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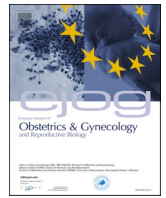
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Full length article



Evaluation of Elastic Venous Compression Device dispensation in pregnant and post-partum women using the French National Health Insurance Claims Database: The PROFIL retrospective cohort study

Olivier Joassard^{a,*}, Anne-Laure Kerveillant^a, Claire Sellal^b, Erwana Coataniec^a,
Violaine Jabbour^a, Guillaume Desjeux^c, Ben Braithwaite^c, Antoine Elias^{d,e},
Arnaud Fauconnier^{f,g}

^a Laboratoires Innothera, 22 Avenue Aristide Briand, 94110 Arcueil, France^b Midwife practice, 14 Rue du Chapeau Rouge, 44000 Nantes, France^c e-Health Services Sanoia, 70 Impasse Allegriat, 13400 Aubagne, France^d Department of Vascular Medicine, Hôpital Sainte Musse, Centre Hospitalier Toulon La Seyne-sur-Mer, 54 Rue Henri Sainte-Claire Deville, 83100 Toulon, France^e Clinical research department, Hôpital Sainte Musse, Centre Hospitalier Toulon La Seyne-sur-Mer, 54 Rue Henri Sainte-Claire Deville, 83100 Toulon, France^f Obstetrics and Gynecology department, Centre Hospitalier Intercommunal de Poissy-Saint-Germain-en-Laye, 10 Rue du Champ Gaillard, BP 3082, 78303 Poissy CEDEX, France^g Paris-Saclay university, UVSQ, research unit 7285 "Risk and safety in clinical medicine for women and perinatal health (RISCO), 2 Avenue de la source de la Bièvre, 78180 Montigny-le Bretonneux, France

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ABSTRACT

Objectives: To describe the real-world use of Elastic Venous Compression Devices (EVCDs) during pregnancy and post-partum using data from a representative subset of the French National Health Insurance Claims Database (the Echantillon Généraliste des Bénéficiaires, EGB).

Study Design: Women aged 15–49 who were pregnant between 1st July 2017 and 15th June 2018 were identified in the EGB using pregnancy-specific acts (certain prenatal examinations or deliveries). Subgroups were defined by age, presence of Venous Thrombo-Embolism (VTE) risk factors, history of VTE, delivery type and time period. EVCD dispensations (format, prescriber, and date) were identified among those for “standard orthotics” using their unique reimbursement tariffs. Dispensation rates were computed for all subgroups, overall and by format and were compared.

Results: 15,528 pregnant women were included: 7,252 [46.7 %] deliveries (5,796 vaginal [79.9 %], 482 planned cesarean sections (C-sections) [6.7 %] and 974 unplanned C-Sections [13.4 %]), 2,734 (17.6 %) terminations and 5,542 (35.7 %) unknown outcomes. Overall, 4,919 (31.7 %) women were dispensed at least one EVCD. Ante-partum dispensation occurred in 43.1 % (n = 3,122) of women whose pregnancy led to a delivery. Dispensation rates were 17.3 % (n = 1,005), 46.7 % (n = 225) and 44.1 % (n = 430) after vaginal delivery, planned C-sections or unplanned C-sections, respectively. Overall, dispensation rates significantly increased with age, the presence of VTE risk factors, and a history of VTE (p < 0.01). EVCD dispensation was most frequent (17.0 %) during the 5th month of pregnancy. Among pregnant women who were dispensed at least one EVCD during ante- or post-partum, 69.0 % had one or two units of compression (27.1 % [one unit], 41.9 % [two units]). Stockings (48.6 %, n = 6,038) were dispensed significantly more frequently than socks (36.9 %, n = 4,586) and tights (14.5 %, n = 1,806) (p < 0.01). The main contributors to mechanical VTE prophylaxis were gynecologists (26.3 % of dispensations, n = 2,280), general practitioners (20.2 %, n = 1,749) and midwives (15.1 %, n = 1,314).

Conclusions: Low observed dispensation rates highlight a discrepancy between the French National Authority for Health (Haute Autorité de Santé, HAS), recommending EVCDs use during pregnancy and after delivery, and the real-life use of EVCD. Prescription sensitization combined with targeted information campaigns for pregnant women would be beneficial to contribute to the prevention of VTE, a health problem for pregnant women.

* Corresponding author at: 22 avenue Aristide Briand, BP 20032, 94111 Arcueil Cedex France.

E-mail addresses: ojassard@innothera.com (O. Joassard), anne-laure.kerveillant@innothera.com (A.-L. Kerveillant), claire.sellals@gmail.com (C. Sellal), erwana.coataniec@gmail.com (E. Coataniec), viojabbour@hotmail.fr (V. Jabbour), gdesjeux@sanoia.com (G. Desjeux), bbraithwaite@sanoia.com (B. Braithwaite), antoinelias@gmail.com (A. Elias), arnaud.fauconnier@ght-yvelinesnord.fr (A. Fauconnier).

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Introduction

During pregnancy, women are at an increased risk of Venous Thrombo-Embolism (VTE), including Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) [1]. VTE risk is further increased in post-partum, being highest during the first 3 weeks after delivery and remaining elevated throughout the first 12 weeks [2]. Between 2013 and 2015, VTE was the fourth cause of death (8.8 %) among pregnant women in France [3] and accounted for 3.2 % of deaths worldwide [4].

Prevention of VTE is therefore key in reducing maternal mortality rates. Prophylaxis can be either pharmaceutical (e.g., low-molecular-weight heparins when the risk of bleeding is low) or mechanical using Elastic Venous Compression Devices (EVCDs) [5–9]. Such devices are recommended for alleviating certain symptoms of venous disease, preventing or reducing leg edema and preventing VTE, with the French National Authority for Health (Haute Autorité de Santé, HAS) endorsing the use of EVCDs during pregnancy and up to 6 weeks after delivery, or even 6 months after Cesarean section (C-section) [10–13].

In 2009, a survey, intended for vascular physicians, members of the French Society of Vascular Medicine, found that 94.3 % of French physicians systematically prescribed compression therapy in patients with DVT [14]. However, a prospective study in 2015 found that only 63.2 % of women were prescribed EVCDs during their pregnancy or after delivery [12], although they are known to be at high risk of VTE [1]. Thus, a more comprehensive study of the prescription of mechanical prophylaxis seems necessary in terms of real-life practice.

In France, reimbursements for healthcare expenses (services or drug and medical device dispensation) are recorded in the National Healthcare Insurance Claims Database (Système National de Données de Santé, SNDS), a representative subset (1/97th scale) of which (the Echantillon Généraliste des Bénéficiaires, EGB) is more readily available and sufficiently complete and robust for our purposes [15–18]. This sample provides comprehensive data on the dispensation of medical devices, including EVCDs.

The aim of this study was therefore to describe the real-world use of EVCDs (all formats, i.e., socks, stockings, or tights) by French women both during their pregnancy and during the post-partum period, using data from the EGB. This aims to provide insights into the dispensation of EVCDs (in terms of quantity, type and frequency), the distribution of prescriptions among medical professionals, the consideration of risk factors and history of VTE, and the evaluation of the real-world application of HAS prophylaxis recommendations.

Material and methods

Identification of pregnant women

The full analysis set (all identified pregnancies) was defined as all women who were both pregnant between 1st July 2017 and 15th June 2018 and aged between 15 and 49 years old (included) at the beginning of their pregnancy.

Pregnancies in the EGB were identified using either their outcome or a combination of medical acts specific to pregnancies (e.g., ultrasounds, analyses or hospital stays related to a pregnancy) when no outcome was found in the analysis period. Outcomes were classified as terminations (spontaneous miscarriage, ectopic pregnancy, elective abortion, therapeutic abortion before the 21st completed Week of Amenorrhea [WA] or other outcomes such as the evacuation of a molar pregnancy) or deliveries (living new-born(s) regardless of number, stillbirths, or therapeutic abortion after the 22nd completed WA). Deliveries were further classified as vaginal, planned C-section, or unplanned C-section. The algorithm was adapted from Blotière, 2019 [19].

Two time periods were described: *i*) ante-partum (between the date of the beginning of pregnancy and the 38th completed WA or the delivery if it took place before then) and *ii*) post-partum (between the 30th day before delivery and the 183rd day after). In accordance with clinical

practice, EVCD dispensations up to 30 days prior to delivery were considered to be prescribed for post-partum use.

The following subgroups were defined: *i*) women with VTE risk factors (presence of at least one of the following risk factors among obesity, history of eclampsia, Medically Assisted Procreation [MAP], multiple pregnancy, ≥ 35 years old, previous deliveries ≥ 3) [20,21]; *ii*) women with a history of VTE (anticoagulant dispensations and/or specific hospital stays for VTE prior to this pregnancy).

Identification of EVCDs

Every dispensation of one or more EVCD(s) is logged in the SNDS under the label “standard orthotics” regardless of format. However, a unique set reimbursement tariff is defined for each format in the French National Products Specification (*Liste des Produits et Prestations Remboursables*). The following algorithm was used to identify and describe EVCD dispensations: every dispensation labeled “standard orthotics” in the EGB over the considered period was deconstructed into a sum of these tariffs and, if it contained an EVCD tariff, the dispensation was counted in the analyses. Each EVCD dispensation was described using the dispensation date, anonymous dispenser and prescriber numbers, and beneficiary.

Statistical analysis

The analysis was performed on all identified pregnant women and then stratified on: *i*) outcome of the pregnancy, *ii*) history of VTE, *iii*) risk of VTE, and *iv*) age group (<20, 20–29, 30–39 and 40–49 years).

The subgroup of pregnancies leading to a delivery was further subdivided by: *i*) time period and *ii*) type of delivery (post-partum only).

The number and percentage of women with at least one EVCD dispensation were reported for each subgroup. EVCD dispensations were broken down by type, prescriber specialty, season and time from the beginning of the pregnancy (ante-partum) or from the delivery (post-partum).

Subgroups were compared using a Chi-square test for proportions. Differences were considered statistically significant for $p < 0.01$ (asterisk on the relevant graphs). This standard was chosen to account for multiple comparison groups and the large population size, as described in previous publications [22,23]. This sample is, by definition, representative of the French population.

Ethical approval

The competent French Authority (Health Data Hub, HDH) approved the use of EGB data on May 6th, 2021. The contract to receive and analyze the requested data was signed on 19th October 2021 granting access to relevant data for a duration of 2 years from October 2021 to October 2023. As such, source data cannot be provided, though subgroup analysis tables may be provided upon request.

Results

Included population

Between 1st July 2017 and 15th June 2018, 15,528 pregnant women (age: 30.5 ± 5.7 years) were identified in the EGB. Outcomes were 7,252 (46.7 %) deliveries (5,796 vaginal deliveries [79.9 %], 482 planned C-sections [6.7 %] and 974 unplanned C-sections [13.4 %]), 2,734 (17.6 %) terminations and 5,542 (35.7 %) unknown outcomes (Fig. 1). Overall, 5,730 (36.9 %) women had VTE risk factors, 650 (4.2 %) had a history of VTE. A detailed description of populations is provided in Table 1 and Table 2.

EVCD dispensation

All identified pregnancies

Among all identified pregnant women (n = 15,528), 4,919 (31.7 %) were dispensed at least one EVCD during ante- or the post-partum period. This proportion was significantly lower in women < 20 years old: 9.4 % (n = 36) compared to 26.6 % (n = 1,689), 36.1 % (n = 2,850) and 35.7 % (n = 344) among women aged 20–29, 30–39 and 40–49 years old respectively (p < 0.01) (Table 3). EVCD dispensation was also more frequent among women who had already been dispensed an EVCD in the past (38.9 %, n = 2,119) than among those who had not (27.8%, n = 2,800) (p < 0.01) (Table 3).

Pregnancies leading to a delivery

Ante-Partum. Among women whose pregnancy led to a delivery (n = 7,252), 43.1 % (n = 3,122) were dispensed at least one EVCD during the ante-partum period. This proportion increased significantly with age (p < 0.01) (Table 3).

Post-Partum. During the post-partum period, 1,005 (17.3 %), 225 (46.7 %) and 430 (44.1 %) women were dispensed at least one EVCD after vaginal delivery, planned C-section or unplanned C-section respectively. This proportion significantly increased with age after a vaginal delivery (p < 0.01) and after planned C-section (p < 0.01) but not after unplanned C-section (p < 0.01) (Table 3).

Influence of risk factors on EVCD dispensation

Considering all pregnancies, EVCD dispensation was more frequent among women with VTE risk factors than not (35.2 %, n = 2,019 vs 29.6 %, n = 2,900 respectively, p < 0.01). This is also observed among women with a history of VTE (42.8 %, n = 278 vs 31.2 %, n = 4,641 respectively, p < 0.01) (Table 3).

Similarly, significant dispensation differences were observed during the ante-partum period of pregnancies leading to a delivery, with significantly higher dispensation rates among women with risk factors for VTE (46.6 %, n = 1,270 vs 40.9 %, n = 1,852 respectively, p < 0.01), a history of VTE (56.7 %, n = 174 vs 42.4 %, n = 2,948 respectively, p < 0.01) (Table 3).

Interestingly, this significance was also observed in post-partum only

Table 1
Description of the included population.

	All identified pregnancies N = 15,528
Age (Mean, SD)	30.5 (5.7)
Age groups (N, %)	
Younger than 20 y.o.	382 (2.5)
From 20 to 29 y.o.	6,295 (40.5)
From 30 to 39 y.o.	7,888 (50.8)
From 40 to 49 y.o.	963 (6.2)
Outcome (N, % of known)	
Live baby	7,195 (72.1)
Stillbirth	39 (0.4)
Therapeutic abortion (after the 22nd completed week of amenorrhea)	18 (0.2)
Elective abortion	2,007 (20.1)
Spontaneous miscarriage	362 (3.6)
Ectopic pregnancy	126 (1.3)
Other outcomes	124 (1.2)
Therapeutic abortion (before the 21st completed week amenorrhea included)	115 (1.2)
Unknown outcome (N, %)	5,542 (35.7)
Universal Health Coverage (N, %)	3,852 (24.8)
Prior use of compression devices (N, %)	5,451 (35.1)
VTE risk factors (N, %)	
History of eclampsia	182 (1.2)
Obesity	1,513 (9.7)
MAP	511 (3.3)
Multiple pregnancy	190 (1.2)
≥ 3 previous deliveries	410 (2.6)
Older than 35	3,987 (25.7)
Total (any risk factor)	5,730 (36.9)
History of VTE (N, %)	650 (4.2)

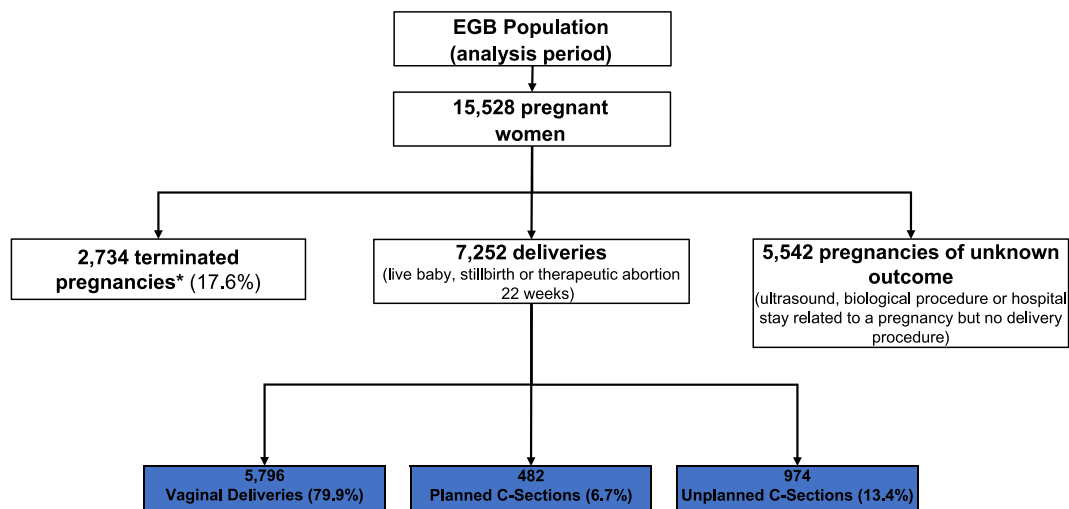
C-Section = Cesarean Section; MAP = Medically Assisted Procreation; N/A = Not Applicable; SD = Standard Deviation; VTE = Venous Thrombo-Embolism.

after vaginal delivery (p < 0.01) (Table 3).

EVCD dispensation formats

Overall, stockings were the most frequent EVCD format, account for 48.6 % (n = 6,083) of dispensed units, followed by socks at 36.9 % (n = 4,586) and tights at 14.5 % (n = 1,806) (p < 0.01) (Table 3).

This order was maintained across all subgroups, regardless of time period, delivery type, age, prescriber or season.



* elective abortions (2,007; 73.4%), spontaneous miscarriages (362; 13.2%), ectopic pregnancies (126; 4.6%), other outcomes (124; 4.6%) ou therapeutic abortion before 22 weeks (115; 4.2%).

Fig. 1. Study Flowchart.

Table 2
Description of populations by delivery type.

	Vaginal Delivery N = 5,796	Planned C-Section N = 482	Unplanned C-Section N = 974	Total Deliveries N = 7,252
Age (Mean, SD)	31.4 (5.2)	34.2 (5.4)	31.8 (5.5)	30.8 (5.4)
Age groups (N, %)				
Younger than 20 y.o.	102 (1.8)	3 (0.6)	12 (1.2)	117 (1.6)
From 20 to 29 y.o.	2,376 (41.0)	112 (23.2)	357 (36.7)	2,845 (39.2)
From 30 to 39 y.o.	3,051 (52.6)	306 (63.5)	516 (53.0)	3,873 (53.4)
From 40 to 49 y.o.	267 (4.6)	61 (12.7)	89 (9.1)	417 (5.8)
Universal Health Coverage (N, %)	1,414 (24.4)	116 (24.1)	229 (23.5)	1,759 (24.3)
Prior use of compression devices (N, %)	1,980 (34.2)	221 (45.9)	327 (33.6)	2,528 (34.9)
Presence of VTE risk factors (N, %)	2,037 (35.1)	257 (53.3)	430 (44.2)	2,724 (37.6)
History of VTE (N, %)	210 (3.6)	44 (9.1)	53 (5.4)	307 (4.2)

C-Section = Cesarean Section; SD = Standard Deviation; VTE = Venous Thrombo-Embolism.

Time to first dispensation, and seasonality

Considering all pregnancies, EVCD dispensation (17.0 %) was most frequent during the 5th month of pregnancy (168.1 ± 75.6 days after the beginning of the pregnancy) (Fig. 2).

Among pregnant women who had EVCD dispensation during ante- or post-partum, 69.0 % had one or two units of EVCD (27.1 % [one unit], 41.9 % [two units]); a unit corresponding to one pair of socks, stockings, or tights).

EVCD dispensations were most frequent in springtime, occurring in 28.3 % (n = 2,323) of pregnancies compared with 12.4 % (n = 1,710), 19.5 % (n = 1,946) and 18.7 % (n = 1,929) of pregnancies during

Table 3
EVCD dispensation rates by age, prior EVCD dispensation, VTE risk factors and history, and EVCD preferred format Dispensation rates across all analyzed pregnancies, during ante-partum and after vaginal delivery, planned C-section and unplanned C-section are presented by age group, prior EVCD dispensation, VTE risk factors, VTE history and format. A significant impact of each variable on the dispensation rate and on the format preference (p < 0.01) is shown with two stars.

	All pregnancies N = 15,528	Ante-Partum N = 7,252	Vaginal Delivery N = 5,796	Planned C-Section N = 482	Unplanned C-Section N = 974
EVCD dispensation rates by age group					
Age groups [% (N)]					
Younger than 20 y.o.	9.4 (36)**	18.8 (22)**	8.8 (9)**	0.0 (0)	58.3 (7)
From 20 to 29 y.o.	26.6 (1,689)**	38.2 (1,088)**	14.7 (350)**	33.9 (38)	38.9 (139)
From 30 to 39 y.o.	36.1 (2,850)**	46.3 (1,794)**	19.1 (584)**	48.0 (147)	47.3 (244)
From 40 to 49 y.o.	35.7 (344)**	52.3 (218)**	23.2 (62)**	65.6 (40)	44.9 (40)
EVCD dispensation rates by prior EVCD dispensation					
Prior EVCD dispensations [% (N)]					
With	38.9 (2,119)**	54.7 (1,383)**	22.1 (437)**	43.4 (96)	43.4 (142)
Without	27.8 (2,800)**	36.8 (1,739)**	14.9 (568)**	49.4 (129)	44.5 (288)
EVCD dispensation rates by VTE risk factors					
VTE risk factors [% (N)]					
With	35.2 (2,019)**	46.6 (1,270)**	21.0 (427)**	50.6 (130)	47.7 (205)
Without	29.6 (2,900)**	40.9 (1,852)**	15.4 (578)**	42.2 (95)	41.4 (225)
EVCD dispensation rates by VTE history					
History of VTE [% (N)]					
With	42.8 (278)**	56.7 (174)**	27.6 (58)**	43.2 (19)	47.2 (25)
Without	31.2 (4,641)**	42.4 (2,948)**	17.0 (947)**	47.0 (206)	44.0 (405)
EVCD preferences					
EVCD format [% (N)]					
Socks	36.9 (4,586)**	36.7 (2,782)**	38.1 (7 5 0)**	28.2 (128)**	38.3 (328)**
Stockings	48.6 (6,038)**	47.4 (3,593)**	49.0 (9 6 2)**	64.8 (294)**	56.1 (480)**
Tights	14.5 (1,806)**	15.9 (1,201)**	12.9 (2 5 3)**	7.0 (32)**	5.6 (48)**

EVCD = Elastic Venous Compression Device; C-Section = Cesarean Section; VTE = Venous Thrombo-Embolism.

summertime, autumn and winter, respectively.

Prescribers

The following prescriber categories were identified: hospital HealthCare Professionals (HCPs) of any specialty accounted for 30.9 % of dispensations (n = 2,683) followed by gynecologist - obstetricians (26.3 %, n = 2,280), general practitioners (20.2 %, n = 1,749), midwives (15.1 %, n = 1,314), other physicians (5.3 %, n = 456) and other HCPs (1.4 %, n = 120), and anesthetists (0.8 %, n = 67). Proportions varied ante- and post-partum. For instance, gynecologists accounted for 27.6 % (n = 1,465) of ante-partum dispensations against only 18.2 % (n = 244) after vaginal delivery.

All categories tended to prescribe stockings the most. Particularly, gynecologists prescribed stockings 49.7 % of the time (n = 1,640), compared to 35.9 % for socks (n = 1,185) and 14.4 % for tights (n = 474). This was also observed both ante- and post-partum, with stockings being prescribed even more frequently after a C-section (planned: 71.2 %, n = 84; unplanned: 61.6 %, n = 141).

Discussion

This study is the first to provide an exhaustive analysis of EVCD use by pregnant women both ante- and post-partum from EGB data, using effective and innovative identification algorithms.

Results showed that, in current practice, EVCD dispensation rates were low regarding the French National Authority for Health recommendations in favor of the EVCDs use during pregnancy and up to 6 weeks after delivery, or even 6 months after C-section [12]. Indeed, fewer than 1 pregnant woman in 3 were dispensed at least one EVCD during the analysis period, with dispensation occurring most often late during the pregnancy, and decreasing to fewer than 1 in 5 after vaginal delivery, even though VTE risk is increased due to decreased mobility (for 6 weeks following the delivery). Dispensation rates were especially low among women younger than 30, though they increased with age, which was expected as the incidence of VTE increases dramatically after age 35 [24]. Furthermore, even if EVCD dispensation was more frequent among women with VTE risk factors and among women with a history of

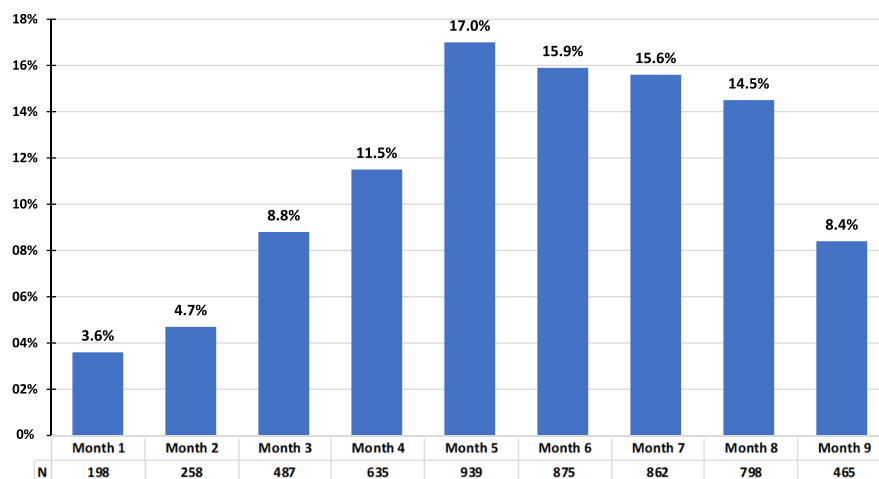


Fig. 2. EVCD dispensations by month of pregnancy. The distribution of dispensations occurring before delivery (N = 5,517) for all identified pregnancies (N = 15,528) by month of pregnancy. Most EVCD dispensations occurred between the 5th and 8th month of pregnancy, and few occurred during early pregnancy.

VTE, EVCD dispensation remained low in this at-risk population.

Stockings were dispensed more frequently than other formats, regardless of time period, delivery type, age, and prescriber.

The included population, identified by adapted algorithms [19], was representative of the French population and in line with available literature [25]. Deliveries and terminations were in line with available literature and French demographic data [25–27], as were the included population's characteristics [28–31]. The identification of pregnant women other than by the outcome of their pregnancy had only ever been performed once before: though the algorithms differed slightly, the included populations were comparable [19,32].

Importantly, observed dispensation rates were surprisingly low, even though it is recommended in France to have at least 2 pairs and replace them every 6 months [12,33]. While it is also recommended considering EVCD for symptoms relief of leg swelling associated with varicose veins during pregnancy or for women at increased risk of VTE in United Kingdom, United States, or Germany [34–36], the rate of dispensation in practice does not appear to have been evaluated or EVCDs are not appropriately addressed and practiced [37]. The results of this study may suggest that recommendations are not being followed by prescribers, or that there are issues with patient compliance [38], problems also identified by previous studies [39–43]. Indeed, seasonality also had an impact on EVCD dispensation, with lower dispensation rates in summer, while it has been shown that hot environments worsen venous disease symptoms [44]. However, our results showed that women who had previously used EVCDs were more likely to use them again, indicating a positive perception of EVCDs [13].

Another reason for non-compliance would be an inappropriate dispensation of the adequate format, the generic expression “compression stockings” being used in prescriptions out of habit over wording specific to other formats, i.e., socks or tights. This may also stem from a lack of knowledge on available EVCD formats, especially as their effectiveness is comparable [9,45,46]. Harmonizing EVCDs under a neutral blanket term such as “graduated elastic compression devices” or “EVCDs” on prescriptions and in the insurance claims database may help reduce these observed disparities by allowing the patient to choose which format he would prefer at the dispensation time.

The algorithm-related methodology used in this study is its main strength. It could be applied to the analysis of other devices, thus expanding the analytical possibilities of the French National Health Insurance Claims database, especially regarding pregnant women. However, although the EGB is a major source for conducting pharmaco-epidemiology studies, this database presents inherent limitations. Women whose outcome was not listed in the EGB (e.g., home births)

could not be accurately analyzed as we were unable to clearly identify the end of the pregnancy. Also, the specialty of salaried hospital HCPs was not available in the database. As such, prescriber specialty was only available for 68.6 % of all dispensations. Furthermore, EVCD prescription rates and potential geographical patterns as well as, ante- and post-partum observance and compliance data were not available and daily EVCD use could not be assessed.

Finally, the observed discrepancies between recommendations and real-life dispensation, and also between prescribers' practices and patient experience are disturbing, and strategies to address them should be developed.

Conclusions

This study provides an assessment of the real-life use of EVCD by pregnant women both ante- and post-partum from EGB data, using effective and innovative identification algorithms. A discrepancy between HAS recommendations and the current management of pregnant women was observed: EVCDs as a means of VTE prophylaxis are not sufficiently dispensed regardless of the risk level of the population and of the period considered.

This, and the observed tendency to majoritarily dispense stockings over other formats, suggest that prescription sensitization combined with information campaigns for prescribers (mainly gynecologists, general practitioners and midwives), pharmacists and pregnant women could be beneficial to highlight of the increased risk of VTE associated with pregnancy and the importance of both pharmaceutical and (apparently underused) mechanical prophylaxis in an effort to align practice with official recommendations.

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CRediT authorship contribution statement

Olivier Joassard: Writing – original draft, Writing – review & editing. **Anne-Laure Kerveillant:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing. **Claire Sellal:** Conceptualization, Methodology, Writing – review & editing. **Erwana Coatantiec:** Conceptualization, Methodology, Writing – review & editing. **Violaine Jabbour:** Conceptualization, Methodology, Writing – review & editing. **Guillaume Desjeux:** Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing –

review & editing. **Ben Braithwaite:** Conceptualization, Data curation, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Antoine Elias:** Conceptualization, Methodology, Writing – review & editing. **Arnaud Fauconnier:** Conceptualization, Methodology, Supervision, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Olivier Joassard is Corporate Medical Manager – Medical Devices at Laboratoires Innothera. He holds a PhD in Biology & Exercise Physiology from University Jean Monnet in Saint-Etienne (France). His main research focused on molecular mechanisms controlling muscle mass. After a postdoctoral fellowship at University of Ottawa (Canada), he worked as Study Director at NAMSA, a Contract Research Organization focusing on Medical Devices. Then, he worked as a Medical Affairs Manager and Global Scientific Support Manager at Lohmann & Rauscher, before joining Laboratoires Innothera. His areas of expertise are orthopedics, foot orthoses, and venous compression medical devices.



Anne-Laure Kerveillant is Clinical Projects Manager at Laboratoires Innothera. She holds a master’s degree in health evaluation and clinical research from University Claude Bernard in Lyon (France). Anne-Laure is responsible for the planning, set-up and coordination of the clinical studies on drugs and medical devices of Laboratoires Innothera.



Claire Sellal is a liberal midwife working in Nantes (France). As part of her studies, she wrote a thesis on the prevalence of wearing venous compression during pregnancy.



Erwana Coatantiec is a Pharmacist in Versailles (France), she is graduated from University of Anger (France). Erwana has been working for Laboratoires Innothera for 10 years as a Clinical Advisor and more recently as a Head of Clinical Projects. She was in charge of the preparation and implementation of the clinical studies plan needed for the development, evaluation of the benefit/risk ratio and scientific communication for all products of Laboratoires Innothera.



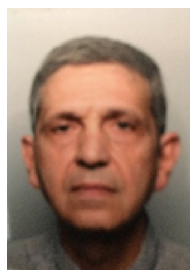
Violaine Jabbour is a Medical Advisor in Venous Disease. She has been working for Laboratoires Innothera - a French pharmaceutical company - for 7 years, and recently moved to another position to work exclusively on medical devices in a company specialised in Urology. Violaine is graduated as a Pharmacist from Paris University (France), holds a master degree in Risk Assessment and developed an extensive preclinical and clinical experience in various area, from hospital settings to health industry. Her main focus is to ensure that benefit-risk profile of drugs or devices is always positive in the best interest of the patients.



Guillaume Desjeux is the CEO of BDMXP, a company specializing in health data analysis. With a doctorate in medicine and public health, he has extensive experience in health data and biostatistics. He is an expert on the French public health care insurance claims databases. He also oversees the collection of health data within a healthcare facility.



Ben Braithwaite is the head of the Science team at Sanoia e-Health Services, a French contract research organization specializing in innovative post-market and data-driven clinical studies. With master’s degrees in both engineering (Ecole polytechnique, Palaiseau) and biomedical sciences (Ecole Polytechnique Montréal), his main focus is the development and structuring of clinical research projects. His other areas of expertise include biophysical modeling and data visualization.



Antoine Elias is the head of the “Clinical Research and Innovation” team at the Toulon Hospital Centre (France). He is a specialist in cardiology and vascular medicine and holds a PhD from the University Oxford. His research projects focus on the diagnosis, prognosis and treatment of venous thrombosis and pulmonary embolism.



Arnaud Fauconnier, MD, is Head of the Gynecology & Obstetrics Department of CHI Poissy-St-Germain. He holds a PhD in clinical epidemiology. Professor at Versailles St-Quentin University (UVSQ), he is Director of the 7285 RISCQ research unit “Clinical risks and safety in women’s health and perinatal health”. His areas of expertise are the methodology of clinical trials, emergencies in Obstetrics & Gynecology; endometriosis and gynecology pelvic pain; and the evaluation of the benefit/risk ratio of implants in surgery for prolapse and urinary incontinence. He regularly participates as a principal investigator in therapeutic trials in endometriosis, pelvic floor surgery and urinary incontinence.