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Use of ulipristal acetate and levonorgestrel for emergency contraception: a follow-up study

Aisling Susan Baird,

Consultant in Sexual & Reproductive Health, Abacus Community Sexual Health Service
Liverpool Community Health, The BEAT, David Lewis Street, Liverpool, L1 4AP

James Trussell, and

Professor of Economics & Public Affairs, Office of Population Research, Princeton University,
Princeton NJ 08544, USA

Visiting Professor, Hull York Medical School, University of Hull, Hull HU6 7RX, UK

Anne Webb

Retired Consultant in Sexual & Reproductive Health, Abacus Community Sexual Health Service
Liverpool Community Health, The BEAT, David Lewis Street, Liverpool, L1 4AP

Aisling Susan Baird: aisling.baird@liverpoolch.nhs.uk

Abstract

Objectives—Previously we showed that increasing choice of emergency contraception (EC) guided by medical eligibility, did not result in wholesale usage of ulipristal acetate (UPA). A further 12 month study assessed:

- Does offering choice of EC lead to change in methods used?
- Are women who choose UPA more likely than those who choose LNG to continue using condoms for subsequent contraception or to decline any ongoing contraception?
- Do more women choosing LNG quick start hormonal contraception?

Methods—Retrospective study of EC episodes (01/04/2012–31/03/2013), by quarters. Among women offered all three methods of EC (49.1%) we noted the method chosen, and decisions on ongoing contraception among those choosing either LNG or UPA. Differences were tested for statistical significance.

Results—In 6110 episodes of EC, LNG was issued in 69.2%, UPA in 26.0%, and in 4.8% a Cu-IUD was fitted. Quarter-by-quarter, the data show a small decline in LNG use, suggesting plateauing by the last quarter, and a significant increase in UPA use between first and other three

Correspondence to: Aisling Susan Baird, aisling.baird@liverpoolch.nhs.uk.

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Competing Interests

Competing Interests: Dr Baird has received an honorarium from HRA Pharma for presenting this data at a UK National Conference.

quarters ($p<0.001$). The use of the Cu-IUD remained static. The percentage offered three methods rose to 54.2%. In women offered full choice (3000; 49.1%), we saw a significant increase in choice of UPA from 39.3% to 48.6% ($p<0.001$).

Women who chose LNG were more likely to quick start ($p=0.02$), or be continuing contraception already used ($p<0.001$).

Overall, those choosing UPA were more likely to use condoms ($p<0.001$) but were no more likely to decline ongoing contraception ($p=0.13$).

Conclusions—There was a significant increase in women using UPA for EC compared with our last study, particularly among those wishing to use condoms for continuing contraception. Women choosing LNG were more likely to be quick starting pills or continue current hormonal contraception. Detailed attention to continuing contraception following EC may be an important factor in the prevention of unwanted pregnancy.

Keywords

Emergency contraception; ongoing contraception; quick starting

Introduction

In a previous study, we examined the effect of the introduction of new emergency contraception (EC) guidance from the UK Faculty of Sexual & Reproductive Healthcare (FSRH) in Liverpool & Knowsley, UK.¹ The guidance was introduced in 2011 and recommended that all women requesting EC have their individual needs assessed and be informed of the available methods, efficacy, adverse effects, interactions, eligibility and additional contraception.² The more costly ulipristal acetate (UPA) has been shown to be active for longer during the days of the cycle when pregnancy risk is highest - around the time of the luteinising hormone surge.³ This finding backs up the superior efficacy seen in the meta-analysis of clinical studies.⁴

Previously, we studied two three-month periods of EC requests immediately prior to and following the adoption of the new FSRH guidance. The use of levonorgestrel (LNG) fell from 93% of EC issued to 76%. The use of UPA rose from 3.0% to 18.7% and the use of the copper intrauterine device (Cu-IUD) remained about the same. We also found that in some cases only LNG was offered and that in a large percentage of these, such action was appropriate. We postulated that if offered all three methods, many women would opt for LNG because they were familiar with it and wished to quick start or continue their current hormonal method of contraception, with a shorter period of need for additional condom use. Quick starting refers to starting hormonal contraception on the same day or the day after taking oral EC rather than waiting until the next menstruation. This is recommended by FSRH as oral EC does not work prospectively and further intercourse in the same cycle has been associated with a higher risk of pregnancy.⁵ Current UK guidance suggest that following quick starting, extra contraceptive precautions should be taken for seven days longer after using UPA than after LNG.⁶

We suggested that the situation be studied again after a year to see whether greater staff familiarity with the FSRH guidance or greater patient familiarity with UPA resulted in a different pattern of use.

The present study assessed what happened to UPA use over 12 months and whether the choice of intended method of contraception following EC varied with the choice of oral EC type (LNG vs UPA). Our study questions were, firstly, do choices offered for EC change with time after full choice training was implemented? Secondly do more women choose UPA when they plan to either continue using condoms for ongoing contraception or decline any ongoing contraceptive method? Thirdly, do more women choosing LNG either start ongoing contraception by 'quick starting' or continue with their current hormonal method?

Our service has been described previously.¹ In brief, a population total of about 600 000 is served in a multiple-site service, with over 25 clinical delivery sites. The majority of this delivery, including EC provision, is undertaken by registered practitioners with a nursing or midwifery background, only a few of whom fit Cu-IUDs. Specialist medical practitioners are available for advice but are not present at every site; although this barrier could affect the provision of Cu-IUD fitting, processes for rapid referral are available.

Methods

We retrospectively studied all EC episodes from 1st April 2012 to 31st March 2013 by interrogating Excelicare, our electronic patient record (EPR) system. We counted the total numbers of EC episodes and broke these down into quarterly time periods. Then, among women offered all three methods of EC we noted the eventual method chosen by the woman. Finally, again among women offered all three methods of EC, their decisions regarding ongoing contraception were determined among those choosing LNG and those choosing UPA. They were grouped into seven categories: continuing current hormonal contraception, quick starting, starting hormonal contraception with next menstrual period, using condoms as a sole method, 'other method' (for example going to see GP to discuss ongoing methods, continuing with diaphragm use); postcoital Cu-IUD fitting; declining contraception altogether. Some women were not able to access a Cu-IUD at their initial visit despite this being their first choice. They have been included in one of the oral methods as they were issued LNG or UPA pending attendance at another site. We defined continuing current hormonal method as someone who was within a week of her hormonal contraception no longer being effective according to current national recommendations. This meant we use the following cutoff points:

Within 14 days of her last active combined hormonal contraceptive dose, or

Within seven days of her last progestogen-only oral contraceptive pill or implant removal, or

Less than 15 weeks since the last dose of depot medroxyprogesterone acetate.

There is a small number of 'duplicates' due to the way in which the EPR interprets a request. They did not affect the overall outcome of the analysis.

Statistical analysis was undertaken with the StatXact software (Cytel, Cambridge MA, USA). For comparison of method of subsequent contraception or no contraception between those choosing UPA or LNG, and change of usage with time, we used Fisher's Exact Test.

Results

In the 12 calendar months, April 2012 to March 2013, there were 6110 episodes of EC. About 60% of episodes overall were undertaken at a clinical site where there was no Cu-IUD fitter present. Most of these were accounted for by the approximately 50% of episodes seen at a city-centre service at which no practical procedures are performed but which is 10 minutes' walk from a larger clinical site where all procedures are available. Doctors saw 13% of women, compared with 8% in our previous study. In 4228 (69.2%) consultations LNG was issued, in 1589 (26.0%) UPA, and in 293 (4.8%) the episode resulted in the fitting of a Cu-IUD. There is a quarterly decline in the use of LNG, with a suggestion of plateauing out by the last quarter, and a significant increase in the use of UPA between the first quarter and the other three ($p < 0.001$). The rate of use of the Cu-IUD remained more-or-less static (Table 1).

Table 2 shows the documented methods of EC offered, by quarters. The figures for offering all three methods rose slightly in the last three quarters, reaching 866 (54.2% of all offers) by the last. Offers of five other combinations of methods remained approximately static, although in four (LNG & UPA, UPA & IUD, IUD alone and UPA alone) the numbers were too small to draw firm conclusions so they have been combined into one category. In 409 records (6.7% of total EC episodes), no offered methods were documented.

Table 3 gives the choice of EC method in women who were offered all three options. We saw an increase in the choice of UPA from 229 (39.3%) to 421 (48.6%), and a corresponding decrease in the choice of LNG from 336 (57.6%) to 423 (48.8%). Most of these changes happened after the first three months. The increase in UPA use from the first quarter to the next three quarters was highly statistically significant ($p < 0.001$).

Table 4 shows the ongoing contraception methods planned by women who chose UPA and LNG after being given full choice. Women who chose LNG were more likely to quick start ($p = 0.02$) or be continuing contraception already used ($p < 0.001$) than women who chose UPA. For either quick starting or continuing current hormonal method considered together, women choosing LNG were more likely to do this than those choosing UPA ($p < 0.001$). Among all women, those choosing UPA were more likely to use condoms ($p < 0.001$) but were no more likely to decline ongoing contraception ($p = 0.23$).

Of 2926 women offered full choice and taking either LNG or UPA, 1818 women wished to use ongoing hormonal contraception of whom 1627 (89.5%) elected to quick start or continue and 191 (10.5%) chose to wait until their next period. Table 5 shows the intended methods of contraception chosen by women who wished to start with the next menstrual period.

Discussion

This study shows how EC is offered and used in a large, open access service in the UK. One of its strengths is that it reflects a 'real world' scenario. Since our previous report we have seen an increase in the issue of UPA from just over 18% to 26% in a year (April 2012 to March 2013). In women offered all three methods of EC, the percentage choosing UPA rose from just under 40% to nearly 50%. While UPA may have the benefit of increased contraceptive efficacy,^{3,4} LNG remains the most frequently-issued method of EC overall (69.2% vs 26.0%). However the percentage using LNG is only slightly higher than that taking UPA (51.3% vs 46.2%) in women offered all three methods of EC, and by the last quarter, the proportions were nearly the same (48.6% UPA versus 48.8% LNG). The accuracy of our data is dependent upon completeness of documentation in the EPR, particularly in the part of the record where choices given to the woman are documented. Overall we have documented evidence that at least 90.5% of women were offered LNG, 66.9% the IUD and 53.6% UPA. It is possible that the percentages were higher as 6.7% had no choices recorded in the tick boxes, which are not mandatory. However our previous study showed that amongst those women only offered LNG, nearly half (47.5%) had clear reasons for this limited choice and 15% did not have clear records. As fewer women, in this study, were offered only LNG (23% versus 33% previously) or had no choice recorded, it suggests that dissemination of previous results has improved both record keeping and offering of choice. The availability of Cu-IUD fitting at the time of request could also be a factor in a small number of cases. Women referred for fitting at an associated site could potentially default. Recognizing this, the clinician offers oral EC at the initial visit. This affected our results because provision of an oral method (either LNG or UPA) where the woman might have opted for an immediate Cu-IUD fit overstated desired oral EC and women attending who have a Cu-IUD fitted will have been counted twice. Among women given full choice and wanting a Cu-IUD but not being able to have it fitted at the time, there were more choosing UPA (1.4%) than LNG (0.5%). However, these are small figures.

Our study supports our previous postulation that greater familiarity with UPA by both women and clinicians would affect patient choice. The use of UPA has increased significantly, but this change was mostly seen after the first three months, corresponding to the time soon after the training occurred. Our training emphasises that choice of EC should only be restricted by medical eligibility as recommended by FSRH guidance which states:

'Health professionals should discuss individual need for ... (EC) and inform women about the different methods with regard to efficacy, adverse effects, interactions, medical eligibility and need for individual contraceptive precautions.'

We do not recommend attempting to quantify the degree of pregnancy risk based on calculated day of the cycle as the evidence does not support this^{7,8,9,10}.

Our results endorse our previous conclusion that introduction of full availability of EC methods does not lead to a wholesale adoption of UPA and our belief that in our service, clinical staff only restrict choice where there are genuine medical eligibility issues. However we acknowledge that, without perfect record keeping, not achievable in the real world, and

manually checking all records where full choice was not given it is not possible to prove this.

We were keen to understand better the contraceptive milieu around choice of UPA versus LNG. We confirmed our hypothesis that in our service, among women offered all three methods and choosing an oral method, UPA is chosen in preference to LNG by women who then continue contraception by means of condom use, but refuted that the same happens in those who declined the offer of ongoing contraception. Another hypothesis was that for both quick starting or continuing their previous hormonal contraception, women choosing LNG were more likely to do either than those choosing UPA. The results support our hypothesis.

Glazier has been critical of the ‘unlinking’ of EC to continuing contraception by making EC more widely available to women by services in which further contraceptive provision is not undertaken.¹¹ Wider availability of EC increases its usage but there has, to date, been no effect seen upon rates of unintended pregnancy.^{12, 13} A recent Cochrane update discusses the high risk of pregnancy observed in women who have additional episodes of sex in the same cycle as that when EC was issued.⁵

An overwhelming majority of women in our service choose to quick start a hormonal contraception method. In both those who chose either LNG or UPA very small numbers of women wished to wait until their next period to commence hormonal contraception. Our staff training emphasizes the need to be non-directive about quick starting, preferring to offer choice. Women themselves clearly choose to quick start if commencing or to continue hormonal contraception if already used. We suggest that if services fail to offer quick start, then their usage of UPA may increase as the difference in duration of need for extra precautions between LNG and UPA will disappear. Cameron and colleagues discuss the recommendation that there is a theoretical risk that UPA will interfere with the progestogen moiety in hormonal contraception. There appears to be no difference between placebo and UPA on chance of ovulation once COC is started.¹⁴ This is early work but nevertheless interesting and may affect future clinical guidance.

It has been asserted recently that UPA is more cost-effective than LNG.^{15,16} However, this result obtains only in models, not in the real world. At a population level, the impact of EC has been disappointing, and Trussell cautions against the ‘overselling’ of EC oral agents to reduce unintended pregnancy and abortion rates overall or to be cost-effective¹⁷, suggesting that the emphasis should be placed upon the efficacy for the individual where the different effectiveness of the various methods can affect outcome.

In the end it is for the woman to make an informed choice as to the method of EC she chooses and many factors may come into play.

Conclusions

There was a significant increase in women using UPA for EC compared with our last study. This was particularly so among those wishing to use the condom for continuing contraception. Women choosing LNG were more likely to be quick starting hormonal contraception or continuing a hormonal method. We agree with the view of others who

suggest that a detailed attention to continuing contraception following EC may be one factor in the prevention of unwanted pregnancy at an individual level.

It is possible that currently women chose LNG over UPA as the length of time for the use of extra contraceptive precautions is shorter. If recent work is further supported, and such usage is found to be unnecessary, the provision of UPA might rise. Also, its use may increase in services which do not use quick starting. The issue should be kept under review.

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Key message points

- A year following the introduction of new FSRH guidance, more women continue to be offered all three available methods of emergency contraception
- Many women continue to choose levonorgestrel (LNG) when offered full choice
- Those who choose UPA more often continue contraception with condoms and those who choose LNG mostly quick start hormonal contraception

Table 1

EC use by quarters from April 2012 to March 2013

Type of EC	April to June	July to September	October to December	January to March	Total
Levonorgestrel	1099 (75.3%)	1079 (69.9%)	1016 (67.3%)	1034 (64.7%)	4228 (69.2%)
Ulipristal acetate	279 (19.1%)	401 (26%)	427 (28.3%)	482 (30.2%)	1589 (26.0%)
Cu-IUD	82 (5.6%)	63 (4.1%)	66 (4.4%)	82 (5.1%)	293 (4.8%)
Total	1460	1543	1509	1598	6110

Table 2

Documented methods of EC offered

Types of EC	April to June	July to September	October to December	January to March	Total
LNG, UPA, Cu- IUD	583 (39.9%)	734 (47.6%)	817 (54.1%)	866 (54.2%)	3000 (49.1%)
LNG	386 (26.4%)	373 (24.2%)	318 (21.1%)	337 (21.1%)	1414 (23.1%)
LNG, Cu- IUD	302 (20.7%)	263 (17.0%)	202 (13.4%)	183 (11.5%)	950 (15.5%)
Other combinations	73 (5.0%)	78 (5.1%)	81 (5.4%)	105 (6.6%)	337 (5.5%)
Not documented	116 (7.9%)	95 (6.2%)	91 (6.0%)	107 (6.7%)	409 (6.7%)
Total	1460	1543	1509	1598	6110

Note: On the electronic patient records there is a tick box which asks what methods of EC have been offered, which is how these data are collated. However this section is not mandatory and relies on clinician fully completing all sections of the record. It is usually possible to get these data by reading free text sections; however, notes were not checked for this missing information.

Table 3

Choice of EC method in women who were offered all three methods of EC

Type of EC chosen	April to June	July to September	October to December	January to March	Total
UPA	229 (39.3%)	355 (48.4%)	382 (46.8%)	421 (48.6%)	1387 (46.2%)
LNG	336 (57.6%)	365 (49.7%)	415 (50.8%)	423 (48.8%)	1539 (51.3%)
Cu-IUD	18 (3.1%)	14 (1.9%)	20 (2.4%)	22 (2.5%)	74 (2.5%)
Total	583	734	817	866	3000

Table 4

Ongoing contraception methods in women who chose LNG or UPA after being given choice of all three EC methods

Contraceptive method after EC pill	LNG group	UPA group
Quick starting	692 (45.0%)	564 (40.7%)
Condoms	397 (25.8%)	534 (38.5%)
Continuing hormonal contraception	285 (18.5%)	86 (6.2%)
Starting hormonal contraception with next period	80 (5.2%)	111 (8.0%)
Declined ongoing contraception	49 (3.2%)	56 (4.0%)
Subsequent emergency Cu-IUD fitting	7 (0.5%)	20 (1.4%)
Other method	7 (0.5%)	3 (0.2%)
Duplicate patient(not allocated to a particular group)	22 (1.4%)	13 (0.9%)
Total	1539	1387

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Table 5

Intended method of contraception chosen by women who were issued LNG or UPA after full choice of EC, choosing to start with their next period

Method	LNG group	UPA group
COC	56	71
POP	13	25
CTP	1	4
SDI	6 α	5 γ
IUS	4 β	4 β
DMPA	0	2
Total	80	111

α 3 women declined fitting at time of EC, although in all cases it could have been fitted and 3 were seen in a service which does not do procedures.

β All used condoms in the interim

γ All women seen in a service which does not do procedures. All bridged with condoms

Legend

COC: Combined oral contraceptive pill

POP: Progestogen only pill

CTP: Combined transdermal patch

SDI: Subdermal implant

IUS: Intrauterine system

DMPA: depot medroxyprogesterone acetate