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Pulmonary Embolism Home Treatment: What GP want?

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Summary

Background: In routine clinical practice, in most countries, patients with pulmonary embolism (PE) are hospitalized for clinical surveillance and to start anticoagulant treatment. Clinical trials and guidelines suggest that patients with stable PE can be safely treated as outpatients. This shift in management may increase general practitioners' (GP) role in PE early management. However, GP opinion regarding PE home treatment has never been assessed.

Methods: Survey conducted in France among a random sample of 360 GP (564 contacted to reach targeted sample size) working in regions representative of national access to French healthcare system. Main objectives were to assess i) GP' acceptability to PE home treatment ii) GP' preferred outpatient pathway.

Results: 87% of GP were favorable to home treatment of stable PE if the medical report is immediately available when the patient is discharged from ER (100%), in the absence of social and medical facility isolation of the patient (99%) and if the patient (99%) and GP (76%) consented. Outpatient pathways should be collaborative, between GP and a thrombosis specialist, and should include specialized follow-up visits at one week (80%), 3-6 months (80%) and when anticoagulant treatment is stopped (97%). 61% of GP felt that direct oral anticoagulants (DOAC) should facilitate PE home treatment, which should improve patient's quality of life.

Conclusion: The vast majority of interviewed GP are favorable to home treatment of stable PE if a formal outpatient pathway is established. DOAC are perceived as another key for the success of the development of PE home treatment.

Keywords:

Pulmonary Embolism, Ambulatory Care, Patient pathway, General Practitioner, Anticoagulants.

List of abbreviations used:

DOAC: direct oral anticoagulants

DVT: deep vein thrombosis

ER: emergency room

GP: general practitioner

LMWH: low molecular weight heparin

PE: pulmonary embolism

VTE: venous thromboembolism

Introduction

Venous thromboembolism (VTE) is the third most common cardiovascular disease with an incidence of 100-200 per 100,000 inhabitants (1). Pulmonary embolism (PE) constitutes its most serious and feared clinical presentation with a natural risk of death if untreated of up to 25% in historical studies (2). Twenty-five years ago, development of low molecular weight heparin (LMWH) prompted initial outpatient management (also named home treatment) of deep vein thrombosis (DVT) but had little impact on PE patients' management, with most of them being hospitalized for clinical surveillance and to start anticoagulant treatment (3). Over the past decade, clinical trials and clinical practice studies have demonstrated the safety of outpatient management of low-risk PE (4-6). All recent clinical practice guidelines on PE management emphasize that some patients with stable PE could be managed exclusively as outpatients (1, 7-9). They also underlined the need to establish a formal PE outpatient pathway (1, 8, 9), as non-standardized management of clinically suspected PE was shown to be associated with increased mortality (10). However, none of these guidelines specifically addressed initial outpatient management of PE from a general practitioner (GP) standpoint. Yet, a shift from initial inpatient to outpatient management of PE is likely to increase GP' role. Furthermore, GP' adherence to an established outpatient PE pathway is key for successful development of PE home treatment as, in current routine clinical practice, 80-98% of patients with PE are still admitted to hospital (4, 5, 11).

From this perspective we conducted a national survey among GP in France. The primary objective was to assess GP's acceptability of home treatment of PE and their preferences in terms of PE outpatient pathway.

Materials and methods

We conducted a national clinical practice survey from March 2015 to August 2017 among a random selection of GP practicing in 6 regions of France representative of patients' national access to healthcare system. The primary objective was to assess GP' acceptability of PE home treatment and predictors of this acceptability. Secondary objectives included GP' preferences in terms of PE outpatient pathway, their current exposure to and management of PE as well as their personal experience with initial outpatient management of PE.

Physicians' selection

The study was conducted among GP practicing in one of the 6 following French region known to be representative of patients' national access to healthcare system: Brittany, Centre, Ile de France (Paris), Languedoc-Roussillon, Nord Pas de Calais, Provence Alpes Côte d'Azur (12). GP were randomly selected from the directory of the French medical council. This directory contains a listing of all physicians in active practice and provides their address and telephone number. A similar number of GP from each region was contacted but, in each region, a weighted sample, based on the medical population within each district, was used to ensure representativeness of the study population.

Thus, in the Languedoc-Roussillon region, as 40% of GP work in the district of Hérault, our sample of GP needed to comprise 40% of GP from the district of Hérault.

All GP working in one of the 6 aforementioned regions were eligible. We only excluded those GP who did not have a permanent medical activity in the region, did not practice family medicine (e.g., emergency room (ER) doctors, homeopaths, nutritionists, some vascular medicine physicians) and those who declined to participate.

Phone survey

First, GP were telephoned by an investigator (Clémence Calais, MD) to ask them whether or not they agreed to participate in the study. Then, in case of agreement, eligibility criteria as described above were assessed, and a phone conference was scheduled to ensure that the physician would have enough time to properly complete the survey. During the telephone survey (mean time 15 minutes), the investigator filled in a questionnaire. This questionnaire had been previously tested by 8 GP to make sure that all questions were clear and unambiguous. The following information was collected: i) physician's characteristics: region and district of medical practice, age (years), sex, mode of practice (alone vs. medical group practice) and location of medical practice (city, semi-rural, rural areas); ii) frequency of exposure to PE patients; iii) current management of clinically suspected PE and of confirmed PE (e.g., in- or outpatient, collaborative management with another specialist); iv) acceptability of outpatient management of PE and in case of refusal, reasons; v) determination of PE outpatient pathway: conditions required for patient's early discharge from emergency room, thrombosis specialist consultations (number, timeline and indication for), role for direct oral anticoagulants (DOAC) in this management; vi) expected impact of outpatient treatment of PE on patient's quality of life. After collection, data were anonymously reported in an electronic case report form via sondageonline®.

In order to better take into account GP suggestions and to improve our questionnaire, 2 campaigns of recruitment (180 GP recruited per campaign) were scheduled. During the second one, the suggestions that had been made by GP during the first one were incorporated into the questionnaire. This study was approved by the ethic committee of Montpellier University Hospital (Comité de Protection des Personnes Sud-Méditerranée IV).

Statistical analyses

Based on data from a previous survey that we conducted locally, which showed that more than 68% of GP would accept outpatient management of PE, a sample size of 360 GP allowed us to estimate with a precision of plus or minus 5% that 70% of GP are favourable to outpatient management of PE (13). Furthermore, anticipating a rate of refusal to participate or of non-eligibility of GP of 30-40% (14), we randomly selected 100 GP in each region and, in each region, included the first 60 GP who agreed to participate.

Categorical variables were expressed as frequencies and percentages and continuous variables as means with 95% confidence interval. Chi-square or student t tests were used for categorical variables. Univariate and multivariate logistic models were conducted to assess predictors of acceptability of outpatient management of PE, including the following variables: region of practice, sex, age, and mode and location of practice. Two-sided p-values of 0.05 or less were considered to be statistically significant. Data were analysed in the Department of Biostatistics (Drs. Grégoire Mercier and Arthur Meusy) using SAS® software (SAS Institute Cary, N.C.).

Results

During the two pre-specified recruitment campaigns (March-June 2015 and June-August 2017), 564 GP were contacted and 360 (64%) agreed to participate. Half of the participating GP were recruited during each period, respecting the prespecified distribution per region and district. Main characteristics of participating GP are presented in Table 1. GP recruited during the second campaign of recruitment were more likely to practice in an urban area than those recruited during the first campaign (63% vs. 54%, $p < 0.05$). Other characteristics were similar between groups.

Current management of PE

Most GP (95%) stated that they manage clinically suspected PE less than once every 6 months. The way GP manage clinically suspected PE and patients with confirmed PE after discharge from hospital is presented in **Figure 1**.

- Current PE pathway: After a patient is discharged from hospital, in most cases (79%), GP usually manages patients in collaboration with a thrombosis specialist (mainly with a cardiologist, a respirologist, or a vascular medicine physician). In such cases, the GP is in charge of daily management of anticoagulant treatment (mainly INR monitoring) and patient education, each in 79% of cases. The thrombosis specialist manages the etiological work-up of PE and decision to extend or stop anticoagulant treatment in 86% and 96% of cases respectively.

- Incidental PE: Eight percent ($n=27$) of GP have previously managed an incidental PE detected on a CT scan that was ordered for another indication. Usually, in such cases, GP state that in 67% ($n=18$) of cases the patient was directly referred by a radiologist to the ER, and in 11% ($n=3$) of cases GP referred him- herself the patient to ER. Patients were managed exclusively in the outpatient setting, either by the GP or by another physician, in only 4% ($n=1$) and 11% ($n=3$) of cases respectively.

- Experience in outpatient management of PE: Overall, 21% of GP (n=76) have already managed at least one patient with acute PE in the outpatient setting only. GP enrolled during the second campaign of recruitment were more likely to have already managed PE patients in the outpatient setting than those recruited during the first campaign (27% vs. 16%, $p < 0.05$). The clinical presentation of PE was in 50% of cases (n=47) a symptomatic stable PE in a young adult, in 37% of cases (n=35) a symptomatic PE in an elderly patient living in a retirement nursing home facility and in 13% of cases (n=12) an asymptomatic or mildly symptomatic PE detected on CT. Usually, the GP managed the patient in collaboration with a thrombosis specialist (81% of cases, n=61).

Acceptability of outpatient management of PE

Overall, 87% (n=312) of GP stated that they were favorable to outpatient management of stable PE (Table 2). This rate was similar during the 2 campaigns of recruitment: 88% (n=158) during the first campaign and 86% (n=154) during the second campaign. According to the GP surveyed, the main conditions to fulfill before discharging a PE patient from ER should include that the patient's medical report be available at discharge from ER, the patient's agreement to be discharged, and absence of social or medical isolation (99-100% of GP agreed with in both cases). In addition, 3/4 of GP wished a phone call from the ER physician before patient's discharge. The objective of the phone call was to communicate initial treatment and to a lesser extent to obtain GP consent for home treatment.

Of the variables assessed, only mode of practice independently influenced GP' acceptability of outpatient management of PE: GP practicing alone were less likely to accept outpatient management of PE (Table 3).

Among the 48 GP that were against outpatient management of PE, the main reasons were seriousness of disease (90% of cases) and bleeding risk (60%) (Table 2). Concern about work overload and anticipation of poor coordination between hospital and the ambulatory care setting were mentioned in 33% and 10% of cases respectively. GP that were in favor of outpatient management of PE were more likely to believe that it would improve patient's quality of life than GP that were against such management (98% vs. 22%, $p < 0.05$).

GP wished for/agreed PE outpatient pathway

Figure 2 and Table 4 summarize GP suggestions and agreement regarding PE outpatient pathway. Overall, regarding thrombosis specialist consultations, GP wished (>80% of GP agreed with) an early consultation at one week to organize the etiological work-up and to assess clinical symptoms and tolerance to PE treatment, a consultation at 3-6 months to assess tolerance to PE treatment, and eventually another visit to stop anticoagulant treatment, if not already done at 3-6 months follow-up (97% of GP agreed).

Impact of DOAC on PE management

Sixty one percent (n=219) of GP believed that the availability of DOAC should facilitate the outpatient management of PE, whereas 16% (n=56) felt that it would have no impact. These proportions were stable over time: 58% vs. 64% felt that DOAC would have a favorable impact during the first and second campaign of recruitment ($p=0.2$).

Discussion

We found that the vast majority of interviewed French GP are favorable to home treatment of stable PE in general, if the medical report is immediately available when the patient is discharged from ER, in the absence of social and medical facility isolation of the patient, if the patient consents and after obtaining GP approval for home treatment. The current PE pathway is already collaborative and includes in the case of suspected PE, the GP and ER department, and in the case of established PE and after discharge from hospital, the GP and a thrombosis specialist (mainly vascular medicine physician).

Our study's primary objective was to assess GP acceptability of home treatment of PE. In contrast with the fact that almost all patients with PE are still hospitalized in France for a mean duration of 10 days (13, 15, 16), the vast majority of our interviewed French GP (88%) are in favor of home treatment of stable PE. Importantly, this rate of acceptability is much higher than the rate of acceptability we reported in a study conducted 3 years earlier (68% in 2012) among 164 GP practicing in the district of Hérault (13). This suggests that there is probably no longer a cultural barrier, at least from a GP standpoint, for development of home treatment of PE in France. GP education on PE, publications of guidelines suggesting home treatment for patients with stable PE (1, 7, 8), and the rise of DOAC use for PE treatment in France (from 56% to 72% during the 2012-2017 period) (17) have undoubtedly contributed to this sharp evolution of GP acceptance of home treatment of PE over this relatively short (3-year) period of time. In addition, regarding DOAC, it should also be pointed out that most GP believed that they would favor home treatment of PE. This is in agreement with what was reported in previous studies, that in addition, showed that DOAC might also be cost-saving by allowing early discharge (4, 18).

Another important step to allow effective home treatment of PE is the development of a formal PE outpatient pathway. Indeed, some studies have reported that in centres that developed established outpatient treatment pathways, up to 50-70% of patients with PE benefit from outpatient management (15, 19). In an effort to promote home treatment of PE and ensure the safety of such management, British and French guidelines have suggested outpatient pathways (8, 9, 20). Both underline the need for specialized thrombosis follow-up and patient's consent and are very similar to what GP who participated in our survey agreed with or wished. As compared with the outpatient pathway suggested in French guidelines, in our survey, interviewed GP asked that the medical report with therapeutic management be immediately available when a patient is discharged from the ER and also that GP provide consent for patient's discharge. Among the 12% of GP that were against home treatment of PE, most practiced family medicine alone and were afraid of PE severity. A formal initial outpatient pathway with in- and out of hours points of contact in the hospital and thrombosis specialist already visits scheduled at discharge from ER should reassure most of the GP that are still reluctant to treat PE at home.

Our study has strengths and limitations. We are aware that type of healthcare system, geographical location, level of medico-legal risk, physician attitudes, and patient preferences strongly influence the proportion of patients with PE treated in the outpatient setting (4, 15, 19, 21, 22); our PE outpatient pathway cannot be transposable to other countries per se.

Another important point regarding the outpatient pathway we developed is that we only focused on initial outpatient management. We did not ask GP about the need for a long-term thrombosis specialist follow-up. We did not capture their beliefs regarding the need for screening and management of long-term complications of PE, as well as the use of and switch to low dose DOAC for long-term secondary VTE prevention. We also did not

ask GP for their definition of stable PE, as we felt this went beyond their expected field of competence. Regarding our questionnaire, some important questions (social and medical isolation, week-end exclusion criteria for home treatment) were not asked in the first version used during the first campaign of recruitment. As those criteria were spontaneously suggested by some GP ('open questions'), we added the questions to the revised questionnaire used during the second campaign of recruitment. No likert scale was used to assess acceptability of PE home treatment. We were thus not able to assess the degree of acceptability. GP had been informed before the beginning of the questionnaire that they would be asked about the conditions they felt were necessary to treat PE in the outpatient setting. A "no" answer meant that GP were totally reluctant to PE home treatment. Furthermore, acceptability to PE home treatment was high in our study also because GP were able to decide under which conditions they would agree with PE home treatment; Acceptability might have been lower if we had suggested an outpatient pathway, where GP role was more important'.

The strengths of our study include the random selection of physicians with a good rate of participation for such type of studies (13, 23), structured, standardized interviews conducted by the same investigator, and previously tested and then updated questionnaires, which should provide a reliable overview of GP acceptance of home treatment of PE as well as their preferred outpatient pathway. Our 2 distinct periods of recruitment allowed us to assess potential changes in acceptability to PE home treatment and medical practice. We were able to show that over a relatively short period of time (2 years) the proportion of GP that had already managed PE in the outpatient setting had slightly but significantly increased (27% vs. 16%). To the best of our knowledge, this survey is the first one that has assessed GP preference and acceptability regarding home treatment of PE on a national basis in France. In terms of generalizability, the mean age and sex ratio of our GP population is identical to that

reported in the national French GP setting (62% vs. 64% of men, 48% vs. 50% of GP aged over 55 years) (24). However, we are aware that our sample size is relatively small compared to the number of GP practicing in France and that we do not have characteristics of GP who refused to participate. We can not exclude that our sample size might not be fully representative of the opinion of the overall French GP population.

In conclusion, the vast majority of interviewed French GP are favorable to home treatment of stable PE and their preferred outpatient pathway is consistent with the ones suggested in PE guidelines. Some important steps are still necessary before implementing home PE treatment on a routine care basis in most countries that do not yet have this management practice. This includes determining the best tool to select patients eligible for PE home treatment and the safety of each individual DOAC for home treatment. Home-PE, Mercury PE and MATHVTE studies should answer these important questions in the near future (clinical trials registration NCT02811237; NCT02584660; NCT03404635 respectively).

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Conflicts of Interests disclosure

JP Galanaud received a research grant from Bayer to conduct the study. Other authors state that they have no conflicts to disclose in relation with this work.

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Authorship contribution

Conception and design of the study: JP Galanaud; Grant funding: JP Galanaud;

Data acquisition: C Calais, G Mercier, A Meusy, L LeCollen, SR Kahn, I Quéré, JP

Galanaud; Data analysis: J.P. Galanaud, C Calais, A Meusy, G Mercier; Drafting of the article: J.P. Galanaud. Critical revision for important intellectual content: JP Galanaud,

C Calais, G Mercier, A Meusy, L Lecollen, SR Kahn, I Quéré Final; approval of the

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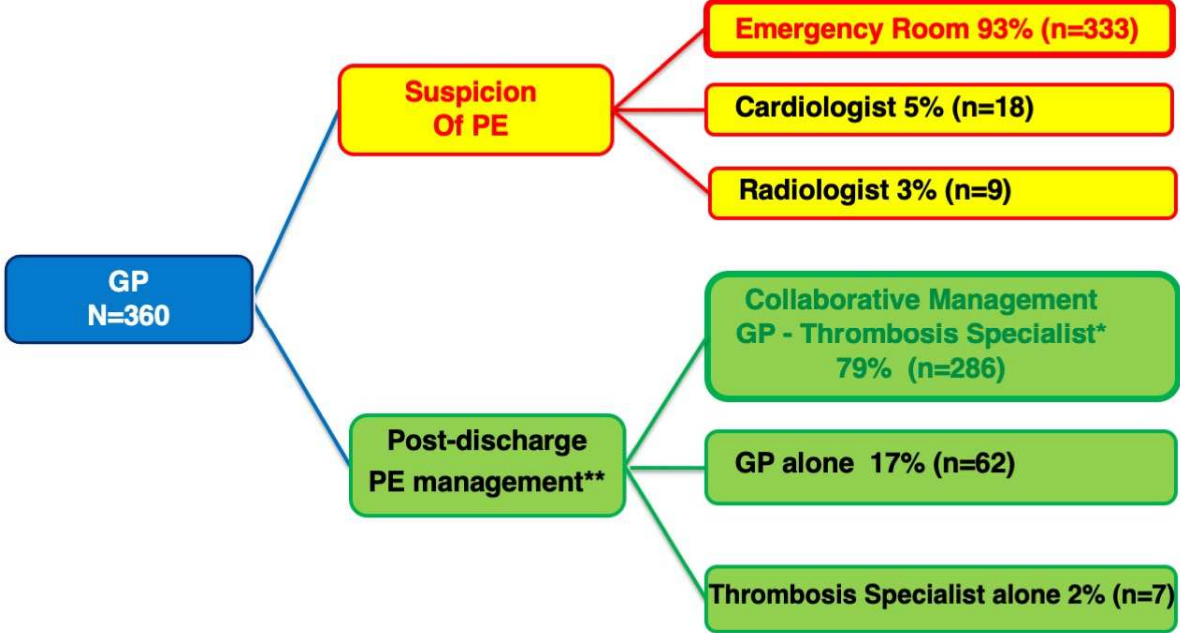
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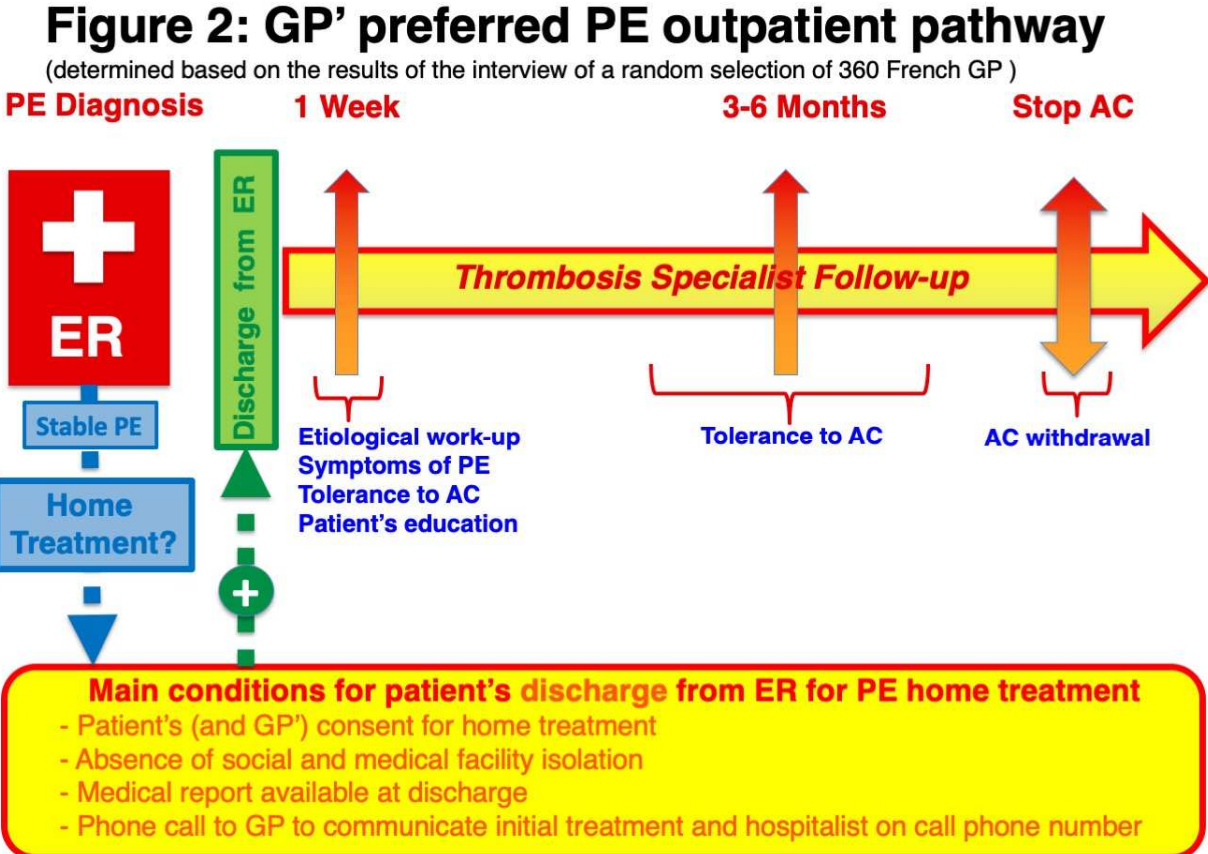
Figure 1 : Current patient’s ambulatory pathway for suspicion of PE and for management of PE after discharge from hospital in France

Figure 1: Current patient’s ambulatory pathway for suspicion of PE and for management of PE after discharge from hospital in France



* Cardiologist, Respirologist or Vascular Medicine Physician
 ** 5 GP, who recently started independent practice, stated they had never managed PE yet

Figure 2 : GP' preferred PE outpatient pathway (determined based on the results of the interview of a random selection of 360 French GP)



AC: Anticoagulant Treatment; ER: Emergency Room; GP: General Practitioner; PE: Pulmonary Embolism;

Table 1: Characteristics of participating GP

Characteristics	N=360
Age, % (n)	
- 25-39 years	14 (51)
- 40-54 years	38 (138)
- ≥ 55 years	48 (171)
Male sex, % (n)	62 (222)
Location of practice, % (n)	
- Rural	14 (50)
- Semi-rural	32 (116)
- City	54 (194)
Mode of practice, % (n)	
- Alone	39 (141)
- Group	61 (219)
- with other GP	89 (193)
Exposure to patients with new acute deep-vein thrombosis, % (n)	18 (63)
- > 1/ month	73 (264)
- 1/3 month	9 (33)
- <1/6 month	
Exposure to patients with new acute pulmonary embolism, % (n)	0 (0)
- > 1/ month	6 (20)
- 1/3 month	95 (340)
- <1/6 month	

Table 2: Acceptability of and conditions to fulfill at discharge from Emergency Room for PE ambulatory management

GP	N=360
Acceptability of PE ambulatory management, yes % (n)	87 (312)
In case of refusal, reasons	
- Severity of disease, % (n)	90 (43)
- Risk of death, % (n)	83 (40)
- Risk of bleeding, % (n)	60 (29)
- Increased work load, % (n)	33 (16)
- Expected poor coordination with hospital, % (n)	10 (5)
Conditions to fulfill before discharge from ER, % (n)	
- Medical report available	100.0 (360)
- Patient's agreement	99 (355)
- Friend/family support available*	99 (178)
- Medical facility close to patient's home*	99 (178)
- Phone call to GP	74 (265)
- Communicate initial treatment	100.0 (265)
- Obtain GP agreement	76 (200)
- Communicate hospitalist on call phone number	76 (202)
- Registered Nurse available in the community	53 (189)
- Weekday (Monday-Thursday) only*	38 (68)
- Electronic transmission of biological and radiological data*	11 (20)

* These questions were added to the questionnaire and asked to the 180 GP recruited during the second campaign of recruitment, based on suggestions made by GP during the first campaign of recruitment

Table 3 : Predictors of acceptability to GP of PE outpatient management of PE (univariate and multivariate analyses)

	Univariate Analysis OR, [95% CI]	Multivariate Analysis OR, [95% CI]
Region		
- Ile de France (ref)	-	-
- Brittany	1.0 [0.4 – 2.9]	0.9 [0.3 – 2.9]
- Centre	1.1 [0.4 – 2.9]	1.3 [0.4 – 3.9]
- Languedoc-Roussillon	2.4 [0.7 – 7.5]	2.9 [0.8 – 10.3]
- Nord Pas de Calais	1.3 [0.4 – 3.5]	1.4 [0.5 – 4.5]
- Provence Alpes Côte d'Azur	1.6 [0.6 – 4.4]	1.8 [0.6 – 5.2]
Location of practice		
- City (ref)	-	-
- Rural	0.4 [0.2 – 0.9]*	0.5 [0.2 – 1.2]
- Semi-rural	1.1 [0.5 – 2.2]	1.0 [0.4 – 2.1]
Mode of practice		
- In Collaboration (ref)	-	-
- Alone	0.2 [0.1 – 0.5]*	0.3 [0.2 – 0.6]*
Age (years)		
- 25-39 (ref)	-	-
- 40-54	0.4 [0.1 – 1.5]	0.3 [0.1 – 1.6]
- ≥ 54	0.2 [0.04 – 0.8]*	0.3 [0.1 – 1.2]
Sex		
- Male (ref)	-	-
- Female	1.6 [0.8 – 3.1]	0.8 [0.3 – 2.2]

* $p \leq 0.05$

Table 4 : GP suggestions and agreement regarding PE outpatient pathway

Characteristics	N= 360
Mode of management, % (n)	
- In collaboration with a thrombosis specialist	86 (309)
- Alone	8 (27)
- Delegation to a thrombosis specialist	7 (24)
Timing of Thrombosis Specialist Consultations	
1 week, % (n)	81 (290)
<i>If yes, why</i>	
- PE etiological work-up	98 (285)
- Assess symptoms of PE and tolerance to treatment	87 (253)
- Patient education	31 (91)
- Anticoagulant treatment management	28 (81)
After 1 week, % (n)	75 (279)
<i>If yes, why</i>	
- Stop anticoagulant treatment decision	98 (273)
- Assess symptoms of PE and tolerance to treatment	61 (170)
- PE etiological work-up	31 (86)
- Patient education	20 (57)
- Anticoagulant treatment management	19 (52)
<i>Timing of this visit</i>	
- 1 month	32 (89)
- 3 months	58 (162)
- 6 months	76 (213)
- At anticoagulant treatment withdrawal	97 (270)