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Original Article

Experiences of Women and Assessment of Efficacy and Side Effects of Sub-dermal Implants in Rural Islamabad

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Abstract

Background: One of the millennium development goals is to improve the quality of women's health through choice, accessibility and gender equality. Contraception plays an important role to reduce maternal and child mortality by avoiding unwanted pregnancies.
Objectives: To study the acceptability, success rate and short term side effects of sub-dermal contraceptive implants (SCI) available as SINO Implant (II) and to determine the reasons for its discontinuation.
Study design, settings and duration Descriptive prospective study conducted at a Private Medical Centre, Trameri, Islamabad from February 2015– February 2016.
Subjects and Methods: All women aged between 25-45 years wishing to use sub-dermal contraceptive implants were included in the study. Women with bleeding disorders and those weighing > 80kg were excluded. All women were explained about the study and written informed consent was taken. The contraceptive implants SINO (II) containing Levonorgestrel were placed under local anesthesia. A questionnaire was used to collect information on demography and study specific variables e.g. side effects, implant acceptability, satisfaction and reasons for discontinuation. Women were followed at the clinic and also telephonically at interval of one and six month post insertion.
Results: Out of 105 women**,** 08 did not meet the criteria for insertion and were excluded, while 97 women were enrolled for the study. Their mean age was 31 years (SD ± 5.34). Minimum parity was 01 and maximum 07. Mean period of last child birth (LCB) before implant insertion was 25.35 months (SD ± 32.86, range 1-156 months). Out of 97 women, 51 (53.4%) were using some kind of contraception prior to the placement of implant. Most common side effect of implant were spotting 17 (18%) followed by irregular vaginal bleeding and weight gain in 11 (12.2%) each. At 6 months, rate of continuation of implant was 82.7% with 62 (64%) women having no complaints at all while 35 (36%) experienced some. After 6 months, 77 women (79%) continued to use the implant, while 12 discontinued it (5 had removed in first 3 months, 7 between 3 and 6 month after insertion).
Conclusion: Sub-dermal contraceptive implants were safe and convenient to use with high acceptability. They can be used as the method of choice for long term reversible contraception.
Key words: Sub-dermal contraceptive implant, reversible contraception, levonorgestrel.

Introduction

Contraception is an important part of reproductive health[1] and significant progress has been made in development of contraceptive devices over the last 50 years. The millennium development goals focus on reproductive health as a major target emphasizing the importance of choice, accessibility and gender equality. Access to contraception is a global issue.

Pakistan is the 6th most populous country in the world. It has approximately 182.1 million population with 63% living in rural areas. In Pakistan use of contraceptives is low (35%) and women induce abortions as a tool of family planning.[2] About 2.2 million induced abortions took place in Pakistan in 2012 with an annual abortion rate of 29 per 1000 women. These figures were 27 per 1000 women in 2000.[3] Pakistan is one of the six countries in the world where more than 50% of the world's all maternal deaths occur i.e. one woman dying every twenty minutes and 30,000 dying annually due to pregnancy-related complications.[4]

Currently Subdermal Contraceptive Implants (SCI) are available as *Implanon®*, *Jadelle®*, and *Sino-implant II®*. These implants provide 3 to 5 years of reliable contraceptive protection. Their insertion requires minor surgical procedure where 1 or 2 plastic rods are placed beneath the skin of the inner upper arm under local anesthesia.[5]

Compliance with SCI is good as it is an implant and not a daily pill. Side effects are few due to sustained blood levels of hormones. Being removable, it is a long acting reversible contraceptive method. Implants do not alter blood pressure.[2] SCI does not provide any safety against AIDS and STDs. A study reported that about one fourth of implant users were at risk of contracting STDS.[3] Side effects of implant include longer, heavier periods, increased spotting and light bleeding between periods and local reaction or sepsis.[6]

Insertion of Sino-implant (II) is done as a minor outdoor surgical procedure which takes few minutes. Implant is inserted in the inner side of upper arm under local anesthesia, through a small incision and is inserted under the skin using trocar. After inserting both rods, the trocar is removed and the incision is bandaged without stitches. For its removal a minor incision is made over the implant and the implant is pushed towards the incision point and pulled out using a forceps.[7]

Globally, 1% women use SCI.[8] Despite the availability of both short and long term contraceptives many women cannot access contraception, and unplanned pregnancy is estimated around 50% of pregnancies in both developed and under developing countries.[9] For this reason Millennium Development Goal # 5 is advocating universal access to contraception which is still lagging far behind.[10] No other reversible contraceptive system has been found so effective.[11]

This study was done to determine the side effects, safety and acceptability of SCI and Sino II (levonorgestrel) in a rural community of Islamabad with the objective to promote SCI as first line long term contraceptive method.

Subjects and Methods

All women aged between 25-45 years who were visiting the private medical center during the study period for the insertion of sub-dermal implants were included in the study. Women were explained about the study and written informed consent was taken from them. Women weighing > 80kg were excluded. A questionnaire was used to collect information on demography and study specific variables like side effects, implant acceptability, satisfaction and reasons for discontinuation. Clients were followed at the clinic during their follow up and also telephonically at an interval of 01 and 06 months post insertion.

Satisfaction was assessed using satisfaction scale. This scale has three variables to calculate the satisfaction and included staff helpfulness towards clients, expertise of provider and availability of staff to manage side effects at follow up. Responses were graded as very satisfactory, satisfactory, ok, dissatisfactory and very dissatisfactory. Serious complaints e.g. heavy vaginal bleeding and local site infections were treated during follow up visits. Implants were removed as per woman's desire if and when desired.

After counseling, insertion site was sterilized. Local anesthesia was given at the site of insertion and two rods of SCI (Jadelle-Trocar, Ref. 81075175, Bayer Pharma AG, Berlin Germany) were placed under the skin on the inner side of upper arm 8 cm above the elbow using a trocar. Clients were asked to come for follow up at 1st and 6th month. Each client was educated about post insertion common side effects e.g. pain, bruise and a contact phone number in case they need any assistance any time. Collected data was entered in excel sheet followed by data cleaning. Analysis was done using Statistical Package for Social Sciences (SPSS) version 20.

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Authors Contribution

NJ have done the conceptualization of project, statistical analysis, drafting, revision and writing of manuscript. TM did the data collection. Literature search was done by HA.

The study was approved by the Institutional Ethical Review Board.

Results

Out of 105 women seen during the study period, 08 did not meet the criteria for insertion and were excluded, while 97 women were enrolled in the study. Their mean age was 31 years (SD ± 5.34). Minimum parity was 01 and maximum 07. Mean period of last child birth (LCB) before implant insertion was 25.35 months (SD ± 32.86, range 1-156 months). Weight of the women ranged from 60-65kg.

Out of 97 women, 31 (53%) were previously using some kind of contraception with intrauterine device being the most common method (12.2%) followed by injectable progesterone (n=11, 19%), oral contraceptive pills (n=3, 5%), barrier methods and emergency contraceptive pills by one each. Six (14%) participants were not using any method while 27 (33%) did not answer.

When questioned why they chose SCI for contraception, counseling by doctor was the common response given by 51 (64%) clients. Lower frequency of side effects (22%), longer (5 years) period of protection (12%), convenient technique (10%), good experience by friends (9%) were other reasons for choosing this method.

One client was lost to follow up at first visit after 1 month and 3 were lost on 2nd follow up. At 2nd follow up, ten women got their implants removed due to side effects like spotting, irregular vaginal bleeding and weight gain (Figure-1). After one month, 61% clients were satisfied with SINO II while at second follow up, 64% were satisfied.

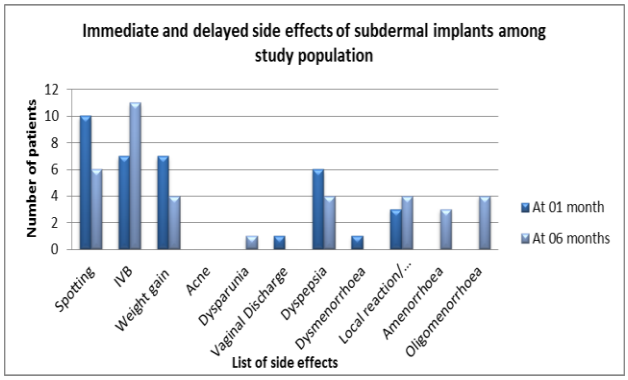

Figure 1: Reasons for implant removal.

After 6 months (second follow up) implant continuation rate was 88%. A total of 12 clients got their implants removed before end of study. Five out of 12 had it removed within first 3 months while 07 got it removed later. Reasons for removal of implants are shown in Figure-2.

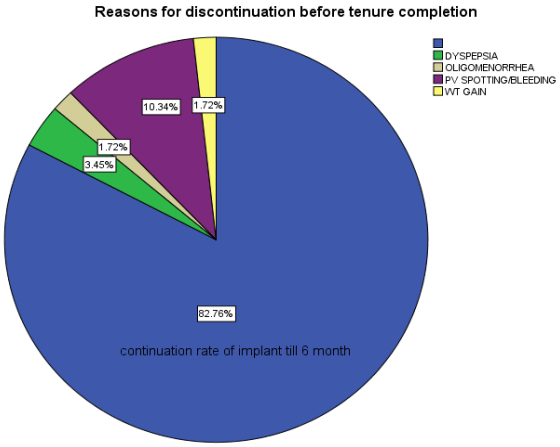

Figure 2: Reasons for implant removal before study period.

Discussion

Present study showed that SDI SINO II was well accepted reversible long acting contraceptive that had fewer side effects and minimum physician consultation.

Weight gain was the second common side effect reported in our study. The mean weight of our study population was 62kg. At first follow up, 07 women (12%) reported weight gain however objectively there was no increase in weight. Previous workers have also reported weight gain, headache and acne jointly leading to > 50% of removal of implants.[12] However in our study weight gain was not the reason for removal of implants.

Post insertion complications of SDIs include spotting, irregular vaginal bleeding for longer periods and amenorrhea.[13] Same complications were reported in our study where 10 clients had spotting (17.54%) and 7 had irregular vaginal bleeding (12.28%) at first and second follow up respectively.

Among many available contraceptive methods, Sub-dermal implants are found effective and convenient contraceptive methods with good compliance.[14] Another study showed that pregnancy probability at first year for sub-dermal implants ranged between (0.0%) to (0.1%).[15] A study conducted in Kenya and Pakistan also reported Sino II to be highly effective, safe and acceptable over 12 months period.[8] Our study showed similar findings. None of the women became pregnant during study follow up period.

Minor side effects of SDIs include headache, acne, weight gain, breast tenderness which occur in only (20 – 30%) clients.[6] In our study at first follow up only two women (3.5%) presented with mastalgia, 1 developed dyspepsia while another had dyspareunia.

Results of another study revealed that there is a low rate of discontinuation for implants at 6 months.[16] Because SDIs are long acting and reversible

contraception devices that have few side effects and minimal follow up is required, therefore they should be propagated as the first line of contraceptive method especially in developing countries.[12] Same is found in present study where out of 97 clients, 85 (88%) women continued with this method.

Conflict of interest: None declared.

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