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BRIEF REPORT

Trends in home treatment and early discharge of patients with low-risk pulmonary embolism

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Abstract

Background: Recent guidelines recommend a strategy of home treatment or early discharge in low-risk pulmonary embolism (PE). Contemporary rates of the implementation of this approach in everyday clinical practice are unknown.

Objective: To determine the proportion of patients with PE who fulfill eligibility criteria for home treatment or early discharge, to investigate in how many of them such a management strategy is actually followed, and to discover differences in early complications between early or later discharge among low-risk patients.

Methods: Based on the United States Nationwide Emergency Department Sample and Nationwide Readmission Database, we identified low-risk PE patients (absence of hemodynamic instability, cor pulmonale, tachycardia, dyspnea, hypothermia, altered mental status, and fulfillment of the Hestia criteria). We analyzed the proportion of direct or early (<48 hours) discharge and the association with demographic and clinical variables. We also studied the 90-day occurrence of venous thromboembolism recurrence and major bleeding.

Results: From 2016 to 2020, 641 621 (30.6%) of 2 099 390 PE cases in the Nationwide Emergency Department Sample database were low risk. Among low-risk PE, 31.5% received home treatment compared with 15.4% of those not classified as low risk. Home treatment for low-risk patients showed an increasing trend over time. In the Nationwide Readmission Database, 481 321 (24.7%) of 1 950 708 PE hospitalizations were classified as low risk. An early discharge strategy was followed in 22.6% of all cases, increasing to 45.9% for low-risk PE admissions, with a rising trend observed from 2016. Factors associated with home treatment or early discharge among low-risk patients included age, sex, and absence of comorbidities. Ninety-day incidence of venous thromboembolism recurrence and major bleeding was low among low-risk patients with early discharge (1.3% and 1.5%, respectively).

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Conclusion: There is an increasing adoption of home treatment and early discharge for low-risk PE in routine practice. This approach appears safe, supporting findings from previous trials.

KEYWORDS
early discharge, home treatment, low risk, pulmonary embolism

1 | INTRODUCTION

Pulmonary embolism (PE) is a cardiovascular emergency, prompting early recognition and management. Although a substantial number of patients with PE will need hospitalization with monitoring and/or advanced treatment strategies, a proportion of patients, reaching nearly a quarter of the whole population with PE, are at low risk for early death [1]. Low-risk PE is generally defined as PE without hemodynamic compromise, without imaging or laboratory evidence of right ventricular compromise or myocardial injury, and without comorbidities such as those included in the simplified PE Severity Index (sPESI) score or the Hestia clinical criteria [2,3].

A concept of ambulatory treatment or early discharge strategy (≤48 hours) of low-risk PE has recently been adopted by guideline recommendations, including the 2019 European Society of Cardiology guidelines on the diagnosis and management of acute PE and the 2020 American Society of Hematology guidelines for the management of venous thromboembolism (VTE) [1,4]. These recommendations are supported by the publication of 3 seminal trials; these showed that patients with low-risk PE who fulfill additional eligibility criteria integrating aspects of PE severity, comorbidity, and the feasibility of home treatment could safely be treated at home or with an early discharge strategy without an increase in recurrent VTE and major bleeding rates [5–7]. The adoption of such a change in paradigm in PE care among "real-world" settings and outside the concept of prospective cohort studies remains outdated and unknown.

Therefore, by using nationwide databases, our aim was to describe the proportion of patients with PE who fulfill eligibility criteria for home treatment or early discharge to investigate how many actually receive such a management strategy and to discover differences in early complications between early or later discharge among low-risk patients.

2 | METHODS

We used 2 nationwide databases provided by the Agency for Healthcare Research and Quality and developed within the Healthcare Cost and Utilization Project, namely the Nationwide Emergency Department Sample (NEDS) and Nationwide Readmission Database (NRD). The NEDS is the largest publicly accessible emergency department database in the United States, containing data from about 28 million visits per year, representing a 20% sample of hospital-owned emergency departments. It captures both admissions and treat-and-release visits. The NRD includes data on roughly 17 million discharges, covering 60.8% of all United States hospitalizations, including those with recurrent visits within a calendar year or in-hospital deaths.

For the purpose of our analysis, we used data from the NEDS and NRD for the years 2016 through 2020. The databases include deidentified data only, and this work was considered exempt from institutional review board approval.

2.1 | Study population and data definition

The International Classification of Diseases, 10th version (ICD-10; ICD-10-CM for diagnoses and ICD-10-PCS for procedures), is used to code the diagnoses and procedures in the NEDS and NRD. The databases contain multiple diagnoses and procedures for each hospital record. For the purpose of the present study, we selected in both datasets all records with a diagnosis code of acute PE (I26.0 and I26.9), both as primary and secondary diagnoses. We defined PE records as low risk when they fulfilled all of the following criteria:

a) Records with an absence of diagnosis codes for shock, vasopressor use, cardiac arrest, or need for cardiopulmonary resuscitation.
b) Records with an absence of cor pulmonale as a consequence of acute PE.
c) Records with an absence of acute symptoms such as tachycardia, dyspnea, hypothermia, and altered mental status.
d) Records fulfilling none of the Hestia criteria [2].

In the NEDS database, we defined the record as indicating home treatment of PE when the patient was treated in the emergency department, not admitted to the same or transferred to a different hospital, and was discharged alive. In the NRD, we defined the record as indicating an early discharge of PE when the length of stay was ≤2 days, while the patient was discharged alive and not transferred to another healthcare facility.

Using the NRD, we studied the 90-day occurrence of VTE recurrence and major bleeding. Because each year in the database contains only the readmissions occurring during the same calendar year and while it is not possible to follow records through different calendar years, for 90-day incidences, we only used the PE records happening during months 1 to 9 of the calendar year while excluding months 10 to 12 of the calendar year. The latter step was necessary to avoid lower estimations in 90-day incidences while accepting any limitations imposed from seasonality in VTE occurrence [8]. VTE recurrence was defined as the diagnosis of deep vein thrombosis and/or PE only as a primary diagnosis to avoid any overestimation that would arise if the index PE hospitalization was registered as a secondary diagnosis code in the readmission record. Major bleeding was defined as the presence of intracranial bleeding, hemopericardium, hemoperitoneum, hemarthrosis, or bleeding requiring transfusion either as a primary or secondary diagnosis code.

2.2 | Statistical analysis

For categorical data, descriptive statistics comprised counts and percentages, and for continuous variables, medians and IQRs. We computed 95% CIs for the 90-day incidence rates using the "logit" method by fitting a logistic regression model and computing a Wald-type interval on the log odds scale, which was then transformed into the probability scale. Differences in contingency tables were examined using the chi-squared test with Rao and Scott's second–order correction. Logistic regression was used to dissect the relative weight of individual parameters among those used to define low risk. We, therefore, evaluated associations between home treatment (in the NEDS database) or early discharge (in the NRD) and the variables of age, sex, and comorbidities (arterial hypertension, diabetes, obesity, chronic kidney disease, chronic heart failure, chronic pulmonary disease, cancer, and frailty defined according to the Johns Hopkins Adjusted Clinical Groups frailty-defining diagnosis indicator [9]). For all analyses, we applied the discharge-level weights provided in the Healthcare Cost and Utilization Project databases and took into account the NEDS/NRD stratification and hospital clustering. A 2-sided *P* value of <.05 was set as the level of statistical significance. Since the percentages of missing data were below 1% for all variables, we conducted a complete case analysis. The statistical analysis was conducted in R (R Project for Statistical Computing, version 4.3.2.).

TABLE 1 Baseline characteristics of patients in the Nationwide Emergency Department Sample and Nationwide Readmission Database according to low-risk status.

	NEDS database			NRD		
Characteristic	Overall, *N* = 2 099 390[a]	Not low-risk PE, *n* = 1 457 770[a]	Low-risk PE, *n* = 641 621[a]	Overall, *N* = 1 950 708[a]	Not low-risk PE, *n* = 1 469 388[a]	Low-risk PE, *n* = 481 321[a]
Age (y)	63 (50, 75)	64 (51, 76)	61 (47, 72)	65 (52, 76)	66 (53, 76)	62 (50, 73)
Female	1 085 472 (52)	746 451 (51)	339 021 (53)	994 986 (51)	742 443 (51)	252 543 (52)
Hypertension	1 180 753 (56)	868 878 (60)	311 875 (49)	1 190 854 (61)	922 183 (63)	268 671 (56)
Diabetes mellitus	476 380 (23)	365 326 (25)	111 054 (17)	486 932 (25)	391 685 (27)	95 247 (20)
Obesity	423 370 (20)	310 591 (21)	112 779 (18)	464 036 (24)	353 380 (24)	110 656 (23)
Renal disease	270 225 (13)	236 459 (16)	33 767 (5.3)	300 494 (15)	267 520 (18)	32 974 (6.9)
Congestive heart failure	391 583 (19)	346 915 (24)	44 668 (7.0)	435 671 (22)	395 922 (27)	39 749 (8.3)
Chronic pulmonary disease	526 838 (25)	411 971 (28)	114 867 (18)	536 390 (27)	438 312 (30)	98 077 (20)
Cancer	516 551 (25)	377 195 (26)	139 356 (22)	556 476 (29)	423 630 (29)	132 847 (28)
Dementia	120 408 (5.7)	96 886 (6.6)	23 522 (3.7)	126 140 (6.5)	103 929 (7.1)	22 211 (4.6)
Frail	369 917 (18)	313 344 (21)	56 573 (8.8)	424 627 (22)	367 820 (25)	56 807 (12)
Hospital area						
Metropolitan area	1 815 378 (87)	1 273 431 (87)	541 946 (85)	1 784 914 (92)	1 348 908 (92)	436 006 (91)
Nonmetropolitan area	282 830 (13)	183 669 (13)	99 161 (15)	165 281 (8.5)	120 103 (8.2)	45 178 (9.4)
Hospital teaching status						
Nonteaching	715 409 (34)	470 503 (32)	244 906 (38)	558 475 (29)	403 244 (27)	155 231 (32)
Teaching	1 382 798 (66)	986 597 (68)	396 201 (62)	1 391 721 (71)	1 065 767 (73)	325 953 (68)
Total ED visits						
Q1	562 933 (27)	366 931 (25)	196 002 (31)	NA	NA	NA
Q2/3	1 045 837 (50)	743 047 (51)	302 790 (47)	NA	NA	NA
Q4	489 437 (23)	347 121 (24)	142 316 (22)	NA	NA	NA

ED, emergency department; NA, not available; NEDS, Nationwide Emergency Department Sample; NRD, Nationwide Readmission Database; PE, pulmonary embolism; Q, quartile.

[a] Median (IQR) or *n*/*N* (%).

TABLE 2 Characteristics leading to the exclusion of records from the low-risk definition in the Nationwide Emergency Department Sample and Nationwide Readmission Database.

Characteristic	NEDS database N = 2 099 390[a]	NRD N = 1 950 708[a]
High-risk PE	97 923 (4.7)	237 524 (12)
Cor pulmonalis	101 940 (4.9)	113 093 (5.8)
Tachycardia	174 614 (8.3)	187 783 (9.6)
Dyspnea or hypoxia	598 395 (29)	637 606 (33)
Altered mental status	59 326 (2.8)	69 479 (3.6)
Hypothermia	1332 (<0.1)	1362 (<0.1)
Bleeding	234 710 (11)	299 089 (15)
Abnormal chemistry	50 302 (2.4)	42 655 (2.2)
Severe renal disease	377 929 (18)	452 936 (23)
Severe liver disease	65 579 (3.1)	78 306 (4.0)
Acute heart failure	140 154 (6.7)	172 873 (8.9)
Acute renal failure	336 049 (16)	409 708 (21)
Pregnant	8365 (0.4)	8726 (0.4)
HIT	6301 (0.3)	8894 (0.5)
Social difficulties	51 426 (2.4)	55 707 (2.9)
Infection	569 918 (27)	660 065 (34)
Anticoagulation	426 655 (20)	361 191 (19)

HIT, heparin-induced thrombocytopenia; NEDS, Nationwide Emergency Department Sample; NRD, Nationwide Readmission Database; PE, pulmonary embolism.
[a] Median (IQR) or n (%).

3 | RESULTS AND DISCUSSION

For the years 2016 to 2020, we estimated 2 099 390 emergency department visits in the NEDS with a diagnosis of PE. Of those, 641 621 fulfilled the criteria for low-risk PE (30.6%), and the baseline characteristics according to low-risk status are shown in Table 1. The characteristics leading to the exclusion of records from the low-risk definition are shown in Table 2.

During the entire study period, 20.3% of patients were treated at home. Of low-risk PE emergency department visits, 31.5% were indicated as having received home treatment, while the percentage was 15.4% for patients not fulfilling the low-risk status. There was an increasing trend for home treatment of PE for low-risk patients from 2016 onward, while this was absent for the rest of the patients (Figure 1A).

Individual baseline variables associated with home treatment among low-risk emergency department visits included younger age, female sex, and the absence of comorbidities (except for diabetes mellitus; Figure 2A). Patients treated in university hospitals, hospitals in nonmetropolitan areas, and hospitals belonging to the first quartile, according to the total number of emergency department records, were more likely to receive home treatment for PE.

For the years 2016 to 2020, we estimated 1 950 708 hospitalizations in the NRD with a diagnosis of PE. Of those, 481 321 fulfilled the criteria for low-risk PE (24.7%), and the baseline characteristics according to the low-risk status are shown in Table 1. The characteristics leading to the exclusion of records from the low-risk definition are shown in Table 2.

During the whole study duration, 22.6% of patients were treated with an early discharge strategy. Of low-risk PE hospitalizations, 45.9% were indicated as having been treated with an early discharge strategy, while the percentage was 15.0% for patients not fulfilling the low-risk status. There was an increasing trend for an early discharge strategy of PE for low-risk patients from 2016 and onward, while this was absent for the rest of the patients (Figure 1B).

Factors associated with an early discharge strategy among low-risk hospitalizations included younger age and the absence of comorbidities (except for chronic kidney disease; Figure 2B). Patients treated in university hospitals and hospitals in metropolitan areas were less likely to receive an early discharge strategy.

The 90-day incidence of VTE recurrence among patients with low risk was 1.3% (95% CI, 1.3% to 1.4%) in the early discharge category and 1.8% (95% CI, 1.7% to 1.9%) in the nonearly discharge category ($P < .0001$). The 90-day incidence of major bleeding among patients with low risk was 1.5% (95% CI, 1.4% to 1.6%) in the early discharge category and 2.8% (95% CI, 2.7% to 2.9%) in the nonearly discharge category ($P < .0001$).

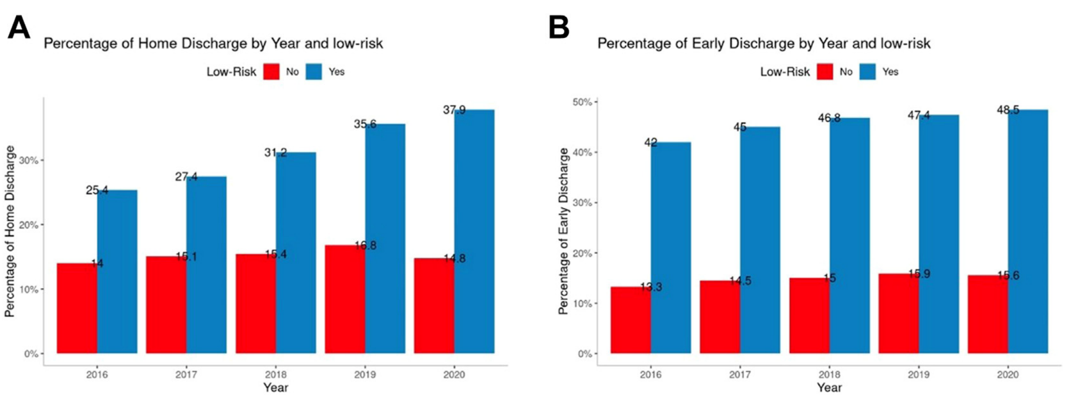

FIGURE 1 Proportion of pulmonary embolism patients treated at home (A, Nationwide Emergency Department Sample database) or treated with an early discharge strategy (B, Nationwide Readmission Database) according to low-risk status.

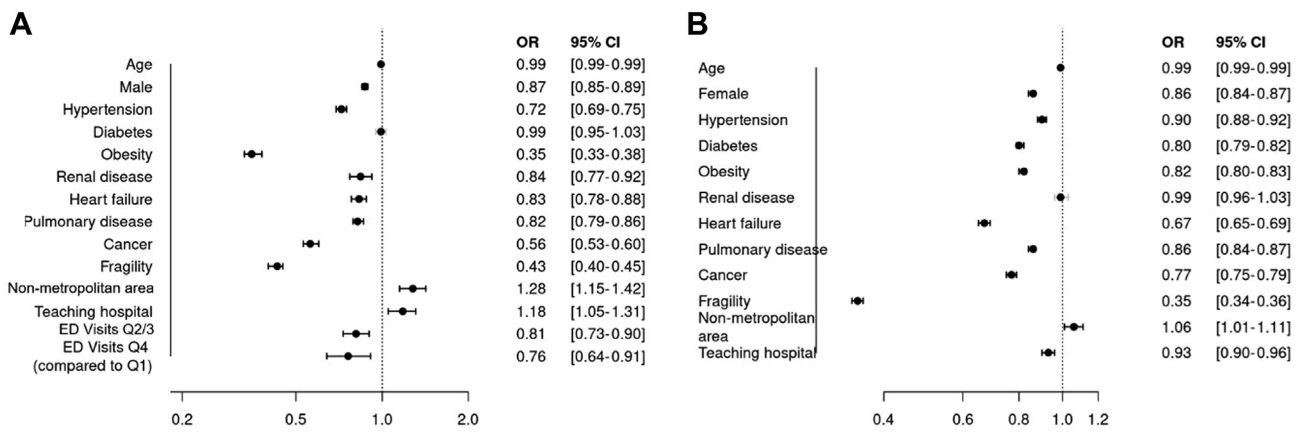

FIGURE 2 Multivariable logistic regression analysis of baseline predictors of (A) home treatment (Nationwide Emergency Department Sample database) and (B) early discharge strategy (Nationwide Readmission Database). ED, emergency department; OR, odds ratio; Q, quartile.

In this nationwide cross-sectional analysis, we found an increase in the home treatment or early discharge strategy of low-risk PE from 2016 to 2020, while the same increase was not observed in patients not fulfilling the criteria of low-risk PE. A previous analysis of the NEDS database of the years 2007 to 2012 reported home treatment in 6% of all stable patients with PE [10]. A similar chronic trend for an increase in the proportion of patients receiving home treatment was observed, with the proportion being approximately 4% in 2007, while it reached 7% to 9% in the years 2011 and 2012. A multicenter study from Canada also found an increased implementation of home treatment in the same time period (5.6% in 2004 to 11.1% in 2010) [11]. Thus, we are observing an overall increasing number of institutions adopting a home treatment for stable patients with PE. In this context, recently reported data from emergency departments participating in the National Hospital Ambulatory Medical Care Survey showed that discharge rates from emergency departments remained largely unchanged during the more contemporary period of our study from 2012 to 2020. The discharge rates from emergency departments reached 36% among low-risk patients according to the sPESI criteria [12]; these rates are comparable with the rate (32% from NEDS) reported in our study. Moreover, and importantly, in our study, by using refined stratification with the Hestia criteria, we were able to show that the home treatment *or* early discharge of low-risk PE is actually augmenting over time at the nationwide level in the United States. This was also shown by the HOME-PE randomized controlled trial where, compared with the sPESI, the Hestia rule deemed fewer patients eligible for home treatment, but it had higher applicability as physicians were less likely to overrule home treatment decisions based on patient preferences [6]. Nevertheless, both studies agree that still two-thirds of low-risk patients with PE require hospitalization. Home treatment or early discharge was 38% in the HOME-PE study among patients fulfilling the low-risk PE criteria. That study was published in 2021, thus later than the study period of the present study. Thus, this strategy was substantially already practiced in the US before the publication of the seminal studies (HoT-PE and HOME-PE), and what is more, the outcomes in the "real-world setting" were good. Therefore, the present study supports the implementation of home treatment of low-risk PE on a broader scale. Since large management studies confirming the safety of ambulatory treatment of PE and the subsequent release of guidelines supporting this practice were published more recently, we expect that the implementation in the real-world setting may further increase in the years to come.

Earlier studies did not identify individuals' baseline patient or hospital characteristics as predictors of outpatient management for acute PE in the "real world." In our study, we were able to associate younger age, sex, frailty, and comorbidities with increased rates of home treatment or early discharge and also identify institution-related characteristics. Teaching hospitals and institutions with a heavy emergency department workload were more likely to discharge low-risk patients from the emergency department, indicating an increased confidence in ambulatory treatment of PE. On the other hand, teaching hospitals and institutions in metropolitan areas were more likely to offer prolonged hospitalization once admitted, possibly due to the increased array of examinations and treatment options offered.

The 90-day incidence of VTE recurrences and major bleeding among low-risk patients who received an early discharge strategy was low, in accordance with prospective cohort studies and trials [2,5,6]. Thus, we could confirm the safety of this strategy under real-world conditions and at a nationwide level. Differences in outcomes according to early discharge are mainly attributed to differences in their baseline characteristics.

The strengths of our study include the use of 2 big data nationwide samples to investigate both home treatment and early discharge strategies, as well as the use of detailed criteria to refine the definition of low-risk status among patients with acute PE. On the other hand, our study relied on administrative data, which comes with certain limitations inherent to this type of evidence. Comorbidities were identified based on ICD-10 codes; therefore, the possibility of misclassification in some cases cannot be entirely ruled out (eg, the use of numerical values for vital signs was not possible). Lastly, the study refers to US nationwide level data; confirmation of these results should also follow in other countries.

To conclude, our results reveal an increasing implementation of early discharge and home treatment for low-risk PE. Factors influencing these strategies are related to demographics, comorbidity, and hospital type. A home treatment or early discharge strategy for low-risk PE was associated with favorable outcomes in the real-world setting, thus supporting the results of previously performed prospective cohort studies and randomized trials.

AUTHOR CONTRIBUTIONS

I.T.F., S.V.K., S.B., and L.V. contributed to the conception or design of the work. I.T.F., K.C.C., and L.V. contributed to the acquisition, analysis, or interpretation of data for the work. I.T.F. and K.C.C. drafted the manuscript. G.G., L.H., K.K., S.B., L.V., P.L., and S.V.K. critically revised the manuscript. All authors gave final approval and agreed to be accountable for all aspects of work, ensuring integrity and accuracy.

DECLARATION OF COMPETING INTERESTS

L.H. received lecture/consultant fees from MSD, Johnson & Johnson, and Boston Scientific, outside the submitted work. G.G. reports speaker or consulting fees from ELPEN Pharmaceuticals, Galenica, GlaxoSmithKline, and Janssen Pharmaceutical Companies of Johnson & Johnson and MSD, outside the submitted work. P.L. has received institutional fees and research grants from Abbott Vascular, Edwards Lifesciences, and ReCor; has received honoraria from Edwards Lifesciences, Abbott Medical, Innoventric, ReCor, Boehringer Ingelheim, and Daiichi Sankyo; and has stock options with Innoventric. S.B. received lecture/consultant fees from Bayer HealthCare, Concept Medical, BTG Pharmaceuticals, INARI, Boston Scientific, and Leo-Pharma; institutional grants from Boston Scientific, Bentley, Bayer HealthCare, INARI, Medtronic, Concept Medical, Bard, and Sanofi; and economical support for travel/congress costs from Daiichi Sankyo, BTG Pharmaceuticals, and Bayer HealthCare, outside the submitted work. S.V.K. reports institutional grants and personal lecture/advisory fees from Bayer AG, Daiichi Sankyo, Boston Scientific, Inari Medical, and Penumbra Inc. The remaining authors report no conflicts of interest.

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