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Etonogestrel implant in adolescents: evaluation of clinical aspects☆

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Abstract

Background: This prospective noncomparative observational study evaluated the clinical aspects of adolescents who received an etonogestrel implant within 6 months of delivery.

Study Design: The study population comprised 44 adolescents managed at the Family Planning Sector of São Paulo Federal University. The implant was inserted, on average, 102 days after delivery and patients were followed during 1 year. At each monthly visit to the clinic, the participants were weighed, had their blood pressure measured and were asked to report on symptoms experienced during the last 30 days.

Results: Approximately one-third (38.6%) of the participants reported symptoms, mostly headaches. There were no complaints of dysmenorrhea, breast tenderness or lower leg edema throughout the 12 months of follow-up. Mean body weight dropped 1.2 kg on average, from 56.4 kg at implant insertion to 55.3 kg at the end of the 1-year period. Body mass index also decreased 0.5 kg/m^2 on average, although these changes did not reach statistical significance. Systolic and diastolic blood pressure remained unchanged throughout the study period. There were no pregnancies and none of the participants discontinued the method (528 women-months).

Conclusion: These findings suggest that the etonogestrel implant is a safe and effective contraceptive method that is well accepted by adolescents after a pregnancy.

Keywords: Etonogestrel; Contraceptive; Metabolism; Adolescent; Blood pressure; Weight; Postpartum

1. Introduction

Pregnancy is one of the most worrisome outcomes of sexual activity in adolescents. Unplanned pregnancy during this period of life can have long-lasting emotional, social and economic consequences. Several factors, such as the lack of information, the feeling of invulnerability and the constant exposure to sexually charged media messages, contribute to the early onset of sexual activity, thus exposing adolescents to unplanned pregnancies [1]. A recent publication suggests that repeat pregnancy in adolescence is increasing worldwide and especially in developing countries [2].

The use of contraceptives during adolescence is complicated by the existence of preconceived ideas, taboos and fears of side effects which frequently lead to incorrect use and decreased effectiveness [3]. The etonogestrel implant can be used after menarche. Since it is a progestogen-only contraceptive, it can safely be used by women who are breastfeeding and should be inserted within 6 weeks of delivery [4–7]. Although there have been studies on its side effects, changes in body weight and blood pressure, these investigations have been carried out in adult users and there is little information on these aspects among adolescent users [8,9].

The objectives of this study were to assess the clinical effects (collateral effects, changes in body weight and blood pressure) associated with the use of an etonogestrel implant inserted in adolescents within 6 months of delivery.

2. Methods

Between 2005 and 2007, all adolescents who attended an educational session on pregnancy prevention at the Family Planning Clinic of São Paulo Federal University (UNIFESP), São Paulo, Brazil, and who voluntarily opted for hormonal contraceptives were invited to participate in the

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study. The university's ethics committee approved the study. Adolescents did not receive any financial incentive to participate in the study.

After signing an informed consent form, all patients had a complete physical and pelvic examination, including blood pressure, weight, height, cardiac and pulmonary auscultation and abdominal palpation. Additional information collected included age at menarche and first sexual intercourse, race, age, parity, marital status and education.

To be included in this study, participants had to be less than 20 years of age and to have had a delivery within the last 6 months.

Exclusion criteria were smoking, undiagnosed uterine bleeding, suspected or known breast malignancy, venous thrombosis, hepatitis, liver tumors, use of any drug known to affect liver enzymes and use of hormonal contraceptives in the last 3 months prior to use of the new method. Smokers were excluded because participants also had laboratory exams to assess the effects of implants on biochemical parameters (study in progress).

All patients had a negative pregnancy test before receiving the implant. The etonogestrel implants (68 mg) were provided free of charge by the clinic and inserted in the non-dominant upper arm, using local anesthesia. Participants were evaluated prospectively monthly, during 12 months. At each monthly visit, the patients were examined and weighed by the attending physician and asked about the occurrence of clinical symptoms in general. Their blood pressure measurements and body mass index (BMI) were recorded. The BMI was analyzed according to the Centers for Disease Control and Prevention recommendations, which uses adjustments according to age [10]. During the monthly visits, the physician also answered any questions and reassured the patient, when necessary.

Contact information (address and telephone number) of each participant was recorded at the clinic. If they missed one follow-up visit, they were immediately contacted through the telephone or by mail. Participants were informed that if they missed more than one appointment, they would automatically be excluded from the study.

Data are presented descriptively, with the mean values for each variable. The χ^2 test was used to detect differences between the initial and final blood pressure, weight and BMI throughout the 12 months of the study [11]. Significance was established as $p<.05$. Since the intention of the study was to provide descriptive information, a power calculation was not performed as our plan was to enroll all potentially eligible adolescents.

3. Results

Between January 2005 and January 2007 a total of 1970 adolescents were managed at UNIFESP Family Planning Sector, 360 of whom were new patients. There were 170 adolescents interested in using the etonogestrel implants and 47 of them fulfilled the inclusion criteria. Three adolescents did not return after implant insertion despite phone and mail contact and were therefore excluded from the clinical analyses. There were no other dropouts or requests to remove the implant during the study period among the 44 participants. The main characteristics of these 44 adolescents are presented in Table 1. These did not differ from the general population of adolescents attending our Family Planning Clinic [12]. The implant was inserted 42 to 178 days after delivery (mean 102 days). No pregnancies occurred during the study period (528 women-months).

At insertion, 66% of the participants were breastfeeding. The mean duration of breastfeeding time was 4.4 months and by the end of 12 months none of the participants was breastfeeding. At insertion, 45% of the adolescents were amenorrheic compared to 38.6% at the end of the study period. Detailed information on bleeding pattern of these patients is presented elsewhere [13]. Briefly, infrequent bleeding occurred in approximately 20%, irregular bleeding was reported by approximately 8% and there were no significant differences in the bleeding patterns of these 44 participants during the 1-year study.

A total of 13 patients (29.5%) complained about headaches during the 1-year study period. The distribution of this side effect did not differ significantly throughout the four 3-month periods: five complaints occurred during the first, two during the second, two during the third and four during the

Table 1
Baseline characteristics of 44 adolescents using contraceptive implants for 1 year

Characteristic	
Sociodemographic characteristics[a]	
Age (year)	17.2 (1.4)
Non-white race	13 (29%)
Education	8.3 (2.1)
Married or common law marriage	20 (45%)
Menarche (year)	12.4 (1.4)
Initiation of sexual activity (year)	14.7 (1.5)
Reproductive history[b]	
Parity	
1	40 (90.9)
2	2 (4.5)
3	2 (4.5)
Route of delivery of last pregnancy	
Vaginal	37 (84)
Cesarean	7 (15.9)
Previous contraceptive use[b]	
Condom	34 (77)
Oral contraception	14 (31.8)
Injectable contraception	3 (6.8)
Implant	1 (2.2)
No contraceptive	6 (13.6)
Breastfeeding	29 (65.9)
Amenorrheic	32 (72.7)

[a] Values presented as mean (SD) or number (%).
[b] Values presented as number (%).

Table 2
Changes in weight and body mass index among 44 adolescents using a contraceptive implant during 1 year

Variable	Initial	Final	Variation Post–Pre	p
Weight (kg)				
Mean (SD)	56.4 (9.6)	55.3 (11.1)	−1.2 (4.6)	.097
Minimum–maximum	38.7 to 85.0	39.5 to 86.2	−11.8 to 12.0	
BMI (kg/m^2)				
Mean (SD)	22.6 (3.4)	22.1 (4.0)	−0.5 (1.9)	.091
Minimum–maximum	16.4 to 32.0	15.7 to 32.4	−4.6 to 4.4	

last period of the study (1–90, 91–181, 182–272 and 273–363 days postinsertion, respectively). Two adolescents complained of emotional instability and feelings of depression, one complained about acne and one about increased alopecia. None of the participants complained of dysmenorrhea, breast tenderness or lower limb edema.

The participants' mean body weight at the beginning of the study was 56.4 kg and decreased to 55.3 kg at the end of the 1-year period [mean decrease of 1.2 kg, standard deviation (SD) 4.6 kg]. Overall, 29 (65.9%) of the adolescents reduced their body weight and the mean BMI dropped by 0.5 kg/m^2 (SD 1.9 kg/m^2). The majority (28, 64.6%) of the participants decreased their BMI, about one third (15, 34.1%) increased their BMI and one participant maintained the same BMI throughout the 1-year study period. However, decreases in mean body weight or BMI did not reach statistical significance (p=.097 and .091, respectively) (Table 2).

There were no significant changes in the systolic or diastolic blood pressure of implant users comparing the mean values at the beginning and end of the study period (p=.323 and .130, respectively). Mean systolic values decreased 1.6 mmHg (SD 10.6), with 18 users (40.9%) exhibiting no changes, 15 (34.1%) having a reduction and 11 (25%) having increases in their measurements. Mean diastolic values also decreased slightly (mean 2.0, SD 8.8 mmHg) with 21 adolescents (47.7%) having no changes, 15 (34.1%) having a decrease and 8 (18.2%) having an increase when comparing their initial and final measurements. All blood pressure measurements were within normal range throughout the year of study (Table 3).

Table 3
Changes in blood pressure among 44 adolescents using a contraceptive implant during 1 year

Variable	Initial	Final	Variation Post–Pre	p
Systolic BP (mmHg)				
Mean (SD)	110.0 (8.9)	108.4 (9.9)	−1.6 (10.6)	.323
Minimum–maximum	90/130	90/140	−30/20	
Diastolic BP (mmHg)				
Mean (SD)	73.2 (7.7)	71.1 (7.2)	−2.0 (8.8)	.130
Minimum–maximum	60/90	60/80	−20/20	

4. Discussion

Our findings suggest that etonogestrel implants seem to be a good contraceptive option for adolescent mothers. The method was effective and had a high continuity rate during the 12-month period of the study. The 0% discontinuation rate of our participants was lower than for adult users, which was 26% within 1 year [14]. Although nondaily methods tend to have good rates of patient compliance, we were pleasantly surprised by our results. Insertion of the implants in the postpartum period may have contributed to the high continuity rate, as well as the fact that this is an easy, practical, nondaily, long-term method that requires medical assistance to be removed. The counseling and support provided by our clinic staff also contributed to our results. Our nurses and psychologist held monthly group sessions with all participants during their visits to the clinic. At these sessions the adolescents were encouraged to ask questions and express any concern they could be having about the implant, side effects or any other worry on their minds, including issues related to caring for their infants. Additionally, all implant users were encouraged to come to the clinic any day, even without an appointment, in case they had any concern.

A study on levonorgestrel implant use by adolescents reported a continuity rate of 95% after 12 months of use [15]. These high continuity rates can be interpreted as an indication of patient satisfaction with a method that is easy to use and has few side effects. There were no pregnancies among our teenage implant users, reinforcing the findings of other studies on this highly effective contraceptive method. Comparatively, a previous study reported that adolescents using combined oral contraceptives had a 20% incidence of pregnancy at the end of 1 year of method use [16].

The discipline required for the correct use of contraceptives, the fear of possible side effects (especially weight gain) and interference with sexual activity are all factors that contribute to the irregular use or discontinuation of contraception by adolescents [2]. To enhance compliance and increase acceptance of contraceptives among adolescents, there has been a growing interest in the development of practical and highly effective hormonal contraceptives which also offer good cycle control and few side effects.

Many of the side effects of hormonal contraceptives, such as headaches, are attributed to their estrogenic component. This symptom occurred in almost one third (29.5%) of our participants and throughout the 1-year study period, although it was not a reason for discontinuation in any of our 44 adolescents. Similar findings have been reported by other investigators [17–20].

There were no reports of dysmenorrhea, breast tenderness or lower limb edema among our users. In fact, many hormonal contraceptives offer non-contraceptive benefits such as amenorrhea or reduction in menstrual blood flow, reduction of dysmenorrhea, protection against pelvic inflammatory diseases and reduction of acne and

hirsutism. However, the knowledge regarding these potential benefits, which could in theory encourage the use of hormonal contraceptives, is not yet widely disseminated among women.

The mean body weight did not change significantly after 1 year of contraceptive use. Weight loss and emotional instability were collateral effects that bothered a few of our participants. However, despite these symptoms, they decided to continue with the method because of its contraceptive effectiveness.

Weight gain has been reported among 12% of adult etonogestrel implant users, but only 3.3% of them requested its removal for this reason [8,17].

Blood pressure remained unchanged in most of our participants during the 1-year study period. Although absolute blood pressure measurement increased in 11 adolescents and decreased in 8, all values remained within the normal range. The lack of any case of hypertension confirms the safety of the method in that aspect. Other investigators have reported similar findings regarding blood pressure in implant users [21,22].

Long-acting contraceptive methods, such as the implant, are considered one of the most effective and safest ways to avoid repeated pregnancies in adolescents. In settings where patients are encouraged to use long-acting contraception, the incidence of pregnancy was lower among women using implants than in those using oral contraceptives (0% vs. 14%) [23].

Our findings indicate that the etonogestrel implant may be a good contraceptive option for adolescents and may help them space future pregnancies. It is a safe and highly effective method that is well accepted by these patients.

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