Early Removal of the Norplant System

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The levonorgestrel contraceptive implant system (Norplant System) is a method of birth control consisting of six soft flexible plastic (Silastic) capsules that are inserted subcutaneously in the upper arm. The system was introduced worldwide in 1975 and was approved for general contraceptive use in the United States in December 1990.[1-3]

The levonorgestrel implant system has been a very successful form of contraception, with many positive features. The typical failure rate is equal to sterilization (Table 1).[2,4] This system is also convenient and retains full effectiveness without patient compliance or interruption of sexual activity. Contraception is usually quickly reversible after surgical removal of the implants.

As with most therapeutic modalities, there are undesirable side effects with the levonorgestrel implants, which cause some women to decide to have the implant removed before the completion of the full 5-year term. The purpose of this study was to determine both the major side effects of and primary reasons for removal of the levonorgestrel implants in women who have the device removed prematurely.

Methods

We reviewed the records of all patients who had their contraceptive implant removed at Louisiana State University Medical Center from June 1992 to July 1993. Patients who had the system removed after 2 years or less were selected for study. These patients were interviewed by a medical student in the clinic or by telephone. Using a structured format, information was recorded on patient demographics, gravity and parity, side effects, main reason for implant removal, how long the implant was in place, and attendance at preinsertion patient education classes.

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Table 1. Typical and Optimal Failure Rates for Commonly Used Birth Control Methods.

Method	Typical Failure Rate	Optimal Failure Rate
Chance	85.0	85.0
Spermicides only	21.0	3.0
Periodic abstinence	20.0	2.0 - 9.0
Withdrawal	18.0	4.0
Cervical caps	18.0	6.0
Diaphragm	18.0	6.0
Condom	12.0	2.0
Intrauterine device	3.0	0.8 - 2.0
Oral contraceptive pill	3.0	0.1
Female sterilization	0.4	0.2
Injected medroxyprogesterone	0.3	0.3
Male sterilization	0.2	0.1
Levonorgestrel implants	0.04	0.04

Modified from Trussell.[4]

Removal Technique

The implanted capsules were located by palpation. A small amount of 2.0 percent lidocaine with epinephrine mixed with 8.3 percent sodium bicarbonate solution (50:50) was applied under the capsule ends nearest the original incision site. An approximately 4-mm incision was made close to the ends of the capsules. Each capsule was exposed and grasped with a mosquito forceps. The tissue sheath was gently opened, and the capsule was removed with a second forceps. The incision was usually closed with sterile adhesive strips and bandaged. Counts were done to document that all six capsules were removed.

Results

Seventy women were found who had their contraceptive implants removed after 2 years or less. Of those women, 40 were contacted and interviewed. Their average age was 22 years; 75 percent were black, and 24 percent were white. The women had given birth to an average of 2 children, with a minimum of 0 and a maximum of 6. The average length of time the women kept the implant was 13.4 months.

The most frequently self-reported side effects associated with the use of the contraceptive im-

Table 2. Reported Side Effects (Percentage) of Levonorgestrel Implants in Adults.

Side Effect	Mayeaux et al	Frank et al[3]	Cullins et al[2]	Cullins et al[5]	Crosby et al[6]
Headache	59	62.0	49.0	4.4	22.5
Irregular uterine bleeding	56	58.0	-	38.2	41.3
Amenorrhea	54	44.0	-	21.3	
Weight gain	49	62.5	22.0	1.1	14.5
Dizziness	44	38.0	18.5	-	-
Mastalgia	43	40.5	-	-	-
Heavy uterine bleeding	41	45.0	-	-	-
Nausea	38	42.5	-	-	-
Mood change	36	-	-	-	8.0
Depression	36	39.0	9	-	-
Itching	33	-	-	-	-
Anxiety	33	35.0	8	-	-
Abdominal pain	31	-	10	3.3	-
Hair loss	31	22.0	24	-	10.1
Local pain	18	30.5	-	13.4	18.1
Weight loss	15	-	-	-	-
Acne	13	39.5	-	1.1	-
Hair growth	13	18.0	-	-	-
Insomnia	13	-	-	-	-
Pregnancy*	8	11.0	-	-	8
Hypertension	5	-	-	-	-
Anemia	5	-	-	-	-
Visual changes	5	-	-	-	-

*Desired to become pregnant or pregnancy was discovered after implantation.

plant were headaches 59 percent, irregular uterine bleeding 56 percent, amenorrhea 54 percent, weight gain 49 percent, dizziness 44 percent, mastalgia 43 percent, heavy uterine bleeding 41 percent, and nausea 38 percent. Mood change, depression, itching, and anxiety were experienced by at least 33 percent of the women (Table 2[2,3,5,6]). Most of the women experienced multiple side effects, with the average number of symptoms being 6.8.

The five major reported reasons that specifically precipitated implant removal were irregular or heavy uterine bleeding 27 percent, amenorrhea 19 percent, headaches 16 percent, weight gain 14 percent, and hair loss 14 percent. Estrogen was administered in an attempt to control symptoms in only 4 percent of the women who were contacted.

Eighty-seven percent of the women in this study attended patient education classes where side effects were discussed. Eighty-two percent said they knew before insertion of the implants that bleeding abnormalities were a common side effect. Only 6 percent of patients said side effects interfered with sexual activity. Of the women who had the implants removed prematurely, 47 percent said they would recommend this birth control method to a friend.

Discussion

The reported side effects in women who had their levonorgestrel implants removed were similar to the side effects reported by all users. This finding is consistent with the findings of previous studies.[2,3,5,6] We found a higher than expected percentage of women in whom headache and amenorrhea precipitated removal. The average number of symptoms in the patients who had the implants removed was 6.8. This finding is similar to the findings of Frank et al,[3] who noted that women who had the levonorgestrel implants removed had an average of 5.1 side effects, which was significantly more than the number of side effects experienced by the patients who retained their implants.

Nevertheless, 47 percent of the patients in this study who had prematurely discontinued levonorgestrel implants said they would recommend this contraceptive method to their friends. If it can be assumed that these patients do care about the well-being of their friends, then this finding might

imply a basic acceptance of the contraceptive method in spite of its side effects. Other studies also suggest a relatively high acceptance rate for levonorgestrel implants among women of various ages and socioeconomic backgrounds, despite side effects associated with the method.[2,7,8] Cullins et al[2] noted that 95 percent of their study patients who had the implants in for 1 month would recommend the method to a friend. Eilers and Swanson[9] found that 74 percent of current users would recommend this form of birth control to a friend. With specific regard to removals, Darney et al[10] found that 61 percent of women who discontinued the contraceptive implant said they would use the method again. It is important to note that these patients were highly motivated and intensely counseled—factors that likely contributed to the high satisfaction rates.[11] This degree of interest and preparation points to the critical role of proper patient screening and counseling to help anticipate and manage expectations about side effects, particularly as women differ in their willingness to accept and tolerate such events.[11]

In several studies counseling about the side effect of irregular bleeding has been shown to have a beneficial effect on continuation rates with levonorgestrel implants.[2,5,6] Nevertheless, 87 percent of the women in our study attended classes that addressed potential side effects, and still they had the capsules removed. This finding underscores the need for more careful patient screening and selection before the contraceptive implant is inserted. No contraceptive method is appropriate for everyone, and presenting the contraceptive implant as a panacea for all women will inevitably lead to some dissatisfied users. Because headaches, weight gain, and hair loss were also commonly cited problems in our study, health care providers might want to stress these specific problems when working with their patients in counseling sessions.

Although patient counseling clearly can help manage expectations about side effects, therapeutic interventions also are available that can help ameliorate the most commonly reported nuisance side effect: irregular bleeding. Ethinyl estradiol and nonsteroidal anti-inflammatory drugs (ibuprofen) have been shown to help temporize dysfunctional uterine bleeding in women with levonorgestrel implants.[12,13] Only 4 percent of physicians in this study, however, were reported to prescribe estrogen to control spotting or prevent amenorrhea. In our study some or all of the 46 percent of patients who indicated that menstrual problems precipitated removal might have benefited from short-term estrogen therapy and might have continued with their contraceptive implants. Not only might this approach have increased user satisfaction, it also would have provided patients with greater economic benefit by allowing amortization of the cost of the implant system for a longer period.

Understanding issues related to patient satisfaction is particularly timely in view of recent publicity concerning the litigation involving the Norplant System manufacturer. Anecdotal evidence suggests that use of the levonorgestrel implant system has dropped in the United States, possibly because of negative media attention surrounding a series of class-action lawsuits. Most of these suits have been based on claims of post-insertion pain, removal difficulties, insufficient warning about potential side effects, and inadequate training of health care professionals regarding insertion and removal. The manufacturer is aggressively fighting all of the lawsuits as baseless.

Norplant System insertion and removal procedures are 15- to 30-minute surgical procedures that are not difficult, although specialized training is provided. Complications with insertions have been reported in 4.5 percent to 7.5 percent of medically prompted discontinuations, and difficult removal cases have been due primarily to improper insertions or the clinician's inexperience in performing the procedures.[14] According to product labeling, the incidence of removal difficulties in women participating in clinical trials has been 13.2 percent.[15] The manufacturer and several independent groups provide training programs and educational videotapes for educating health professionals about insertion and removal procedures.

In the event of difficult removals, alternative removal techniques are also available. Darney and colleagues[16] have developed the "pop-out" technique, which involves manual manipulation of the capsules through a transverse incision. The "U" method and modified "U" method use a vertical incision and an oval ring-tipped forceps to remove the capsules.[17,18] Techniques, such as sonography, to better visualize capsules for removal have also been described.[19]

In this current atmosphere of health care reform, cost-effectiveness of contraceptive options will likely come under increased scrutiny by both physicians and patients. Continued use of the levonorgestrel implants is very cost-effective during a 5-year period but is less so with shorter periods of use. One study of eight contraceptive methods, including the levonorgestrel implants, medroxyprogesterone acetate injection, oral contraceptives, and diaphragm, reported that the implant system was among the most cost-effective reversible methods for 5 years of use, second only to the intrauterine device.[20] Similar findings were reported by Trussell et al[21] in an analysis of 15 contraceptive methods that took into account direct medical costs associated with type of method, side effects, and unintended pregnancies. The cost-effectiveness of the implant system increased with duration of use, so that it was among the most cost-effective methods at 5 years of use. Even with a more limited duration of use, however, the cost of the implant system approached that of an oral contraceptive method after about 2 years. We also found a similar level of cost-effectiveness when comparing the cost of the levonorgestrel implant system with that of oral contraceptives in Shreveport, La. According to our local analysis based on a $350 Norplant kit and $150 insertion fee, the cost of levonorgestrel implants equals the cost of oral contraceptives (which average about $21 per month) at 24 months of use.

Conclusions

Headaches, weight gain, and hair loss, in addition to irregular uterine bleeding and amenorrhea, can be annoying side effects of levonorgestrel implants. Because such side effects can lead to early removal in patients who might otherwise benefit from this contraceptive method, it is important for clinicians to help patients carefully evaluate and understand the advantages and disadvantages of the method. Diligent patient screening and counseling are essential to prepare patients for possible side effects as well as for the surgical procedures associated with insertion and removal. Furthermore, because studies have shown that the addition of estrogen can improve dysfunctional uterine bleeding, such treatment should be considered by physicians for patients who experience bleeding problems and who wish to continue with the method. With appropriate counseling and medical treatment to manage side effects, primary care clinicians can help patients understand and maximize the benefits of the long-term, compliance-free contraception offered by the levonorgestrel implant system.

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