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Long-Acting Reversible Contraceptive Methods, Same-Day Initiation and Early Removal

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Abstract

Long-Acting Reversible Contraceptive Methods, Same-Day Initiation and Early Removal

Objective: The study was conducted to identify the early removal rate of Long-Acting Reversible Contraceptive (LARC) methods and factors associated with early removal.

Study Design: A non-experimental descriptive design based upon retrospective chart review of electronic medical records (EMR) was used. There was a total of 96 subjects, ages 15-47 years who had a LARC method inserted within a 12-month time period and subsequent removal within 6-months of insertion date. Subjects were grouped according to same-day insertion versus non-same-day insertion.

Results: Seventy percent of study subjects with early removal had their LARC method inserted under a same-day protocol. Most subjects were over 20 years of age, single, and of Hispanic ethnicity. The overall early removal rate for all LARC methods was 5%. Implant was the method most commonly removed followed by the levonorgestrel intrauterine system (IUS). Pain and bleeding were the most commonly cited reasons for removal. Oral contraceptive pills (OCPs) were the most commonly selected birth control method after removal of the LARC.

Conclusion: A strategy to reduce barriers to contraceptive initiation is same-day insertion of the requested LARC method. However, research on LARC methods in conjunction with same-day initiation and continuation rates has not been done. This pilot study demonstrates a low early removal rate for LARC methods and offers support for a same-day initiation protocol.

Sandra Loehner,
May, 2014

Long-Acting Reversible Contraceptive Methods,
Same-Day Initiation and Early Removal

by

Sandra Mary Loehner

A project submitted in partial

fulfillment of the requirement for the degree of

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May, 2014

APPROVED

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INTRODUCTION

Unintended pregnancy, defined as a mistimed, unplanned, or unwanted pregnancy (Centers for Disease Control and Prevention, CDC, 2013) is a growing public health concern. Forty-nine percent of pregnancies each year in the United States are classified as unwanted or mistimed (Trussell, 2007; CDC, 2013). The cost associated with unintended pregnancy is significant with nationwide public expenditures reaching \$11.1 billion in 2006 (Sonfeld, Kost, Benson, Gold & Finer, 2011). Moreover, in 2006, California was among the states spending the most on publicly-funded births, at a rate of \$1.3 billion (Sonfeld et al., 2011).

Adolescent unintended pregnancy is of particular concern. Greater than 80% of adolescent pregnancies are unplanned, accounting for one-fifth of all unintended pregnancies in the United States (American Congress of Obstetricians & Gynecologists, ACOG, 2012). Specific to California, the teen pregnancy rate for ages 15-19 years is 38.4/1000 women, lower than the national average of 41.5/1000 women respectively (Mathews, Sutton, Hamilton, & Ventura, 2010). Government expenditures associated with unintended pregnancies in the Central Valley of California are unknown. However, State teen pregnancy rates, most of which are also assumed to be unplanned, are highest in San Joaquin Valley counties (California Department of Education, 2012).

Along with adolescents, economically disadvantaged women demonstrate some of the greatest unintended pregnancy rates (CDC, 2013; Finer & Zolna, 2011; Guttmacher Institute, 2013). *Healthy People, 2020* has set an agenda of reducing unintended pregnancy due to the national health implications inherent to unplanned births ("*Healthy People, 2020*", 2013). Likewise, the Affordable Care Act (Health and

Human Services, 2013) provides reproductive and family planning services coverage in the hope to reduce unwanted pregnancies.

Despite national attention on the unintended pregnancy rate, research on effective strategies to achieve this goal is minimal (Taylor & James, 2011).

Contraceptive options currently available in the United States are varied and include barrier methods (male/female condoms, diaphragm), combined hormonal contraception (oral contraceptive pills (OCPs), contraceptive patch, vaginal ring), and progestin methods (progestin-only pills, depo-medroxyprogesterone acetate injection (DMPA)). Long-acting reversible contraceptive (LARC) devices which include the intrauterine copper contraceptive (IUD), the levonorgestrel-releasing intrauterine system (IUS) and the etonogestrel contraceptive implant are also among the currently available contraceptive options. These methods are classified as long-acting methods due to the long-term contraceptive efficacy of each: the IUD is effective for 10 years, the IUS is effective for 5 years, and the contraceptive implant is effective for 3 years. However, LARC methods have some of the lowest rates of use among women of reproductive age. Only 8.5% of all women using contraception in 2009 used a LARC method, with 4.5% of women between 15-19 years of age using a LARC device (ACOG, 2012).

Short-acting contraceptive methods such as OCPs, contraceptive patch, vaginal ring, and DMPA are more frequently prescribed, but have greater likelihood of lower continuations rates and higher pregnancy rates than LARC methods. Unintended pregnancy rates were two times greater in women younger than 21 years using short-acting contraceptives as compared to older women using short-acting contraceptive methods (ACOG, 2012). It is reported that nationally, 1 million pregnancies each year

arise from discontinuation or incorrect use of OCPs (Garbers, Meserve, Kottke, Hatcher & Chiasson, 2012). Most women in the United States use contraceptives with adherence requirements. Incorrect or inconsistent use of short-acting contraceptives results in pregnancy rates higher than rates in LARC method users (Peipert et al., 2011).

Cost effectiveness of any contraception, in part, is contingent upon compliance with and continuation of the method. Early discontinuation of LARC methods especially, has a negative impact on expense since higher cost at initiation is not offset by continued use of the method (Mavrenozouli, 2009).

Contraception initiation using the Quick Start method has been researched in terms of contraceptive continuation rates and barriers to starting contraceptives. Quick Start, defined as the immediate, in-clinic start of hormonal methods, has demonstrated at least equal if not greater short-term continuation rates for the chosen birth control method over traditional start (Sunday after next expected menses) option (Lopez, Newmann, Grimes, Nanda & Schulz, 2012; Nelson & Katz, 2007; Westhoff, Heartwell, et al., 2007). Quick-Start initiation is also a strategy to reduce barriers to starting contraception, and was first used for OCPs (Westhoff, Kerns, et al., 2002). Quick start has now been adapted to include other hormonal methods such as contraceptive patch, (Murthy, Creinin, Harwood, & Schreiber, 2005; Lopez et al, 2012); DMPA injection (Nelson & Katz, 2007, Lopez et al. 2012); and the vaginal ring (Lopez et al., 2012).

To date, Quick-Start and LARC methods have not been reported in the literature. However, a similar concept, same-day initiation, is practiced at the study sites. The U.S. Selected Practice Recommendations for Contraceptive Use: 2013 (CDC, 2013)

supports LARC insertion any day of the menstrual cycle as long as it is reasonably certain the woman is not pregnant. Thus far, no research has examined the relationship between LARC methods, same day initiation and continuation rates of the LARC method. Therefore, the purpose of this study is to explore same day insertion of LARC methods and subsequent removal rates within 6 months of original insertion date.

This research study aims to answer the following questions:

1. What is the rate of early LARC removal?
2. Is there an association between mean number of days LARC used and same day insertion?
3. Is there an association between demographic factors (age, body mass index (BMI)) and early removal rates?
4. What are the most common reasons for early LARC removal?
5. What is the most common birth control method chosen after LARC removal?

Theoretical Framework

The conceptual framework for this study is based upon the theory of planned behavior (TPB) (Ajzen, 1991, Ajzen, 1992). The TPB is a model that addresses behavioral action and attitudes involved with decision making while providing a framework for understanding patient motivations in decision making. There are three main assumptions of TPB: perceived behavioral control, behavioral beliefs, and subjective norm. Perceived behavioral control is the perception of ability to perform an action. Behavioral beliefs form the attitude toward a behavior. Subjective norm is the perception of how others will perceive a given action. Intention to act results from the

interplay of TPB's main assumptions and is the immediate antecedent to the actual behavior.

The assumptions found in the TPB model are congruent with the current project. The patient who chooses/acts to have an early removal of a LARC method (not related to physiologic complaints) has a strong sense of control or ability to follow through with making and getting to her appointment for removal, does not feel a strong sense of negative consequence from her family or significant others in removing the method, and either does not have a strong attitude or commitment to effective birth control or minimizes the threat of pregnancy when not using a LARC method. The relationship of all these factors results in the behavior of asking for early removal of her birth control method.

Perhaps better education on pregnancy risk or discussion on the efficacy of the LARC method will be necessary to strengthen the patient's attitude toward not removing the method. Improved understanding of LARC efficacy, in turn, may override subjective norms and behavioral control attitudes so intention to remove the method is dampened and the behavior does not occur. The results of this project, in conjunction with TPB, may offer avenues for further research on patient education options to reduce frequency of early LARC removal.

REVIEW OF LITERATURE

The current study aims to examine early LARC removal rate among women attending two women's health clinics. Additionally, this study aims to identify any demographic characteristics associated with early LARC removal among women undergoing same day insertion of a LARC device. Other areas aim to explore reasons for early LARC removal and choice of birth control after LARC removal.

To date, little research has examined early LARC device removal in conjunction with same day insertion. There is some research that has examined immediate post-partum or post-abortal insertion; however the focus of this project is on early LARC removal in women having same day insertion unrelated to delivery or abortion.

The following review of the literature will focus on research discussing continuation and satisfaction rates of contraception methods which include LARC in the design, as well as continuation studies specific to LARC methods. Research exploring characteristics of users of LARC methods will also be presented.

Continuation/Satisfaction Rates of Contraceptive Methods

Peipert et al. (2011) compared 12-month satisfaction and continuation rates among women using LARC methods (copper IUD, levonorgestrel IUS, contraceptive implant) (n= 2,846; 68%) to women using non-long-acting methods (OCPs, contraceptive patch, vaginal ring, DMPA) (n=1,321; 32%). Demographics for all study participants included an age range between 14-45 years, with a mean age of approximately 25 years (sd=5.7); 47% were African American; 34% had a high school diploma or less; 48% were nulliparous; 66% had a history of unintended pregnancy; and 40% had a history of abortion. Overall, LARC method users were older (p=.001), had a higher parity (p=.001), unintended pregnancy history (p=.001), and were less educated

($p=.004$) than subjects who chose non-long-acting methods. Continuation rates for participants using LARC methods were high ranging from 83-88% dependent upon LARC method used compared to 45% continuation rate for those using OCPs, contraceptive patch, vaginal ring or DMPA.

Moreau, Cleland, and Trussell (2007) explored contraceptive discontinuation in conjunction with method dissatisfaction in a retrospective survey. Women aged 15-44 years ($N=6,724$) living in the United States, completed an 85-minute questionnaire assessing contraceptive methods, dissatisfaction, and reasons for discontinuation. Forty-six percent ($n=2448$) reported discontinuing at least one type of contraception due to method dissatisfaction. Primary reasons included side effects and menstrual changes. Thirty-six percent ($n=145$) of women who had used the IUD reported stopping this method due to dissatisfaction, however specific reason(s) were not presented. Twenty-nine percent ($n=1,637$) of subjects stopped OCPs due to method dissatisfaction which was one of the lowest for all medical methods of contraception. However, the lowest rates of discontinuation due to dissatisfaction were condoms (11.9%), withdrawal, (12.6%) and fertility awareness (14.6%).

Continuation/Satisfaction Rates of LARC Methods

Understanding satisfaction rates, reasons for LARC early removal and side effects of LARC devices has been the impetus of several research studies. Jeffreys and Clark (2012) prospectively followed 131 women from contraceptive implant insertion through point of removal. Twenty-five percent ($n=33$) kept the implant for the full approved duration (36 months). At 1 year post-insertion, 90% ($n=118$) had implants in place with a 53% ($n=69$) retention rate at year 2. Irregular bleeding was the primary

reason for early implant removal. A two-stage procedure was used for device insertion with intensive counseling regarding side effects and ways to manage the most common side effect of irregular bleeding. The second step was the actual appointment for the implant insertion during the first 5 days of the menstrual cycle. Although this study demonstrated high continuation rates for the contraceptive implant, a time delay barrier to insertion was created by a 2-stage insertion process.

Lakha and Glasier (2006) examined medical record data to identify continuation rates for the contraceptive implant among women in the United Kingdom. A combination of medical record data and mailed questionnaire were used for data analysis. Data was available for 277 women. An 89% (N=246) continuation rate was noted at 6 months, 75% (n= 207) at 1 year, 59% (n=163) at 2 years, and 47% (n=130) at 2 years and 9 months. The primary reasons for removal within the first year included unpredictable bleeding pattern, weight gain, and mood changes.

Contraceptive implant continuation rate was also examined in a retrospective chart review of 767 Australian women (Harvey, Seib, & Lucke, 2009) with results similar to Lakha and Glasier (2006). Continuation rates were 94% (n=563) at 6 months, 74% (n=440) at 1 year and 50% (n=364) at 2 years. Bleeding pattern disruption was cited as the primary reason for discontinuation, with over 50% of women offering this as the reason for premature removal.

Alton et al. (2012) focused on IUD/IUS continuation rates and risk factors for IUD/IUS removal in a sample including both adolescents and young women (N= 233). A retrospective, descriptive study design was used to evaluate outcomes after IUD/IUS insertion in patients 21 years of age or younger, spanning an 8-year study time frame.

Median age at insertion was 16 years (range 11-21 years). Thirty percent of subjects (n=71) were nulliparous with 69.9% of subjects (n=164) having a prior pregnancy. Findings suggested participants \leq 18 years of age were 3.5 times more likely to remove or expel their device compared to participants 18-21 years of age ($p < 0.001$). Nulliparous patients were 2.9 times more likely to remove or expel their device compared to multiparous women ($p = 0.001$). a 50% continuation rate was noted among those < 18 years of age (n=34) compared with a 71.5% continuation rate for those between 18-21 years of age (n=117). The highest levels of removal occurred in the first 2 years of use regardless of subject age.

Using a 17-item telephone survey, Dickerson et al. (2013) identified level of satisfaction, side effects, and early removal data for LARC method users (contraceptive implant, IUD, IUS). The sample included 129 women 18 years of age or older for a total of 132 responses (3 women were surveyed twice due to both IUD and implant use during the study period). Black women accounted for 66.7% (n=88) of subjects; 32.6% (n=43) were white. LARC satisfaction was categorized on a Likert scale (very satisfied, rather satisfied, rather dissatisfied, and very dissatisfied). Likert responses were grouped into either satisfied or dissatisfied categories. Early removal rates were defined as follows; contraceptive implant before 34 months (36 month maximum), and IUD 58 months for both the 60 month levonorgesterel IUS and 120 month copper IUD. Fifty-eight percent (n=77) of the sample chose IUDs and 41.7% (n=55) chose the contraceptive implant. Results indicated 72.7% (n=96) were satisfied with their LARC method with 24.2% (n= 32) requesting early removal. Pain and bleeding irregularity were the most common complaints for IUD. However, multivariate analysis did not

demonstrate any correlation to pain, or bleeding and early removal. Depression, though, was a statistically significant reason for removal ($p < .01$). Although there is no consensus regarding a definition for early LARC removal, Dickerson et al. (2013) are the only researchers who have categorized early removal as removal within months of LARC device expiration making comparison to other studies challenging given such a different time-frame definition.

In a qualitative study Hoggart and Newton (2013) explored reasons for early contraceptive implant removal. Twenty participants, aged 16-22 years were interviewed individually using a semi-structured interview guide. Most of the participants reported having their implant removed within a year of insertion. A main theme included reassertion of bodily control influencing contraceptive implant removal and choice of contraceptive method after removal. Secondary side effects included weight gain, mood changes, acne, and pain at insertion site.

Demographic Characteristics Associated with LARC Methods

Xu et al. (2011) examined demographic characteristics of study participants using the IUD (levonorgesterel IUS, copper IUD), reasons for choosing the IUD over other contraceptive methods, and satisfaction with the IUD. The National Survey of Family Growth data (2006, 2008) and a Guttmacher Institute telephone survey (2004) were analyzed. The study size was 3,005 women, aged 18-44 years. Type of contraceptive method being used by the subject at the time of the interview was determined with results indicating 5.2% ($n=156$) of participants were IUD users, while 43.4% ($N= 1,304$) used either OCPs or the contraceptive patch. IUD users had higher family incomes (43.4%), reported some college education (61.7%), were of Hispanic

descent (24.6%), and had private health insurance (59%). IUD users reported the highest proportion of complete satisfaction with this method (82.3%) in comparison to 74.7% complete satisfaction rating by users of other hormonal methods.

Grunloh, Casner, Secura, Peipert and Madden (2013) used phone interview at 3 and 6 months post LARC insertion along with review of clinic LARC removal logs to examine demographic characteristics associated with women removing their LARC method within the first 6 months of use. Sample size consisted of 5, 928 women 14 years of age and older. Logistic regression was used in data analysis. Sixty-one percent of subjects (n= 3,610) had the levonorgestrel IUS, 23% (n=1, 366) the implant, and 16% (n= 952) the copper IUD. Characteristics between 2 subject groups: LARC users > 6 months and LARC user \leq 6 months were compared. Seven percent (n=433) of total subjects had early LARC removal. There was similarity in discontinuation rates for all 3 LARC methods: 7.3% for IUS, 8% for copper IUD, and 6.9% for implant users (sd=.60). Researchers compared demographic characteristics for women continuing their LARC method to subjects who removed their LARC. There were no significant differences in age, education, insurance coverage status, parity, prior unintended pregnancy history, and body mass index (BMI) between the 2 groups. Subjects who were single (adjusted OR 1.26, 95% CI 1.01-1.59), divorced, separated or widowed (adjusted OR 1.62, 95% CI 1.11-2.37) were more likely to discontinue the LARC method by 6 months. Young age (14-19 years) showed no association with early discontinuation (odds ratio = 1.16; CI = .87-1.54). Irregular bleeding was a reason for removal for all 3 LARC methods: IUS, 9.5% (N= 14), copper IUD, 19.2% (N= 10) and implant 53.2% (N= 50). Pain or

cramping complaint was only found in the copper IUD (35%, n=18) and IUS (28%, n=41) subjects.

Research on reasons for LARC removal, continuation rates of LARC methods and demographic characteristics of LARC users all add to the body of knowledge available to clinicians providing this form of contraception. The current research study will build upon what has previously been examined, and offer LARC data on early removal rates and same day initiation.

METHODOLOGY

The following sections discuss the study's methodology. The research design, sample selection, setting, data collection, and data analysis will be addressed.

Research Design

A non-experimental, correlational, descriptive design based upon retrospective chart review of electronic health records (EHR) was conducted after approval by the institutional review board at the University. A retrospective chart review offered important data to assess percentage of early removal rates, percentage of patients having same-day insertion of a LARC method, as well as selected demographic characteristics of the sample subjects.

There is no consensus on a definition for early LARC removal in the literature. Any LARC method removed prior to the life of the device constitutes early removal. Studies in the literature on early LARC removal range from 6 months to greater than 2 years (Alton et al., 2012; Dickerson et al., 2013; Grunloh et al, 2013; Harvey, Seib & Lucke, 2009; Lakha & Glasier, 2006). This study defined early LARC removal as device removal within 6 months of original insertion date which falls within the time frame of other studies.

Sample

Participant Electronic Health Records (EHR) were included in this study if they had a LARC method of birth control inserted at one of the two identified community clinics and were between 12-50 years of age. Exclusion criteria were immediate post-abortal/postpartum LARC insertion or removal of expired LARC device. A de-identified study data set was assembled of all LARC insertions between June 2012 through June

2013 using specific billing codes (see Table 1). This list was then used to identify the total LARC removals within 6 months of insertion. The total number of early removals that were same-day insertions were captured by individual chart review.

Study Setting

The study setting included two community clinics that are part of a non-profit women's health organization. Both of the clinics are located in urban areas with the first clinic located in Santa Clara County, California, and the second located in Fresno County, California. Both clinics are staffed with a comparable clinician mix, see a similar number of patients, and offer a similar range of health care services including; primary care, family planning, women's health, male health services, and prenatal care.

Data Collection

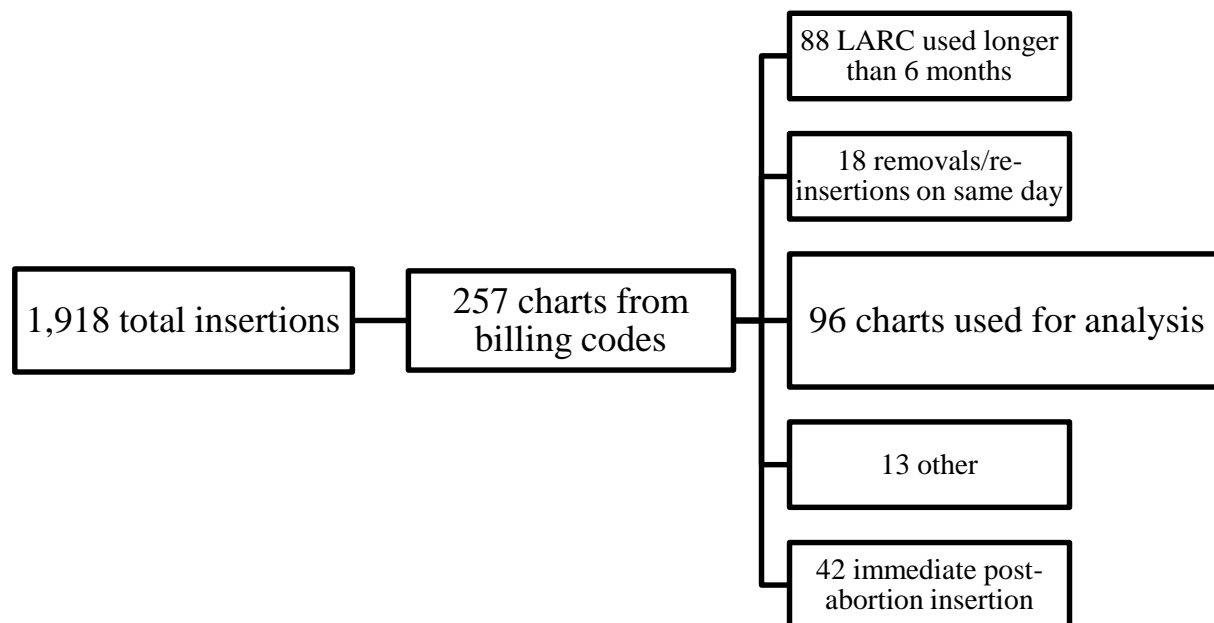
The Information Technology (IT) department of the organization compiled chart numbers for the researcher using the following diagnostic codes (Table 1) to achieve the total number of LARC insertions and early removals during the designated time frame.

Table 1. *LARC Insertion and Removal Codes*

Insertion Code	Explanation
S 30.1	Implant initial evaluation
S 30.2	Implant Follow-up
S 40.1	IUC initial evaluation
S 40.2	IUC follow-up
V 25.5	Implant insertion
V25.11	IUC insertion
V25.22	IUC insertion
Removal Code	
S 30.2	Implant follow-up
V25.43	Implant check or removal
S 40.2	IUC follow-up

A total of 96 subjects met the study parameters and were used in data analysis. There was a total of 1, 918 total LARC insertions from both sites compiled from billing codes. Of those, 257 charts were selected for a removal diagnosis. Some records were omitted because LARC insertion did occur post-abortion when the record was reviewed on-line. One subject was eliminated due to pregnancy as reason for removal; 13 other charts were captured under the billing codes but did not fall under study criteria. See Figure 1 for further information on accounting of study subjects.

Figure 1: Subject Selection



A de-identified dataset was compiled from the EHR of subjects meeting study criteria. Data extracted included a) demographic data; b) reason for removal; c) whether the participant underwent same-day LARC insertion; and d) method of birth control chosen after LARC removal. Standardization of reasons for LARC removal is present in

EHR (see Appendix A). Viewing selected radio buttons determined which reason(s) for removal was extracted.

Demographic characteristics compiled included age, race/ethnicity, marital status, pregnancy history, body mass index, and monthly income. Same-day LARC initiation was determined by assessing whether the study participant received her LARC method on the day first requested without evidence of prior use of LARC method or previous counseling on LARC method. If prior use, prior counseling, or free text clinician comments indicated prior information on LARC method discussed within a clinic setting, the subjects was classified as a non-same day initiation. Contraceptive method chosen after removal was obtained either through indication in the EHR on birth control method at end of visit indicator, type of contraceptive supply provided the day of removal, or through the billing code.

Data Analysis

Descriptive data was analyzed using means, frequencies, and measures of central tendency. Associations were assessed using inferential statistics appropriate to data collected (independent samples *t*-test and ANOVA).

Ethical Considerations

University nursing department IRB approval was granted on the basis of a retrospective chart review, in conjunction with de-identification of participant data. All data were kept secure in a locked file cabinet at the researcher's place of employment. Given the study design, individual informed consent was waived by the IRB. Consent for medical services obtained through the clinic sites was obtained on the date of service.

Organizational approval was obtained via the organization's Chief Medical Officer after review of the study proposal.

Bias

Bias for this study was nominal. A retrospective chart review of EHR minimizes the researcher's ability to distort or manipulate findings in any systematic way. Selection bias was also reduced by including all subjects who met the early removal criteria of the study (excluding post-abortal/ post-partum and device expiration insertion as previously addressed) and not selectively choosing subjects for analysis. Additionally, the early removal subject list was extracted from billing codes by someone other than the researcher, to further reduce the risk for subject selection bias (Melynk & Fineout-Overholt, 2011).

RESULTS

Demographics

Of the 96 eligible participants, 75% (n=67) were single, 48% (n=45) self-identified as Hispanic, and 48% (n=43) reported no current monthly income (range \$0-\$2,688). Mean age of subjects was 24 (sd=6.4) years, with a range of 15 to 47 years. Please see Table 2 for more complete demographic data.

Table 2.

Demographic Data

Participant	N* (%)	Mean (in years)	SD
Age		24	(6.4)
Gravidity			
0	36 (37.5)		
1	24 (25)		
≥2	36 (37.5)		
Parity			
0	49 (51%)		
1	28 (29%)		
≥2	19 (20%)		
Marital Status*			
Single	67 (75%)		
Married	10 (11%)		
Other	12 (13%)		
Race			
Caucasian	24 (25%)		
Hispanic	45 (48%)		
African	4 (4%)		
Asian	3 (3%)		
Other	20 (21%)		
Income*			
\$0/month	43 (48%)		
\$100-	31 (35%)		
\$≥1,000/month	15 (17%)		

*Missing data in respective category

LARC Early Removal Rate

During the study time frame, 1,918 total LARCs were inserted with the IUS most frequently inserted at a rate of 45% (n=880), the implant was the next most requested LARC device at 35% (n=674), with the IUD third, at 20% (n= 364). The first study question was to address the rate of early LARC removal. The early LARC removal rate was 5%. Same day insertion occurred in 70% of study subjects. See Table 3 for the frequency of early LARC removal by type.

Table 3.

Frequency and Percent of Early LARC Removal by Type (N = 96)

LARC Type	<i>n</i>	%
Implant	43	44.2
IUS	33	34.7
IUD	20	21.1

Days LARC Used and Same Day Insertion

The second study question was to determine if there was a correlation between mean number of days LARC was used and same day insertion. An independent samples *t*-test was conducted for this analysis. An independent groups *t*-test indicated no significant difference in the mean number of days LARC was used between same-day LARC insertion (Table 4).

Table 4.

Mean Number of Days Used and Standard Deviation for LARC Insertion (N = 96)

LARC Insertion	<i>n</i>	<i>M</i>	<i>SD</i>
Same-day insertion	67	88.51	54.473
Non-same-day	29	95.21	55.696

Demographics and Early LARC Removal

The third study question was to determine if age or BMI demonstrated an association with early LARC removal. A Pearson correlation was conducted to analyze age and early LARC removal. Correlation results indicated there was no significant relationship between age and the number of days LARC was used; $r(96) = -.174$, $p = .090$, $r^2 = .030$. BMI also demonstrated no significant relationship with number of days LARC was used; $r(96) = -.045$, $p = .662$, $r^2 = .002$.

Reasons for Early LARC Removal

The fourth study question was common reasons for early LARC removal. Pain (30%, n=29) and bleeding (28%, n= 27) were the most often cited reasons in this study. The category of symptoms/side effects accounted for 25% (n=24) (see Table 5) of subjects having early removal. Only if clinicians free texted symptom or side effect detail could specific information be extracted from EHR. Reasons that were found included headache, depression, shortness of breath and partner feels the string. However, these free text complaints accounted for only 1 or 2 subjects per complaint and therefore did not warrant discrete analysis.

Table 5.

Frequency and Percent of Early LARC Removal by Reason (N = 95)*

Reason for Removal	<i>n</i>	%
Pain	29	30.5
Bleeding	27	28.4
Symptoms/Side Effects	24	25.3
Other	7	7.4
Desires pregnancy	4	4.2
Requests other BCM	3	3.2
No longer needs BCM	1	1.1

*Missing data in 1 chart

BCM= birth control method

Additionally, a one-way analysis of variance was conducted to determine the mean difference on the number of days LARC was used and reasons for removal (symptoms / side effects, pain, or bleeding). ANOVA results showed the mean number of days LARC was used and reason for removal was statistically significant, $F(2, 77) = 3.131, p = .049$. Post-hoc LSD test revealed that women who report pain as a reason for removal used LARC significantly less number of days ($M = 71.31, SD = 55.711$) than women who report bleeding as a reason for removal ($M = 103.67, SD = 48.450$). Women who report symptoms or side effects did not significantly differ in the number of days LARC was used ($M = 98.50, SD = 50.988$) between the other two groups.

Contraception after Early Removal

The final study question examined the most common birth control method chosen after early removal. Forty percent ($n=38$) of participants chose OCPs as their post-removal contraceptive. Thirty-eight percent of women chose non-hormonal methods of birth control. Condoms combined with using no method accounted for the second largest number of participants. Only 5% of women chose to continue with a different LARC method after removal of the first device (see Table 6).

Table 6.

Frequency and Percent of Birth Control Method after Removal (N = 95)*

Birth Control Method	<i>n</i>	%
Oral Contraceptive Pills	38	40.0
Condoms	25	26.3
Other/Nothing	11	11.6
Contraceptive Ring	9	9.5
DMPA	4	4.1
Contraceptive Patch	2	2.1
IUS	2	2.1
IUD	2	2.1
Implant	1	1.1

Diaphragm

1

1.1

*Missing data in 1 chart

***DMPA = depo-medroxyprogesterone acetate injection; IUS = levonorgestrel-releasing system
IUD = intrauterine copper contraceptive***

DISCUSSION

The purpose of this pilot study was to explore same day insertion of LARC methods and subsequent removal rates within 6 months of original insertion date. Results will be discussed in relation to previous research and propose areas for future research. Strengths and weaknesses of the study will also be evaluated.

The study found low rates of LARC early removal, (5%), which were lower than rates reported in other research. Grunloh, Casner, Secura, Peipert and Madden (2013) reported an early removal rate at 6 months of use of 7.3% for the IUS, 8.0% for the IUD, and 6.9% for the implant. Jeffreys & Clark (2012) reported a 12-month removal rate of 10%. Peipert et al. (2011) demonstrated a 17% early removal rate in implant users at 12 months, while IUD/IUS users had a 12-16% early removal rate depending upon type of device. Dickerson et al. (2013) reported a 24% early removal rate at 34 months of use. This study in conjunction with other research on LARC continuation rates suggests high rates of retention shortly after insertion with increasing rates of early removal over time. Early removal of LARC methods as a function of same day insertion was specific to this study and was not previously addressed in other research. Although 70% of early removal subjects were classified as same day insertions, an independent group *t*-test indicated no significant difference in mean number of days LARC used and same-day LARC insertion.

Demographic characteristics of age and BMI did not demonstrate any significant correlation to early LARC removal. However, an unexpected finding was the minimal number of teen subjects (21%, n=20) in the study population. Grunloh, Casner, Secura, Peipert and Madden (2013) reported only 16% (n=71) of their subjects were 14-19

years of age in the 6 month LARC early removal group. Participant mean age was similar for this study (24 years) as Peipert et al. (2011) which demonstrated a mean age of 25 years. Mestad et al. (2011) specifically analyzed LARC use in adolescents 14-17 years and women 18-20 years and found a 70% (n=3557) rate of LARC use, however, continuation rates were not analyzed. Further research on rates of LARC use in a teen population, LARC continuation rates in teens, as well as strategies to increase teen utilization of LARC methods may still be needed.

Pain complaint was associated with the shortest time of LARC use, approximately 2 ½ months (M=71.31 days). Bleeding, the second most common reason for removal, demonstrated a one month longer LARC use time (M=103.67 days). Hoggart and Newton (2013) found bleeding irregularities the most common reason for implant removal. Grunloh, Casner, Secura, Peipert and Madden (2013) also found pain or cramping the most common complaint for early removal of IUS/IUD at 62% combined (n= 200), while 53% (n=50) of implant users reported bleeding irregularities as reason for early removal. Dickerson et al. (2013) reported pain complaint most commonly associated with the Levonorgestrel IUD, and bleeding the most common complaint for the implant, however, there was no association to complaint and early removal rates. Analysis by type of LARC and reason for removal was not performed with this study, but could be an area for future research.

Type of birth control method chosen after LARC removal was the final question addressed in this study. Combined hormonal contraception was the most common category selected. Condoms were the second choice, followed by no method as the third choice. Selecting a different LARC device was one of the least preferred options

for study participants. The decision to choose a less reliable form of contraception after LARC removal has consequences for the patient who could risk an unplanned pregnancy. Hoggart and Newton (2013) found less reliable contraception choices after implant removal in their qualitative study (80%, n=16) as well. However, other research already presented did not analyze method of birth control after LARC removal (Dickerson et al, 2013; Grunloh, Casner, Secura, Peipert, Madden, 2013; Mestad et al, 2011; Peipert et al., 2011). Further research on birth control selection post-removal is still needed.

In the current study, participant decision to use a method post-removal that regulates bleeding patterns such as OCPs may reflect a desire to end bleeding irregularities and still maintain a degree of contraceptive effectiveness. Choosing condoms or no method may demonstrate a desire to move away from artificial hormone regulation in general, similar to the motivations found by Hoggart and Newton (2013). In their study, the action of removing the implant was a means for the participant to re-assert bodily control that had been lost. Emphasizing bodily control over reproductive control impacted contraceptive choice after implant removal. Participants opted for less reliable contraception in the form of pills, condoms, or no method of birth control to reduce perceived hormonal side effects or eliminate bleeding irregularities. Future research could better explore bodily control or behavioral action within the context of the theory of planned behavior via a prospective study design. Likewise, strategies to improve patient counseling on common side effects and emphasis on efficacy of LARC methods may be an area for future research to reduce the frequency of pill or condom choice post-LARC removal.

All studies have strengths and limitations. A strength of this study is pilot research done on an emerging issue in contraception. Given the impetus to reduce barriers to contraceptive availability and expanded use of LARC methods, studies on consequences of same day initiation and LARC methods is necessary. Results from the study will contribute to the literature on LARC devices especially in the area of early removal rates and provision of LARC within the context of same-day insertion. A second strength is the study setting. Utilizing participants who have received care within a nationally recognized women's health organization which standardizes patient education and has clinicians comfortable with providing LARC methods reduces potential bias compared to a study performed in a private practice setting.

A limitation of this study is the defined participant group characteristics which limit generalizability to women outside of the study setting. Retrospective chart review is another limitation. Accuracy of data collected from electronic health records is contingent upon the accuracy of the clinician who provided the service and not the researcher looking for key data points. Omissions in documentation on whom previously received LARC counseling or lack of charting on reasons for removal could have altered the study's findings. The concept of same-day insertion is also an area that risks study bias. Same-day insertion suggests the patient has had no previous counseling on a method and makes a decision at point of service to choose a LARC method. However, this is not always the case. Patients have the ability to do their own research on a method, talk with family and friends using that method and reflect on how that method would work for them. In fact, a patient could come to the clinic appointment for LARC insertion with a better understanding of the LARC method they desire than a patient

with previous counseling classified as a non-same day insertion. Finally, the lack of comparison group in this study design weakens the study findings. If the early removal subjects were compared to subjects who had retained their LARC on factors such as demographics, or pain and bleeding complaints, validity of findings would have been strengthened

Unintended pregnancy in the United States continues to be a public health concern. Further research on LARC methods may be one strategy to improve patient education and counseling on these highly effective devices. Increased provider confidence and acceptance of LARC methods for most reproductive-aged women, including teens, would also be a beneficial outcome of continued studies.

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APPENDIX A

Reasons for Removal: Implant

04/09/2014 02:15 PM : "PP Implant Remove" X

PP Navigation

Reasons for removal

Desires pregnancy
 End of 3 years
 Medical indications
 Other
 Requests other method
 Side effects
 Headache
 Infection in arm
 Bleeding
 Other

Reasons for Removal: IUD/IUS

LMP N/A estimated unknown

UPIC since LMP no yes

Reason for removal Services/supplies offered

desires pregnancy
 having symptoms
 pain
 bleeding
 device expired
 no longer requires contraception
 Other