

## Review Article

# Treatment of acute pulmonary embolism as outpatients or following early discharge

## A systematic review

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### Summary

The purpose of this systematic review is to test the hypothesis that carefully selected low-risk patients with acute pulmonary embolism (PE) can safely be treated entirely as outpatients or after early hospital discharge. Included articles were required to describe inclusion or exclusion criteria and outcome of patients treated for PE. Early hospital discharge was defined as an average hospital stay  $\leq 3$  days. Six investigations included patients with PE who were treated entirely as outpatients; two investigations included patients with PE who were treated after early discharge. All investigations included only low-risk patients or patients with small or medium sized PE. Outcome after 3–46 months in

patients treated entirely as outpatients showed recurrent PE in 0% to 6.2% of patients, major bleeding in 0% to 2.8% with one death from an intracerebral bleed. Definite death from PE did not occur, but there was one possible death from PE. Outcome in three months in patients treated after early discharge showed no instances of recurrent PE. Major bleeding occurred in 0% to 3.7% of patients. There were no deaths from PE, but there was one death from bleeding. In conclusion, outpatient therapy of acute PE is probably safe in low-risk, carefully selected compliant patients who have access to outpatient care if necessary. Such outpatient treatment would be cost-effective.

### Keywords

Pulmonary embolism, deep venous thrombosis, outpatient treatment

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## Introduction

Outpatient treatment of deep venous thrombosis (DVT) with low-molecular-weight heparin (LMWH) followed by vitamin K antagonists was shown in 1996 to be safe and effective in carefully chosen patients (1, 2). Subsequent investigations supported the outpatient approach to the treatment of DVT (3–9). Patients with pulmonary embolism (PE) were excluded from most investigations of outpatient treatment of DVT or treatment after early discharge (1–3, 7–9). PE is a more ominous and potentially fatal form of venous thromboembolism (VTE) than DVT (10). The risk of fatal recurrent PE in patients treated for PE is greater than the risk of fatal PE in patients treated for DVT (1.5% vs. 0.4%) (11). By 2002, patients with DVT who also had PE were sometimes included (12). Several investigations of the outpatient treatment or early discharge treatment of acute PE have now been reported. The British Thoracic Society in 2003 made a grade C recommendation that the current organization for out-

patient management of DVT should be extended to include stable patients with PE (13). However, questions remain of whether outpatient treatment is appropriate for PE, and if so, which patients are suitable candidates (10). The American College of Chest Physicians (ACCP) Clinical Practice Guidelines (8<sup>th</sup> Edition) indicated that the feasibility of treating a substantial proportion of patients with symptomatic PE with LMWH at home is supported by data in patients with PE included in randomized trials and data in observational studies, but no recommendation was made (14). The purpose of this systematic review is to test the hypothesis that carefully selected low-risk patients with acute PE can safely be treated in this manner.

## Methods

We used established methods for systematic review (15–17). A broad search of the literature in all languages was performed incorporating both electronic and manual components. The elec-

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tronic search was performed using PubMed, which includes MEDLINE, OLDMEDLINE, OVID and we also searched Embase. The dates of the searches were from 1964 through March 2008 with MEDLINE and 1991 through June 2008 with Embase. We used combined medical subject headings (MeSH). Combined search terms were: Pulmonary embolism matched with outpatient treatment, ambulatory management, ambulatory, ambulatory treatment, outpatient, home treatment, early discharge, office treatment, community based treatment, treatment in the community setting, home management home care. Manual reference checks of recent reviews and all original investigations were performed to supplement the electronic searches.

### Study selection for data extraction

Two reviewers independently screened the abstracts and titles of the search results and eliminated articles only if they clearly did not relate to outpatient treatment of PE. Inclusion required that PE and recurrent PE or DVT on follow-up were objectively confirmed. Inclusion also required that patients with PE were treated entirely as outpatients or discharged from hospital after an average of  $\leq 3$  days. Articles that described results of patients discharged early were required to describe the length of hospital stay. Articles were required to describe inclusion or exclusion criteria, and outcome of patients treated for PE. Studies may have been prospective or retrospective. In order to obtain a broad impression of results of outpatient treatment of PE, we included investigations of selected populations (cancer patients) as well as unselected populations. We included studies with various exclusion criteria and studies that used various anticoagulant regimens.

Articles were excluded if patients with PE were included among those with DVT without giving specific results of those with PE. One study was excluded because patients were treated in a "hospital in the home", that had several aspects of hospital care (18). We also excluded abstracts, case reports, comments, reviews, and case-series with  $\leq 10$  patients. Full articles were obtained if a determination of exclusion criteria could not be made from the title or the abstract.

Information collected in each article included number of patients, study characteristics, inclusion criteria, exclusion criteria, treatment, length of follow-up, methods of diagnosis of PE, methods of diagnosis of PE or DVT on follow-up, definitions of major bleeding, incidence of recurrent PE, major bleeds, death from PE, and death from bleeding.

### Data retrieval

A flow diagram outlining the systematic review process is provided (Fig. 1). The literature search identified 935 citations for screening. Of these, 928 were rejected for the reasons shown in Figure 1 after reviewing the titles, abstracts, or the entire article. Seven investigations met the inclusion criteria.

### Statistical analysis

95% confidence intervals (CI) were calculated using calculator for confidence intervals of relative risk ([www.sign.ac.uk/methodology/risk.xls](http://www.sign.ac.uk/methodology/risk.xls)).

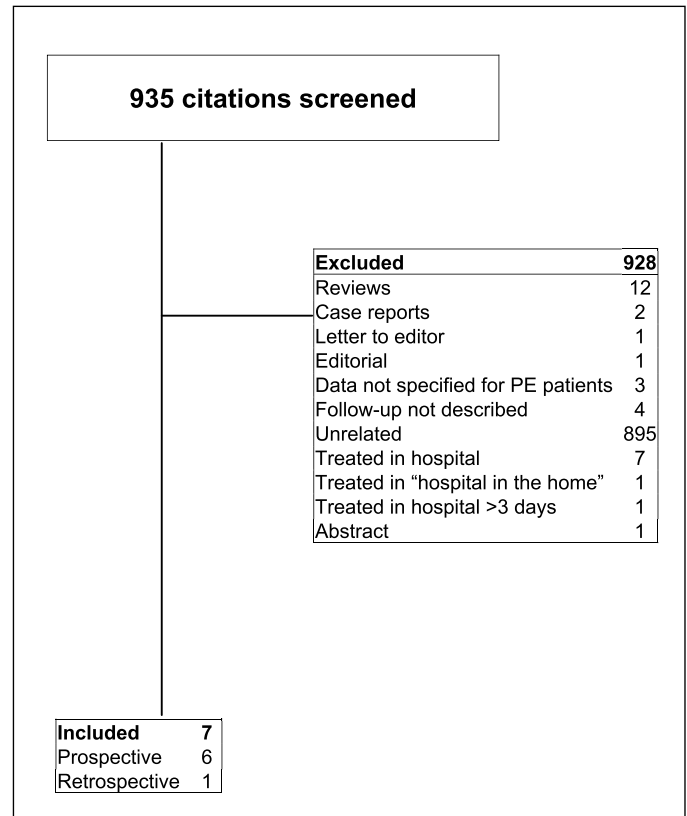


Figure 1: Study attrition diagram.

## Results

Six investigations were prospective (19–24) and one was retrospective (25) (Table 1). Six investigations included patients with PE who were treated entirely as outpatients (19, 21–25). In one of these, patients were maintained an average of five days in a "patient hotel close to the hospital" (21). Two investigations included patients with PE who were treated after hospitalization  $\leq 3$  days (20, 22).

Inclusion and exclusion criteria are shown in Table 1. Methods of diagnosis and definitions of major bleeding are shown in Table 2. All investigations included only low-risk patients which was specifically stated (19, 20) or described as small or medium-sized (21) or submassive PE (25), or with exclusions indicative of high risk such as hemodynamic instability (22, 25), high risk of bleeding or active bleeding (19–25), poor oxygenation (20, 22, 24, 25), renal insufficiency (19, 23, 24) or low platelets (19, 24). Additional frequent exclusions were for concomitant illness requiring hospitalization (20, 22–24), intense pain (21–25), requirement for parenteral drugs (20, 22–25), and likelihood of poor compliance (20, 22, 23, 25).

Treatment was usually with LMWH followed by oral anti-coagulants, although some received intravenous unfractionated heparin (UFH) during a short admission (22).

Outcome within one week after outpatient treatment was described in one investigation (21). A new perfusion defect was described in nine of 100 patients (9%) (21). Hospitalization was required in five patients (21).

**Table 1: Study characteristics, inclusion and exclusion criteria, and treatment of patients in included studies.**

First author, year (Reference)	No. of patients	Study characteristics	Inclusion criteria	Exclusion criteria	Treatment
Beer 2003 (19)	43	Outpatients	Low risk (Geneva criteria*)	Contraindication to anticoagulation Contraindication to LMWH or UFH History of drug addiction, Non-compliant Body weight >110 kg Psychiatric conditions Creatinine clearance < 30 ml/min Platelets <120 ×10 <sup>3</sup> /μl Fibrinolytic therapy Treatment with oral anticoagulants < 24 hours prior to study.	Nadroparin 171 U/kg 5–10 days Oral anticoagulation 6–12 months
Davies 2007 (20)	156	Early discharge (Median hospital stay 1 day (0–3 days))	Low risk Diagnosis ≤72 hours Age >18years	Hospitalized for concomitant illness Monitoring required O <sub>2</sub> therapy Intravenous drugs Previous or recurrent PE on anticoagulants Co-existing major DVT Bleeding disorder or active bleeding, Pregnancy Poor compliance (i.e elderly, infirm, immobile)	Tinzaparin 7days, warfarin
Olsson 2006 (21)	100	Outpatients (hotel) median stay 5 days.	Small or medium sized PE on VQ scan	Extensive PE (> 40% lung perfusion), Ancillary lung disease (> 20% of lung parenchyma), Intense pain Post surgery Active bleeding Logistic and technical reasons	Tinzaparin 175 U/kg 5–6 days, warfarin
Kovacs 2000 (22)	108	81 outpatient 27 early discharge (1– to 3 days)	All except those with exclusion criteria	Hospitalized for other medical condition Active or high-risk bleeding Haemodynamic instability Pain requiring parenteral narcotics Required O <sub>2</sub> Age <18 years Poor compliance	Dalteparin 200 U/kg daily >5 days or UFH in hospital, Warfarin
Siragusa 2005 (23)	36	All cancer patients Outpatient	All except those with exclusion criteria	Concomitant illness that required hospitalization Poor compliance, High risk of bleeding or active bleeding Renal insufficiency Acute anemia Pain requiring parenteral narcotics	LMWH and warfarin or LMWH alone
Wells 2005 (24)	90	Outpatient	All except those with exclusion criteria	Active bleeding or high risk of bleeding Stroke ≤10 days Gastrointestinal bleeding ≤14 days Platelets < 75×10 <sup>3</sup> /μl Asymptomatic DVT Age<18 years No fixed address Previous heparin induced thrombocytopenia Renal failure (creatinine >2.3 mg/dl) Treatment with UH or LMWH >36hours Hypotension Required O <sub>2</sub> , Pain requiring intravenous narcotics Hospitalization for comorbidity	LMWH tinzaparin (175 U/kg daily) or dalteparin (200 U/kg daily) >5days warfarin
Ong ** 2005 (25)	60	Outpatient	Submassive PE	Haemodynamic instability Pain requiring narcotics O <sub>2</sub> saturation < 90% Active bleeding Intercurrent illness requiring admission Poor compliance Lack of telephone, transport or home support	LMWH Oral anticoagulants

\*Wicki Geneva criteria = Wicki et al. (31). \*\*Retrospective. All others were prospective. VQ = ventilation perfusion lung scan; LMWH = low-molecular-weight heparin; UH unfractionated heparin; PE = pulmonary embolism; DVT = deep venous thrombosis; O<sub>2</sub> = oxygen.

**Table 2: Methods of diagnosis and definition of major bleeding in included studies.**

First author, year (Reference)	Diagnosis of pulmonary embolism	Diagnosis of recurrent PE or DVT	Major bleed
Beer 2003 (19)	"Objectively confirmed"	"Objectively confirmed"	Not defined
Davies 2007 (20)	High prob V/Q, CT angio, Clinical PE & DVT by imaging	"Objective confirmation"	Overt & fall in Hgb >2 g/dl, transfusion >2 units, retroperitoneal or intracranial bleed, bleeding into major prosthetic joint
Olsson 2006 (21)	V/Q >1 segmental or subsegmental mismatch	V/Q	Not defined
Kovacs 2000 (22)	High prob V/Q, CT angio, Clinical PE & non-diagnostic V/Q & pos ultrasound or venogram	DVT: ultrasound or venography or impedance plethysmography. PE: High prob V/Q or pulm angio	Overt & fall in Hgb >2 g/dl, transfusion >2 units, retroperitoneal or intracranial bleed
Siragusa 2005 (23)	CT angio, high prob V/Q, high clin prob & non-diagnostic V/Q, clinical PE & pos ultrasound	DVT: New or extended thrombus on ultrasound or venography. PE: New defect on V/Q or CT angio or clinical PE with positive ultrasound	Overt & fall in Hgb >2 g/dl, transfusion >2 units
Wells 2005 (24)	High prob. V/Q & high or mod. clinical probability, CT angio, pulm angio	DVT: New or extended thrombus on ultrasound PE: New defect on V/Q or pulm angio	Overt & fall in Hgb >2 g/dl, transfusion >2 units, retroperitoneal or intracranial bleed, or if it warranted permanent discontinuation of anticoagulants
Ong ** 2005 (25)	High prob V/Q, CT angio, clinical PE & non-diagnostic V/Q & documented DVT	DVT: new defect on ultrasound PE: new defect on V/Q, or CT angio	Overt & fall in Hgb >2 g/dl, any transfusion, intraabdominal or intracranial or intraocular or required hospitalization or resulted in death

V/Q = ventilation perfusion lung scan, Prob = probability, Angio= angiogram, CT= computed tomography, PE = pulmonary embolism; DVT = deep venous thrombosis, Pos= possible, Clin= clinical, Mod= moderate, Pulm= pulmonary, Hgb= haemoglobin.

**Table 3: Outcomes in 3-46 months of patients with acute pulmonary embolism treated entirely as outpatients.**

First author, year (Ref.)	Follow-up (months)	Recurrent PE (%)	95% CI	Major bleed (%)	95% CI	Death from PE (%)	95% CI	Death from bleeding (%)	95% CI
Beer 2003 (19)	3	1/43 (2.3)	0.6–12.0	0/43 (0)	0–8	0/43 (0)	0–8.0	0/43 (0)	0–8.0
Olsson 2006(21)	4-46	0/100 (0)	0.2–5.4	1/ 100 (1.0)	0.2–5.4	0/100 (0)	0.2–5.4	1/100 (1.0)	0.2–5.4
Kovacs 2000(22)	3	5/81 (6.2)	2.7–13.7	1/81 (1.2)	0.3–6.6	0/81 (0)	0–4.3	0/81 (0)	0–4.3
Siragusa 2005 (23)	6	2/36 (5.6)*	1.7–18.2	1/36 (2.8)	0.6–14.1	?		?	
Wells 2005 (24)	3	1/90 (1.1)	0.3–6.0	0/90 (0)	0–3.9	0/90 (0)	0–3.9	0/90 (0)	0–3.9
Ong 2005 (25)	3	?		?		0/60 (0)	0–5.8	0/60 (0)	0–5.8

\*Patients had venous thromboembolism. CI = confidence interval.

Outcome after 3-46 months in patients treated entirely as outpatients showed recurrent PE in 0% to 6.2% of patients (19, 21–24) (Table 3). Major bleeding, in five investigations that reported bleeding, occurred in 0–2.8% of patients (19, 21–24). Definite death from PE did not occur (19, 21, 22, 24, 25). One patient died from an intracerebral bleed (21).

Outcome in three months in patients treated after discharge  $\leq 3$  days showed no instances of recurrent PE (20, 22) (Table 4). Major bleeding occurred in 0.6–3.7% of patients (20, 22). There were no deaths from PE (20, 22). One death from bleeding occurred in a patient who also had septicemia and neutropenia (20).

## Discussion

All investigations included only patients in whom the risks of death from PE were low and the risks of bleeding from treatment were also low based on various methods of assessment and exclusion criteria as listed in Table 1. Some patients were treated entirely as outpatients and some were treated in-hospital for  $\leq 3$  days. Treatment regimens also varied. In this sense, there was large heterogeneity in the investigations. All of the data are from observational studies. Most were prospective (19–24), but one retrospective investigation was included (25). None of the investigations randomized patients for outpatient versus inpatient treatment. Within this context, outpatient treatment of acute PE was reported in 410 patients (19, 21–25)

**Table 4: Outcome in three months after treatment of pulmonary embolism following early hospital discharge.**

First author, year (Ref.)	Follow-up (months)	Recurrent PE (%)	95% CI	Major bleed (%)	95% CI	Death from PE (%)	95% CI	Death from bleeding (%)	95% CI
Davies 2007 (20)	3	0/156 (0)	0–2.3	1/156 (0.6)	0.2–3.5	0/156 (0)	0–2.3	1/156 (0.6)	0.2–3.5
Kovacs 2000 (22)	3	0/27 (0)	0–12.3	1/27 (3.7)	0.9–18.3	0/27 (0)	0–12.3	0/27 (0)	0–12.3

CI = confidence interval.

and home treatment after  $\leq 3$  days hospitalization was reported in 183 patients (20, 22). Death from PE did not occur among 557 patients in whom the cause of death was reported (19–22, 24, 25). There were two deaths from bleeding among these 557 patients (19–22, 24, 25). Recurrent PE was observed only among those treated as outpatients (0–6.2%)(19, 21–24). Recurrent PE was not observed among those treated after early discharge (20,22). Major bleeding occurred in 0–3.7% (19–24). There is a clear need for a randomized clinical trial comparing results of in-patient with outpatient management of low-risk patients with acute PE.

The average length of hospital stay for patients with acute PE throughout the United States decreased from 14 days in 1979 to 8.5 days in 1999 (26). The median length of hospital stay for PE in 2002 in Pennsylvania was six days (27). We excluded investigations in which the average length of stay was four days (range 0–17 days) (28) and we excluded the early discharge arm of the investigation by Ong et al. (25) in which the average length of stay was 5.7 days (range 2–19 days).

The proportion of hospitalized patients with acute PE who were assessed as low risk has been reported as 34% (29), 47% (30) and 67% (31). Assuming a cost difference of \$4,500 between inpatient and outpatient treatment, and an annual PE incidence of 126,000 cases, up to \$284 million per year could be saved in the United States if half of the patients were treated as outpatients (30).

Based on the available data, it appears that outpatient treatment of acute PE is safe providing the patient is at low risk of an adverse outcome including death, a recurrent thromboembolic event, or major bleeding. Risk stratification facilitates identification of high-risk patients who should not be treated as outpatients and may be helpful in guiding initial and long-term management (32). Wicki et al. identified six independent predictors of death, recurrent thromboembolic events, or major bleeding in three months (31) (Table 5). Aujesky et al. developed a prediction rule to identify low risk patients with PE based on 10 factors (29) (Table 5). Aujesky et al. also developed a Pulmonary Embolism Severity Index (PESI) for low risk of death at three months that included 11 factors (30) (Table 5). Additional tools for risk stratification include electrocardiography, echocardiography, cardiac biomarkers, and chest computed tomography (32). Reasons for requiring inpatient treatment, not included in the prognostic models but used by some, were large PE based on the size of the perfusion scan defect, high risk of bleeding or active bleeding, low platelet count, concomitant illness, intense pain, requirement for parenteral drugs, and likelihood of poor compliance.

In conclusion, outpatient therapy of acute PE is probably safe in low-risk, carefully selected compliant patients who have access to outpatient care if necessary. Appropriate selection of patients for outpatient treatment would be cost effective.

Geneva Score (31) Predictor	Point Score*	Clinical Prediction Rule (29) Predictor**	Pulmonary Embolism Severity Index (30)	Point Score***
Cancer	2	Age $\geq 70$ years	Age (years)	1 / year
Heart failure	1	History of cancer	Male	10
Previous DVT	1	Heart failure	Cancer (History or active)	30
Syst BP <100mmHg	2	Chronic lung disease	Heart failure	10
P <sub>a</sub> O <sub>2</sub> <8 kPa	1	Chronic renal disease	Chronic lung disease	10
DVT Ultrasound	1	Cerebral vascular disease	Pulse $\geq 110$ /min	20
		Pulse $\geq 110$ /min	Syst BP <100 mmHg	30
		Syst BP <100 mmHg Altered mental status	Resp rate $\geq 30$ /min (with or without O <sub>2</sub> )	20
		Arterial O <sub>2</sub> sat <90%	Temperature <36°C	20
			Altered mental status (disorientation, stupor, lethargy, coma)	60
			Arterial O <sub>2</sub> sat <90%	20

\* Low risk = score  $\leq 2$  (31). \*\*Low risk = none of these factors (29). \*\*\*Low risk = score  $\leq 85$  (30). Syst = systolic, sat = saturation, PE = pulmonary embolism, DVT = deep venous thrombosis, resp = respiratory, O<sub>2</sub> = oxygen, yr = year.

**Table 5: Predictors of low risk according to pulmonary embolism prognostic models.**

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