Full length article

Factors associated with removal difficulties of etonogestrel-containing contraceptive implants (Nexplanon®)

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ABSTRACT

Objectives: Nexplanon®'s new applicator system was designed to limit deep implant placements, known to lead to difficult removals. However, removal difficulties still exist and induce specific and potentially severe complications. Our objective was to identify risk factors associated with difficult removals.
Study design: A retrospective single-center study was performed from January 2015 to December 2016. Participants were divided into two groups depending on whether implant was removed during a standard ("standard removal" group) or difficult consultation ("difficult removal" group) after an initial failed removal attempt.
Results: The difficult and standard removal groups comprised 63 and 660 women, respectively. In a univariate analysis, significant intergroup differences were found for weight gain (3.7 ± 7.3 kg in the difficult removal group vs. 1.3 ± 5.1 in the standard removal group), proportion of placements performed in private practice (66.7% vs. 19.8%, respectively), and duration of Nexplanon® placement (29.4 ± 11.3 months versus 26 ± 13.6, respectively). We also reported more frequent sub-brachial fascia placements when Nexplanon® was implanted by a private practitioner (7.5% cases versus 0.4% in hospital implantations, $p < 0.001$). In a stepwise binary logistic regression analysis, placement by a private practitioner, weight gain >1 kg since placement, and duration of implant placement >25 months were confirmed as independent risk factors for removal difficulties (respective risk ratios 7.63 [95% IC 4.35–13.33], 2.10 [1.18–3.70], and 1.91 [1.06–3.44], $p < 0.05$).
Conclusions: Awareness of these three simple parameters might help physicians to identify "at risk-patients", and suggest a specific consultation before risking a potentially hazardous removal (with its associated, specific morbidity). Our results also emphasize importance of training in implant insertion.

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Introduction

Nexplanon® is a progestin sub-dermal contraceptive implant that contains 68 mg of etonogestrel. Its contraceptive effect is obtained through two complementary mechanisms: ovulation is inhibited by blockage of the pre-ovulatory luteinizing hormone surge (primary mechanism); concomitantly, an elevation of the cervical mucus' viscosity inhibits sperm penetration.

Implanon® (the prior version of Nexplanon®) was replaced in 2010 by the manufacturer (Merck Inc., Whitehouse Station, NJ, USA; https://www.merck.com) with the objective of limiting improper implant placements, notably by means of a new applicator which theoretically diminishes deep implantations, known to lead to difficult removals [1,2].

However, cases of difficult Nexplanon® removals are still being reported. Hence, the primary objective of the present study was to identify risk factors for difficult removal. This knowledge might enable practitioners to suggest specific, dedicated consultations for "at-risk" patients, in order to decrease the number of interventions and reduce the associated morbidity.

Material and methods

A retrospective single-center study was performed at Amiens-Picardie University Hospital (Amiens, France) from January the 1st 2015 to December the 31st 2016. Our institution is the referral center for a region of two million inhabitants, and was where approximately 22% of the region's implant ablations were carried

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out during the analyzed period according to social security records (the other 78% being processed in private practice offices).

All women having undergone a Nexplanon® implant removal during the study period were identified. Removal was performed either during a standard gynecologic consultation, during a specific, dedicated "difficult removal" consultation, or in the surgery ward. For standard procedures, the practitioner was a senior gynecologist, a gynecologic resident, or a hospital mid-wife. Patients attending a specific, dedicated "difficult removal" consultation had all experienced a failed removal attempt. This attempt variously took place in our hospital or in a private practitioner's office, and consisted of either (a) the absence of a palpable implant, and no skin incision, or (b) skin incision without removal of the implant. One hour before the specific "difficult removal" appointment, the implant's position was determined on ultrasound, and the skin directly above the device was marked to indicate the subsequent skin incision site (with the patient in the supine position, the shoulder abducted at 90° with external rotation, and the elbow flexed at 90°). The radiologist also assessed the implant's depth and its position relative to the brachial fascia. With the assistance of a specifically trained nurse, a senior gynecologist then attempted to remove the implant under local anesthesia and using appropriate surgical equipment (notably Farabeuf retractors, if required). If this second attempt also failed, the implant was removed in the surgical department under regional or general anesthesia.

Study participants were divided into two groups: a "standard removal" (SR) group, and a "difficult removal" (DR) group. The following data were recorded for both groups: age at removal, parity, tobacco use, implant body side (left/right) of insertion, reason for removal, body mass index (BMI), weight gain since implant placement, the type of practice in which the Nexplanon® was implanted (private practice or hospital), the duration of implant placement, and placement beneath the brachial fascia (evaluated clinically or, when available, by ultrasound). In the DR group, depth of placement (measured by ultrasound), as well as whether removal had occurred in the surgery ward, were also recorded. Lastly, we compared data on the removal of Nexplanon® implanted in a hospital vs. by a private practitioner. Patients whose medical records lacked data for one or more study variables were excluded from the analysis.

Data were expressed as the mean ± standard deviation (SD) for continuous variables and as the number (percentage) for qualitative variables. Continuous variables were compared using the Mann-Whitney test or the Student t-test (as appropriate), while categorical variables were compared using a $\chi2$ test, the Kruskal-Wallis test or Fisher's exact test. Binary logistic regression with a backward stepwise (Wald) procedure was used to study factors found to be significantly associated with difficult implant removal in a univariate analysis. In this model, thresholds for quantitative variables (weight gain and duration of implant installment) were defined after the generation of a receiver operating characteristic (ROC) curve, and selection of the optimal thresholds according to sensitivity and specificity. Statistical analyses were performed with SPSS® software for Mac (version 21, IBM SPSS). The threshold for statistical significance was set to $p < 0.05$ (two-sided).

Data were gathered from our institution's centralized electronic patient records. The study was approved by the local institutional review board (20th of September 2017, Amiens, France).

Results

Over the two-year study period, 738 women underwent Nexplanon® removal in our institution. Fifteen women (all having undergone SR) were excluded from the study due to missing data. The DR and SR groups comprised 63 and 660 women, respectively. All implants were placed in the medial arm approximately 8–10 cm above the medial epicondyle.

Patients' characteristics are summarized in Table 1. The DR and SR groups were similar in terms of age at implant removal, parity, tobacco intoxication and laterality. In both populations, first indication for removal was the expiry of the implant's function lifetime, followed by irregular and heavy menstruation; the next two other indications were weight gain and pregnancy desire. There were no significant intergroup differences according to the reasons for removal. Although there was no intergroup difference in BMI (whether before or after stratification), the women in the DR group had gained significantly more weight since implant placement than the women in the SR group (3.7 ± 7.3 kg vs. 1.3 ± 5.1, respectively; $p < 0.05$). Patients in the DR group were more likely to have undergone implant placement by a private practitioner (42 women (66.7%) vs. 131 (19.8%) placements in hospital; $p < 0.001$) and have used the device for longer period, relative to the SR group (29.4 ± 11.3 months vs. 26 ± 13.6 months, respectively; $p < 0.05$). Our records also showed 15 cases of placement beneath the brachial fascia (23.8%) in the DR group but none in the SR group.

Table 1
Patients' characteristics according to implant removal difficulty.

	"Difficult removal" group	"Standard removal" group	_p_-value
n	63	660	–
Mean age at removal, in years ± SD	29.6 ± 9.8	29 ± 9.3	0.65
Mean parity, ±SD	1.4 ± 1.5	1.1 ± 1.4	0.14
Nulliparity, n (%)	25 (39.7%)	323 (48.9%)	0.16
Tobacco use, n (%)	23 (36.5%)	269 (40.8%)	0.64
Right side implantation, n (%)	6 (9.5%)	55 (8.3%)	0.75
Removal indication, n (%):			
Implant function term	39 (62%)	332 (50.3%)	
Irregular and heavy menstruation	13 (20.6%)	176 (26.7%)	
Weight gain	6 (9.5%)	39 (5.9%)	
Pregnancy desire	4 (6.3%)	71 (10.8%)	
Others	1 (1.6%)	42 (6.4%)	0.15
Mean BMI, in kg/m^2 ± SD	25.3 ± 6.6	24.7 ± 5.9	0.47
< 25	35 (55.6%)	368 (55.8%)	
25–30	13 (20.6%)	176 (26.7%)	
> 30	15 (23.8%)	116 (17.6%)	0.39
Mean weight gain, in kg ± SD	3.7 ± 7.3	1.3 ± 5.1	<0.05*
Implant placement by a private practitioner, n (%)	42 (66.7%)	131 (19.8%)	<0.001*
Mean duration of implant placement, in years ± SD	29.4 ± 11.3	26 ± 13.6	<0.05*
Sub-brachial fascia placement, n (%)	15 (23.8%)	0 (0%)	–

BMI = Body Mass Index; kg = kilograms; SD = Standard Deviation; * = statistically significant.