Practice Guideline

2025 ESVM Guidelines on interventional treatment of venous thromboembolism

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Summary: The number of endovascular interventional procedures for catheter-based therapy (CBT) of acute venous thromboembolism (VTE), comprising deep vein thrombosis (DVT) and pulmonary embolism (PE), has been increasing over the past years. The development of more efficient thrombectomy systems for CBT of VTE has potentially enhanced the efficacy of interventional treatment of VTE. Nevertheless, indications for CBT of VTE, i.e. catheter-directed thrombolysis (CDT) or catheter-based mechanical thrombus removal, need to be established based on existing data and expert consensus. Vascular experts should be involved in the decision-making process on CBTs in patients with acute VTE, and thrombus removal procedures should be performed in centers with experience in interventional treatment of VTE. This guideline document of the European Society of Vascular Medicine (ESVM) provides recommendations on indications and management of CBT in acute VTE and is endorsed by the European national societies of Vascular Medicine.

Keywords: Thrombus removal, catheter-based treatment, catheter directed thrombolysis, venous thromboembolism, deep vein thrombosis, pulmonary embolism, guidelines

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Abbreviations

CBT	Catheter-based therapy
CDT	Catheter-directed thrombolysis
CPES	Composite Pulmonary Embolism Shock Score
CT	Conservative therapy
CTEPH	Chronic thrombo-embolic pulmonary hypertension
CTPA	Computed tomography pulmonary angiography
DVT	Deep vein thrombosis

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ICU	Intensive care unit
IVC	Inferior vena cava
LV	Left ventricular
NEWS	National Early Warning Score
NYHA	New York Heart Association
PE	Pulmonary embolism
PERT	Pulmonary embolism response team
PTS	Postthrombotic syndrome
RCT	Randomized controlled trial
rt-PA	Recombinant tissue plasminogen activator
RV	Right ventricular
TAPSE	Tricuspid annular plane systolic excursion
UFH	Unfractionated heparin
USAT	Ultrasound assisted thrombolysis
VTE	Venous thromboembolism

1. The process of compilation of these guidelines

1.1 Timeline of work

- Approval of the Guideline committee of the European Society of Vascular Medicine (ESVM) 1.9.2023
- Finalization of first draft 31.7.2024
- Finalization of first round of internal review 31.7.2024
- Finalization of first round of patients' and nurse's review 30.8.2024
- Finalization of second round of internal and review 17.3.2025
- External review by European national societies of vascular medicine (reviewer assignments through presidents of national societies of vascular medicine) 24.3.2025
- Completion of second round of patients' and nurse's review, and of external review process 13.5.2025

1.2 Recommendations and levels of evidence

For the grading of recommendations and of the supporting evidence of this guideline document we refer to the recommendations as provided by the European Society of Cardiology (ESC) [1]. The strengths of recommendations were classified into Class I, II, or III, and the levels of evidence were graded A, B, or C.

Classes of recommendation used in these guidelines

Class of recommendation	Definition	Proposal
Class I	Evidence and/or general agreement, that a given treatment or procedure is beneficial, useful, effective	Recommended/ indicated
Class II	Conflicting evidence and/or divergence of opinion about usefulness/efficacy of the treatment or procedure	
	Weight of evidence/ opinion in favour of usefulness/efficacy	Should be considered
	Usefulness/efficacy is less well established by evidence/opinion	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases may be harmful	Not recommended

Levels of evidence

Levels of evidence	
Level of evidence A	Data derived from multiple randomized clinical trials or meta-analysis
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies
Level of evidence C	Consensus of opinion of experts and/or small studies, retrospective studies, registries

1.3 Review process and involvement of stakeholders

This ESVM guideline document underwent a review process involving European national Vascular Medicine societies. Each European national society of Vascular Medicine was invited to nominate reviewers.

Regarding this review process, the following medical disciplines were represented among the reviewers, which were nominated by the European national society of Vascular Medicine: Vascular Medicine/Angiology, Cardiology, Vascular Surgery, Interventional Radiology, and Internal Medicine.

In addition, this ESVM guideline document was sent for review to 2 laypersons (patients) with a personal history and experience with interventional treatment of venous thromboembolism (VTE), and to a vascular nurse. Standardized review forms were used to collect comments of the respective stakeholders through the review process and the comments were implemented whenever possible.

2. Background and purpose

VTE most commonly comprises deep vein thrombosis (DVT) and/or pulmonary embolism (PE) and has an estimated global incidence of approximately 1 per 1,000 adults annually [2]. The incidence rates of VTE increase by age

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and are higher in men than women with a sex ratio of 1.2:1 [3, 4, 5].

In patients with first-time DVT or PE an estimated 30-day case fatality of 4.6% or 9.7% (DVT/PE) was reported, while in recent years a decline in mortality rates has been observed [5, 6, 7]. According to a recent European analysis, PE accounted for 6.5 deaths per 100,000 population in 2015, a decline compared to 12.8 deaths per 100,000 population in 2000 [8]. Among PE-related deaths, 34% of patients with acute PE died suddenly or within a few hours of the event, before therapy could be initiated or take effect [9]. Regarding the distribution of different risk categories among patients with PE, recent observational data found a prevalence of 3.4% of patients with PE categorized as high-risk, 63.6% as intermediate risk and 33% as low-risk PE (PE risk categorization according to 2019 Guidelines for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology, developed in collaboration with the European Respiratory Society) [10, 11]. Beyond the mortality risk and despite timely initiation of anticoagulation, VTE may be regarded as chronic condition (especially in cases without identifiable risk-factor), as approximately 30% of patients experience recurrence within 10 years [2]. Importantly, VTE can be severely disabling, the most important long-term sequelae are the post-thrombotic syndrome (PTS) in DVT and chronic thromboembolic pulmonary hypertension (CTEPH) or post pulmonary embolism syndrome (PPS) in PE patients [2, 3].

The development of interventional thrombus removal strategies has expanded the treatment options for patients with acute DVT and PE, however, therapeutic aims of thrombus removal differ between DVT and PE. In acute DVT catheter-based therapy (CBT), i.e. catheter-directed thrombolysis (CDT) or catheter-based mechanical thrombectomy, primarily targets the reduction of pain and swelling and the prevention of the occurrence of the PTS as long-term complication. In PE early thrombus removal primarily aims at a prompt, short-term reduction of pulmonary artery pressure, right ventricular strain and the occurrence of shock and cardiac arrest.

In recent years, the numbers of interventional procedures performed in patients with acute DVT, and acute PE have substantially increased. This can be attributed to an increasing awareness of the diseases, but also to the development of more efficient and safer thrombectomy devices for treatment of both entities, DVT and PE.

Nevertheless, not all patients diagnosed with acute DVT or PE benefit from interventional treatment. A multidisciplinary team involving vascular medicine specialists should be responsible for patient selection, periinterventional decision making, and structured clinical pathways to maximize the potentially positive effects of this therapeutic approach and to minimize procedure-related risks (Figure 1).

The purpose of this practice guideline document of the European Society of Vascular Medicine is to provide recommendations for the decision process on interventional treatment of acute DVT and PE and the related periinterventional patient-management.

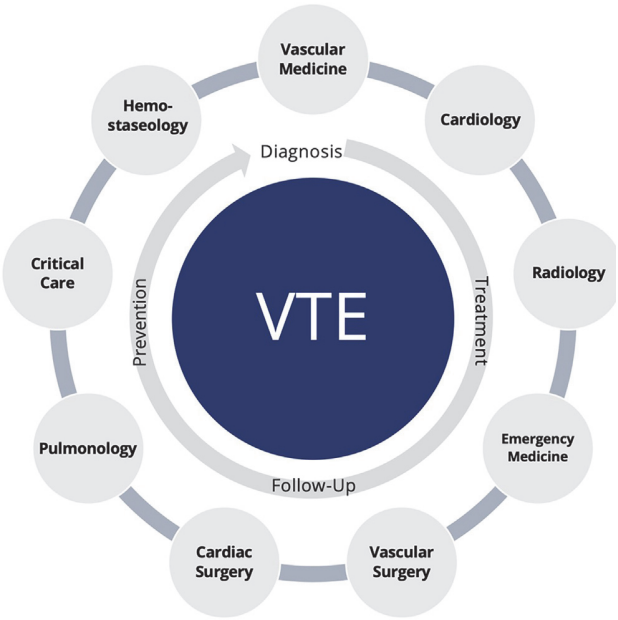

Figure 1. Multidisciplinary management of acute venous thromboembolism (VTE): acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE).

3. Interventional therapy of acute deep vein thrombosis (DVT)

3.1 Therapeutic aims

CBT of acute DVT yields at thrombus removal and restoration of venous drainage of the affected limb. The main short-term aim of CBT of acute DVT is to rapidly reduce DVT-symptoms, such as pain and leg swelling, by reducing venous pressure, venous distension, and local inflammation. The major long-term aim is the prevention of the development of a clinically-relevant PTS. This approach is based on the "open-vein hypothesis", which proposes a reduction of the risk of venous lesion chronification by early thrombus removal. Chronic thrombus potentially causes venous wall and valve damage, and impairs venous drainage of the legs, which subsequently leads to venous hypertension. Venous hypertension is the pathophysiological correlate underlying the PTS, which comprises a broad spectrum of different clinical signs and symptoms. Depending on its severity, the PTS may affect up to 50% of patients after acute DVT [12]. The clinical severity of the PTS can be assessed by using clinical scores, such as the Villalta score or the revised venous clinical severity score [13]. However, it needs to be acknowledged that both scores do not capture the whole spectrum of symptoms of the PTS: e.g. venous claudication, which is commonly observed in patients with chronic iliofemoral venous obstructions, potentially affects patients' walking capacity and quality of life.

Referring to the location of DVT, iliofemoral location of thrombosis might potentially be associated with a higher impact on venous pressure. Moreover, the risk of the development of a clinically relevant PTS is higher in patients

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Table I. Published randomized controlled trials (RCT) comparing catheter-based therapy (CBT) on top of anticoagulation versus conservative therapy (anticoagulation alone) in patients with acute deep vein thrombosis (DVT) with the primary aim to prevent the development of the postthrombotic syndrome (PTS). Table shows primary endpoint data not including post-hoc and additional long-term outcome analyses

Study	Type	Patients randomized	Indication	Experimental arm	Comparator arm	Primary endpoint(s)	Follow-up duration	Main hypothesis validated
CaVenT [14]	Multicenter RCT (20 sites)	209	• DVT in upper half of the thigh, common iliac vein, or combined iliofemoral segment • Onset within past 21 days	Catheter-directed thrombolysis on top of anticoagulation	Anticoagulation	• Iliofemoral patency at 6 months • Frequency of PTS at 24 months	5 years	**Yes**: Patency at 6 months (CBT vs. anticoagulation alone: 65.9% (95% CI 55.5–75%) vs. 47.4% (95% CI 37.6–57.3%), p=0.012) PTS at 24 months (CBT vs. anticoagulation alone: 41.1% (95% CI 31.5–51.4%) vs. 55.6% (95% CI 45.7–65%), p=0.047)
TORPEDO [18]	Singlecenter RCT	183	• DVT of popliteal vein or more proximal veins	Pharmacomechanical thrombolysis on top of anticoagulation	Anticoagulation	• Frequency of PTS at 6 months • Frequency of recurrent VTE at 6 months	6 months	**Yes**: PTS at 6 months (CBT vs. anticoagulation alone: 3.4% vs. 27.2%, p<0.001) Recurrent VTE at 6 months (CBT vs. anticoagulation alone: 2.3% vs. 14.8%, p=0.003)
ATTRACT [20]	Multicenter RCT (56 sites)	692	• DVT in femoral vein, common femoral, or iliac vein • Onset within past 14 days	Pharmacomechanical thrombolysis on top of anticoagulation	Anticoagulation	• Frequency of PTS between 6 and 24 months	24 months	**No**: PTS between 6 and 24 months, CBT vs. anticoagulation alone: 47% vs. 48% (risk ratio 0.96; 95% CI 0.82–1.11, p=0.56)
CAVA [24]	Multicenter RCT (15 sites)	120	• Iliofemoral DVT • Onset within past 14 days	Pharmacomechanical thrombolysis on top of anticoagulation	Anticoagulation	• Frequency of PTS at 12 months	39 months	**No**: PTS at 12 months (CBT vs. anticoagulation alone: 12.9% vs. 10.3% (OR 1.28; 95% CI 0.42-3.96)

Abbreviations. CBT – catheter-based therapy, CDT – catheter-directed thrombolysis, CT – computed tomography, CTA – computed tomography angiography, DVT – deep vein thrombosis, PTS – postthrombotic syndrome, RCT – randomized controlled trial, RV/LV – right ventricle/left ventricle, tPA – tissue plasminogen activator, USAT – ultrasound assisted thrombolysis.

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with more proximal location of DVT than in patients with further distal manifestations of DVT [12].

3.2 Available data

So far, four randomized controlled trials (RCT) compared CBT of acute DVT with CT (Table I). The *Catheter-directed Venous Thrombolysis* (CaVenT) study was a Norwegian multicentre RCT, in which patients with acute DVT above mid-thigh level were included across 20 participating hospitals [14]. Patients with phlegmasia cerulea dolens or isolated inferior vena cava (IVC) thrombosis were not included in this trial. Included patients were randomly assigned to either CBT with CDT in addition to anticoagulation (CBT group: n=90) or to conservative therapy (CT) by anticoagulation with vitamin K antagonists (CT group: n=99) [14]. In addition, all patients were advised to use knee-high elastic compression stockings (class II) for 24 months.

CDT was performed by inserting an infusion catheter with multiple side-holes into the thrombosed segment, mostly via an antegrade popliteal access. Recombinant tissue plasminogen activator (rt-PA) was administered with the side-hole catheter with an infusion rate of 0.01 mg/kg per hour for a maximum 96 hours and a maximum dose of 20 mg/24h [14].

Regarding the primary study endpoint, CBT was associated with a reduction of PTS, as assessed by determining the Villalta scale, after 2 years, which further improved after 5 years (CBT vs. CT: 43%, 95% CI 33%–53% vs. 71%, 95% CI 61%–79%, p<0.0001) [14], 15]. At 6 months, iliofemoral venous patency was higher in the CBT group that in the CT group (CBT vs. CT: 65.9%, 95% CI 55.5%–75% vs. 47.4%, 95% CI 37.6%–57.3%, p=0.012) [14]. In the CBT group, 20 bleeding complications (3 major bleedings, 5 clinically relevant bleedings) were observed [14]. CBT was not associated with the occurrence of PE, cerebral hemorrhage or death. DVT recurrence did not differ between groups. Quality of life did not differ between both treatment arms [16]. In an economic evaluation CBT appeared to be a cost-effective alternative to CT [17]. The main limitation of this study is the use of CDT only which nowadays is mostly replaced by CBT with catheter-based mechanical thrombus removal. CDT is potentially related to an increased risk of bleeding due to the prolonged application of thrombolytic agents [14].

In the *Thrombus Obliteration by Rapid Percutaneous Endovenous Intervention in Deep Venous Occlusion* (TORPEDO) trial, patients with acute DVT of the popliteal or more proximal veins were randomly assigned to CBT with mainly pharmacomechanical thrombolysis (combination of mechanical thrombectomy with pharmacological CDT) on top of anticoagulation or to anticoagulation only [18]. The two primary outcome measures, the occurrence of the PTS and recurrence of VTE after 6 months, were less frequently observed in the interventional treatment arm than in the conservative treatment arm and these results appeared to persist over a longer period of follow up (PTS at 6 months CT vs. CBT 27.2% vs. 3.4%, p<0.001; recurrence of VTE at 6 months CT vs. CBT 14.8% vs. 2.3%, p=0.003) [18, 19]. The main limitation of this study is the missing implementation of an established evaluation method of the PTS, which was the primary endpoint. Instead, the authors relied on their own definition of the presence or absence of the PTS.

The largest RCT, the *Acute Venous Thrombosis: Thrombus Removal with Adjunctive Catheter-Directed Thrombolysis* (ATTRACT) trial, randomly assigned patients with acute DVT to either CBT by pharmacomechanical thrombolysis or – in case of involvement of the popliteal vein or IVC – a combination of CDT and pharmacomechanical thrombolysis versus to CT (i.e. anticoagulation alone) [20]. In summary, this large RCT failed to demonstrate a significant benefit of CBT of acute DVT: the prevalence of the PTS, defined as combination of a Villalta score of $\geq$5 points or an ulcer of the index limb after 6 to 24 months of follow up, did not differ between CBT and CT (risk ratio 0.96, 95% CI 0.82-1.11). However, interventional treatment led to a reduction in leg symptoms, PTS severity scores, and the proportion of patients with moderate-to-severe PTS over a period of 24 months [21].

Apart from RCTs, which compared CBT with CT, the *BERN Ultrasound-Assisted Thrombolysis for Ilio-Femoral Deep Vein Thrombosis Versus Standard Catheter Directed Thrombolysis* (BERNUTIFUL) RCT compared the application of ultrasound assisted catheter directed thrombolysis (USAT) as pharmacomechanical approach with conventional CDT in patients with acute iliofemoral DVT. BERNUTIFUL did not demonstrate superiority of USAT in CBT of acute iliofemoral DVT in comparison with CBT by conventional CDT [22].

The efficacy and safety of interventional therapy of acute DVT by USAT in comparison with CT was assessed in the fourth RCT, which compared CBT with CT, the *Ultrasound-Accelerated Catheter-Directed Thrombolysis Versus Anticoagulation for the Prevention of Post-Thrombotic Syndrome* (CAVA) trial [23]. The CAVA trial focused on patients with iliofemoral location of DVT. Patients were randomly assigned to CBT by means of pharmacomechnical thrombolysis with ultrasound-assisted thrombolysis (USAT), or to CT. USAT combines catheter-directed infusion of a thrombolytic agent with the local delivery of high-frequency ultrasound aiming to disaggregate and separate fibrin fibres, and to further enhance the penetration of the thrombolytic agent into the thrombus.

In the CAVA trial, the stent rate was higher than in former studies, which appeared to better reflect daily practice in CBT of acute DVT patients. Nevertheless, no clinical benefit of USAT was demonstrated in patients with iliofemoral DVT in this study. When following patients for >3 years, the between-group difference in the prevalence of the PTS increased but did not reach statistical significance [24].

The above listed trials have to viewed in the light of their strengths and weaknesses: in the ATTRACT trial, the relatively large number of patients were a mix of patients with iliofemoral DVT and patients with more distal location of DVT. This warrants mention, since the risk of the

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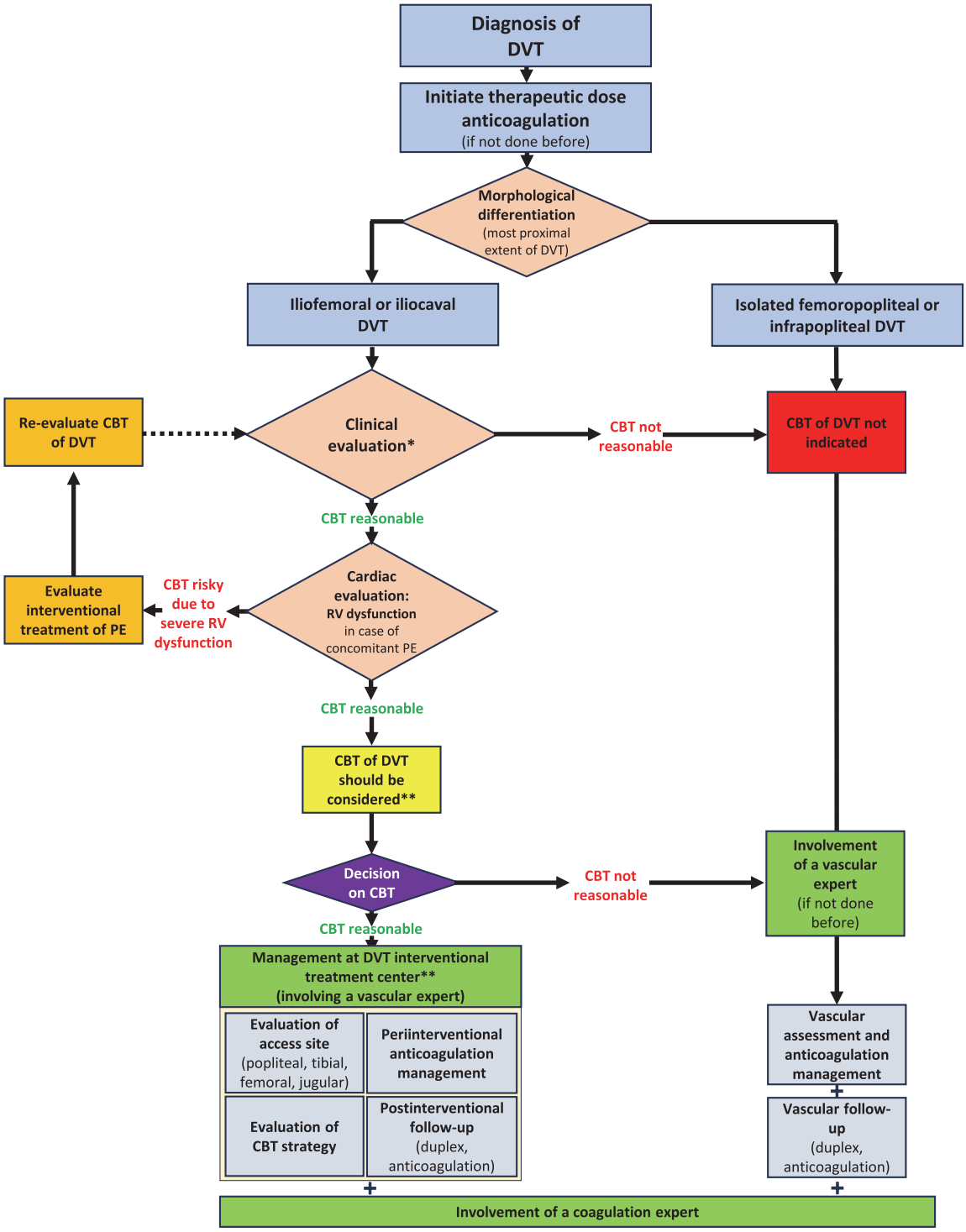

Figure 2. Flow chart showing the clinical algorithm and decision process as proposed for patients with acute deep vein thrombosis (DVT); CBT – Catheter-based therapy; PE – pulmonary embolism; RV - right ventricular. *Severity of symptoms, patients' age, comorbidities, and life expectancy; **Interventionalists with experience in the endovascular treatment of acute DVT and availability of thrombectomy devices, IVUS and dedicated venous stents.

development of the PTS, which was the primary endpoint in this study, depends on the location of DVT with a lower risk in patients with femoropopliteal manifestation of DVT than in patients with iliofemoral location of DVT [12].

Moreover, intravascular ultrasound (IVUS) was not routinely applied for the detection of underlying mechanical obstructions or residual thrombus in ATTRACT. Previous statements suggest that the implementation of IVUS in venous recanalization procedures potentially affects endovascular treatment strategies [25, [26, 27]. In contrast to the CaVenT study, which suggested cost effectiveness of CBT of DVT, the ATTRACT trial questioned the cost-effectiveness of CBT [28]. Focusing on quality of life, however, the ATTRACT trial demonstrated greater improvements of

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disease-specific quality of life in the CBT group than in the CT group [29].

Finally, the CAVA trial, was statistically underpowered: only 58 patients (75%) of the interventional treatment arm, and 57 patients (76%) of the standard treatment arm could be included in the per-protocol analysis (initially planned sample size 180 patients) [23].

Two metaanalyses of these RCT data demonstrated that CBT potentially reduced the risk of moderate to severe forms of the PTS in patients with acute proximal DVT [30, 31].

Recent propensity-score matched post-hoc analyses comparing a single-arm registry with RCT-data suggest a clear benefit of a pure mechanical CBT of acute DVT in comparison with catheter-based thrombolysis [32, 33].

3.3 Clinical perspective

In recent years new catheter-based mechanical thrombectomy systems have been developed, which have potentially improved the efficacy and safety of CBT in acute DVT, which may be confirmed by ongoing clinical trials. In any case, it warrants mention that the success of CBT in acute DVT substantially depends on patient selection, timing of the procedure, decision making on stent placement, and periinterventional anticoagulation management (therapeutic dose low-molecular weight heparin vs. direct oral anticoagulants vs. vitamin K antagonists; Figure 2). Regarding the timing of thrombus removal, a time window of up to 2 weeks after onset of symptoms has most commonly been applied.

Apart from the thrombus removal strategy, the application of IVUS for the assessment of residual thrombus and underlying mechanical obstructions, as well as the use of dedicated venous stents (if stent placement is needed) are recommended [25, [26, 27, 34]. Especially young patients with severe symptoms due to an iliocaval or iliofemoral location of acute DVT are likely to have a benefit from CBT [35]. CBT of acute DVT should therefore be conducted in centers with expertise in interventional management of VTE. It warrants mention, that, although endovascular CBT has largely replaced open surgical thrombectomy in acute proximal DVT, a multidisciplinary management is recommended in patients qualifying for thrombus removal.

Vascular and coagulation experts with expertise in endovascular thrombus removal strategies should be involved in the decision making, the periinterventional management and the postinterventional duplexsonographic and clinical follow-up of these patients (Figure 2). Continuous periinterventional full-dose anticoagulation is essential in patients with acute DVT undergoing CBT [36, 37]. Up to now, there are no data supporting different anticoagulation regimens between patients with acute DVT who are managed by CBT vs. patients with acute DVT who are managed conservatively [36]. Moreover, there are no data supporting the routine use of antiplatelet agents in patients who underwent stent placement for acute DVT. Even in patients who underwent stent placement for chronic iliac vein obstructions no benefit of antiplatelets was shown [38].

3.4 Ongoing studies

Newer endovascular thrombectomy devices allow thrombus removal by a pure mechanical approach. The use of modern catheter-based mechanical thrombectomy systems allow the CBT of acute DVT without need for thrombolytic agents, which has the potential to further reduce the risk of bleeding associated with interventional thrombectomy procedures. Up to now, data from RCTs are missing. The results of ongoing studies will provide data on the efficacy and safety of mechanical CBT in acute DVT (Table III).

3.5 Gaps in evidence

- Objectifiable hemodynamic parameters that may be used to define the presence or absence of the PTS
- Need of stent placement depending on interventional approach (mechanical versus pharmacomechanical techniques)
- Impact of long-segment stent placement on duration of anticoagulation
- Impact of iliocaval/iliofemoral thrombus removal on future rates of silent pulmonary embolism
- Benefit of CBT with modern thrombectomy systems on the risk of PTS in patients with infrainguinal DVT

Recommendations for interventional therapy of acute DVT

Recommendation	Class of recommendation	Level of evidence
In patients with severe symptoms due to iliofemoral and/or iliocaval location of acute DVT CBT should be considered [14, 15, 18, 19, 20, 23, 24].	IIa	A
The involvement of a vascular expert in the decision-making process and the periinterventional management of patients undergoing CBT is recommended.	I	C
It is recommended that interventionalists with expertise in endovascular treatment of iliofemoral and/or iliocaval obstructions are involved in CBT of DVT.	I	C
For endovascular treatment of acute DVT the use of catheter-based mechanical thrombectomy should be preferred over CDT or USAT [32, 33].	IIa	B
For endovascular treatment of acute DVT the use of intravascular ultrasound should be considered to assess the presence of residual iliofemoral/iliocaval obstructions after CBT and to guide stent placement [25, 26, 27].	IIa	B

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Table II. Published randomized controlled trials (RCT) comparing catheter-based therapy (CBT) on top of anticoagulation versus conservative therapy (anticoagulation alone) in patients with acute pulmonary embolism (PE). Table shows primary endpoint data not including post-hoc and additional long-term outcome analyses

Study	Type	Patients randomized	Indication	Experimental arm	Comparator arm	Primary endpoint(s)	Follow-up duration	Hypothesis validated
ULTIMA [41]	Multicenter RCT (8 sites)	59	• intermediate high-risk PE • Onset within past 14 days • RV/LV ratio ≥ 1	CDT on top of anticoagulation	Anticoagulation	• difference in the RV/LV ratio from baseline to 24 hours-	90 days	**Yes**: mean difference RV/LV ratio from baseline to 24 hours CBT 0.30±0.20 versus anticoagulation 0.03±0.16 (P<0.001)
SUNSET PE [39]	Multicenter RCT (3 sites)	81	• intermediate high-risk PE • Onset within past 14 days • RV/LV ratio ≥ 1	USAT	Standard CDT	• thrombus load reduction measured by CT using a modified Miller scoring system	90 days	**Yes**: mean reduction of thrombus score from baseline to 48 hours: USAT 31±4 to 22±7 vs. standard CDT 33±4 to 23±7 (P =0.76)
OPTALYSE [45]	Multicenter RCT (27 sites)	101	• intermediate risk • Onset within past 14 days • RV/LV ratio 0.9	CDT	Compared 4 tPA regimens Arm 1 (4 mg/site/2 h), arm 2 (4 mg/site/4 h), arm 3 (6 mg/site/6 h), and arm 4 (12 mg/site/6 h).	change in RV/LV ratio measured by CTA from baseline to 48	365 days	**Yes**: Change RV/LV ratio from baseline to 48 hours Arm 1: −0.40 ±0.37 (P<0.0001) Arm 2: −0.35 ±0.27 (P<0.0001) Arm 3: −0.42 ±0.32 (P<0.0001) Arm 4: −0.48±0.51 (P=0.0011)
CANARY [77]	Multicenter RCT (2 sites)	94	• intermediate high-risk PE	Catheter-directed thrombolysis on top of anticoagulation	Anticoagulation	• proportion of patients with RV/LV ratio greater than 0.9 at 3-month follow-up	90 days	**Yes**: patients with an RV/LV ratio >0.9 at 3-month follow-up: CDT 4.3% vs. 12.8% (OR, 0.31; 95% CI, 0.06-1.69; P = .24)

Abbreviations. CBT – catheter-based therapy, CDT – catheter-directed thrombolysis, CT – computed tomography, CTA – computed tomography angiography, PE – pulmonary embolism, RCT – randomized controlled trial, RV/LV – right ventricle/left ventricle, tPA – tissue plasminogen activator, USAT – ultrasound assisted thrombolysis.

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Recommendation	Class of recommendation	Level of evidence
If stent placement is required to reduce residual iliofemoral/iliocaval obstructions after CBT of DVT, the use of dedicated venous stents is recommended.	I	C
In patients undergoing CBT with or without stent placement for symptomatic acute iliofemoral and/or iliocaval DVT full dose anticoagulation is recommended [14, 15, 18, 19, 20, 23, 24].	I	B
After CBT of acute DVT with or without stent placement a regular follow-up including clinical and duplexsonographic assessment, as well as anticoagulation management is recommended.	I	C

4. Interventional therapy of pulmonary embolism (PE)

4.1 Therapeutic aims

The aim of CBT of PE is to fragment, dissolve or remove clots from the pulmonary arteries and thereby improve hemodynamics (increase in systemic pressure, decrease in pulmonary pressure, reduction in heart rate, reduction in right ventricular afterload and improvement in gas exchange) with a lower risk of bleeding compared to systemic thrombolysis. Over the last decade, the scientific debate on these therapeutic approaches has substantially intensified and a growing body of knowledge and evidence has been accumulated through the publication of mostly single-arm studies, registries, small randomized trials and case series [39, 40, 41, 42, 43, 44, 45, 46, 47].

Overall, success rates are close to 90% and bleeding complications are low; especially with lytic-free CBT or low dose local thrombolysis 45, 46. Recent data from a retrospective analysis and a meta-analysis show that CBT is superior to anticoagulation alone in patients with intermediate-high risk or high-risk PE in terms of mortality and readmission for VTE [48, 49]. Moreover, data from the FLASH registry and an interim analysis of the STRIKE-PE study could show immediate reduction of the mean pulmonary artery pressure [46, 50].

According to recent recommendations of the European Society of Cardiology, the use of CBT should be restricted to high-risk patients with contraindications to systemic thrombolysis or failure of systemic thrombolysis, or to patients with an intermediate high-risk PE presenting with hemodynamic deterioration [51]. Based on newer data, recent consensus documents advocate a more liberal approach considering certain red flags associated with clinical deterioration [52, 53].

Table III. Ongoing randomized controlled trials (RCT) on thrombus removal strategies in patients with deep vein thrombosis (DVT) as listed on ClinicalTrials.gov

Study title	ClinicalTrials.gov ID	Population	Design	Comparator arm	Experimental arm	Primary endpoint	Status
RCT of ClotTriever system versus anticoagulation in deep vein thrombosis (DEFIANCE)	NCT05701917	Iliofemoral DVT	RCT	Anticoagulation	Anticoagulation + mechanical catheter-based thrombectomy	Composite clinical endpoint constructed as a win ratio, a hierarchy of the following, occurrence of treatment failure or therapy escalation, assessment of PTS severity (assessed with the Villalta scale)	Recruiting

Abbreviations. DVT – deep vein thrombosis, PTS – postthrombotic syndrome, RCT – randomized controlled trial.

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4.2 Available data

Data from large-scale RCTs comparing CBT with CT of PE are limited (Table II). Especially RCTs addressing clinical endpoints are scarce and several studies refer to surrogate parameters, such as change in the right ventricular to left ventricular (RV/LV) ratio, reduction of thrombus burden on computed tomography pulmonary angiogram (CTPA), or change in pulmonary pressure, while conclusions on the effect of CBT on mortality are largely missing [39, 41, 42, 43, 45, 46, 47, 54].

The *Ultrasound Accelerated Thrombolysis of Pulmonary Embolism* (ULTIMA) trial was the first RCT comparing the effect of USAT on top of anticoagulation on RV function with anticoagulation alone with UFH in intermediate high-risk patients [41]. Patients included in the study were randomized to anticoagulation as standard of care or to USAT on top of anticoagulation. USAT was conducted by using rt-PA at a maximum dose of 20 ± 1 mg (in patients with bilateral device placement 10 ± 0.5 mg per side). As primary outcome the RV/LV ratio between baseline and 24 hours after initiation was significantly reduced (1.28 ± 0.19 at baseline to 0.99 ± 0.17 at 24 hours, $p<0.001$) [41]. No significant reduction of the RV/LV ratio was observed in the control group (1.20 ± 0.14 at baseline to 1.17 ± 0.20 at 24 hours, $p=0.31$). No serious adverse events, particularly no major bleeding complications, were recorded in relation to the interventional procedure. It needs to be noted, that this study was not sufficiently powered to draw conclusions regarding the prevention of CTEPH with USAT.

While in the ULTIMA trial 10 mg of rt-PA was used per side and the mean therapy time was 15 hours modified protocols with shorter duration and less rt-PA were investigated in the The *Optimum Duration of Acoustic Pulse Thrombolysis Procedure in Acute Pulmonary Embolism* (OPTALYSE) trial showing that even USAT with low dose rt-PA is effective in improving RV function [41, 45]. The OPTALYSE trial aimed to determine the lowest possible rt-PA dose for USAT in patients with acute intermediate risk PE. In this trial, a shorter duration and a lower dose of rt-PA delivery was safe and effective in reducing clot burden and the RV/LV ratio.

In analogy to the BERNUTIFUL trial, the efficacy and safety of USAT *vs.* conventional CDT of submassive PE was assessed in the *Standard versus Ultrasound-Assisted Catheter Thrombolysis for Submassive Pulmonary Embolism* (SUNSET sPE) trial, which did not demonstrate a benefit of USAT in this group of patients [39]: The primary endpoint – a pulmonary artery thrombus reduction assessed by a modified Miller Score – was equal between USAT and CDT [39]. Other studies comparing these two treatment modalities drew similar conclusions [55, 56]. It needs to be acknowledged, that the number of patients with high-risk PE included in some of the above-mentioned studies was low (approximately 10%) and therefore potentially limits a robust conclusion on the efficacy of USAT in this risk category.

Apart from USAT, manual catheter-based thrombus-fragmentation (e.g. by using a pigtail catheter) is a simple and cheap technique to promote catheter-based thrombus removal in PE. However, RCT-based data are missing, and new effective large-bore aspiration catheters have increasingly replaced this approach in recent years [48].

Regarding mechanical CBT of PE with large-bore thrombectomy devices, the *FlowTriever Pulmonary Embolectomy Clinical Study* (FLARE) was a prospective multicentre, single-arm study demonstrating a 25% reduction of RV/LV-ratio by using a large-bore (20F or 24F) mechanical aspiration device in patients with intermediate high-risk PE [47]. The major bleeding rate in this prospective study was 0.9%, and no intracranial hemorrhage was observed. With 93 minutes, the mean procedure time was longer compared to other CBT trials. Assessing the same device, procedure times were further reduced in the *FlowTriever All-Comer Registry for Patient Safety and Hemodynamics* (FLASH) registry (43 minutes) [46]. Overall, the data from FLARE were confirmed in the FLASH registry with a reduction in mean pulmonary artery pressure, improvement in cardiac index and improvement in right ventricular function. Safety of mechanical thrombectomy procedures was demonstrated, as well. Since two-thirds of patients were not referred to an intensive care unit in these studies, this approach seems to be a cost- and personnel saving approach [54].

The *Evaluating the Safety and Efficacy of the Indigo aspiration system in Acute Pulmonary Embolism* (EXTRACT PE) study was another prospective, single arm multicentre study demonstrating hemodynamic improvement and significant reduction of RV/LV ratio in parallel with a satisfying safety profile (1.7% major bleedings) by using an 8 French aspiration device [43].

Further development of this aspiration system aimed at a reduction of blood loss. In *A Prospective, Multicenter Study of the Indigo Aspiration System Seeking to Evaluate the Long-Term Safety and Outcomes of Treating Pulmonary Embolism* (STRIKE-PE) this technology showed a significant reduction in the RV/LV ratio and the pulmonary artery pressure. The positive effects on these parameters were also reflected in improved Borg Scale and the classification of the New York Heart Association (NYHA). In addition, the median procedure time of 33.5 minutes requires mentioning as well as the low rate of major adverse events (2.7%) demonstrating safety of these procedures [57].

Most recently, the results of the *Randomized controlled trial of mechanical thrombectomy vs. catheter-directed thrombolysis for acute hemodynamically stable pulmonary embolism* (PEERLESS) study suggested a potential benefit of mechanical thrombectomy over CDT in patients with intermediate high-risk PE [54]. The primary endpoint of this RCT, a composite of all-cause mortality, intracranial hemorrhage, major bleeding, clinical deterioration and/or escalation to bailout, and postprocedural intensive care unit admission and length of stay, occurred less frequently in patients undergoing mechanical thrombectomy in comparison with patients who underwent CDT (win ratio 5.01, 95% CI 3.68–6.97). This difference was primarily attributed to lesser admissions to an intensive care unit (ICU) in

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patients who underwent mechanical thrombectomy than in patients who underwent CDT (OR 95.4, 95% CI 34.6–263.6). Moreover, the intensive care unit stays >24 hours were lower in patients who underwent mechanical thrombectomy vs. CDT (OR 2.18, 95% CI 1.4–3.4), as well as clinical deterioration and/or escalation to bailout therapy was less frequent in patients who underwent mechanical thrombectomy (3.09, 95% 1.11–8.63). There were no differences in mortality, intracranial hemorrhage or major bleeding. These findings are corroborated by real-world retrospective data [58].

The major aim in the contemporary management of patients with PE should be the early involvement of a pulmonary embolism response team (PERT) including interventionalists with expertise in endovascular thrombus removal strategies. Vascular experts should be integrated in the PERT to optimize the decision-making process, the (peri)interventional patient management, and the follow-up of patients with PE (Figure 1).

The definition of clearly defined criteria for lack of treatment success is the subject of ongoing studies, and there is currently some gap in evidence. The use of different scores, e.g. the National Early Warning Score (NEWS) or the Composite Pulmonary Embolism Shock Score (CPES) may be helpful for further treatment strategy planning [59, 60]. For example, NEWS in pulmonary embolism is currently being investigated in the *Ultrasound-facilitated, catheter-directed thrombolysis in intermediate-high risk pulmonary embolism* (HI-PEITHO, NCT04790370) trial. So far, it appears reasonable to consider hemodynamic and respiratory parameters (e.g. heart rate, oxygen demand, blood pressure) in patients with acute PE and continuous anticoagulation within 24 hours for the evaluation as lack of therapeutic success [61].

4.3 Clinical perspective

Over the last years the use of catheter-based therapies for PE has steadily increased and a growing number of newer devices for CBT of PE is now available. Up to now, robust evidence supporting a routine use of CBT in PE is scarce since available studies have been single-arm registries, retrospective analyses, or small, underpowered randomized trials. However, several large-scaled prospective randomized controlled trials are currently recruiting (Table IV).

Patients with complex PE should be managed at centers with appropriate expertise in advanced management of VTE (e.g. CBT, surgical thrombus removal or extracorporal circulatory support) and patient selection should be carried out by the PERT.

Skills and knowledge of the following disciplines should be integrated in the management of patients with acute VTE: vascular medicine, cardiology, radiology, emergency medicine, vascular surgery, cardiac surgery, pulmonology, intensive care, and hemostaseology.

Data on the impact of a PERT on patient outcomes are heterogeneous, partly due to the retrospective nature of many studies. Nevertheless, PERT implementation has been associated with more standardized care, increased use of advanced therapies such as extracorporal membrane oxygenation (ECMO) and CBT [62]. In addition, the establishment of a PERT appears to reduce ICU stay duration and mortality [63].

A key role of a PERT is to determine the optimal timing for advanced interventions (Figure 3). This question is the subject of current research. However, recent studies suggest that patients with intermediate-high and high-risk PE may benefit from an early interventional approach.

In a retrospective cohort study, Zhang et al. evaluated 133 patients who underwent either early (<12 hours) or late (>12 hours) CBT. The primary composite endpoint included 30-day mortality, cardiac arrest, hemodynamic instability, and 90-day readmission. Early intervention was associated with a significant reduction in this composite endpoint, along with shorter ICU and overall hospital stays [64]. Similar findings were reported in a large-scale study involving nearly 12,000 patients. Using a cutoff of 24 hours the study demonstrated that early CBT significantly reduces 90-day mortality and rehospitalization rates [61]. However, definitive conclusions regarding optimal timing and patient selection will require data from prospective randomized trials.

Finally, it needs to be addressed that open surgical embolectomy might be a suitable therapeutic option for pulmonary embolism, for example in patients with clots in transit through a patent foramen ovale. In-hospital mortality of patients undergoing open surgery is higher compared with patients allocated for CBT and highly associated with pre-hospital cardiopulmonary resuscitation [65, 66]. Prospective randomized trials are lacking and decisions on surgical embolectomy in selected cases remain to be consensus based within the PERT.

Beyond acute management, appropriate follow-up is crucial for patients recovering from PE. Those experiencing persistent dyspnea or reduced exercise capacity should be referred to specialized centers for evaluation of CTEPH or PPS and for referral to suitable therapies (e.g., balloon angioplasty, surgical embolectomy) if necessary.

4.4 Ongoing studies

Currently, there is a lack of large RCTs in the field of interventional treatment of PE. Recently several trials investigating the efficacy and safety of CBT versus anticoagulation have been initiated and are currently enrolling. In these trials, the above-mentioned interventional techniques, USAT as well as large-bore catheter aspiration systems, are applied on top of anticoagulation to assess their efficacy and safety in comparison with anticoagulation alone. The data of these trials will help us to get a better understanding of potential benefits of CBT in patients with intermediate-high risk and high-risk PE and are likely to modify future treatment strategies (Table IV). The use of systemic thrombolysis in patients with intermediate-risk PE is also the subject of ongoing clinical trials. In the Pulmonary embolism Thrombolysis Trial (PEITHO trial),

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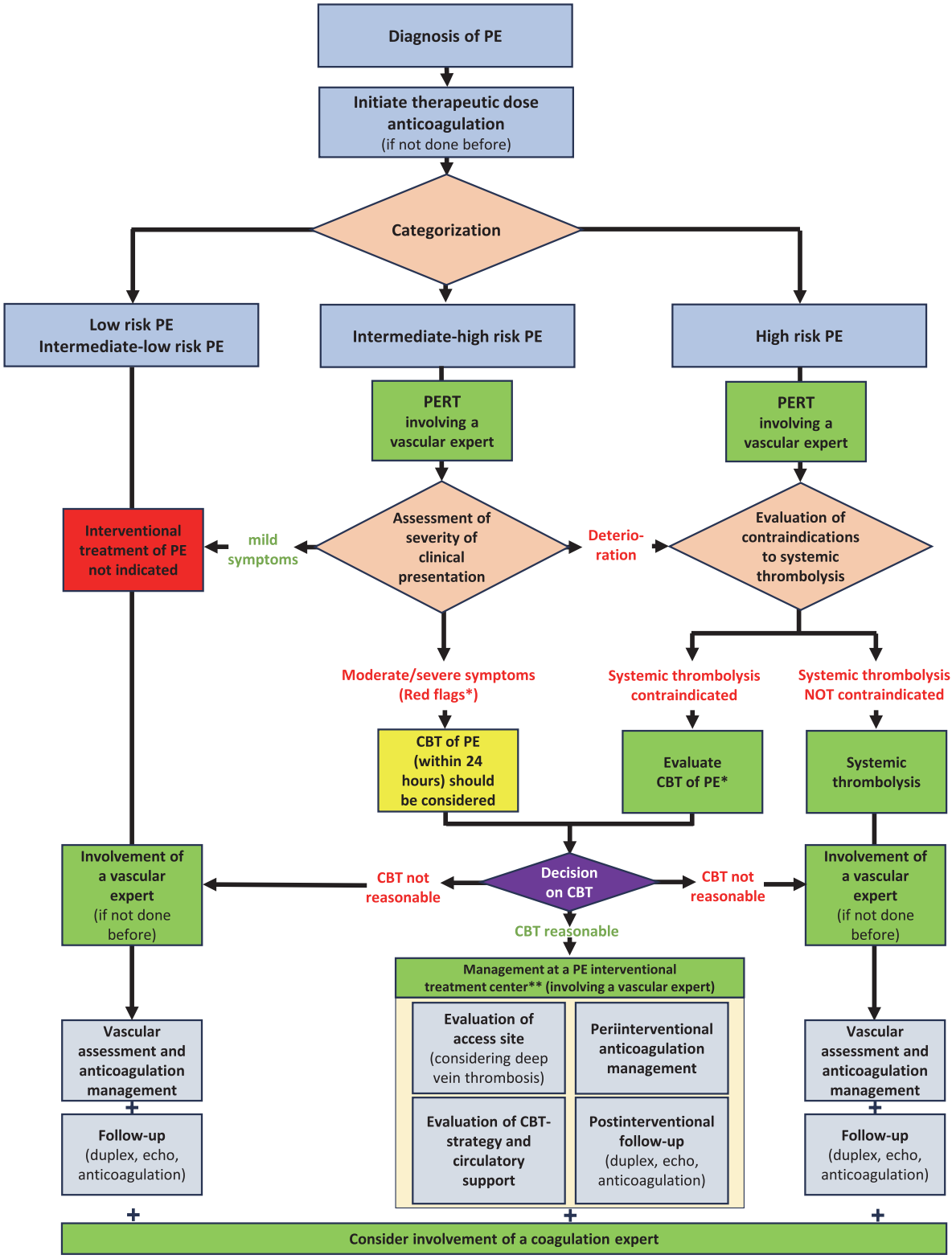

Figure 3. Flow chart showing the clinical algorithm and decision process as proposed for patients with acute pulmonary embolism (PE). CBT – catheter-based therapy, PERT – pulmonary embolism response team. List of red flags [73, 74, 75, 76]. *Heart rate ≥ 100/min, respiratory rate > 20/min, systolic blood pressure <110 mmHg, lactate level > 2 mmol/L, RV/LV ratio > 1, TAPSE < 16 mm, heart failure, active malignancy. **Interventionalists with experience in the endovascular treatment of acute PE and availability of thrombectomy devices and circulatory support.

systemic thrombolysis with tenecteplase significantly protected patients from hemodynamic decompensation [67]. However, the beneficial effect was reduced by bleeding complications, and therefore systemic fibrinolysis is not currently recommended as routine treatment for intermediate high-risk PE. Data from the currently enrolling PEITHO 3 trial, which is comparing a reduced-dose alteplase regime with anticoagulation, are awaited [68].

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Table IV. Ongoing randomized controlled trials (RCT) on thrombus removal strategies in patients with pulmonary embolism (PE) as listed on ClinicalTrials.gov

Study title	ClinicalTrials.gov ID	Population	Design	Comparator arm	Experimental arm	Primary endpoint	Status
Ultrasound-facilitated, catheter-directed thrombolysis in intermediate-high risk pulmonary embolism (HI-PEITHO)	NCT04790370	Patients with intermediate-high risk PE	RCT	Anticoagulation	Anticoagulation + USAT	PE-related mortality, PE recurrence, cardiorespiratory decompensation or collapse	Recruiting
RCT of large-bore thrombectomy versus anticoagulation in intermediate-risk pulmonary embolism (The PEERLESS II)	NCT06055920	Patients with intermediate risk PE	RCT	Anticoagulation	Anticoagulation + mechanical catheter-based thrombectomy	Composite clinical endpoint constructed as a win ratio, a hierarchy of the following, which are assessed post randomization: clinical deterioration (hemodynamic or respiratory worsening up to 30 days), all-cause hospital re-admission by 30 days, bailout therapy up to 30 days, dyspnea my modified medical research council at 48-hour visit	Recruiting
RCT of high-risk pulmonary embolism comparing FlowTriever system vs. standard of care (PERSEVERE)	NCT06588634	Patients with high-risk PE	RCT	Anticoagulation	Anticoagulation + mechanical catheter-based thrombectomy	Composite clinical endpoint of all-cause mortality, cardiac arrest, bailout to an alternative therapeutic strategy, major bleeding	Recruiting
A prospective, multicenter, RCT evaluating anticoagulation alone vs. anticoagulation plus mechanical aspiration with Indigo® aspiration system for the treatment of intermediate high risk acute pulmonary embolism (STORM PE)	NCT05684796	Patients with intermediate-high risk PE	RCT	Anticoagulation	Anticoagulation + mechanical catheter-based thrombectomy	Change in RV/LV ratio at 48 hours	Recruiting
Pulmonary Embolism - Thrombus Removal With Catheter-Directed Therapy (PE-TRACT)	NCT05591118	Patients with submassive PE	RCT	Anticoagulation	any CDT device cleared by the FDA (thrombectomy or infusion catheter;	Peak Oxygen Consumption (PVO2): time frame 3 month NYHA Classification: time frame 12 month Incidence of Major Bleeding at Day 7	Recruiting

Abbreviations. PE – pulmonary embolism, RCT – randomized controlled trial, USAT – ultrasound assisted thrombolysis.

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4.5 Circulatory support

Veno-arterial ECMO or other circulatory support devices may be used in situations with severe right ventricular failure. Although data from large trials in this area are lacking, there are data suggesting a benefit of circulatory support in the treatment of high-risk PE [69, 70].

4.6 Gaps in evidence

- Periinterventional anticoagulation, especially heparin dosing
- Optimal timing of CBT
- Definition of "failure of CT"
- Value of reduced dose systemic thrombolysis and comparison with CBT
- Effect of CBT on development of post-PE syndromes and/or CTEPH
- Systemic thrombolysis in intermediate high-risk pulmonary embolism (e.g. PEITHO 3 trial)
- Benefit of mechanical circulatory support in high-risk PE patients
- Management of clots in transit

Recommendations for interventional therapy of acute PE

Recommendation	Class of recommendation	Level of evidence
It is recommended to implement a PERT with the involvement of a vascular expert in the decision making on interventional treatment of acute PE.	I	C
The involvement of a vascular expert in the periinterventional management of patients undergoing CBT is recommended.	I	C
It is recommended that interventionalists with expertise in endovascular treatment of PE are involved in CBT of PE.	I	C
It is recommended that CBT of PE is performed in centers with the possibility of hemodynamic, respiratory, and circulatory support during and following thrombus removal.	I	C
In patients with intermediate-high risk PE and insufficient clinical improvement within 24 hours of anticoagulation, CBT should be considered [41, 49].	IIa	B
In patients presenting with high-risk PE and contraindication to systemic thrombolysis or failure of systemic thrombolysis, it is recommended to consider CBT.	I	C
UFH is the anticoagulant of choice in the periinterventional phase of planned CBT or systemic thrombolysis.	I	C
After CBT, a clinical follow-up is recommended including echocardiographic and duplexsonographic assessment, as well as anticoagulation management.	I	C

5. Inferior vena cava (IVC) filters

While there are data suggesting that IVC filters may prevent the occurrence of (subsequent) massive PE, the overall quality of evidence on their efficacy and safety is limited and inconsistent [71, 72]. It needs to be acknowledged that IVC filters potentially may increase the risk of DVT and the risk of persisting scarring or obliteration of the IVC, while the effect on overall mortality can be questioned.

Recommendations for insertion of IVC filters

Recommendation	Class of recommendation	Level of evidence
The routine implantation of IVC filters in patients diagnosed with acute DVT is not recommended.	III	A
The routine implantation of IVC filters in patients diagnosed with acute PE is not recommended.	III	A
Placement of IVC filters may be considered in patients with PE and progression of DVT or PE despite therapeutic dose anticoagulation [72].	IIb	C
Placement of IVC filters may be considered in patients with acute proximal DVT and/or PE and contraindication to therapeutic dose anticoagulation [72].	IIb	B
The involvement of a vascular expert in the decision- making process on the implantation of IVC-filter is recommended.	I	C

Conclusion

The field of interventional therapy for VTE, including both DVT and PE, has rapidly evolved over recent years, driven by technological advancements and increasing clinical

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experience. While catheter-based therapies (CBT) have demonstrated promising results in selected patients, optimal patient selection, timing, and periinterventional management remain crucial to maximize clinical benefits and to minimize risks. Current evidence supports the use of CBT primarily in patients with severe symptoms or at high risk, under the guidance of vascular experts and in specialized centers. Data from ongoing and future randomized controlled trials are expected to provide further insights into the safety and efficacy of novel CBT devices, ultimately shaping more precise treatment recommendations and enhancing patient outcomes.

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