

Women's satisfaction with and ongoing use of hormonal long acting methods compared to the oral contraceptive pill: findings from an Australian general practice cluster randomised trial (ACCORD).

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Conflicts of interest

KIB attended one international advisory board meeting for Bayer Australia for which no personal fees were retained. DM has received research funding and sponsorship to attend conferences and has been involved in training and education activities and advisory boards outside this submitted work related to Bayer Australia and Merck Sharp & Dohme Corp (MSD); KM has received sponsorship from Bayer Australia and New Zealand to attend an educational event on behalf of Family Planning Victoria. Family Planning Victoria receive funding for educational courses and training from Bayer Australia and New Zealand and MSD Australia. JFP has received research funding and support from CooperSurgical, Bayer, and Merck and serves on Advisory Boards for CooperSurgical and Bayer Healthcare Pharmaceuticals. The remaining authors report no conflict of interest.

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Women's satisfaction with and ongoing use of hormonal long acting methods compared to the oral contraceptive pill: findings from an Australian general practice cluster randomised trial (ACCORd).

Short running title: Hormonal contraception continuation and satisfaction

Key words: Contraceptive Methods, Long-Acting Reversible Contraception, Patient Satisfaction, Contraception/adverse effects

Abstract: 250 words

Background

The Australian Contraceptive ChOice pRoject (ACCORD) aimed to assess the impact of a complex general practice intervention on the uptake of long-acting reversible contraceptives (LARC).

Aims

Using survey data from enrolled women, we aimed to compare the ongoing use and satisfaction of women who chose one of the hormonal LARC methods including the levonogestrel intrauterine system (LNG-IUS) or etonogestrel implant compared to the oral contraceptive pill (OCP).

Materials and methods

We used the data from participants' baseline, 6 and 12-month surveys to identify new users of implants, LNG-IUS or OCP. We included demographic information, ongoing use of the contraceptive method, reasons for dissatisfaction and discontinuation and experience of side-effects. Proportions were compared using chi square tests.

Results

Of the 740 women enrolled in ACCORD, 176 started using a hormonal LARC or OCP in the study's first six months with 76 using the IUS (43%), 60 the implant (34%) and 40 (23%) the OCP. Twelve-month continuation rates for the LNG-IUS, implant and OCP were 93%, 83% and 65% respectively ($P < 0.001$). Satisfaction was highest amongst the LNG-IUS users; 86% were very/somewhat satisfied compared to 75% of implant users and 61% of OCP users ($P < 0.001$).

Main reasons for method dissatisfaction were irregular bleeding and mood changes which were similar for all methods.

Conclusions

This study provides further evidence that hormonal LARC methods have higher continuation and satisfaction rates compared to the OCP with similar side-effects. Since hormonal LARC methods have the highest contraceptive efficacy, these should be offered first-line to women.

Introduction

Women's satisfaction with their contraceptive method is a crucial factor in ongoing use and the prevention of unintended pregnancies. One of the best documented factors influencing satisfaction with and continuing use of a method is the type and duration of side-effects.¹⁻³ In recent studies, the long acting reversible methods of contraception (LARC) – including the levonorgestrel intrauterine system (LNG-IUS), copper intrauterine devices (IUDs) and implants have been found to have higher continuation rates than the oral contraceptive pill (OCP).^{4,5} In both the Contraceptive CHOICE cohort study in the US⁶ and a randomised controlled trial of women willing to try a LARC method,⁷ women who chose a LARC method experienced fewer side-effects, greater satisfaction and consequently higher continuation rates at 12 months compared to all other reversible hormonal methods.⁴ In the CHOICE studies, higher satisfaction rates, together with higher continuation rates and higher efficacy, resulted in significantly fewer unintended pregnancies at 2 and 3 years of follow-up.⁸

Despite this evidence, the combined oral contraceptive pill (OCP) remains the most commonly used hormonal method in countries such as the US, Australia and the UK.⁹⁻¹¹ In Australia, most women consult their general practitioner (GP) for contraceptive advice; and the OCP remains the focus of over two thirds of contraceptive consultations.¹² This is reflected in the results of a national survey of women aged 16-49 years conducted in 2012-2013 which reported 33% of women using the OCP compared to 11% using LARC methods (6.1% for LNG-IUS and IUDs

and 4.9% for implants).⁹ While some recent qualitative studies have documented the experience of implant users, little is known about how satisfaction and continuation rates compare between the LARC and OCP users in the general practice setting.

The Australian Contraceptive Choice project (ACCORD), adapted from the US Contraceptive CHOICE Project, aimed to evaluate whether a complex intervention involving education of general practitioners and rapid referral pathways to facilitate LARC insertion resulted in increased LARC uptake.^{13,14} Using data from women's baseline, six month and 12 month surveys, this paper reports uptake and satisfaction among women who chose to use the OCP, or one of the hormonal LARC methods- the implant or LNG-IUS.

Methods

Our sample was derived from the ACCORD project and study methods are described elsewhere.¹³ Participants were women attending general practices in metropolitan Melbourne. They were eligible to participate if they were aged between 16 and 45 years, had been sexually active with a male partner in the previous six months or anticipated sexual activity in the subsequent six months, had not undergone a tubal ligation or hysterectomy, had partner(s) who had not undergone a vasectomy, were not pregnant or had no desire to become pregnant in the next year, spoke proficient English, and were interested in discussing contraception or in starting a new, reversible contraceptive method.

Upon enrolment, eligible women completed a telephone baseline questionnaire including demographic information and questions related to contraceptive utilisation, and satisfaction with their contraceptive method. Women then completed an online survey at six and 12 months following enrolment which included questions about their contraceptive use, levels of satisfaction and reasons for dissatisfaction.

We used data recorded in the women's six month survey to identify women who reported starting a new method of contraception since the commencement of the study and extracted data

from the six month and 12 month surveys on their levels of satisfaction with that method. Counts and proportions were used to summarise the characteristics of participants in the study and satisfaction with their current method. Those who discontinued use were regarded as being dissatisfied as no woman reported that she ceased usage of her contraceptive method to conceive. Chi-square tests were used to assess associations between pairs of categorical variables.

The ACCORd study was approved by the Monash University Human Research Ethics Committee: CF 14/3990-2014002066 and CF 16/188-2016000080, and conformed to the CONSORT guidelines.¹⁵

Results

There were 740 participants in ACCORd (307 intervention; 433 control). Between the time of enrolment and the six-month survey, 176 women reported commencing use of a long-acting hormonal method or the OCP. Of these, 76 (43%) reported commencing use of the LNG-IUS 60 (34%) reported commencing use of an implant, and 40 (23%) reported starting the OCP. The median number of weeks from enrollment to commencement of a new method was 8 for IUS, 5 for implant and 14 for OCP. Figure 1 presents a study flow chart for participant numbers in the intervention and control arms and uptake of hormonal contraceptive options.

Characteristics of the women using hormonal LARCs

The characteristics of women using the methods is reported in Table 1. There were no statistically significant associations between choice of method and the characteristics age group ($P=0.12$), parity ($P = 0.12$), education ($P=0.71$) and marital status ($P=0.90$). Higher proportions

of women who started an IUS or implant compared to the OCP were from the intervention arm of the trial ($P < 0.001$).

Discontinuation and reasons for discontinuation at 6 month survey

When surveyed six months after enrolment, 16% (29/176) had discontinued use of their method (Table 2). Discontinuation rates were highest among those using the OCP (14/76; 35%) compared with using the implant (10/60; 17%) and the LNG-IUS (5/76; 7%, $p < 0.0001$). When OCP users were asked about why they had stopped using the method, 64% (9/14) of women did not give a reason but of those that answered, the most common reason was that they did not like how it made them feel. Irregular, frequent, or heavy bleeding was reported by half of the implant users who discontinued use. The five LNG-IUS users who discontinued gave a range of reasons for stopping the method including bleeding, cramping and expulsion, as well as not liking the way it made them feel.

Satisfaction at 6 months

Of all the hormonal contraceptives, women were more likely to be very satisfied with the LNG-IUS followed by the implant (Table 2) ($P < 0.001$). Under a quarter (18%; 7/40) of OCP users were very satisfied at six months. The reasons reported by women for not being totally satisfied are documented in Table 3.

Discontinuation and reasons for discontinuation at 12 month survey

By 12 months, survey data was available for 91% women (160/176) (Table 2). Of these, 93% (64/69) were still using the LNG-IUS, 73% (40/55) were still using the implant and 58% (21/36) continued to use the OCP ($P < 0.001$). Similar main reasons for discontinuation were given by implant and OCP users: dislike of the way it made them feel, and heavy bleeding. Although the loss to follow-up was minor, among women who did not complete the twelve month survey the level of discontinuation/dissatisfaction at 6 months reflected those who did complete at 12 months.

Satisfaction at 12 months

Users of the LNG-IUS remained the most satisfied at 12 months (Table 2) with 62% (43/69) reporting being very satisfied. Compared to the LNG-IUS, rates of “very satisfied” fell to 31% (17/55) amongst implant users and 25% (9/36) amongst COC users ($P < 0.001$). Reasons for dissatisfaction were similar for all methods (Table 4)

Discussion

In this study we found that women who commenced a new method of contraception were most satisfied with the LNG-IUS compared with the implant or the OCP. Satisfaction rates for the implant and OCP were similar at six months; however, one quarter of women had discontinued pill use by this time. These findings are consistent with international studies that report greater satisfaction with the hormonal LARC methods over OCP.¹⁶ The continuation rates at 12 months for the LNG-IUS, implant and COC in the CHOICE study followed a similar pattern; 88% for the LNG-IUS, 83% for the implant and 55% for the OCP.⁴

While reasons for discontinuation varied between methods, one-third of participants gave no reason. It is not uncommon that women’s motives for stopping a method may not be captured in medical language.³ Consistent with other studies, abnormal bleeding patterns and hormonal side-effects were the most common issues cited by OCP and implant users.^{5,17} Free text comments, allowing women to report their reasons for dissatisfaction, indicated that all hormonal contraception method shared similar side-effects, including irregular bleeding and effects on mood. Complaints regarding acne were more common among the LNG-IUS and implant users, and complaints of weight gain were more common in implant and OCP users. Overall, women were more likely to persist with the hormonal LARC methods compared to the pill. This has important impacts for unintended pregnancy given that half occur when no contraception is being used and another 40% where the method is not used consistently.¹⁸

Our findings are important in the context of numerous studies indicating ongoing provider and patient barriers to LARC initiation.¹⁹ The “first line” providers in the delivery of contraception to women in Australia are general practitioners whose views and experience can influence the

advice they give to potential users, the contraceptive methods they deliver, and the type of contraception selected by patients.^{20 21} In the Australian Study of Contraceptive Use, Pregnancy Intentions and Decisions (CUPID), 158 participants commented on a contraceptive consultation they had in primary care.²² Many believed they were offered limited choices because of their age, many reported that their GPs focused only on the OCP, and many felt that their GPs did not give them information about the potential side-effects of the different methods. If advice and comprehensive counselling about possible side-effects of LARC is provided at method initiation, studies indicate that uptake, satisfaction and continuation of LARC methods can be enhanced.

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Strengths and limitations

This is the first study to focus on the satisfaction with and rates of continuation of hormonal contraceptive methods in the primary care setting. It demonstrates the value of general practitioners emphasising the importance of efficacy and duration of methods given that similar side-effects for OCP and LARC methods are experienced. Whilst we captured the reasons for dissatisfaction, we did not uncover the drivers of satisfaction. The baseline survey was undertaken after enrolment but many of the questionnaires were completed by participants after the initial contraceptive consultation with the GP, which may have affected, either positively or negatively a woman's level of satisfaction with the new method they commenced.

Findings from this study provide further evidence of the positive impacts of promoting use of hormonal LARC methods, which have similar side-effects to the OCP but significantly higher continuation rates. Since hormonal LARC methods have higher contraceptive efficacy, they should be the first-line contraceptive methods offered to patients.

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Table 1: Demographics of women who started each method

	Method			P-value*
	LNG-IUS	Implant	OCP	
	n (%)	n (%)	n (%)	
<u>Age group</u>				0.12
16 to 24	27 (36)	23 (38)	17 (43)	
25 to 34	32 (42)	30 (50)	12 (30)	
35 to 45	17 (22)	7 (12)	11 (28)	
<u>Parity</u>				0.12
0	54 (71)	47 (78)	25 (63)	
1	2 (3)	6 (10)	5 (13)	
2	16 (21)	6 (10)	8 (20)	
3 or more	4 (5)	1 (2)	2 (5)	
<u>Education</u>				0.71
≤ 12 years	27 (36)	21 (35)	17 (43)	
> 12 years	49 (65)	39 (65)	23 (57)	
<u>Marital</u>				0.90

status				
Married/de	29 (38)	24 (40)	17 (43)	
facto				
Single	47 (62)	36 (60)	23 (57)	
Study arm				<0.001
Interventio	51 (67)	22 (37)	13 (33)	
n				
Control	25 (33)	38 (63)	27 (67)	

* P-value testing equality of distribution of characteristics across the three methods

Table 2: Discontinuation of method and satisfaction with current method among women who started hormonal contraception between the start of the study and 6, or 12, month questionnaire (women with available data only)

	6 months n (%)				12 months n (%)			
	LNG-IUS	Implant	OCP	P-value	LNG-IUS	Implant	OCP	P-Value
Number of women who started method within 6 months and who had data available at 6 months	76	60	40					
Number of women who started method within 6 months and who had data available at 12 months					69	55	36	
Discontinued	5 (7)	10 (17)	14 (35)	<0.0001*	5 (7)	15 (27)	15 (42)	<0.001*
Not satisfied	2 (3)	5 (8)	2 (5)	<0.001#	2 (3)	7 (13)	3 (8)	<0.001#
Somewhat	18(24)	24 (40)	17 (43)		19 (28)	16 (29)	9 (25)	

satisfied

Very satisfied 47 (62) 21 (35) 7 (18) 43 (62) 17 (31) 9 (25)

Missing 4 (5)

* P-value testing equality of discontinuation proportions across the three methods

P-value testing equal distributions of satisfaction levels across the three methods. Note Discontinued are combined with Not satisfied.

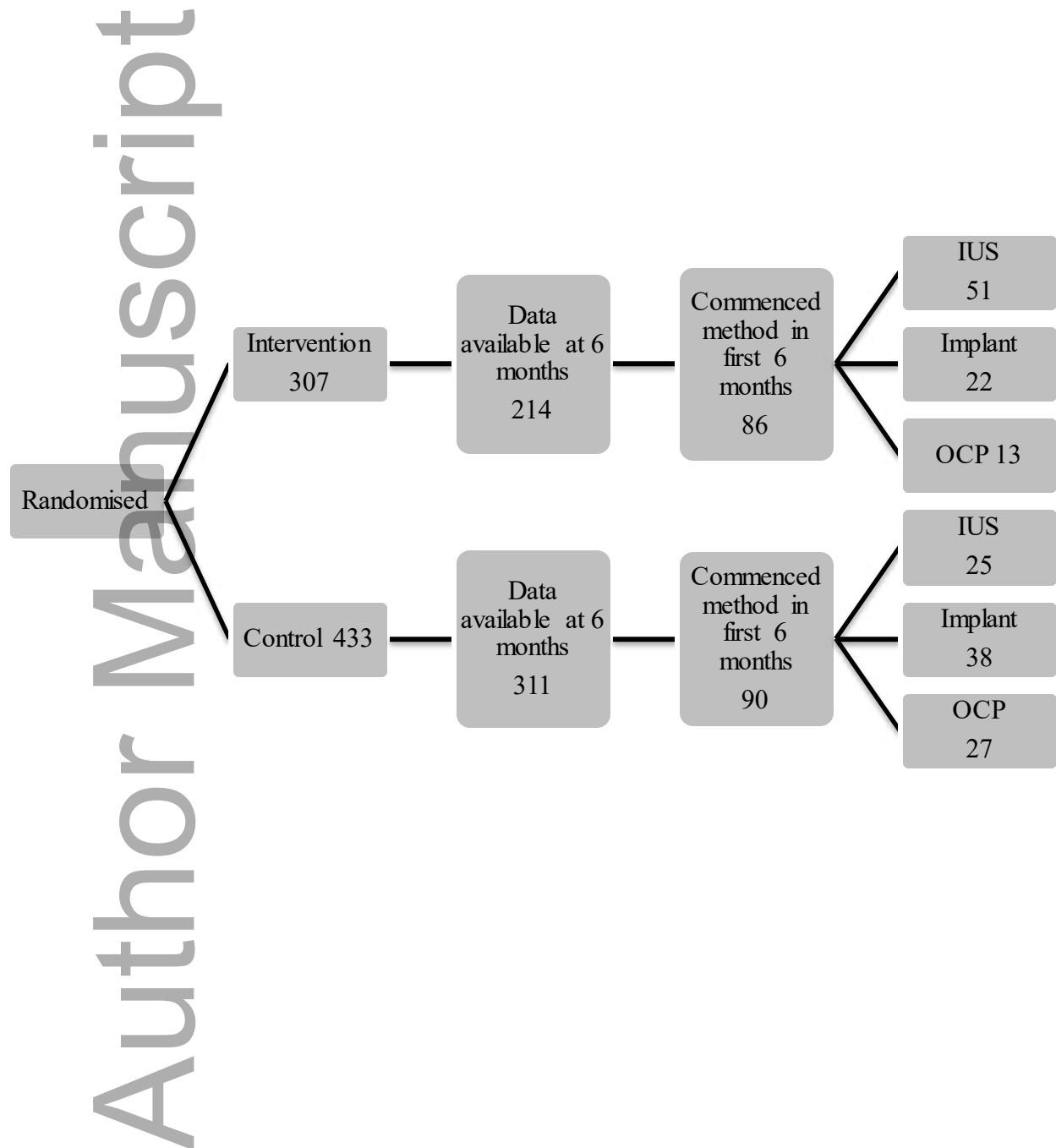
Table 3: Reasons for not being very satisfied with contraceptive method (6 month survey)

LNG-IUS (n=20)	Implant (n=27)	OCP (n=18)
Acne (1) Irregular or heavy bleeding (10), Mood changes(4), Pain (5) Impact on sexual function (2) Bloating (2) Weight gain (1) Other (4) B	Acne (4) Irregular or heavy bleeding (12) Mood changes (4) Insertion site issues (2) Weight gain/difficulty losing weight (6) Impact on sexual function (1) Headaches (1) Other (3) ,I	Forgetting to take it Irregular bleeding (6) Breast tenderness (3) Headaches (2) Weight gain/difficulty losing weight (3) Mood changes (6) Remembering to take it (3) Other (2)

Table 4: Reasons for not being very satisfied with the method (12 month survey)

LNG-IUS (n=20)	Implant (n=23)	OCP (n=12)
Acne(9) (3) Post-coital bleeding (1) Irregular bleeding (3) Bloating (1) Mood changes (7) Dyspareunia (1) Pain (1) Anxiety (1) Wanted amenorrhoea (1)	Irregular or prolonged bleeding (16) Hair loss (1) Pain/discomfort at insertion site (1) Acne (2) weight gain (1) Mood changes (1)	Irregular Bleeding (6) Breast tenderness (2) Cramping during period (1) Mood changes (2) Weight gain (1) Having to remember to take it (3)

Figure 1: Flow chart of study participants and hormonal method choice





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