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Short communication

A French survey of contraceptive implant migration to the pulmonary artery☆,☆☆

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ABSTRACT

Objective(s): To quantify implant migration to the pulmonary artery in France since 2012 and to describe the diagnoses and treatments.
Study design: We surveyed 780 physicians of the French national implant-referral network, the French Society of Chest and Cardiovascular Surgery, and the French Radiology Society about diagnosis of implant migration to the pulmonary artery vasculature. We evaluated total implant insertions in France using data from the Medic'AM database.
Results: We identified 12 cases from 2012 to 2017. Ten of the cases were asymptomatic. Five devices were removed via interventional radiology, five surgically, and two were left in place. The number of insertions in France during the same years was approximately 1,200,000.
Conclusion(s): Pulmonary artery migration following contraceptive implant insertion is rare with a migration incidence of 1 in 100,000. Most cases were diagnosed incidentally.

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1. Introduction

Etonogestrel-based contraceptive implants are a contraceptive device available in France since 2012 as a redesigned version [1]. This redesigned device has two new features: a new inserter designed to avoid the implant from being placed too deep and radio-opacity. Despite the development of a new inserter, the risk of the implant being nonpalpable after its placement has persisted [2].

Inadvertent intravascular implant injection risks migration of the implant to the pulmonary vasculature [3]. Direct injection into the basilica vein may rarely occur upon placement of the device, but we do not know how often this might occur. Few data are available concerning incidence, risk factors and consequences of this migration.

Several cases of pulmonary artery migration of implants in France have been published as case reports only [4–8]. A more substantial series may yield more information and also allow us to estimate the incidence of these events. We therefore carried out a national survey of cases of pulmonary artery migration of contraceptive implants.

2. Materials and methods

We carried out this survey in France between December 2016 and July 2017. We suggested the survey to 80 referring physicians who are part of the national network of implant experts put in place by MSD (Merck Sharp & Dohme). We asked these physicians to report to us the cases that they were aware of involving pulmonary artery migration of radio-opaque implants that had been placed with the new inserter (from 2012 to 2017). Over the same period, we provided the same survey to the 550 members of the French Chest and Cardiovascular Society and to the heads of 150 interventional radiology centers. On behalf of the investigators, these two societies informed their members by individual email of the existence of this survey. The email address of the main person in charge of this survey was communicated to them to contact for more information or to report some case.

The survey collected patient characteristics (body mass index: BMI, prior placement of an implant, side of the placement); the conditions of placement (type of professional, characteristics of the placement (unusual pain, immediate local reaction); the circumstances of discovering

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Table 1
Characteristics of women in France who had a diagnosis of a contraceptive implant migration to the lung from 2012 to 2017

Cases	Arm side	Local reaction
1	Left	No local reaction
2	Left	HEMATOMA
3	Right	HEMATOMA
4	Left	None reported
5	Left	No local reaction
6	Right	No local reaction
7	Left	No local reaction
Gallon et al. [4]	Left	No local reaction
Thomas et al. [5]	Left	No local reaction
Heudes et al. [6]	Left	Hematoma
Maroteix et al. [7]	Left	Edema
D'Journo et al. [8]	Left	Hematoma

the migration; the occurrence of respiratory problems; and the mode of removal and any consequences. If the migration event occurred in a woman who underwent a same-day removal and reinsertion, we noted whether the reinsertion took place through the same incision.

We consulted the Medic'AM database in September 2018 to learn the number of implants sold in France between January 2012 and July 2017 [9]. This database reports the number of medications or medical devices reimbursed by the national healthcare insurance (CNAM).

This study received approval from the ethics committee of the Faculty of Medicine of Marseille, France (2018-24-01-002).

3. Results

From the Medic'AM database, we learned that 1.2 million implants had been reimbursed to the patients in France from January 2012 until July 2017 [9]. We sent surveys to 780 French physicians, and from them, we learned of 12 cases of pulmonary migration. Seven of the migrations were novel, and five had been previously published [4–8]. Twelve migrations following 1.2 million insertions suggest that the complication of pulmonary migration is diagnosed after 1/100,000 insertions.

Tables 1 and 2 present data from the 12 individual patients. The BMI was reported for 8 patients, all of whom had BMIs of less than 24 kg/m^2. Seven of the cases followed the first placement of an implant; three cases followed a removal–reinsertion carried out through the same orifice in 2 cases (cases no. 5 and no. 6). Four cases reported unusual pain at the time of insertion. In 7 of 12 cases, the notes did not document whether the implant had been palpable immediately after insertion. The implant was documented as immediately palpable in two cases, and in three cases, implant was searched for and was nonpalpable immediately after placement. Thus, in 9 of the 12 cases, the distant implant location was first identified at the time of removal request by patients. Survey respondent did not report the reasons for the removal requests.

4. Discussion

This national survey found 12 cases of implant pulmonary artery migration, including 7 new cases not previously reported in the literature. Based on our calculations of implant use in France during these years, implant migration is an exceptional occurrence with an approximate migration incidence of 1 in 100,000. Our results may, however, underestimate the migration frequency for several reasons: first, some physicians who cared for such a patient may not have received this survey or did not respond to the survey. Second, and more important, is that most migrations had been diagnosed not because of pulmonary symptoms but due to the diagnostic evaluation of a nonpalpable implant, usually at the time of a removal request. Thus, additional migrations may be diagnosed only when all women have returned for implant removal. We ascertained the number of implants reimbursed by the CNAM which covers more than 95% of the French patients. Possibly, not all of the reimbursed implants have been inserted; if so, then the correct denominator may be slightly smaller.

We suspect that, in most of the cases, the implant had passed directly into the basilic vein at the time of placement. All of these patients had normal BMIs of less than 24 kg/m^2. In women with little subcutaneous fat, perhaps even a superficial implant placement will sometimes be very close to that vein. The bruising or edema reported in five cases may have been associated with the vascular damage, but the absence of an immediate local reaction does not rule out the possibility of vascular migration. Secondary migration, as hypothesized by Pelligrino et al. [3], may also be possible.

In the USA, clinicians must participate in a mandatory training program before being allowed to place implants [10]. In the UK, the FSRH provides a training program [2]. In France, no formal training exists. Any training is carried out in partnership with the manufacturer and upon request by the physician. In our survey, the physicians reported substantial implant placement experience in two thirds of the cases. However, the notion of experience was evaluated by the care provider based on the number of implants already placed and not by an observer who evaluated the quality of the procedure.

A study of the neurovascular anatomy of the arm shows an absence of important structures over the triceps muscle [11]; based on these findings, advice is now to insert these implants over the triceps muscle, which could further reduce the occurrence of the rare events described here.

Table 2
Symptoms and removal of 12 contraceptive implants that had migrated to the pulmonary artery in France, 2012–2017

Cases	Pulmonary symptoms	Pulmonary location	Months since insertion	Removal
1	None	Left anterobasal segment artery	12	IR
2	None	Right basal lobe artery	16	IR
3	None	Left basal lobe segment artery	18	Failure of IR Surgical removal
4	None	Right lobe apical segment artery	10	Failure of IR Left in place
5	None	Right pulmonary artery	36	Surgical removal
6	None	Right lobe apical segment artery	28	No attempt at removal
7	Chest pain	Left pulmonary lobe artery	20	Surgical removal
Gallon et al. [4]	None	Lower right lobe segment artery	6	IR
Thomas et al. [5]	None	Lower left lobe segment artery	8	Surgical removal
Heudes et al. [6]	None	Upper right lobe artery	5	IR
Maroteix et al. [7]	Chest pain	Left pulmonary artery	10	IR
D'Journo et al. [8]	None	Left basal lobe segment artery	18	Surgical removal

IR, interventional radiology.

In this series, implant migration may have been somewhat underestimated but nonetheless appears to be very rare. Of greatest importance to patients is that none of these patients experienced any cardiovascular problems due to the migrated implant.

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