

Complications Related to the Insertion Technique of Jadelle® Contraceptive Implants

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Abstract

Introduction: Contraceptive implants are one of the most effective methods of birth spacing. Jadelle® implants consist of two strands that are easy to insert and remove. Although their effectiveness is no longer in question, their use (insertion) requires a surgical procedure with the corollary possibility of complications. These are mainly insertions that are too deep (in the arm muscle), vascular and nerve damage. **Material and Methods:** Our study focused on complications related to implant insertion. It was a descriptive and retrospective study over thirty-four months, from October 2016 to July 2019, and concerned all patients seen in consultation and who presented a complication related to the insertion of contraceptive implants in the Department of Gynecology and Obstetrics of the National Hospital of Pikine. **Results:** We collected nine complications managed at the Gynecology and Obstetrics Department of the Centre Hospitalier National de Pikine from 2016 to 2019. These were insertions that were too deep with sometimes nerve damage, infection or incident during anesthesia. The operative procedures were based on the type of complication. **Conclusion:** Although Jadelle® has the advantage of having only 2 rods compared to its predecessor Norplant®, its use is also conditioned by insertion and removal procedures which may experience complications.

Keywords

Contraception, Implants, Incidents, Insertion, Removal

1. Introduction

JADELLE® contraceptive implants are 2 match-sized Silastique® rods containing

75 mg of levonogestrel that is delivered in small doses for 5 years. Although this method is almost 100% effective (World Health Organisation) [1], it requires a qualified provider trained in both insertion and removal. Levonorgestrel is widely used as a progestin, with or without estrogen, in contraceptive pills [2], but also in other injectable and implantable substances, intrauterine devices, and vaginal rings currently under study [3]. The best sites for inserting the implant are the arm or forearm. The capsules must be inserted firmly because the deeper they sit, the more difficult it is to remove them. As with any surgery, complications are possible, although they are rare. We thought it would be useful to list them in order to learn from them. They are mainly insertions that are too deep (in the arm muscle), vascular and nerve damage.

Our study focuses on these complications related to the insertion of implants and we report, here, nine complications managed at the Department of Gynecology and Obstetrics of the National Hospital Center of Pikine from 2016 to 2019.

2. Material and Methods

General objective

To review specific complications of contraceptive implant insertion that occurred during the period from October 2016 to July 2019.

Specific objectives

- To identify these complications
- Evaluate treatment initiated and establish preventive measures

Type and time period of study

This is a descriptive and retrospective study. It took place over thirty-four months, from October 2016 to July 2019. Our study took place in the Gynecology-Obstetrics Department of the National Hospital of Pikine located in the former Military Camp of Thiaroye (Dakar, Senegal).

Study population

All patients seen in consultation who presented a complication related to the insertion of contraceptive implants.

Inclusion criteria

Any patient seen with one of the complications related to implant insertion. These were:

- migration or deep insertion of one or more implants
- rejection of the implant
- or any skin lesion that occurred during the insertion procedure

Non-inclusion Criteria

All patients with complications other than those related to the insertion technique.

Data Collection

Data were collected primarily from the family planning registry and patient records.

3. Results

We diagnosed 9 cases of complications related to poor insertion technique of Jadelle[®] implants during the study period out of a total of 997 insertions, which represented 0.09% (**Table 1**).

The mean age was 28 years with extremes of 19 and 35 years (**Figure 1**).

All implants were inserted in family planning clinics by midwives. Although these midwives are trained in contraceptive technologies and are authorized to perform this method, we do not exclude the possibility that insertions are done by trainees under their supervision.

All removals, 8 cases, were performed by the gynecological surgeon.

Table 1. Summary of patient characteristics.

	Body mass index (kg/m ²)	Admissibility criteria	Delay between insertion and complication (months)	Type of complication	Symptoms
Case 1	28	Class 1	No delay	Nerve damage	Pains
Case 2	32	Class 1	No delay	Skin necrosis	Wound
Case 3	35	Class 2	24	Failure	Pregnancy
Case 4	33	Class 1	37	Intolerance	Anxiety
Case 5	32	Class 1	48	Menstrual cycle disorders	Amenorrhea
Case 6	19	Class 1	36	Difficult removal	No
Case 7	23	Class 1	18	Infection	Pustule
Case 8	25	Class 1	60	Spontaneous expulsion	No
Case 9	25	Class 1	2	Deep insertion	No

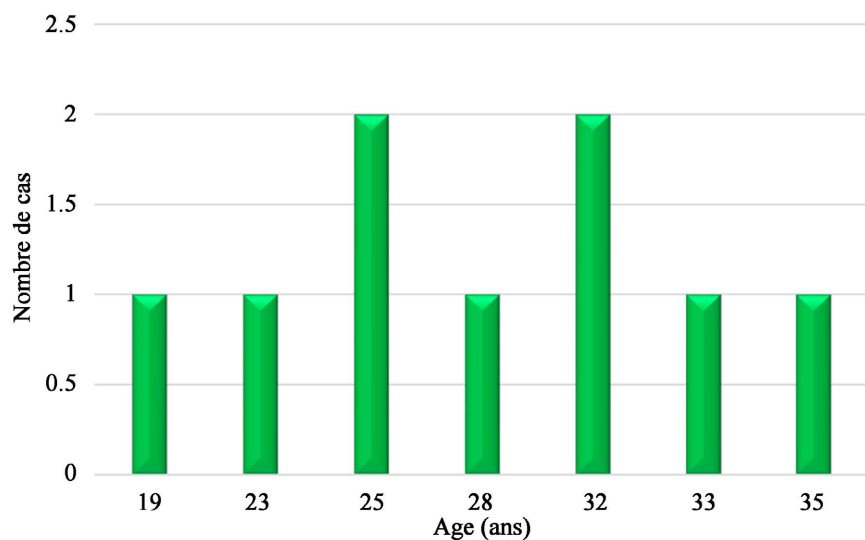


Figure 1. Age distribution of patients.

5 patients had a BMI between 18.5 and 24.5 and 8 patients could use this contraceptive method without restriction (Class 1).

Types of complications (**Figure 2**):

- Deep insertion in the muscle in 66.7% of cases
- Deep insertion and nerve damage in 11.1% of cases
- Infection and expulsion of the implant in one patient (11.1% of cases)
- Anaesthetic accidents (**Figure 3**) in one patient (11.1% of cases)

4. Diagnostic Time

Complications requiring removal: 25 months.

The check-ups performed were X-rays of the arm and ultrasound of the insertion site in 77.8% of patients (**Figure 4**). The 22.2% did not need them.

Radiographic appearance: radiopaque rods.

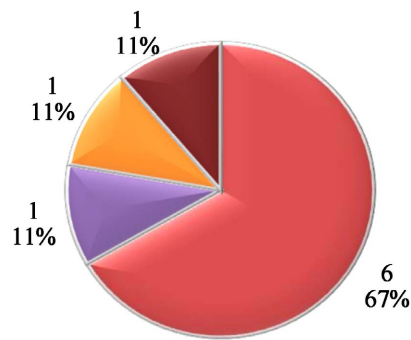


Figure 2. Distribution according to the type of complications.



Figure 3. Evolutionary aspects of a cutaneous-muscular lesion of the arm after accidental injection of formaldehyde (anesthetic accident).



Figure 4. Ultrasonographic, radiographic and intraoperative aspects of a muscle insertion implant.

Sonographic appearance: posterior shadow cone.

5. Management

Local anesthesia was used in 77.8% of cases.

The operative procedure was based on the type of complication.

Apart from one case of pressure sores secondary to formaldehyde injection, all other patients were removed under local or general anesthesia (**Figure 5**).

In all cases, a precise localization of the implants was carried out with the help of an ultrasound of the soft parts.

Post-operative care.

No complications were noted. For four patients (44.4%), an immediate re-insertion of the implant was performed near the surgical area.

6. Discussion

Contraceptive implants are effective methods of providing long-term protection against pregnancy. Norplant, the first form, was discontinued in 2002 in favor of other implants that are equally effective but without certain inherent constraints. Norplant 2 (Jadelle[®]), mainly offered to developing countries, is intended to overcome the difficulties of laborious insertion and removal. The most common side effects are menstrual cycle disturbances (irregular, absent or increased bleeding). Other less frequent effects may occur, such as slight weight gain, increased acne problems, emotional lability, headaches and breast pain. However, it must be noted that complications related to implant insertion remain.

Our results, based on the management of patients referred for serious adverse events, must be interpreted with the understanding that they significantly underestimate the incidence. Only a cohort follow-up with exhaustive registration of adverse events would allow to obtain incidences closer to reality.

In our cohort, complications related to implant placement and removal were rare, with an incidence of 0.09%. This is in agreement with the 0.3% rate found



Figure 5. Removal after local anesthesia.

in the literature [4].

The insertion of the hormonal implant is performed according to a well-defined strict technique with few accidents published in the literature [5]. These insertion and removal techniques are available to most health care providers.

All implants in this study were inserted in family planning clinics by trained midwives.

In France, where the single-strand implant (Implanon[®]) has been marketed since 2001, there are still many physicians who do not know how to insert or remove it [6]. In a survey of members of the Society of Adolescent Health and Medicine in the United States [7], it was found that only 88% of physicians trained in obstetrics and gynecology or general medicine offered patients Long Acting Reversible Contraceptives (LARCs), and only 47% of them offered the implant.

Complications of implants do not appear to vary according to the provider's profession but rather according to the skills acquired during practical training.

In addition, the diagnosis of complications varies from case to case on several points, notably on the duration between the placement and the first signs of alarm when they exist. In our study, an average of 25 months elapsed between the insertion of the implant and its removal. It is worth noting that some immediate complications required immediate removal or were observed at the time of insertion.

Complications related to the implant insertion technique may be evident at the time of removal and even characterize a laborious removal.

In an article published in 2005, Osman and Mirlesse report two cases of iatrogenic ulnar nerve injury in the arm following Implanon[®] implant insertion in a thin woman. The diagnosis of ulnar nerve injury was formally made during the removal of the implant one year after its insertion in one of the cases. In the second case, the nerve complication was discovered after the implant was removed and the treatment was carried out one and a half years later.

If we look at the reasons for removal of the implants in our group of patients, 55.5% of the removals were done at the request of the patients for reasons other than lesions caused by the insertion. We conclude that the contraceptive implant is definitely considered to have been well inserted when it can be easily removed.

As for the complications observed in our study of Jadelle[®] implants, we counted cases of deep insertion (66.7%), one case of nerve damage (11.1%), one case of post-insertion infection with expulsion of the strand (11.1%) and one case of anesthetic accident (11.1%). The check-ups performed were X-rays of the arm and ultrasound of the insertion site in 77.8% of patients. Local anesthesia was used during strand removal in 7 patients. One case required general anesthesia. All removals (8 cases) were performed by the gynecologic surgeon.

Several investigations of rod insertion or removal difficulties are based on the Implanon[®] implant. Unlike Jadelle[®], the insertion of Implanon[®] was facilitated by the use of a pre-filled applicator with a single contraceptive strand, which did not negate the long-discussed embarrassments.

In 2005, Bensouda-Grimaldi *et al.* published the results of a survey of pregnancies (contraceptive failures), migrations and difficulties in inserting or withdrawing Implanon[®] notified in France to the Regional Pharmacovigilance Centres and the Organon laboratory between May 2001 and September 2002 [8]. It was found that during these 16 months, 28 cases of migration, difficulties in insertion or removal of the implant had been reported. These included 11 suspected migrations (39.3%), six insertion difficulties (21.1%), and 11 removal difficulties or failures (39.3%), for an incidence of 0.257/103 implants sold [0.162 - 0.363].

The 11 notifications of migration were situations where the implant was not found at the supposed location of placement, for an incidence of 0.101/1000 implants [0.05 - 0.181]. They were secondary to trauma in 2 of 11 cases. The extent of displacement ranged from a few centimeters (four cases) to the posterior part of the forearm or the elbow crease (two cases).

The search for the implant required an etonogestrel dosage (once) and its localization, an ultrasound (six times), an X-ray (once), and a CT scan (once). Two implants were removed under general anesthesia and two under local anesthesia. Three others remained in place after failed removal under general anesthesia.

The six reports of placement difficulties corresponded to an incidence of 0.055/103 implants [0.02 - 0.12]. Twice, local complications of placement occurred (hematoma, paresthesias related to ulnar nerve damage). The six placement difficulties required ultrasound (four times), radiography (once) and MRI (once) because of doubts about the reality of the placement. The 11 reports of implant removal difficulties or failures corresponded to an incidence of 0.101/103 implants [0.05 - 0.181]. They were probably secondary to incorrect placement (too deep, twice; perpendicular to the skin, once; intramuscular, twice). The search for the implant required etonogestrel dosage (twice) and its location, ultrasound (eight times), X-ray (four times), CT scan (twice), MRI (once). Nine implants were removed, two under general anesthesia and three under local anesthesia, twice after several attempts.

In the end, the complications identified were divided between implant migration, deep insertion, nerve damage and failed removal.

Rowlands published an article on the legal aspect of contraceptive implants in 2010. According to the article, deep insertion is recognized as associated with insertion technique rather than migration of a properly inserted implant [9] [10]. Deep insertion is more likely to occur in thin women with little subcutaneous tissue [10]. Weight gain after insertion could make the implant less palpable and therefore more difficult to remove [11]. In some cases, the proximal end of the implant is found deep to the distal end, suggesting a downward tilt of the applicator at the time of insertion [8]. However, some degree of migration has been reported with implant insertion into the wound immediately after Norplant removal [10] [11].

The recommendations that emerge are as follows:

- There should be an accurate location of the implant before the incision is

made.

- If an implant cannot be easily palpated, a more experienced team member should attempt to remove it. Implants that are completely impalpable should be referred to a regional center where removal of non-palpable implants is well codified.
- Women should be referred to a surgeon.

Finally, infectious complications related to implant insertion have also been identified. In our study, only one case occurred two months after insertion and resulted in expulsion of one of the rods.

Infections have also been reported with an incidence varying between 0% and 1.4% [12]. Many infections occur within two months after insertion and others much later, such as two years after infection. The complication that can arise from infection is expulsion of the implant, but spontaneous expulsion has also been reported in less than 0.6% of patients [12]. According to Klavon *et al*, 35.7% of expulsions occurred in the first two months after implant insertion and 70% of expulsions in the first 4 months [13]. A few cases of cellulitis and one case of necrotizing fasciitis have been reported to pharmacovigilance in France [7]. The main risk associated with the implant, rare but serious, is migration into the pulmonary artery.

7. Conclusions and Recommendations

Contraceptive implants are very effective and provide long-term protection against pregnancy. Two-stick implants provide five years of protection and return to fertility without delay. They are a viable option for breastfeeding women or other women who cannot use methods that contain estrogen. They are an acceptable method for younger women with the benefit of better compliance. One contraceptive implant insertion replaces an average of 1800 days on the pill.

Although Jadelle[®] has the advantage of having only 2 rods compared to its predecessor, its use is conditioned by insertion and removal procedures that may be subject to complications.

Our study allowed us to conclude that an implant is only truly well inserted when it can be extracted without difficulty. In the event of any difficulty in removal and non-palpable implants, the patient should be referred to a specialized center.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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