n = 35$) of the girls in the IG who reported unprotected intercourse during the study period had used their advance supply of ECP, whereas 39% ($n = 25$) still had the package at home. Four of the girls had given it away.

As shown in Table III, there were no significant differences between the groups regarding contraceptive use and sexual risk taking at either follow-up.

More than every third participant (37%, $n = 121$) had changed partner at least once during the study period. At the 3-month follow up, girls in the CG

Table II. ECP use and time span from unprotected intercourse to ECP intake in the intervention and control groups at the 3- and 6-month follow-ups.

	ECP-use <i>n</i> (%)	Time interval (h) Mean (SD)
3-month follow-up		
Intervention group (<i>n</i> = 154)	37 (24%)	13.61 (10.36)
Control group (<i>n</i> = 150)	20 (13%)	25.47 (18.73)
	$p = 0.02^\dagger$	$p = 0.007^\ddagger$
6-month follow-up*		
Intervention group (<i>n</i> = 172)	54 (31%)	15.57 (12.69)
Control group (<i>n</i> = 157)	29 (19%)	26.38 (19.34)
	$p = 0.01^\dagger$	$p = 0.006^\ddagger$

[†]Fischer's Exact Test.

[‡]Student's *t*-test.

*Cumulative numbers of participants reporting ECP use at 3-month follow-up, 6-month follow-up or both.

Table III. Unprotected intercourse and contraceptive use at the 3- and 6-month follow-up.

	Intercourse without any contraception		Condom use at last intercourse		OC use at last intercourse		Condom use at first intercourse with new partner	
	<i>N</i>	<i>n</i> (%)	<i>N</i>	<i>n</i> (%)	<i>N</i>	<i>n</i> (%)	<i>N</i>	<i>n</i> (%)
3-month follow-up*								
Intervention group	134	48 (35.8%)	149	48 (32.2%)	149	77 (51.7%)	38	18 (47.4%)
Control group	126	40 (31.7%)	147	56 (38.1%)	147	65 (44.2%)	55	33 (60%)
		<i>p</i> = 0.51		<i>p</i> = 0.33		<i>p</i> = 0.20		<i>p</i> = 0.29
6-month follow-up**								
Intervention group	156	37 (23.7%)	157	46 (29.3%)	157	89 (56.7%)	37	19 (51.4%)
Control group	136	30 (22.1%)	136	47 (34.6%)	136	67 (49.3%)	45	21 (46.7%)
		<i>p</i> = 0.78		<i>p</i> = 0.38		<i>p</i> = 0.24		<i>p</i> = 0.83

*From baseline to 3 months post-intervention.

**From 3–6 months post-intervention.

reported partner change more often and with more partners than girls in the IG (partner change CG: 33%, IG: 21.5%, $p=0.03$; and mean number of partners CG: 1.59, IG: 1.19, $p=0.014$). The differences did not remain at the second follow-up.

Among those reporting intercourse with a new partner at the 3-month follow-up, 16 of 31 IG members (52%) and 17 of 46 controls (37%) recalled at least one occasion when condoms had *not* been used ($p=0.198$); the corresponding figures at the 6-month follow-up were 62% in both groups.

Six months post-recruitment, 7 girls had acquired an STI (5 IG members and 2 controls). Seven had become pregnant (4 IG members and 3 controls), one of them twice. Three pregnancies were terminated, 3 ended in early miscarriage, and 2 were continued.

Discussion

Many teenage girls in Sweden delay administration of ECP by waiting until after the weekend to obtain it from youth clinics free of charge. Hence, we designed an intervention to evaluate the effect of advance ECP provision to teenage girls in need of emergency contraception.

We found that girls provided with ECP in advance used it more frequently and approximately 12 h sooner after unprotected intercourse compared with controls. This is important since earlier onset of treatment increases its efficacy, which in turn could lead to reduced numbers of unwanted pregnancies. Although it is recommended that ECP should be taken as soon as possible after unprotected intercourse, studies disagree over the exact level of efficacy and the extent to which effectiveness declines with treatment delay (16–18). Therefore,

it is difficult to estimate the clinical impact of the present intervention.

About half of the girls in our study who had risked pregnancy did not take ECP after unprotected intercourse – even when they had been provided with ECP in advance. This highlights the complex nature of ECP use; although ECP has a tremendous theoretical potential to reduce the number of unintended pregnancies, in reality it is still largely under-utilised among women, even when it is readily available (19–21). One explanation for this could be that young women may underestimate the risk of pregnancy, or lack knowledge about the menstrual cycle and the distinction between high-risk and low-risk coital acts (8,22, 23). A Swedish study among 518 abortion applicants found that half of those under 19 had not used any kind of contraception at the time of conception due to underestimation of pregnancy risk. Only about half of the women stated that they would have used ECP to prevent pregnancy if they had had it available at home (24).

ECP use is still a worldwide issue of concern due to fears that it may promote increased sexual risk taking. In our study, nearly 40% of the girls reported unprotected intercourse, only half had used oral contraceptives at their most recent intercourse and more than every third had changed partner within the 6-month period. Negative attitudes towards hormonal contraception and condom-use are commonly expressed among teenagers and inconsistent contraceptive use occurs frequently – especially in situations of unplanned sex with a new partner (23,25). However, we detected no significant differences between the groups regarding increased sexual risk taking or compromised use of other contraceptives. Our findings are in agreement with previous international studies, and conclude that the

possible health risks of providing increased ECP access to teenagers appear to be minimal (9–12).

Since our data was based on self-reported measures, recall bias may have occurred. Furthermore, the high attrition rate among immigrant girls might have affected the representativeness of our sample. Immigrant girls constitute a particularly vulnerable group concerning reproductive health issues (26), and the intervention may therefore not have reached those who perhaps needed it the most. We cannot rule out that, for some, refusal to participate may have been due to concern over family members finding out about the study.

The aim of the present study was not to evaluate the effect of advance ECP provision on pregnancy rates. However, the underlying assumption was that increased ECP use and faster onset of treatment might lead to reduced numbers of unintended pregnancies. No study has yet been able to show reduced pregnancy rates at a population level (9–12). However, the positive effects of easy ECP access for individual women should not be ignored. Teenage girls in need of emergency contraception are known to be at risk for unintended pregnancies (27). Therefore, advance distribution of ECP on a routine basis could be beneficial, but it may not be the sole solution. Complementary studies are needed on how to further enhance ECP use among teenagers at risk for unintended pregnancy.

Conclusion

Advance provision of ECP shortens the time between unprotected intercourse and pill intake without jeopardising regular contraceptive use. Teenage girls requesting ECP may therefore benefit from advance provision of ECP on a routine basis, but complementary studies are needed on how to further enhance ECP use in order to prevent unintended pregnancies.

Acknowledgements

Financial support was provided by the Swedish Research Council. We are most grateful to Eva Grönlund and the other midwives at the youth clinic in Uppsala for their outstanding dedication and valuable help with recruitment of study participants. We have no conflict of interest or funding.

References

1. Induced Abortions. Official Statistics of Sweden: National Board of Health and Welfare. Centre of Epidemiology; 2006. Report No.: 2007:7.

2. von Hertzen H, Piaggio G, Ding J, Chen J, Song S, Bartfai G, et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet*. 2002;360(9348):1803–10.
3. Rodrigues I, Grou F, Joly J. Effectiveness of emergency contraceptive pills between 72 and 120 hours after unprotected sexual intercourse. *Am J Obstet Gynecol*. 2001;184(4):531–7.
4. Ellertson C, Evans M, Ferden S, Leadbetter C, Spears A, Johnstone K, et al. Extending the time limit for starting the Yuzpe regimen of emergency contraception to 120 hours. *Obstet Gynecol*. 2003;101(6):1168–71.
5. von Hertzen H, Piaggio G, Van Look PF. Emergency contraception with levonorgestrel or the Yuzpe regimen. Task Force on Postovulatory Methods of Fertility Regulation. *Lancet*. 1998;352(9144):1939.
6. Trussell J, Stewart F, Guest F, Hatcher RA. Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. *Fam Plann Perspect*. 1992;24(6):269–73.
7. Aneblom G, Larsson M, von Essen L, Tyden T. Women's voices about emergency contraceptive pills "over-the-counter": a Swedish perspective. *Contraception*. 2002;66(5):339–43.
8. Gainer E, Blum J, Toverud EL, Portugal N, Tyden T, Nesheim BI, et al. Bringing emergency contraception over the counter: experiences of nonprescription users in France, Norway, Sweden and Portugal. *Contraception*. 2003;68(2):117–24.
9. Polis CB, Schaffer K, Blanchard K, Glasier A, Harper CC, Grimes DA. Advance provision of emergency contraception for pregnancy prevention (full review). *Cochrane Database Syst Rev*. 2007;(2):CD005497.
10. Raymond EG, Trussell J, Polis CB. Population effect of increased access to emergency contraceptive pills: a systematic review. *Obstet Gynecol*. 2007;109(1):181–8.
11. Glasier A, Fairhurst K, Wyke S, Ziebland S, Seaman P, Walker J, et al. Advanced provision of emergency contraception does not reduce abortion rates. *Contraception*. 2004;69(5):361–6.
12. Harper CC, Cheong M, Rocca CH, Darney PD, Raine TR. The effect of increased access to emergency contraception among young adolescents. *Obstet Gynecol*. 2005;106(3):483–91.
13. Gold MA, Wolford JE, Smith KA, Parker AM. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *J Pediatr Adolesc Gynecol*. 2004;17(2):87–96.
14. Belzer M, Sanchez K, Olson J, Jacobs AM, Tucker D. Advance supply of emergency contraception: a randomized trial in adolescent mothers. *J Pediatr Adolesc Gynecol*. 2005;18(5):347–54.
15. Haggstrom-Nordin E, Hanson U, Tyden T. Sex behavior among high school students in Sweden: improvement in contraceptive use over time. *J Adolesc Health*. 2002;30(4):288–95.
16. 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(9154):721.
17. Trussell J, Ellertson C, von Hertzen H, Bigrigg A, Webb A, Evans M, et al. Estimating the effectiveness of emergency contraceptive pills. *Contraception*. 2003;67(4):259–65.
18. Mikolajczyk RT, Stanford JB. A new method for estimating the effectiveness of emergency contraception that accounts for

- variation in timing of ovulation and previous cycle length. *Fertil Steril*. 2005;83(6):1764–70.
19. Nelson AL. Recent use of condoms and emergency contraception by women who selected condoms as their contraceptive method. *Am J Obstet Gynecol*. 2006;194(6):1710–15; discussion 1715–6.
 20. Goulard H, Moreau C, Gilbert F, Job-Spira N, Bajos N. Contraceptive failures and determinants of emergency contraception use. *Contraception*. 2006;74(3):208–13.
 21. Walsh TL, Freziers RG. Patterns of emergency contraception use by age and ethnicity from a randomized trial comparing advance provision and information only. *Contraception*. 2006;74(2):110–7.
 22. Larsson M, Aneblom G, Od Lind V, Tyden T. Reasons for pregnancy termination, contraceptive habits and contraceptive failure among Swedish women requesting an early pregnancy termination. *Acta Obstet Gynecol Scand*. 2002;81(1):64–71.
 23. Ekstrand M, Larsson M, von Essen L, Tyden T. Swedish teenager perceptions of teenage pregnancy, abortion, sexual behavior, and contraceptive habits – a focus group study among 17-year-old female high-school students. *Acta Obstet Gynecol Scand*. 2005;84(10):980–6.
 24. Aneblom G, Larsson M, Od Lind V, Tyden T. Knowledge, use and attitudes towards emergency contraceptive pills among Swedish women presenting for induced abortion. *BJOG*. 2002;109(2):155–60.
 25. Darj E, Bondestam K. [Adolescents' view on the use of condoms.] *Lakartidningen*. 2003;100(44):3510–2, 3515–6.
 26. Helstrom L, Zatterstrom C, Od Lind V. Abortion rate and contraceptive practices in immigrant and Swedish adolescents. *J Pediatr Adolesc Gynecol*. 2006;19(3):209–13.
 27. Falk G, Falk L, Hanson U, Milsom I. Young women requesting emergency contraception are, despite contraceptive counselling, a high risk group for new unintended pregnancies. *Contraception*. 2001;64(1):23–7.