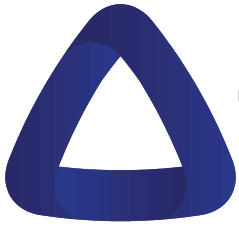

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Temporal Trends - Final

Temporal trends in the uptake and continuation of the etonogestrel implant in a large private practice setting.

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Short title: Trends in uptake of the etonogestrel implant.

Abstract

Objective: To assess temporal trends in the uptake and continuation of the etonogestrel subdermal implant in a large private practice setting.

Methods: This was a retrospective cohort study based on billing records from a large multi-specialty private practice in Las Vegas, Nevada. We looked at women of all ages seeking long-acting reversible contraception (LARC) between January 1, 2013, and December 31, 2016. The main outcome measure was uptake of the etonogestrel subdermal implant, expressed as a fraction of all insertions of LARC across 4 calendar years (2013-2016). The Kaplan-Meier method was used to estimate 12-month continuation stratified by year of insertion.

Results: There were 3,477 total LARC insertions across the 4-year study period. In unadjusted analyses, the uptake of the etonogestrel implant increased from 3.0% of LARC insertions in 2013 to 9% in 2016 among women 30 years and older. For women under 30 years old, the uptake of the implant stayed stable from 2013-2015 (22.8%, 21.7%, 22.4%, respectively) but increased to 30.9% in 2016. We modeled the uptake of the implant as a function of year of insertion adjusted for age (continuous) and insurance status (private vs. Medicaid), and we stratified the models by age (less than 30 and 30 years and older). The positive association between year of insertion and uptake of the implant was significantly stronger for women 30 and older, compared to women under 30 years old. There was a progressive decrease in the 12-month continuation of implant from 2013 (95.7%) to 2015 (57.7%).

Conclusions: In this large private practice setting, among women 30 years and older, we observed a threefold increase in the uptake of the subdermal implant from 2013-2016. We also

observed a significant decrease in the 12-month continuation of the implant over time. Further studies of implant uptake and continuation in the private practice setting are needed.

Keywords: etonogestrel subdermal implant, intra-uterine device, long-acting reversible contraception.

Introduction

There are two broad categories of long-acting reversible contraception (LARC) in the United States. In one category, there is the etonogestrel subdermal implant, and, in the other, there are levonorgestrel containing intra-uterine devices (IUDs) and the non-hormonal copper containing IUD.[1]

In the largest prospective study of LARC uptake in the United States, the overall uptake of the subdermal implant was 23%[2]. These women had their insertions between 2007 and 2011, and all women received the contraception of their choice at no cost. The uptake of the subdermal implant was similar in the largest retrospective study of LARC uptake in the United States[3]. These women were beneficiaries in the United States military health care system, which is characterized by universal health care with no copays for contraception. In the largest "real-world" retrospective study of women in a mixed-payer setting that included self-pay, Medicaid, and commercial insurance, the uptake of the implant was only 11.7%.

The uptake of the implant appears to be even higher among adolescents and women desiring immediate post-partum LARC insertion. Among women aged 14-19 years old in the Contraceptive CHOICE study, 51% chose the subdermal implant[2]. Two single institution studies examining women desiring a LARC method immediately post-partum found the implant uptake to be between 35%[4] and 43%[5].

In terms of continuation rates, some studies show higher continuation for IUDs, compared to the implant, at 1 year[3,6,7], 2 years[8], and 3 years[3,9]. Others, however, have found essentially identical rates of continuation for the implant and IUDs at 6 months[4] and at 2 years[10]. In contrast, a meta-analysis of observational studies found a significantly higher 12-month continuation of the

implant, compared to IUDs, among adolescents[11]. Another study found that among implant users, adolescents had the highest 3-year continuation rate[3].

Although the 52mg levonorgestrel IUD has enjoyed dominance among types of LARCs, there has been an increase over time in the negative publicity surrounding the complications associated with IUDs—specifically uterine perforation and device migration. Dozens of federal lawsuits have been filed against the manufacturer of the 52mg levonorgestrel IUD, alleging that the device can perforate the uterus and migrate in the body. These were consolidated in a multidistrict litigation in the Southern District of New York (In Re: Mirena IUD Products Liability Litigation, MDL Docket No. 2434, JPMDL). It is unclear whether this increase in negative publicity surrounding IUDs is having any impact on women's contraceptive decision making.

The studies discussed above were either conducted in "ideal" settings with no out of pocket costs[3,6,8,9] or in teaching hospitals[4,5,10]. The primary aim of this study was to assess temporal trends in the uptake and continuation of the etonogestrel subdermal implant, specifically in the private practice setting.

Materials and Methods

Study design: Retrospective cohort study.

Study population: Women receiving a LARC insertion at a single large multispecialty practice in Las Vegas, Nevada, between January 1, 2013, and December 31, 2016 (n=3,477 women).

Data source: The exclusive data source for this report was billing records.

Primary outcome variable: Etonogestrel implant uptake. Etonogestrel implant procedures (insertions and removals) were identified by CPT codes 11981 (insertion, non-biodegradable drug delivery implant), 11982 (removal, non-biodegradable drug delivery implant), and 11983 (removal with reinsertion, non-biodegradable drug delivery implant). IUD procedures were identified by the CPT codes 58300 (insertion of IUD) and 58301 (removal of IUD). These two codes, 58300 and 58301, do not distinguish between the copper IUD and the levonorgestrel IUD.

For each calendar year from 2013 to 2016, we identified all LARC insertions and classified each as "implant" or "IUD." We then analyzed the fraction of all LARC insertions that were implant insertions for each study year.

Confounding variables: To compute age, we subtracted the date of LARC insertion from the date of birth and divided by 365.25 to convert from days to years. Age was then categorized into "less than 30 years" and "30 years and older." The patient's insurance status at the time of LARC insertion was classified as "private/commercial" versus "Medicaid/self-pay." Self-paying women were grouped with Medicaid participants due to the extremely small number of these women (less than 1%).

Primary exposure variable: Year of insertion (2013, 2014, 2015, and 2016).

Statistical methods: In our bivariate analyses, we assessed the association between age and year of insertion and between insurance status and year of insertion. We also assessed the association between insurance status and uptake of the implant (as a fraction of LARC insertions) within strata defined by age. These analyses were done using the chi-square test. Our significance level was set at 0.05, but we adjusted this using the Bonferroni correction whenever there were multiple comparisons.

In our multivariate analyses the dependent variable was a dichotomous variable indicating whether the LARC inserted was an implant versus an IUD. The primary independent variable was year of insertion modeled as a series of dummy variables: 2014 vs. 2013, 2015 vs. 2013, and 2016 vs. 2013. Also included as covariates were age modeled as a continuous variable and insurance status modeled as a dichotomous variable. We used logistic regression modeling, and we conducted models in two strata: one comprising women under 30 years old and one comprising women 30 years and older.

We modeled 12-month continuation of the implant using the Kaplan-Meier method. Women with a claim for an implant insertion but no claim for removal over the ensuing 12 months were censored at 12 months. We could not assess 12-month continuation for insertions in 2016 because, at the time of this analysis, 12 months had not yet passed from the end of 2016.

We used STATA (College Station, TX, version 14) for all analyses. This study was approved by the Institutional Review Board at Tuoro University, Nevada.

Results

We studied 3,477 LARC insertions, of which 2,930 (84.3%) were insertions of IUDs and 547 (15.7%) were insertions of subdermal implants. Of the 3,477 insertions, 249 occurred in women under 20 years old. Within this adolescent subgroup, the uptake of the implant was 54.6%, compared to 45.4% for IUDs ($p<0.001$). The average age of women receiving the implant was 24.9 (± 6.5) years, compared to 31.7 (± 7.2) years for women receiving an IUD ($p<0.001$).

In bivariate analyses, the proportion of LARC insertions that occurred in women under 30 years old decreased slightly from 51.6% in 2013 to 47.7% in 2016 (Table 1). In 2013, only 5.1% of all

LARC insertions were in women with Medicaid/self-pay status, but this progressively increased to 19.6% by 2016 ($p<0.001$) (Table 1).

In terms of the overall uptake of the implant, it was 6.1% among women 30 years and older but 25.5% among women under 30 years old (Table 2). There was no association between insurance status and implant uptake among women 30 and older, but among women under 30, those with private insurance were more likely to have had an implant inserted, compared to those with Medicaid/self-pay status (26.8% versus 18.4%, $p=0.003$).

In our unadjusted temporal analyses, the uptake of the etonogestrel implant increased from 3.0% of LARC insertions in 2013 to 4.5% in 2015 and to 9% in 2016 among women 30 years and older. For women under 30 years old, the uptake of the implant stayed stable from 2013-2015 (22.8%, 21.7%, 22.4%, respectively) but increased to 30.9% in 2016.

In multivariate analyses, shown in Table 3, there was a positive association between year of insertion and odds of receiving an implant (versus an IUD), but the association was stronger for women 30 and older, where the odds of receiving an implant were 3.4 times higher in 2016 than in 2013. Among women under 30 years old, there was a negative association between increasing age and implant uptake and a positive association between implant uptake and having private insurance.

In terms of continuation of the implant over time, the 12-month continuation rate was 95.7% for insertions in 2013 (95%CI 72.9-99.4%), 82.7% for insertions in 2014 (95%CI 70.0-90.3%), and 57.7% for insertions in 2015 (95%CI 31.0-77.3%). The survivor curves are illustrated in Figure 1, and, when compared using the log-rank test, the three curves were significantly different ($p=0.009$).

Discussion

In this large retrospective study based in a private-practice setting in the United States, we found a significant increase over time in the uptake of the etonogestrel implant among women 30 years and older. In this group, the unadjusted uptake of the implant increased threefold from 2013 to 2016. We also found a progressive decrease in the 12-month continuation of the implant over time.

Our findings of an increase in the uptake of the etonogestrel implant over time are broadly consistent with the findings from a large retrospective study in the United States military health care system characterized by universal health care with no copays for contraception. In that study[3], initiation rates for the implant increased almost fourfold over the 5-year study period (2009-2014). In the same study, initiation rates for IUDs were essentially stable over time. The study, like ours, found that users of IUDs were significantly older than implant users (26.9 years vs. 23.0 years), although the age difference in our study was wider (31.7 vs. 24.9 years).

Another study using health insurance claims looked at women with a claim for any LARC between 2007 and 2011[12]. In 2007, 3.8% of the LARC insertions were implant insertions, and by 2011, 13.7% of LARC insertions were implant insertions. This study found that the increase in the uptake of the implant (versus IUDs) over time was strongest for the youngest women (15-19 years old). The results of our study, conducted in a later era, were the opposite. In our study, the association between the uptake of the implant and year of insertion was strongest among women 30 years and older (Table 3). We suspect that the timing of the two studies may play a large role in explaining the differences. The period from 2007 to 2011 was the first 4 years after the

introduction of the implant, and it is well established that this method was much more attractive to adolescents.

The results of our study and the study by Chiles, Roberts, and Klein, though similar to each other, are different from another earlier study using data from the National Survey of Family Growth[13]. In that study, there was indeed a significant increase in the uptake of LARCs from 2009 to 2012, but the increase was accounted for entirely by increases in the uptake of IUDs. Of note, this entire period was before the implementation of the Affordable Care Act in 2013. Considering that our study period extends from 2013 to 2016, we suspect that when the next analysis from the National Survey of Family Growth is conducted to examine trends from 2012 to 2015 or 2016, it will probably show an increase in the uptake of the implant as both our study and the study by Chiles et al. showed.

No other study of which we are aware has looked at 12-month continuation of the implant over time. In a large retrospective study also using billing records, Sanders et al.[10] looked at 2-year continuation of LARCs. As part of their analyses, they included "year of insertion" as a continuous variable in their adjusted and unadjusted models. Year of insertion was not associated with 2-year continuation rates in this study. Of note, this study did not separate the implant from IUDs in the analyses that included year of insertion as a covariate.

Another unique finding from this study was the association between type of insurance and type of LARC selected and the interaction between this association and age. Among women under 30 years old, privately insured women were more likely to select the implant than women on Medicaid. But among women 30 years and older, there was no such association. Other studies have shown that decreasing out-of-pocket costs can increase the uptake of LARCs as a whole,

231 but we are not aware of another study that showed that type of insurance is associated with the
232 type of LARC selected. This issue deserves further study.

233 It was intriguing to see the significant increase in the proportion of LARC insertions in this
234 private practice setting that were paid for by Medicaid. If our practice was located in a rural area,
235 we would not be so surprised. However, our practice and its nine clinics are in Las Vegas, a
236 major metropolitan area. By 2016, the fraction of LARC insertions in our practice paid for by
237 Medicaid increased to just under 20%, compared to 5% in 2013. Our speculation is that the
238 expansion of Medicaid as part of the Affordable Care Act may be a contributing factor. The role
239 of Medicaid as a payor for contraception is critical at this juncture as the United States considers
240 repealing the Affordable Care Act and reducing spending on Medicaid. Again, this issue
241 deserves further study.

242 This study has some notable strengths. This is the first study we know of that looked at temporal
243 trends in the continuation of the etonogestrel implant over time. Like other studies using billing
244 records, our sample size was large enough to permit meaningful analyses and stratification of
245 those analyses. This study also focused on patients in the private practice setting. Most large-
246 scale studies of LARCs in the United States have been done in teaching/research hospitals.
247 Further, although our billing records did not contain the race of each patient, our practice is
248 located in Las Vegas, which has a very racially diverse population.

249 This study also has notable limitations. Billing records are not created for research purposes, so
250 they do not have detailed clinical information. Additionally, billing records are based on “codes,”
251 and, because codes are input by human beings, there is always a chance of coding
252 error/misclassification. Misclassification due to coding error would mainly be a problem if it was
253 not random across comparison groups. Our practice employs certified coders who go back

though a patient's chart to ensure the documentation in the chart supports the claim submitted by the physician. This increases our confidence that our findings are not spurious. One mistake that coders cannot catch, however, is the scenario in which a physician inserts or removes a LARC but forgets to bill for that procedure. It is possible that during the study period some women may have had LARC removals and LARC insertions that were never billed for, and, therefore, those procedures would not be included in our analytic data set.

Conclusions

In this large private practice setting, we found an increase over time in the uptake of the etonogestrel implant, particularly among women 30 years and older. We also found a decrease in the 12-month continuation of the implant over time. Further studies of LARC uptake and continuation in the private practice setting are needed.

Acknowledgement

We would like to thank Jasmine Hankey for editorial assistance in preparing this manuscript.

Author Disclosure Statement

For all the authors, no competing financial interests exist.

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