

# Evaluation of Levonorgestrel Subdermal Implant as Long Term Reversible Contraceptive

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## Abstract

**Background:** To study the reasons of acceptability, efficacy, short term and long term side effects of Levonorgestrel Subdermal implant as long term reversible contraceptive.

**Methods:** In this descriptive study women (n=13) were counselled regarding Levonorgestrel SDI. Levonorgestrel SDI was inserted sub-dermally in the upper arm under local anaesthesia. Information was collected regarding study specific variables. Follow up was performed at 1 and 6 months and 12, 24 and 36 months.

**Results:** Maximum number of patients wanting levonorgestrel subdermal implants were between 30-35 years. Majority of women opting for this procedure had 3-4 live issues. Majority (44%) of the women choose this method based on personal information. Most common side effect was heavy and irregular vaginal bleeding 18.7% after 6 months, and 17.3% after 12 months. Patients advised medical treatment for heavy menstrual bleeding did not respond well (cyclical progestogens and tranexamic acid). Fifteen percent of users got SDI removed by end of 12 months, mainly due to above side effects. The 3-year cumulative pregnancy rate was zero.

**Conclusion:** Levonorgestrel SDI can be an acceptable, convenient and effective long term reversible contraceptive method. Menstrual disturbances and feeling of weight gain are the major reported side effects, leading to discontinuation of the method.

**Key Words:** Long term reversible contraception, Levonorgestrel, Irregular vaginal bleeding.

## Introduction

Pakistan is a developing country with high maternal mortality and perinatal mortality and significant maternal and child morbidity. This situation can only be improved if pregnancies are planned and unwanted pregnancies are avoided through promotion of appropriate methods of contraception in young women. Rapid population growth high rates of unintended pregnancies and hazards of unsafe abortions are problems faced by developing countries

like Pakistan. Maternal mortality and morbidity is higher in patients without contraception use.<sup>1</sup> Most of the women (75.8 %), in reproductive age, require and seek family planning services.<sup>2</sup>

In 2011 Peripert et al proposed that long acting reversible contraceptives (LARC) have high efficacy and in order to reduce the number of unwanted pregnancies clinicians should offer long term reversible contraceptives as first line options.<sup>3</sup> Recent advances in contraception have developed methods which are safe, reversible and more easily available.<sup>4</sup> Levonorgestrel Subdermal Implants (SCI) were introduced nearly 28 years back and are marketed in more than 25 countries. Currently they are available in Pakistan with Trade name of Jedelle and Sino II. Levonorgestrel SDI are two flexible rods containing 150 mg of Levonorgestrel which is released slowly over 3-4 years causing anovulation, endometrial thinning and thickened cervical mucus.<sup>5</sup> These implants provide contraception for 3-5 years.<sup>1</sup>

They are inserted by minor surgical procedure where two match stick size, soft rods are placed sub-dermally in the upper arm under local anaesthesia.<sup>4</sup> Levonorgestrel SDI can be removed any time before the specified period on clients wish. This method has many advantages e.g. is free from hassle of daily pill taking and there is no need of monthly clinical visits as in case of injectable contraceptives. SCI becomes active in nearly 48 hours after insertion and does not interfere with coital activity. They are suitable for patients suffering from medical disorders like mild hypertension and diabetes and safer regarding thromboembolic effects. But they offer no protection against sexually transmitted diseases.<sup>6</sup> Common side effects include irregular menses, breast tenderness, headache, dyspepsia and feeling of weight gain.

Insertion of the implants is done as an outdoor surgical procedure. Under aseptic measures and local anaesthesia two flexible rods containing Levonorgestrel are inserted under the skin of upper arm with the help of a trocar. Small aseptic dressing is applied to cover the wound. For removal, a small incision is made at the lower edge of the inserted rods

which then are removed with the help of small artery forceps.<sup>7</sup>

## Subjects and Methods

This prospective observational study was performed at Contraception Clinic, Department of Gynae/Obs, Rawal Institute of Health Sciences, Islamabad, from July 2014 to December 2017. Women, 20 to 45 years old (n=130), opting for the study were told about its purpose, method of insertion and plan of follow up. Follow up was performed at 1, 6, 12, 24, and 36 months interval. Insertion was performed in the minor operating theatre. After evaluation patient was advised to come on 4<sup>th</sup> to 5<sup>th</sup> day of menses. The inner side of upper arm was cleaned and draped, under local anaesthesia two rods of levonorgestrel subdermal implant (Jedelle - Trocar, reference 81075175 Bayer Pharma AG, Berlin Germany) were placed under the skin 8 cm above the elbow (Figure 1 & 2). Women with BMI  $\geq$  30 Kg/m<sup>2</sup>, with severe liver disease, with high risk for thromboembolism and who were within first 6 weeks postpartum, were excluded. Clients were counselled regarding possible side effects and care of insertion site. Follow up was performed in the contraceptive clinic or on telephone at specified intervals. Women were informed that they can come to the clinic any time they need help or treatment.



Figure 1&2. Subcutaneous Levonorgestrel Subdermal implant placed under the skin 8 cm above the elbow

## Results

Mean age of implant users was 32 years, with maximum number between 31-35 years. Women having 1-4 children were equally interested in the method. Majority (38%) had 3-4 children. Weight of women ranged from 60-65 kg (Table 1). More than half (58.6 %) of the clients were previously using a contraceptive method, but wanted a new, safe and convenient method (Table 2). Fifty four (42%) adopted Levonorgestrel on doctor or health care providers advice (Table 3). The most common short term side effect was dyspepsia and loss of appetite (7.7 %), and feeling of weight gain (7.7%). The most common long term side effect was heavy menstrual bleeding mostly

reported at 6 to 12 months by 14% and 13.3% respectively (Table 4). This was also the major cause for removal of SDI. Cumulative pregnancy rate over 3 years was zero (Table 4).

**Table 1: Sociodemographic characteristics**  
(n = 130)

Age / years	No	Percentage
20 - 25	22	17 %
26 - 30	38	29%
31 - 35	52	40%
36 - 40	14	11%
41 - 45	4	03 %
Number of live children		
1-2	48	37%
3-4	50	38%
5-6	22	17%
>6	12	09%
Last child born /years		
<1	56	43%
1-2	30	23%
3-4	24	18%
>5	10	7.6%
Not known	10	7.6%

**Table 2: Previous Contraception Used By Levonorgestrel SDI Users**

Method	No	Percentage
Contraceptive pills	16	12%
Contraceptive injections	18	13%
Condoms	10	08%
Withdrawal method	-	-
IUCD	32	24%
None	54	41%

**Table 3: Reason for accepting Levonorgestrel SDI (n=130)**

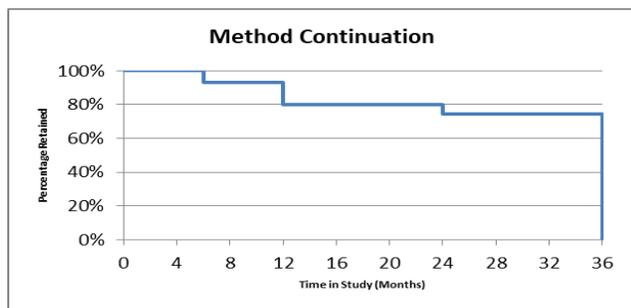
Reason	No	Percentage
Doctor's/ Health-care Provider's Advice	54	42%
Personal Decision (information through social media, literature, etc.)	57	44%
Good Experience By Relative / Friend	19	14%

The method continuation at end of 24 months was 79%. At 36 months it was 73% (Figure 3). The main reason for discontinuation was menstrual problems, 18 users were unable to tolerate this side effect. The second-most common reason for discontinuation was

gastric problems (dyspepsia and loss of appetite) weight gain resulting in device removal in 3 cases each (Table 5)

**Table 4: Frequency of side effects over 3 years**

Side Effect	1 month	6 months	12 months	24 months	36 months
	(n= 130)	(n= 129)	(n= 120)	(n= 101)	(n=: 94)
	No(%)	No(%)	No(%)	No(%)	No(%)
No Complaint	92(70.8)	88(68.2)	55(45.8)	70(69.3)	78(83.0)
P/V Spotting	4(3.1)	2(1.6)	4(3.3)	2(2.0)	1(1.1)
Irregular menses	0(0.0)	4(3.1)	10(8.3)	4(4.0)	4(4.3)
Heavy menstrual Bleeding	10(7.7)	18(14.0)	16(13.3)	8(7.9)	2(2.1)
Amenorrhoea	1(0.8)	2(1.6)	4(3.3)	0(0.0)	0(0.0)
Vaginal Discharge	2(1.5)	0(0.0)	0(0.0)	0(0.0)	0(0.0)
Change of Appetite / Dyspepsia	10(7.7)	4(3.1)	2(1.7)	4(4.0)	0(0.0)
Weight gain	10(7.7)	2(1.6)	12(10.0)	4(4.0)	4(4.3)
Reported Pregnancy	0(0.0)	0(0.0)	0(0.0)	0(0.0)	0
Lost	1(0.8)	3(2.3)	3(2.5)	4(4.0)	0(0.0)
Removed	0(0.0)	6(4.7)	14(11.7)	5(5.0)	5(5.3)



**Figure 3: Method continuation over study period**

**Table 5: Reason for discontinuation Levonorgestrel SDI (n= 30)**

Reason	Frequency	Percentage
Planning next pregnancy	05	16%
Menstrual problems	18	60%
Medical reasons	01	3.3%
Weight gain	03	10%
Gastric problems	03	10%
Social reasons	--	--
Reported pregnancy	--	--

## Discussion

Unwanted and unintended pregnancies are major cause of maternal morbidity and mortality in terms of induced abortions, social problems and uncontrolled medical diseases like severe anaemia, diabetes and hypertension. This grave problem can only be solved if these women are advised appropriate and effective contraceptive method. Pakistan being a developing country needs LARC (long acting reversible contraceptives) to be included in public welfare programs. Levonorgestrel SDI are on WHolist of essential medicine as most effective and safe medicine needed for health care system. <sup>8</sup>This method is highly effective birth control method with one year failure rate of 0.05.<sup>9,10</sup> This is consistent with our study where no pregnancy was reported during implant use. Also it was acceptable by women of all parities.

In Pakistan use of Levonorgestrel SDI is nearly 1% according to statistics provided by Marie Stopes Society, Pakistan.<sup>11</sup> We wanted to determine the reason of acceptability of levonorgestrel SDI, in our study. Majority (42%) users opted for the method on doctors' advice, hence health care providers play important role in helping women's decision making. Similar results were shown by a study carried at Family Planning Centre of Liaquat University Hospital.<sup>12</sup> But majority of women 44% who opted for the method, made their own choice based on media and social information. These findings were inconsistent with an international study carried out in Greece, Germany and Turkey stating that women's decision regarding family planning method is influenced more by family members and health care provider.<sup>13</sup> We found out that if media campaigns, information leaflets and lectures are designed keeping in view cultural, religious and economic factors. They are highly effective in promoting the use and continuity.

Different side effects were reported by Levonorgestrel SDI users. In USA even lawsuits were filed against the manufacturer and the doctors who prescribed the method.<sup>14</sup> In our study the most intolerable side effects reported were irregular menstrual bleeding, weight gain. Less common effects were headache, nausea, dyspepsia and feeling of weight gain. Implanon, a SDI consisting a single match stick size rod containing etonogestrel, now it has been replaced by Naxplanon.<sup>15</sup> Implanon users also reported side effects e.g. irregular menstrual bleeding, breast tenderness, loss of libido, headache and mood changes.<sup>16</sup> Severity of this side effect was not emphasized in previous studies by Azmat SK, Bahamondes L, and Ali M.<sup>11,17,18</sup> We found out that

most common side effect was irregular menstrual bleeding but its frequency was higher than reported by previous studies 18.7%).<sup>17,18</sup> In most women it was not so heavy so as to cause medical problems like anaemia but had serious religious and social impact, this is consistent with a multicentre study carried by Population Welfare department Sind.<sup>11</sup> The affected women were unable to perform prayer regularly or maintain fast. They were unable to have desired sexual relationship due to irregular vaginal bleeding which caused marital discord. Demographic features, religious beliefs and husband and wife communications greatly influence the choice and continuation of family planning method.<sup>19</sup> We also experienced that most women who were willing for medical treatment with tranexamic acid and cyclical progestogens did not respond well to this treatment and ultimately got the implant removed.

### Conclusion

1. Levonorgestrel SDI is a convenient, effective and acceptable long term reversible contraceptive method for our population.
2. Services provided by trained health care provider with good clinical judgment increases acceptability of the method.
3. Menstrual disturbances is major side effect and its incidence is higher than reported in previous studies. Intolerance to irregular and heavy menses was the most common reason which compelled users to discontinue this method.
4. Regular follow up is important because early recognition of users' problems, timely education and treatment improves long term adherence of the method.

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