Reasons for Premature Removal of Implanon among Users in Arsi Zone, Oromia Region, Ethiopia, 2013

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Abstract

**Back ground:** Ethiopian government is dedicated to expansion of Implanon insertion service to meet the huge unmet need in family planning since the beginning of 2010. Nevertheless, opting for premature removal of Implanon by the users is very rampant at this early stage of the initiative.

**Objective:** to identify reasons for premature removal of Implanon among users

**Method:** descriptive cross-sectional study was conducted from February 2012 to June 30, 2013 in Arsi Zone, Southeast Ethiopia. A total sample size of 103 was decided for data collection. Data were entered through Epi info version 3.5.3 and imported to SPSS version 16 software for cleaning and analysis. Numerical summary measures and probabilities were computed as found important. Kaplan Meier survival analysis and error bar were also employed for comparison of reasons for premature removal.

**Result:** with 97% response rate, the main reasons for premature removal of Implanon among users were heavy/prolonged menstrual bleeding, plan to conceive in the near future, about to leave for abroad and pain on insertion arm representing 36%, 24%, 15% and 13% of the reasons, respectively. The median duration the study subjects used Implanon was 19.5 months. Median duration of premature removal was significantly earlier in those who reasoned heavy/prolonged menstrual bleeding compared with those presented with plan to conceive in the near future as their reason for premature removal.

**Conclusion and recommendation:** Heavy/prolonged menstrual bleeding, plan to conceive in the near future, about to leave for abroad and pain on insertion arm were the main reasons for premature removal of Implanon and the duration of Implanon use was not long enough to be cost effective. Hence, thorough pre-insertion counseling on Implanon side effects and discussing future fertility desire and revising effective management of side effects are indispensable to increase the duration Implanon is being used.

Keywords: Implanon; In Arsi Zone; Oromia Region; Premature removal; Reasons

Introduction

Contraceptive implants are inserted sub-dermally under the skin in the upper arm. Implanon is a single-rod progestogen-only contraceptive implant with length of 40 mm and diameter of 2 mm containing 68 mg of etonogestrel (ENG) dispersed in a membrane of ethylene vinyl acetate. It delivers ENG at a dose sufficient to suppress ovulation in every cycle throughout the 3 years of use [1-3].

Although it involves minor surgical procedures, the woman should be adequately counseled, including the usual information on general advantages and disadvantages of implants. The counseling should also include offering the woman the right to discontinue Implanon use at any time, information that implant site-related adverse events could occur, as well as clarification of the rapid return to fertility once the implant is removed [2,4,5].

Menstrual disturbances are common; these menstrual side effects should be explained to women so that they can make an informed choice as to whether or not implants are the most appropriate method of contraception for them [1,3,4].

Considering the simplicity of insertion, the Federal Ministry of Health (FMoH) of Ethiopia decided to delegate Implanon insertion service to the Health Extension Workers (HEWs) so that counseling, Implanon insertion and follow-up service is available at health post and house hold level [6,7].

Training of HEWs on Implanon insertion was initially implemented in eight woredas of the Amhara, Oromia, Southern Nations, Nationalities and People (SNNP), and Tigrai regions at beginning of 2010. From Oromia Region, Worejaro woreda in North Shoa zone and Munesa woreda in Arsi zone were selected for the implementation. The ministry strongly believes that this will help to meet the needs of the clients, particularly populations living in rural areas of the country; help to prove Implanon as long-acting family planning (LAFP) method at the community level and as a means to further accelerate the successful achievements in increasing Contraceptive Prevalence Rate (CPR) faster, and thus control the population growth rate [6,7].

Nevertheless, opting for premature removal of Implanon by the users is very rampant at this early stage of the initiative which can be evidenced by the survey data of premature discontinuation rate of 54% before 1 year of use [8]. Hence, reasons for premature removal need to be identified and appropriate interventions should be designed.

Objectives of the Study

- To identify main reasons for premature removal of Implanon among users
- To compute median duration Implanon was used by

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clients who opted for its premature removal and to describe its cost-effectiveness

- To assess difference in probability of premature removal of Implanon for the identified reasons at different durations following insertion

Methodology

Study area

The study was conducted in Arsi zone which is found in Oromia Regional State and whose administrative town is named Assela. Assela is located at 175 kilometers from Addis Ababa city (capital of Ethiopia) in the Southeast direction and 75 kilometers Southeast from Adama town which in turn is 100 kilometers to East of Addis Ababa. Out of eight health facilities rendering Implanon insertion service within the zone, four were randomly selected by lottery method for data collection. Namely; Assela Marie Stopes clinic located in Assela town, Korean International Cooperative Agency-Korea Ethiopia Yonsie Family Planning (KOICA-KEYFP) project center found in Iteya town which is located 25 kilometers to Assela on the way from Adama to Assela town, Dera health center which is located in Dera town at about 20 kilometers on the way from Adama to Assela and Bokoji health center located at 54 kilometers to South of Assela town.

Study design and period

A facility based descriptive cross-sectional study was conducted through February 2012 to June 2013.

Source population

All women of reproductive age group (15-49 years of age) who were using Implanon as method of contraception

Study population

All women who requested removal of Implanon before 3 years of use following insertion during the study period at the study areas for any reason.

Sample size determination

A final study sample size of 103 was built up by adding 10% non-response rate on initial sample size of 93 which was determined using Epi-info 3.5.3 sample size determination for descriptive study with assumption of excessive or prolonged menstrual bleeding is accountable for 41% of premature removal of Implanon, from previous study, the study population size of 200 for the study period, worst proportion of 50% and confidence level of 95%.

Sampling method

The client loads requesting pre-mature removal during the study period, from the facilities’ annual report experience, at Assela Marie Stopes clinic, Iteya family planning center, Dera and Bokoji health centers were assumed to be 79, 59, 41 and 21, respectively. Then the study sample size was proportionately allotted as to get 40, 30, 21 and 11 study subjects from the health facilities in their aforementioned order. The individual study subjects from each health facility were then systematically selected using sampling interval (K) of 2. Accordingly, 40, 30, 20 ad 10 study subjects were obtained from Assela Marie Stopes clinic, Iteya family planning center, Dera and Bokoji health centers, respectively.

Data collection process

Four midwives providing Implanon removal service were employed (one from each study site) for data collection and one day intensive training was given to them on the questionnaire for data collection. Data were collected by face to face interview of study participant using a structured questionnaire after oral consent had been obtained from them. Consultation of participant’s record of Implanon insertion was made when pre-insertion or during insertion records were required. Investigating hemoglobin level for the clients who complained heavy or prolonged menstrual bleeding was also used as means of the data collection. To abolish the effect of bleeding during removal on the measurements, if taken after removal, hemoglobin level was gauged just prior to Implanon removal operation.

Operational definitions of terms

- Heavy menstrual bleeding- menstrual blood flow which client perceives as larger in amount than the usual (that learnt)
- Premature removal of Implanon- when a woman using Implanon contraceptive method requested to get it removed and done so by a health worker before 3 years of use following insertion for any reason the woman presents
- Prolonged menstrual bleeding- menstrual flow lasting more than 7 consecutive days

Data quality management

In order to assure the quality of data, training of data collectors, pre-testing of questionnaire, reviewing filled questionnaire for completeness and consistency and data cleaning before analysis were performed.

Data processing and analysis

The coded data were entered using Epi-info version 3.5.3 and imported to SPSS version 16.0 for cleaning and analysis. Data cleaning was done by displaying entered numerical data in ascending/descending orders to easily observe extreme values which were wrongly entered and corrected them referring back the hard copy (questionnaire).

Both descriptive and analytical statistical procedures were utilized. Kaplan-Meier analysis was utilized to estimate the difference of probability of premature removal of Implanon at a given durations following insertion among different reasons of removal. Error bar was also employed to show significance of difference between reasons for premature removal of Implanon.

Ethical consideration

Ethical clearance was obtained from Institutional Review Board School of Health and Hospital, Adama Science and Technology University. Using ethical clearance and letter of permission from the School of Health, permission to undertake the study was obtained from heads of study sites. Informed consent and privacy were ensured before interviewing the clients. Because study participants complaining heavy or prolonged bleeding need to have investigation of hemoglobin level so as to get treatment if found anemic, asking such participants to have hemoglobin level investigation was assumed to be harmless to them. During data collection, names and identifiers of the mothers and name of health workers who inserted and/or removed the Implanon were omitted.

Result

This study surveyed 100 women, making the response rate 97%, who were using Implanon to avoid or delay pregnancy but who opted for its removal before three years of use-the duration it was intended to serve as contraceptive.
The study assessed socio demographic characteristics, obstetric and contraceptive history of the study women, the median duration of use of implanon among users who opted for premature removal and significance of difference between contributing reasons for premature removal.

In the assessment of the socio-demographic characteristics of the study women, residence was rural for majority (55%) of them. The mean with standard deviation (SD), median and inter-quartile range (which includes 50% of study women’s age) of the study subjects’ ages were 26.6 (5.6), 27 and 22 to 30.8 years, respectively. Hence, from the inter-quartile it could be pointed out that 75% of the study women who opted for premature removal of implanon were below 31 years of age. Majority of the study women were Muslim (51%) followed by Orthodox (41%) by religion and were married (79%) by marital status. Concerning the educational background of the women, only 30% attended formal schooling and the remaining 70% had no formal schooling. Occupation of the study women was also assessed and accordingly majority of them (66%) were housewives. The socio demographic characteristics of the women who opted for premature removal of implanon are shown in Table 1.

Obstetric history was also one of the factors that were assessed in the survey. Accordingly, majority (93%) of the study women had experienced pregnancy at least once before implanon was inserted for them. Out of those who had experienced pregnancy 69 (74%) possessed 4 or less and the rest possessed 5 or more children who were alive at the time of interview. Only slightly more than half (57%) of the women experienced no abortion in the past. Table 2 below demonstrates some obstetric history of the study women.

Looking at significance of difference between contributions of obstetric factors for premature removal, Kaplan Meier survival distribution was employed and demonstrated no statistically significant difference between ever been pregnant and not pregnant women. Likewise no significant difference detected amongst those who possessed 4 or less and those who had 5 or more currently alive children, and between those who had ever experienced abortion and not.

Contraceptive related assessment of the study subjects indicated that 45% were not using any of modern contraceptives before the currently removed implanon. Whereas among those who were using contraceptive (55 women) before insertion of implanon, those who were using Depo-provera (injectable) were dominant accounting for 45 (90%) of them. One of the main concerns of this study was to assess the length of time implanon was used by those women who opted for its premature removal. Consequently, the study subjects had premature removal of implanon from as early as 4 months to as late as 35 months. The median duration of use indicated that 50% of the study subjects used implanon only for 19.5 months (i.e. they removed it before 24 months or 2 years of use). From the distribution of duration of utilization, it was identified that a big number of women (80%) got their implanon removed before 30 months (2.5 years) of utilization. An assessment of study subjects’ reasons for opting for premature removal of implanon before due date identified that heavy/prolonged menstrual bleeding which accounted for 36% of the reasons followed by plan to conceive in the near future which represented 24% and about to leave for abroad/overseas to look for job shared 15% of the reasons. Pain at the insertion arm also couldn’t be an undermined reason as it accounted for 13% of the reasons for premature removal. In 67% of the cases; partners were against using implanon as contraceptive method choice though it was not among the reasons that insisted on the study subjects to opt for premature implanon removal. The contraceptive choice of the study subjects after removal of implanon was no method in majorities (51%) and shifting from implanon to Depo-provera (injectable) accounted for 26% pursued by 15% pills and 6% loop. Assessment on contraceptive related history is shown in Table 3.

The Kaplan Meier survival distribution was employed to detect if there were differences among main reasons for premature removal in contributing for premature removal. As it is displayed in Figure 1, the plot for heavy/prolonged menstrual bleeding reason runs below those of planned to conceive in the near future, planned to leave for abroad and pain on the insertion arm reasons throughout most of the trial which suggests that women who experienced heavy/prolonged bleeding were hastier to opt for premature removal of implanon than those women with the remaining reasons.

To determine whether these differences are due to chance or not, comparisons were made between mean durations of implanon use by the reasons for premature removal with their 95% confidence intervals as it is shown in Table 4.

| Variable                  | Frequency | Percentage |
|---------------------------|-----------|------------|
| Residence                 |           |            |
| Rural                     | 55        | 55         |
| Urban                     | 45        | 45         |
| Age group (years)         |           |            |
| 15-19                     | 10        | 10         |
| 20-24                     | 28        | 28         |
| 25-29                     | 30        | 30         |
| 30-34                     | 23        | 23         |
| 35-39                     | 10        | 10         |
| 40-44                     | 1         | 1          |
| Religion                  |           |            |
| Muslim                    | 51        | 51         |
| Orthodox                  | 44        | 44         |
| Others                    | 5         | 5          |
| Marital status            |           |            |
| Married                   | 79        | 79         |
| Single                    | 16        | 16         |
| Others(divorced, widowed) | 5         | 5          |
| Educational status        |           |            |
| Didn’t attend formal school| 70        | 70         |
| Attended formal school    | 30        | 30         |
| Occupation                |           |            |
| Housewife                 | 66        | 66         |
| Employee                  | 16        | 16         |
| Student                   | 11        | 11         |
| Trader                    | 7         | 7          |

Table 1: Socio demographic characteristics of women who opted for premature removal of implanon in Arsi Zone, Oromia Region, Ethiopia, 2013

| Variable                  | Frequency | Percentage |
|---------------------------|-----------|------------|
| Ever been pregnant        |           |            |
| Yes                       | 93        | 93         |
| No                        | 7         | 7          |
| possessed number of alive children | | |
| ≤ 4                       | 68        | 74         |
| ≥ 5                       | 24        | 26         |
| Ever experienced abortion |           |            |
| No                        | 53        | 57         |
| Yes                       | 40        | 43         |

Table 2: Obstetric history of women who opted for premature removal of implanon in Arsi Zone, Oromia Region, Ethiopia, 2013
The mean durations of use of implanon before premature removal by the reasons for the premature removal offer a quick numerical comparison of earlier removal by reasons. Since there was a lot of overlap in the 95% confidence intervals of heavy/prolonged menstrual bleeding, pain at insertion arm and planned to leave for abroad reasons, it was unlikely that there was much difference in faster to remove implanon prematurely between them. However, the comparison between 95% confidence intervals for mean durations of use between heavy/prolonged menstrual bleeding and planned to conceive in the near future demonstrated that they were hardly overlap. This suggests that heavy/prolonged menstrual bleeding side effect urges implanon users to prematurely remove it significantly earlier than those who prematurely remove it because of planning to conceive in near future. Significance of difference in causing earlier premature removal of implanon among heavy/prolonged menstrual bleeding and planned to conceive in the near future reasons is further demonstrated pictorial as shown by the error bar in Figure 2.

As it is clearly displayed by the error bar, the error bar for the main reasons for premature removal overlaps each other except between heavy/prolonged and planned to conceive reasons concurring that women complaining heavy/prolonged menstrual bleeding were significantly more likely to opt for earlier premature removal of implanon.

Implanon insertion/removal & related services quality to the women under study were also assessed. Majority of the women (95%) received implanon insertion service by either diploma nurse or diploma midwifery. Only the remaining 5% of the women got insertion by trained health extension workers. The side-effects of implanon such as alterations in menstrual bleeding were informed to the women prior to insertion in 85% of the women. Among the women who opted for premature removal, slightly less than half (47%) refused reassurance and treatment to extend duration of use and received removal service on the first visit to health facility for complaint. Of those who were part of revisit (53), majority (68.8%) did so because of either reassurance or side effect treatment at first visit for their complaint couldn’t bring improvement. However, revisits because of absence of removal service provider and unready set for removal were not that small to undermine for they accounted for 30.2% of revisit reasons. In the assessment of hemoglobin level of women who complained heavy/prolonged menstrual bleeding as a reason for premature removal of implanon, the mean and the median values were 11 g/dl for both. The inter quartile range of their hemoglobin level was from 10.3 to 11.6 g/dl as it is shown in Table 5.

Discussion

This study examined the main reasons for premature discontinuation of implanon among users and median duration it was used before removal. As expected, heavy/prolonged bleeding was the main reason for premature removal representing 36% of the reasons. This figure is lower compared with findings of the studies in Australia and Scotland for which bleeding pattern dissatisfaction was the commonest reason for premature removal accounting for 50.6% and 62% of the reasons, respectively [9-13]. Report from study in Southern Nigeria identified heavy menstrual bleeding as a reason for premature removal in 28.6% of the study participants. On the other hand the figure is higher than that of other regions such as United States, Europe and Asia. Discontinuation rates owing to heavy/prolonged menstrual bleeding were approximately 14% in United States and Europe, but only 4% in Southeast Asia, Chile and Russia [9-16].

The second commonest identified reason (24%) for premature discontinuation of implanon was plan to conceive in the near future. This can be related with the fact that majority of the study subjects (75%) were below age of 31 years and majority (74%) possessed ≤ 4 currently alive children. Plan to conceive in the near future was the main reason (71.4%) in a cross-sectional study conducted in Southern Nigeria and accounted for 63.5% of premature removal reason as identified by the cross-sectional study in Islamabad which were far higher than the figure of similar reason (24%) for the current study [16,17].

As was demonstrated in the result part employing KM distribution and error bars, it could be pointed out heavy/prolonged bleeding was

| Variable | Frequency | Percentage |
|----------|-----------|------------|
| Contraceptive being used before implanon | | |
| None | 45 | 45 |
| Depo-Provera | 45 | 45 |
| Pills | 9 | 9 |
| Others | 1 | 1 |
| Duration implanon used (months) | | |
| Range | 4.0 to 35.0 |
| Inter-quartile range | 13.0 to 28.8 |
| Median | 19.5 |
| 80th percentile | 30 |
| Reasons for premature removal | | |
| heavy/prolonged bleeding | 36 | 36 |
| planned to conceive | 24 | 24 |
| About to leave for abroad | 15 | 15 |
| Pain at insertion arm | 13 | 13 |
| Unusual head ache | 6 | 6 |
| Others | 6 | 6 |
| Partner is against implanon use | | |
| Yes | 67 | 67 |
| No | 33 | 33 |
| Contraceptive chosen after implanon removed | | |
| No contraceptive | 51 | 51 |
| Depo-Provera | 26 | 26 |
| Pills | 15 | 15 |
| Loop | 6 | 6 |
| Others | 2 | 2 |

Table 3: Contraceptive use history and reasons for premature removal of implanon among users in Arsi Zone, Oromia Region, Ethiopia, 2013

Figure 1: Kaplan Meier survival distribution of the main reasons for premature removal of implanon among users in Arsi Zone, Oromia Region, Ethiopia, 2013
Reasons for premature removal | Mean duration of use (95% CI) in months
---|---
Heavy/prolonged menstrual bleeding | 15.6 (12.5-18.8)
Planned to conceive | 23.8 (20.3-27.3)
Pain at insertion arm | 22.7 (17.8-27.6)
Planned to leave for abroad | 22.3 (16.6-28.1)

Table 4: demonstrating comparison of mean durations with 95% confidence intervals implanon used before premature removal by the reasons for the removal, Arsi Zone, Oromia Region, Ethiopia, 2013

Figure 2: Demonstration of significance of difference in contributing for earlier removal Between reasons for premature removal of implanon among users in Arsi Zone, Oromi.

| Variable | Frequency | Percentage |
|---|---|---|
| Implanon inserted by | | |
| Diploma nurse/midwifery | 95 | 95 |
| Health Extension Worker | 5 | 5 |
| Informed side-effect before insertion | | |
| Yes | 85 | 85 |
| No | 15 | 15 |
| Number of visits to get removal service | | |
| On first visit | 47 | 47 |
| Second visit | 39 | 39 |
| Third visit | 14 | 14 |
| Reasons for repeated visits | | |
| Treated for the complaint at first visit | 23 | 43.4 |
| Reassured at first visit | 14 | 26.4 |
| Service provider absent at first visit | 11 | 20.8 |
| Removal set unmarried at first visit | 5 | 9.4 |
| Hemoglobin level on removal (g/dl) for those who complained heavy/prolonged bleeding | | |
| Mean | 11.0 |
| Median | 11.0 |
| Range | 9.0 to 13.0 |
| Inter-quartile range | 10.3 to 11.6 |

Table 5: Implanon related service quality to women who opted for premature removal of implanon in Arsi Zone, Oromia Region, Ethiopia, 2013

One of the important concerns of this study was to assess duration of implanon use. Implanon is assumed cost effective if used for 24 months by majority of the users [1,2]. The result of this study identified median duration of use was 19.5 months (i.e. 4.5 months earlier than 2 years) and the mean duration (SD) of use was 20.3 (9) months.

The result of the study on safety and efficacy from 11 clinical trials undertaken in United States, Chile, Asia and Europe showed the mean duration of use of implanon was slightly more than 2 years (24.3 months) and only nearly 20% of the study participants discontinue as prematurely as before one year of use which is comparable with 25% of this study’s. The slight difference between the figures could be because of the denominator in this study was only those who discontinued prematurely (included duration of use of up to 35 months) which makes the proportion larger than when the whole cohort of users considered.

To compare with injectable (Depo Provera) which has similar content & side effects with implanon, total 12-month discontinuation rates for injectables varied widely, from 18 percent in Indonesia in 2002/03 to 67% in the Dominican Republic in 2002. The variability in these rates may be due to in part to greater availability of monthly injectables in Latin American countries than in other regions [18]. Majority of the study participants (85%) reported pre-insertion information about side effect was given to them by the service providers as opposed to the survey done in 4 regions of Ethiopia which reported only 32% told about side effect though association was not found between premature discontinuation and pre-insertion information about side-effects in that study [8].

Conclusion

The main reasons for premature removal of implanon among users were heavy/prolonged menstrual bleeding, plan to conceive in the near future, about to leave for abroad and pain on insertion arm. Women who gave plan to conceive as reason for premature removal were found to postpone the removal significantly for longer time compared with those who were reasoning heavy/prolonged menstrual bleeding indicating the former was easier to reassure on than the later reason for premature removal. Though heavy/prolonged bleeding complainers were earlier to prematurely remove when compared with plan to leave for abroad and pain on insertion arm reasons, the difference was not found significant. In this study, the duration of implanon use was hardly long enough to conclude it as cost effective method.

Recommendation

As presence of dissatisfaction with alteration in menstrual bleeding desperately insists implanon users for premature removal, users should be well informed about tolerability of the side-effect during pre-implanon insertion counseling. Additionally, treatment options for heavy/prolonged menstrual bleeding side effect arising from using implanon should be identified and need to be instituted to prevent potential complications that could follow the side effect.

Pre-implanon insertion meticulous assessment about future fertility desire and plan especially among women less than 31 years of age and those possessed fewer than 5 children should be given due attention as the problem of premature removal was also substantial for the reason near future fertility plan by those users. Similarly, thorough pre-insertion assessment should be done to predict those who have plan to leave for abroad and advise them to prefer short acting family planning methods like injectables rather than long acting implanon. Furthermore, reassurance and pain management for those complaining insertion arm pain is recommended to increase the duration implanon is being used.
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