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Long-acting Reversible Contraception in Women with Medical Comorbidities

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Long-acting Reversible Contraception in Women with Medical Comorbidities

By

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Advisor: Carrie Cwiak, MD MPH

An abstract of
A thesis submitted to the Faculty of the
James T. Laney School of Graduate Studies of Emory University
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Master of Science
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2016

ABSTRACT

Long-acting Reversible Contraception in Women with Medical Comorbidities
By Lucy Fu

Objective

To evaluate how medical comorbidities, which are considered contraindications to combined hormonal (estrogen-progestin) contraception, effect continuation of long acting reversible contraception (LARC).

Methods

We described the patient population who received a LARC method at Grady Memorial Hospital. We then randomly selected a subset of patients for a retrospective chart review. Our exposure of interest was any medical comorbidity listed as category 3 or 4 in the CDC MEC. Our outcome was LARC continuation. Discontinuation included removal, expulsion, or pregnancy. We compared the proportions of patients continuing LARC at one year between exposure and non-exposure groups. We plotted Kaplan Meier Survival plots and performed Cox Proportional Hazards modelling to compare rates of continuation between exposure and non-exposure groups.

Results

From 11/01/2010 to 03/31/2014, LARC methods were inserted in 2338 patients at Grady Memorial Hospital: 1350 Implants (57.8%), 747 Mirenas (32.0%), and 239 Paragards (10.2%). In our selected cohort, there were 347 patients (45.8%) with the exposure of interest and 410 patients (54.2%) without. Continuation of LARC at one year in the exposure group was 55.0%; in the non-exposure group, 61.5%. The hazard ratio for discontinuation in one-year of LARC method comparing exposure and non-exposure groups was 1.17 (95% CI 0.99 – 1.37; p-value 0.06). The Kaplan Meier survival plots for our non-exposure and exposure groups differ significantly (Log-rank test p-value = 0.002, Wilcoxon test p-value 0.005), with the difference occurring in the first two months.

Conclusion

Our study suggests that presence of medical comorbidities does not decrease continuation of LARC at one year but that there is a decrease in the first 2 months. By contributing to the literature of contraceptive use among women with medical comorbidities, we hope our results will increase access to safe, effective contraception for this vulnerable population.

Long-acting Reversible Contraception in Women with Medical Comorbidities

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INTRODUCTION

Unintended pregnancy remains a public health concern, rising from 48% to 51% between 2001 and 2008, resulting in $12.5 billion combined public expenditures. 95% of all unintended pregnancies can be attributed to lack of proper contraception, a combination of user error, inherent ineffectiveness of certain birth control methods, and lack of reliable access.

Long-acting reversible contraception (LARC) – the progestin implant (Implanon, Nexplanon), the progestin IUD (Mirena), and the copper IUD (Paragard)– are superior to short-term methods and well-tolerated. The proportion of patients continuing LARC at three years is 77% vs. the proportion of patients continuing short-term methods at three years (41%). However, the most popular reversible methods are still barrier and short-term hormonal methods.

There are several reasons why short-term contraception is inferior to long-term contraception. Certain medical comorbidities are contraindications to combined hormonal short-term contraceptives (pill, patch, ring),such as hypertension and other cardiovascular diseases. Women with such medical comorbidities may be told to stop the most popular birth-control methods due to such concerns. LARC methods offer safer alternatives for these women. The prevalence of LARC utilization and its rate of adherence amongst these women is not known but may be useful for future population-health initiatives. This may help to plan future interventions aimed at increasing LARC adherence in a

population of women in which LARC is uniquely qualified to prevent unintended pregnancy.

We conducted a retrospective cohort study of Atlanta-area women who received LARC methods at Grady Memorial Hospital between 2010-2014, and investigated the relationship between medical comorbidities and continuation of LARC methods. We first assessed the demographic and medical characteristics of the patient sample who received a LARC. Our exposure of interest was any medical comorbidity listed as category 3 or 4 in the CDC MEC, which are contraindications to combined hormonal (estrogen-progestin) contraception. Our outcome was LARC continuation, defined as continued use with no complication, removal, or pregnancy for 1 year. Using Kaplan Meier Survival plots and Cox Proportional Hazards modeling, we compared rates of continuation between exposure and non-exposure groups. Finally, we explored reasons for discontinuation and complications/dissatisfaction (without discontinuation) of LARC methods using qualitative methods.

BACKGROUND

Unintended pregnancy remains a public health concern in the United States. Between 2001 and 2008, rates of unintended pregnancy rose from 48% to 51%, corresponding to about 3.4 million pregnancies each year that are unplanned (1). An unplanned pregnancy, whether it ends in abortion or birth, places health and financial hardship on the mother, and the financial burden is often transferred to the state. The combined public expenditures for births resulting from unintended pregnancies was estimated to be about $12.5 billion in 2008 (2). Most unintended pregnancies could be prevented by consistent and correct use of contraception. Women who use contraception inconsistently or incorrectly made up 43% of all unintended pregnancies, and those who did not use any form of contraception made up 52%; together, that's 95%, almost all unintended pregnancies (3). There are many reasons why women either do not use contraception or use them inconsistently/incorrectly. But of those women who desire contraception, the cost and availability of contraception may be insurmountable barriers. And even among those women who are able to reliably obtain contraception, user--error and the inherent ineffectiveness of certain methods of birth control can lead to contraceptive failure.

In recent years, long-acting reversible contraception (LARC), which includes the progestin intrauterine device (IUD), copper IUD, and progestin implant, have proven to be both effective and to have high rates of patient continuation. Since these devices are placed by a physician, there is no patient error to decrease the effectiveness, and LARC are inherently efficacious with failure rates for the implant, progestin IUD, and copper

IUD as low as 0.05%, 0.2%, and 0.8% respectively (4). This is much lower than failure rates for typical use of traditional contraceptive methods like the pill, patch, or ring (all at 8%) (5). In fact, LARC rival permanent female and male sterilization, which have failure rates of 0.5% and 0.15% (5). The Centers of Disease Control and Prevention (CDC) illustrates the differences in effectiveness of family planning methods in *FIGURE 1*. This chart clearly categorizes LARC methods with sterilization as top-tier contraception methods; combined hormonal methods are included in the middle-tier; other traditional methods, including barrier and natural family planning, are least effective. Despite their inferior effectiveness, barrier and short-term hormonal methods are still more popular methods of birth control than LARC methods.

Unfortunately, combined hormonal methods pose a health risk to women with certain underlying medical conditions and comorbidities including: smoking, cardiovascular disease, hypertension, history of deep venous thrombosis or pulmonary embolus, stroke, etc. In these women, the risk of harm from using certain methods of birth control outweighs the advantage of using the method; or worse, there is actually an unacceptable health risk to using the contraceptive method (5). These women at high risk for complications find a narrowed field of contraceptive options and are often not able to obtain one that is accessible, affordable, and also medically safe. LARC methods, which are rarely contraindicated, provide a safe and effective option for preventing unintended pregnancy (4).

In a prospective cohort in which financial and access barriers were removed and women were educated about both short-term and LARC methods of birth control, the majority of women (68%) opted for a LARC method rather than short-term contraceptive methods (contraceptive pill, patch, ring, or shot) (6). At two years, the proportion of patients continuing LARC methods was 77% compared to just 41% for non-LARC methods (7). The hazard ratio comparing risk of discontinuation of LARC methods to non-LARC methods was 0.29, showing that LARC-users were at significantly lower risk of contraceptive method discontinuation (7).

No work has been done specifically looking at LARC continuation in high risk women with medical comorbidities. Our overall research purpose was to evaluate how having medical comorbidities, considered contraindications to combined hormonal (estrogen-progestin) contraception, is associated with continuation of LARC methods. We aimed to show that LARC methods are equally tolerated in high-risk women with medical comorbidities when compared to healthy women. We identified predictors for discontinuation. And finally we briefly explored reasons for discontinuation and complications/dissatisfaction (without discontinuation) of LARC methods. We hope our results will facilitate the sometimes complex decision as to which contraceptive method women with comorbidities should choose that will be adhered to with no complications.

METHODS

Hypothesis

Presence of medical comorbidities that are contraindications to combined hormonal contraception does not decrease continuation of LARC methods.

Specific Aims

a. To characterize the patient population who received LARC methods through the Ryan LARC Program Grant at Grady Memorial Hospital (Emory University).
b. To compare the rate of continuation of LARC methods of women WITH medical comorbidities to the rate of continuation of LARC methods of women WITHOUT comorbidities.
c. To investigate predictor variables for discontinuation of LARC methods.
d. Exploratory aim: to investigate reasons for discontinuation and complications/dissatisfaction (without discontinuation) of LARC methods.

Study Design Overview

Our project includes a broad descriptive study of patients who received a LARC method at Emory University.

To answer our research question, we randomly selected a subset of patients for a retrospective cohort. Our exposure of interest was any medical comorbidity listed as category 3 or 4 in the Centers for Disease Control and Prevention (CDC) Medical Eligibility Criteria for Contraceptive Use. Our outcome was LARC discontinuation. Discontinuation included removal, expulsion, or pregnancy. We compared the proportions of patients still continuing LARC at one year between exposure and non-exposure groups. We plotted Kaplan Meier Survival plots and performed Cox Proportional Hazards modeling to compare discontinuation between exposure and non-exposure groups. We briefly explored reasons for discontinuation and complications/dissatisfaction (without discontinuation) of LARC methods in our selected cohort.

Population

From 2008 till now, the Emory University Family Planning Division has provided LARC methods to patients in whom all of the following categories apply (under Ryan LARC Grant provisions): placement occurs during a training situation, income is <300% current Federal Poverty Level, patient has no insurance coverage for LARC, patient is post-abortal or post-partum (<10 weeks) at time of placement, or patient is part of a vulnerable population (i.e. adolescent or medically complex). The grant provided over 4,000 LARC methods to patients. We restricted our cohort to patients seen at Grady Memorial Hospital, which serves a disadvantaged, primarily minority population from the Southeast region with less access to healthcare and high rates of medical

comorbidities. Grady also utilizes the Epic electronic medical record. (A minority of patients (less than 20% of all patients) was seen at other clinical sites that still use paper charts and was excluded from our cohort.) Patients randomly selected for chart review were also restricted to dates of service between 11/01/2010 - 03/31/2014. The first date marks the beginning of Grady's Epic electronic medical record system; the latter date allows chart review through one year (till 03/31/2015), in accordance with the investigator's degree timeline.

We randomly selected 800 patients by random number generator for a retrospective chart review. We anticipated an adequate distribution of exposure vs. non-exposure patients (1 to 1) given high prevalence of medical comorbidities among the population.

Sample Size

Based on literature review, we assumed that the proportion of women continuing LARC in the unexposed group would be 77%, and that a decrease of 10% or more in the continuation rate of LARC in the exposed group would be clinically significant. We chose a difference of 10%, which is less than the 36% difference between non-LARC (41%) vs. LARC method (77%) continuation (7). A sample size of 606 would allow us to detect a 10% difference with 80% power and a significance level = 0.05. Because we expected that some charts had incomplete data or information about follow--up, we selected 800 patient charts to review.

Sources of Data

From 2008 to 2012, paper surveys were completed by the provider at each LARC method encounter. Information collected included: type of encounter (insertion, removal, or expulsion), patient identification, patient demographics, reproductive characteristics, level of trainee placing the method, etc. per grant requirements. Patient data was then entered aggregately into REDCap, a secure electronic database, by our research coordinator and medical student research assistant (LF). Since 2012, patient data has been individually entered directly into REDCap by providers at the time of patient encounter.

For our retrospective cohort study, investigators reviewed all randomly selected, eligible charts, including the clinical and physician records which contained: patient history/physical, lab values, procedure notes (for insertion/removal), medication list, and progress notes.

Study Variables and Definitions

The exposure in our study was any medical condition listed as category 3 or 4 in the Centers for Disease Control and Prevention (CDC) Medical Eligibility Criteria (MEC) for Contraceptive Use. Medical conditions in category 3 are those for which the theoretical or proven risks usually outweigh the advantages of using the method, and those in category 4 represent an unacceptable health risk if the contraceptive method is

used. Medical conditions which fall into categories 1 and 2 are those for which there is no restriction for the use of the contraceptive method and those for which the advantages of using the method generally outweigh the theoretical or proven risks, respectively, and were not considered an exposure in this study.

For both the exposure group and non-exposure groups, we investigated the chart for our primary outcome of LARC discontinuation at one year. We defined the event (outcome) and censorship as follows:

- Patients WITH evidence of Grady physician follow-up beyond 12 months of insertion date
    - discontinuation (removal/expulsion) documented within 12 months
        - → **event**
    - continuation (physical exam, history) documented at/beyond 12 months
        - → **no event, censored** at 12 months
    - neither discontinuation/continuation documented (“assumed” continuation)
        - → **no event**, **censored** at 12 months
- Patients WITHOUT evidence of Grady physician follow-up beyond 12 months of insertion date
    - discontinuation (removal/expulsion) documented
        - → **event**
    - neither discontinuation/continuation documented
        - → **no event**, **censored** at date of last encounter (before 12 months)

From both the baseline grant data collection tool and the chart review, we considered other aspects of their health history including: demographic information, reproductive history, socioeconomic factors, and insertion data to investigate all potential confounders and effect modifiers. We also collected information about any interval complications or complaints about the patient's LARC experience, especially if the LARC method was discontinued.

Analytic Plan

All analyses were performed with SAS 9.4.

Descriptive statistics for all patients seen between 11/01/2010 and 03/31/2014 were performed with frequencies, percentages, means, and standard deviations as appropriate for data type.

For our randomly selected 800--patient cohort, baseline characteristics between exposure and non-exposure groups were compared using Chi-square (or Fischer's exact) tests for categorical variables and Student's t tests for continuous, normally distributed variables. Normality was assessed by evaluating histogram of continuous variables. We compared the proportion of exposure patients continuing LARC at one year vs. the proportion of non-exposure patients continuing LARC at one year.

Cox Proportional Hazard models were used to estimate the hazard ratios for our exposure of interest and of possible predictor variables. Proportional hazard assumptions were checked by plotting log-log of survival probability curves. Effect modification was checked by including interaction terms between exposure and covariate of interest in the model. Effect modification was detected if the interaction term was statistically significant at the pre-specified alpha = 0.05. Confounding was defined as a greater than 10% relative change in the association between discontinuation and exposure with or without the covariate of interest in the model.

To look for differences in discontinuation over time, we compared cumulative rates of discontinuation at each month (1, 2, 3...12) using the Kaplan-Meier survival function, stratifying on exposure.

RESULTS

Between 11/01/2010 and 03/31/2014, LARC methods were inserted in 2338 patients at Grady Memorial Hospital. This included 1350 Implants (57.8%), 747 Mirenas (32.0%), and 239 (10.2%) Paragards. Patient ages ranged from 12 to 67 years old, and the mean age was 26.7 years-old (std dev 8.2 years). Demographics and characteristics of our N = 2338 sample and their LARC insertion data are described in *TABLE 1*.

We selected 800 patients by random number generator for our retrospective chart review. Thirty-four patients were not able to be located in the electronic medical record from identifying information recorded at initial encounter; 9 patients had no evidence of LARC insertion in the chart. We excluded these patients from our retrospective chart review, leaving 757 patients in our cohort; 347 patients (45.8%) had the exposure of interest, 410 patients (54.2%) did not. Patient demographics and characteristics of our final cohort (n = 757) are described in *TABLE 2.* Distribution of age, race, ethnicity, gravidity, previous birth-control method, insurance status, relationship status, LARC method inserted, and training level of provider were significantly different between non-exposure and exposure groups with p-values < 0.05.

In our exposure group, MEC category 3 medical comorbidities were more prevalent than category 4 comorbidities. Thirty-eight percent of exposure patients were post-partum, breastfeeding <21 days status; 16.4% had adequately controlled hypertension;

14.4% were post-partum, non-breastfeeding <21 days status; and 12.7% had hyperlipidemia. *TABLE 3*

Of the 347 patients in our exposure group, 24 (6.9%) discontinued their LARC method, 191 (55.0%) continued their LARC method at one year, and 132 (38.0%) were lost to follow-up. Of the 410 patients in our non-exposure group, 42 (10.2%) discontinued their LARC method, 252 (61.5%) continued their LARC method at one year, and 116 (28.3%) were lost to follow-up. Presence of medical comorbidity decreased continuation of LARC method at one year by 6.5%. *TABLE 4*

50.7% of our patients were missing data on employment status, 51.1% on education level, and 50.9% on Relationship status. We excluded these three variables from our Kaplan Meier Survival plot and Cox Proportional Hazards analysis. *TABLE 5*

The proportional hazards assumption was satisfied for all variables by visual inspection of parallel log-log survival plots. The hazard ratio (HR) for LARC discontinuation comparing women with medical comorbidities to healthy women was 1.17 (95% CI 0.99 – 1.37; p-value 0.06) and had a non-significant trend. The only variable with a HR that had statistical significance was gravidity, HR = 1.37 (95% CI 1.03 – 1.82; p-value 0.03). *TABLE 6*

Covariates (Age, Race, Ethnicity, Previous Birth Control method, Insurance, LARC method, and Provider Level) were evaluated for confounding and effect modification. There were no statistically significant covariates.

The Kaplan Meier (KM) Survival plot uses a red curve for our exposure group and a blue curve for our non-exposure group. The plot shows an increased rate of discontinuation of women who have a medical comorbidity when compared with healthy women. Log-rank test p-value = 0.002, Wilcoxon test p-value 0.005. However, the difference occurs within 1-2 months of insertion, and the survival curves are then parallel until the 12-month mark. *FIGURE 2*

Of the 66 patients who discontinued LARC, their providers described the reasons for discontinuation in their notes. The most prevalent response was bleeding (change in menstrual bleeding pattern)—25 patients. Twenty-one patients reported discomfort at insertion site; 14 LARC methods were expulsed (or partially expulsed); 8 patients had a subsequent hysterectomy (when LARC method to control abnormal uterine bleeding did not achieve desired results); 7 patients became pregnant or desired pregnancy; 19 patients reported other side effects. *TABLE 7*

Of the reasons for complications and side effects of LARC methods NOT leading to discontinuation, bleeding (change in menstrual bleeding pattern) was the most prevalent complaint—40 patients. 26 patients reported discomfort at insertion site; 7 patients

reported infection; 7 patients reported headaches; 7 patients reported weight change; and 24 patients reported other side effects. *TABLE 8*

DISCUSSION

The entire N = 2338 cohort who received LARC methods between 11/01/2010 and 03/31/2014 have characteristics reflective of Grady Memorial Hospital's patient population. Women were predominantly black or hispanic, unemployed, uninsured, and had only completed a high school education or less. About 15% of our patients had been pregnant at least 5 times; the highest number of pregnancies was 13. This may also reflect this high-risk patient population with decreased access to healthcare and family planning resources.

The patients' ages were distributed normally and ranged from 12 to 67 years old. The mean age was 26.7 years old (std dev 8.2 years). Although women with medical comorbidities were older than those without, the inclusion of adolescents in the population is important, as high effectiveness and continuation of LARC are seen in adolescents as well as adults. Also, women past child bearing age opted to use LARC, indicating that women were using LARC methods for reasons other than contraception such as abnormal uterine bleeding.

The Implant was the most popular LARC method; in our N = 2338 group, 1350 Implants (57.8%) were inserted. This may be due to a variety of factors including ease of immediate post-partum use, overall ease of insertion, and patient preference based on counseling information.

Over 70% of inserting providers were resident trainees (plus 7.9% medical student trainees and 2.3% fellow trainees) which is in accordance with Ryan Program provisions that LARC grant methods be used in a training setting. LARC methods can feasibly be provided in a training setting.

In our random sub-sample, 347 patients (45.8%) of 757 had the exposure of interest. This reflects the relatively high prevalence of medical comorbidities in the Atlanta Grady population. More women with medical comorbidities had a MEC category 3 medical comorbidity rather than a category 4 medical comorbidity. We captured many post-partum patients (38.0% breastfeeding <21 days; 14.4% non-breastfeeding <21 days) since LARC methods are often used while women are in Labor and Delivery. The next most prevalent conditions were adequately controlled hypertension (16.4%) and hyperlipidemias (12.7%), which is expected in our high-risk population.

Comparing one-year continuation of LARC methods in our healthy (61.5%) and medical comorbidity (55.0%) groups, the difference was 6.5% . Women with medical comorbidities had a decreased one-year continuation of LARC, but the difference is less than our hypothesized level of clinical significance (10%). This is supported by our Cox model in which the HR for LARC discontinuation comparing the exposure to the non-exposure group was 1.17 (95% CI 0.99 – 1.37; p-value 0.06). Women with medical comorbidities had an increased hazard of discontinuation. However the HR is low, and the p-value trends towards insignificance. Gravidity (previous pregnancies vs.

nulligravid status) was the only statistically significant predictor of LARC discontinuation, HR = 1.37 (95% CI 1.03 – 1.82; p-value 0.03).

This small decrease seen in the continuation rate is not clinically significant. Compare the 6.5% difference in LARC method continuation between our exposure and non-exposure groups with the 36% difference between non-LARC (41%) vs. LARC method (77%) continuation (7). Furthermore, the HR of discontinuation of LARC method comparing exposure and non-exposure groups (1.17) is smaller than the HR of discontinuation comparing non-LARC to LARC methods (3.45; calculated reciprocal from cited HR for continuation 0.29) (7). In other words, the effect of medical comorbidities on continuation of LARC methods is less dramatic than the effect of non-LARC methods on continuation of contraception overall. Healthy women currently tolerate traditional non-LARC methods with significantly lower continuation rates and with 3-fold chance of discontinuation. For high-risk women who cannot use many traditional non-LARC methods or who cannot tolerate method discontinuation/failure, having a slightly lower LARC method continuation rate when compared to their healthy counterparts would still allow them the superior contraceptive and other benefits of long-acting birth control. Gravidity is a statistically significant predictor of LARC discontinuation with HR 1.37. Again, this HR for discontinuation is less than the HR for discontinuation of using non-LARC methods, which are still the most commonly-used methods of birth control.

The Kaplan Meier survival plots for our healthy and medical comorbidity groups do differ significantly (Log-rank test p-value = 0.002, Wilcoxon test p-value 0.005). The KM survival plot reflects that the increase in discontinuation in the medical comorbidity group occurs within the first two months after insertion of a LARC method. After this time, the survival plots appear to be parallel until the end of the study period; this likely explains why our HR trended toward insignificance. Perhaps overall continuation in LARC method is the same between our exposure and non-exposure groups. But early follow-up and intervention could address the difference in continuation rate immediately after insertion.

Overall, our proportion of patients continuing LARC method is 58.5%. This is lower than previously reported continuation of LARC 77%. This result may partially be due to how we considered lost-to-follow-up patients as non-continuation (when, in fact, a number of these patients likely continued their LARC unbeknownst to providers at Grady). This may also reflect unique patient beliefs and experiences of our Grady population which may have led to a lower proportion of LARC continuation.

Bleeding pattern changes and discomfort at insertion site were the most commonly reported complications, which sometimes led to discontinuation. Though changes in menses may cause distress and are intolerable for some patients, these changes are physiologically harmless and can even be beneficial. Addressing these topics during pre-insertion counseling may prevent patient distress and discontinuation of LARC methods. The trend of our Kaplan Meier survival plots suggests that the significant

difference in rate of continuation of LARC methods for women with medical comorbidities vs. healthy women occurs in the first month or two after insertion. Perhaps women with medical comorbidities would benefit from follow-up 1-2 months after insertion. Future studies can focus on this crucial time and produce strategies for more targeted counseling and follow-up.

Limitations

A limitation in our study was the retrospective nature of the data collection and so the amount of missing data which led to our exclusion of three variables-- employment, education, and relationship. Insurance status could be considered a proxy for employment status and perhaps also education level achieved as these are all markers of socio-economic status. However, there was no other variable by which we could approximate the effect of relationship status on continuation of LARC, so we lost that information in the analysis.

Three hundred and fifty-one of the 757 cohort patients (46.4%) did not have definitive proof of either continuation or discontinuation in the chart. Two hundred and forty-eight of these patients did not have Grady physician follow-up at one year; we counted these as censored before 12 months (aka lost to follow-up and did not count towards our continuers); it is unclear what proportion of these patients had true discontinuation of LARC. On the other hand, 103 of these patients did have Grady physician follow-up at one year; we counted these as “assumed continuation” as their follow-up visits did

not remark of complications related to LARC and so censored them at the end of the study. We felt comfortable giving these patients this designation because if removal had occurred, it would have been documented in the chart as removal requires an in-office procedure; perhaps strict documentation of LARC presence was not asked for or seen on non-pelvic physical exam when patients were seen by non-Obstetric/Gynecologic physicians or at a visit that was not family-planning-focused.

Our Grady population was suitable and reflective of a high-risk population with many medical comorbidities. However, it is not necessarily generalizable to other patient populations.

Conclusions

Women with medical contraindications to estrogen-containing methods are typically eligible for a LARC method and would benefit from their superior effectiveness. Our study suggests that presence of medical comorbidities does not decrease continuation of LARC at one year but that there is a decrease in the first 2 months. By contributing to the literature of contraceptive use among women with medical comorbidities, we hope our results will increase access to safe, effective contraception for this vulnerable population. Future studies should further explore reasons for discontinuation and dissatisfaction for LARC, especially immediately following LARC placement; results would guide targeted counseling and decision-making to optimize contraceptive satisfaction.

FIGURE 1

Effectiveness of Family Planning Methods (CDC)

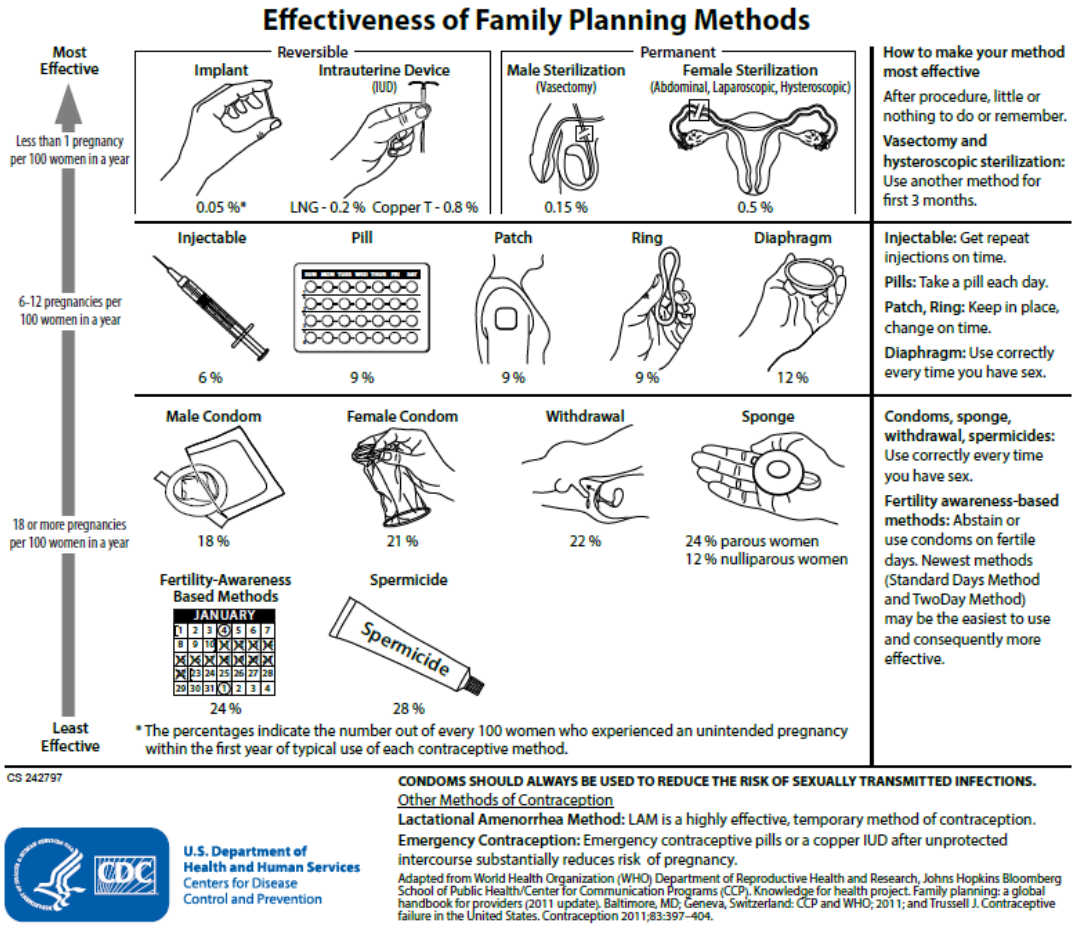

FIGURE 2

Kaplan Meier Survival Plot of Discontinuation of LARC Method Comparing Non-exposure and Exposure Groups

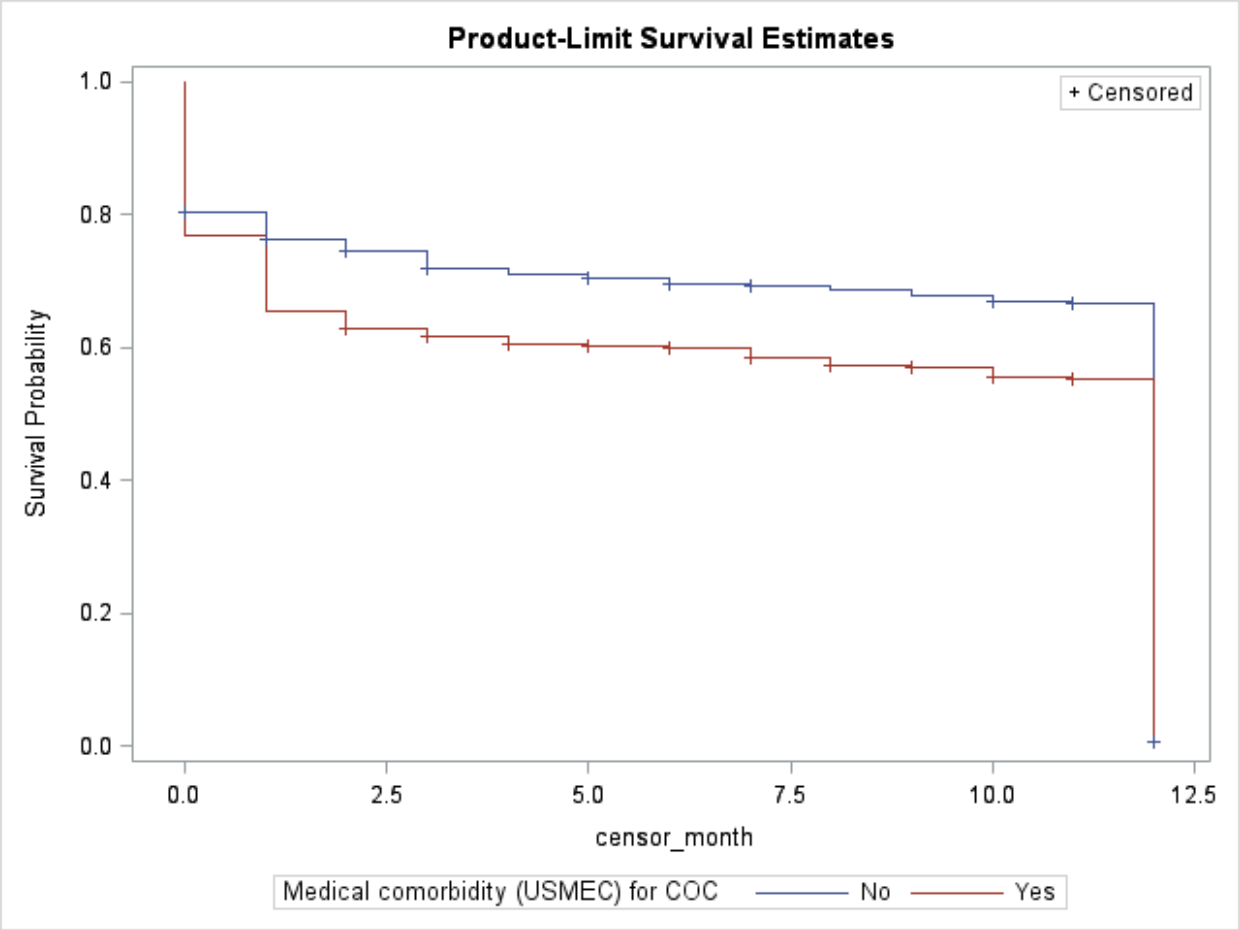

TABLE 1

Baseline Characteristics and Insertion Data for Patients Who Received LARC Methods at Grady Memorial Hospital Between 11/01/2010 - 03/31/2014

	N = 2338
Age (y)	26.7 (+/- 8.2)
	age range: 12 - 67
Race	
Black	1623 (70.0)
White	613 (26.5)
Other	82 (3.5)
missing (20)	
Ethnicity	
Hispanic	600 (28.3)
Non-hispanic	1517 (71.7)
missing (221)	
Gravidity	
Nulligravid	217 (10.4)
1	428 (20.6)
2	453 (21.8)
3	382 (18.4)
4	266 (12.8)
5 or more	336 (14.4)
missing (256)	
Previous BC method *	
None	957 (42.2)
Barrier	277 (12.2)
Hormonal	764 (33.7)
Permanent	46 (2.0)
LARC	176 (7.8)
Other	46 (2.0)
missing (72)	
Employment	
None	808 (70.9)
Part-time	186 (16.3)
Full-time	145 (12.7)
missing (1199)	
Education (highest achieved)	
None	11 (1.0)
Pre-highschool	477 (42.1)
High school	514 (45.4)
Post-highschool	131 (11.6)
missing (1205)	
Insurance	
None	1475 (63.6)
Medicare/Medicaid	824 (35.6)
Private	19 (0.8)
missing (20)	
Relationship	
Single	492 (43.3)
Coupled	644 (56.7)
missing (1202)	
LARC method	
Implant	1350 (57.8)
Mirena	747 (32.0)
Paragard	239 (10.2)
missing (2)	
Provider	
Medical student	185 (7.9)
Resident	1711 (73.3)
Fellow	54 (2.3)
Faculty	384 (16.5)
missing (4)	

Data are reported as mean (+/- std dev) or as n (%)

* Previous birth control method used before most recent pregnancy

TABLE 2
Baseline Characteristics and Insertion Data for Randomly Selected Cohort

	Non-exposure (n = 410)	Exposure** (n = 347)	p-value
Age (y)	25.4 (+/- 7.1)	28.0 (+/- 7.9)	<0.0001
Race			0.0196
Black	263 (64.1)	252 (72.6)	
White	123 (30.0)	73 (21.0)	
Other	22 (5.3)	20 (5.8)	
missing (4)			
Ethnicity			0.0053
Hispanic	126 (30.7)	71 (20.5)	
Non-hispanic	263 (64.1)	240 (69.2)	
missing (57)			
Gravidity			0.0044
Nulligravid	48 (11.7)	15 (4.3)	
>/= 1	313 (76.3)	301 (86.7)	
missing (80)			
Previous BC method *			<0.0001
None	130 (31.7)	167 (48.1)	
Barrier	55 (13.4)	36 (10.4)	
Hormonal	158 (38.5)	94 (27.1)	
Permanent	4 (0.10)	10 (2.9)	
LARC	39 (9.5)	28 (8.1)	
Other	13 (3.2)	2 (0.6)	
missing (21)			
Employment			0.1293
None	122 (29.8)	143 (41.2)	
Part-time	37 (9.0)	29 (8.4)	
Full-time	25 (6.1)	17 (4.9)	
missing (384)			
Education (highest achieved)			0.1051
None	2 (0.5)	0 (0.0)	
Pre-highschool	79 (19.3)	68 (19.6)	
High school	84 (20.5)	91 (26.2)	
Post-highschool	17 (4.1)	29 (8.4)	
missing (387)			
Insurance			0.0011
None	281 (68.5)	192 (55.3)	
Medicare/Medicaid	125 (30.5)	147 (42.4)	
Private	2 (0.5)	4 (1.2)	
missing (6)			
Relationship			0.0441
Single	63 (15.4)	84 (24.2)	
Coupled	121 (29.5)	104 (30.0)	
missing (385)			
LARC method			<0.0001
Implant	202 (49.3)	227 (65.4)	
Mirena	140 (34.1	98 (28.2)	
Paragard	68 (16.6)	21 (6.1)	
missing (1)			
Provider			<0.0001
Medical student	55 (13.4)	17 (4.9)	
Resident	239 (58.3)	281 (81.0)	
Fellow	7 (1.7)	6 (1.7)	
Faculty	107 (26.1)	42 (12.1)	
missing (3)			

Data are reported as mean (+/- std dev) or as n (%)

* Previous birth control method used before most recent pregnancy

** Exposure defined as CDC MEC category 3 or 4 medical conditions

TABLE 3

Distribution of MEC Category 3 and Category 4 Medical Comorbidities in Exposure Group

	n = 347	%
Category 3		
Post partum: Breastfeeding < 1 mo	132	38.0
Post partum: Non-breastfeeding < 21 days	50	14.4
Smoking: >/= 35 yo, < 15 cigarettes/day	12	3.5
Bariatric surgery: malabsorptive procedures (roux-en-Y bypass, biliopancreatic diversion)	0	0.0
Htn: adequately controlled	57	16.4
Htn: Elevated bp systolic 140-159 OR diastolic 90-99	27	7.8
DVT/PE: +History, no anticoags, no risk factors	2	0.6
DVT/PE: +History, anticoags >3 mths, no risk factors	2	0.6
Hyperlipidemias	44	12.7
Peripartum cardiomyopathy: NYHA Class I/II, >/= 6 mths	0	0.0
SLE: severe thrombocytopenia	1	0.3
Migraine headaches: without aura <35 yo	13	3.7
Gestational trophoblatic disease: decreasing or undetectable B-hCG levels	0	0.0
Breast cancer: no evidence of current disease 5 yrs	1	0.3
STIs: increased risk for STIs	11	3.2
AIDS (not clinically well)	0	0.0
IBD (Crohn, ulcerative colitis)	1	0.3
Gallbladder: symptomatic, medically treated	0	0.0
Gallbladder: symptomatic, current	0	0.0
Cholestatis: past COC-related	1	0.3
ARVs: nucleoside reverse transcriptase inhibitors	9	2.6
ARVs: non-nucleoside reverse transcriptase inhibitors	2	0.6
ARVs: ritonavir-boosted protease inhibitors	5	1.4
Anticonvulsants: phenytoin, carbamezepine, barbiturates, primidone, topiramate, oxcarbazepine	6	1.7
Anticonvulsants: lamotrigine	2	0.6
Antimicrobials: rifampicin, rifabutin	0	0.0
Category 4		
Pregnancy	1	0.3
Postpartum: puerperal sepsis	0	0.0
Postabortion: immediate postseptic abortion	2	0.6
Smoking: >/= 35 yo, >/= 15 cigarettes/day	6	1.7
Htn: elevated bp, systolic >/= 160 OR diastolic >/= 100	5	1.4
Htn: +vascular disease	0	0.0
DVT/PE: + history, no anticoags, >/= 1 risk factor	3	0.9
DVT/PE: acute DVT/PE	1	0.3
DVT/PE: + history, + anticoags > 3 mths, >/= 1 risk factor	8	2.3
DVT/PE: major surgery, prolonged immobilization	0	0.0
Thrombogenic mutations (factor V Leiden, prothrombin, protein S, protein C, antithrombin)	0	0.0
Ischemic heart disease: current OR + history	4	1.2
Stroke: + history	6	1.7
Valvular heart disease: complicated (pulm htn, risk for afib, subacute bacterial endocarditis)	3	0.9
Peripartum cardiomyopathy: NYHA class I/II, < 6 mths	1	0.3
Peripartum cardiomyopathy: NYHA class III/IV	2	0.6
SLE: + (or unknown) antiphospholipid antibodies	3	0.9
Migraine headaches: w/o aura >/= 35 yo	5	1.4
Migraine headaches: with aura	5	1.4
Unexplained vaginal bleeding: before evaluation	5	1.4
Gestational trophoblastic disease: persistently elevated B-hCG levels or malignant disease	2	0.6
Cervical cancer: awaiting treatment	0	0.0
Breast cancer: current	0	0.0
Endometrial cancer	0	0.0
Anatomical abnormalities: distorted uterine cavity (congenital/acquired; incompatible with IUD insertion)	1	0.3
Pelvic inflammatory disease: current	5	1.4
STIs: current purulent cervicitis or chlamydial infection or gonorrhea	5	1.4
Tuberculosis: pelvic	0	0.0
Diabetes: + nephropathy/retinopathy/neuropathy	1	0.3
Diabetes: + other vascular disease OR > 20 yrs	6	1.7
Viral hepatitis: acute/flare	1	0.3
Cirrhosis: severe	0	0.0
Liver tumors: benign hepatocellular adenoma	0	0.0
Liver tumors: malignant	0	0.0
Solid organ transplantation: complicated (acute/chronic graft failure, rejection, cardiac allograft vasculopathy)	0	0.0

TABLE 4

Discontinuation, Censorship, and Survival (Continuation) Between Non-exposure and Exposure Groups

	Non-exposure (n = 410)	Exposure (n = 347)
Discontinued before 12 months	42 (10.2)	24 (6.9)
Censored before 12 months	116 (28.3)	132 (38.0)
Censored at 12 months (Survived)	252 (61.5)	191 (55.0)

Data expressed as n (%)

TABLE 5
Missing Data by Variable (in Selected Cohort)

Variable	n Missing	%
Age	0	0
Race	4	0.5
Ethnicity	57	7.5
Gravidity	80	10.6
Previous BC Method	21	2.8
Employment*	384	50.7
Education (highest achieved)*	387	51.1
Insurance	6	0.8
Relationship*	385	50.9
LARC method	1	0.1
Provider	3	0.4

* Variable excluded from analysis

TABLE 6

Cox Proportional Hazards Model Parameters for Possible Predictors of LARC Discontinuation

Variable	Hazard Ratio	95% Wald CI	p-value
Medical Comorbidity	1.17	0.99 - 1.37	0.06
Present vs not present			
Age	0.82	0.62 - 1.10	0.18
Adolescent (<18 yo) vs adult			
Race	0.93	0.78 - 1.10	0.37
Black vs not			
Ethnicity	1.02	0.86 - 1.22	0.81
Hispanic vs not			
Gravidity	1.37	1.03 - 1.82	0.03
Previously pregnant vs nulligravid			
Previous BC method	0.90	0.77 - 1.07	0.24
Use of any BC method before most previous pregnancy vs none			
Insurance	1.07	0.90 - 1.27	0.44
Insured vs not			
LARC method			0.52
Implant vs Mirena	1.11	0.93 - 1.33	
Implant vs. Paragard	1.07	0.82 - 1.39	
Mirena vs. Paragard	0.96	0.73 - 1.28	
Provider	0.999	0.81 - 1.22	0.99
Trainee (student, resident, fellow) vs faculty			

TABLE 7
Reasons for Discontinuation for Selected Cohort

	Non-exposure	Exposure*	Total
Bleeding	11	14	**25**
Discomfort	16	5	**21**
Expulsion	13	1	**14**
Pregnancy	5	2	**7**
Hysterectomy	1	7	**8**
Other	8	11	**19**
None	2	2	**2**

***** Exposure defined as CDC MEC category 3 or 4 medical conditions

TABLE 8
Complications/Dissatisfaction WITHOUT Discontinuation for Selected Cohort

	Non-exposure	Exposure*	Total
Infection	6	1	**7**
Bleeding	21	19	**40**
Discomfort	15	11	**26**
Headache	5	2	**7**
Weight changes	3	4	**7**
Other	14	10	**24**

***** Exposure defined as CDC MEC category 3 or 4 medical conditions

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