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Videosurgery

Treatment of high- and intermediate-risk pulmonary embolism using the AngioJet percutaneous mechanical thrombectomy system in patients with contraindications for thrombolytic treatment – a pilot study

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Abstract

Introduction: *Intravenous thrombolysis is the treatment of choice in patients presenting with high- and intermediate-risk pulmonary embolism. The role of percutaneous mechanical pulmonary thrombectomy (PMPT) is not fully established, although selected patients can be managed with this method.*
Aim: *This open-label single-centre prospective pilot study was aimed at assessing the feasibility of PMPT for the treatment of severe pulmonary embolism in a Polish hospital. We also evaluated the safety and efficacy of such management.*
Material and methods: *We managed 7 patients, aged 52.7 ±16.6 years, presenting with high- and intermediate-risk pulmonary embolism (4 patients with class 5 and one patient with class 4 of the Pulmonary Embolism Severity Index), with occlusion of at least 2 lobar arteries and contraindications for thrombolysis. Percutaneous mechanical pulmonary thrombectomy was performed using the AngioJet system.*
Results: *It was possible to introduce the thrombectomy system to the pulmonary arteries in all patients. The procedure was successful in 6 patients (technical success rate: 85.7%). Two (28.6%) patients died during the hospital stay, one patient with unsuccessful thrombectomy and the other due to pneumonia. In all survivors control echocardiography demonstrated normalised function of the right ventricle. Also, dyspnoea disappeared and blood gas parameters normalised. There was no recurrent thromboembolism during 3–14 months of follow-up.*
Conclusions: *In the Polish setting, in selected patients, management of high- and intermediate-risk pulmonary embolism with PMPT is technically feasible. Such treatment is relatively safe and effective. It can be an alternative to standard management, especially in patients with contraindications for fibrinolysis or surgical embolectomy.*

Key words: *thromboembolic disease, pulmonary embolism, mechanical thrombectomy system, pulmonary artery.*

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Introduction

Venous thromboembolic disease represents the third most common cause of cardiovascular death in the United States and Europe [1–3]. Symptomatic pulmonary embolism (PE) occurs in about 500,000 patients annually, with an estimated mortality as high as 30% in high-risk patients [2, 3]. According to current guidelines, based on clinical and haemodynamic criteria and the risk of early mortality, severe PE can be categorised into two main groups [2–5]. The first one comprises high-risk PE, which clinically manifests with haemodynamic instability and systemic hypotension (systolic blood pressure < 90 mm Hg, pressure drop of more than 40 mm Hg or requiring administration of inotropic agents [5, 6]). In this form of PE imaging studies usually reveal a "saddle embolus" at the bifurcation of the pulmonary trunk, embolism of the main pulmonary artery, or embolic occlusion of at least two lobar arteries [3–6]. Mortality in high-risk PE is at the level of 60%, and in 66% of these patients fatal outcomes take place during the first hours from the onset of clinical symptoms [3–5]. The remaining patients with severe PE, those with intermediate risk of mortality, do not reveal hypotension, but present with clinical symptoms comprising dyspnoea and/or tachycardia. Laboratory diagnostics, ECG and imaging studies demonstrate in these patients significant overload of the right ventricle, severe blood gas disturbances and in some patients also markers of myocardial necrosis. Estimated 30-day mortality in patients with intermediate risk PE is at the level of 15–20%, and these patients are at a risk of developing pulmonary hypertension and right ventricle heart failure [7–9].

Pulmonary embolism is primarily managed with anticoagulants and fibrinolytic agents, while surgical pulmonary embolectomy is performed in selected patients [5, 7–11]. Given the fact that as many as 40% of patients with class 4 or 5 of the Pulmonary Embolism Severity Index (PESI) present with contraindications for both surgical embolectomy and fibrinolytic therapy, percutaneous mechanical pulmonary thrombectomy (PMPT) seems to be an attractive alternative treatment modality [6, 10, 12–17]. Recently a number of studies on the use of PMPT for the management of PE in patients presenting with high or intermediate risk have been published. They primarily comprised open-label studies and retrospective analyses of the cohorts, but also a few prospective trials. Still, to the best of our knowledge, a similar paper on Polish patients has not yet been published.

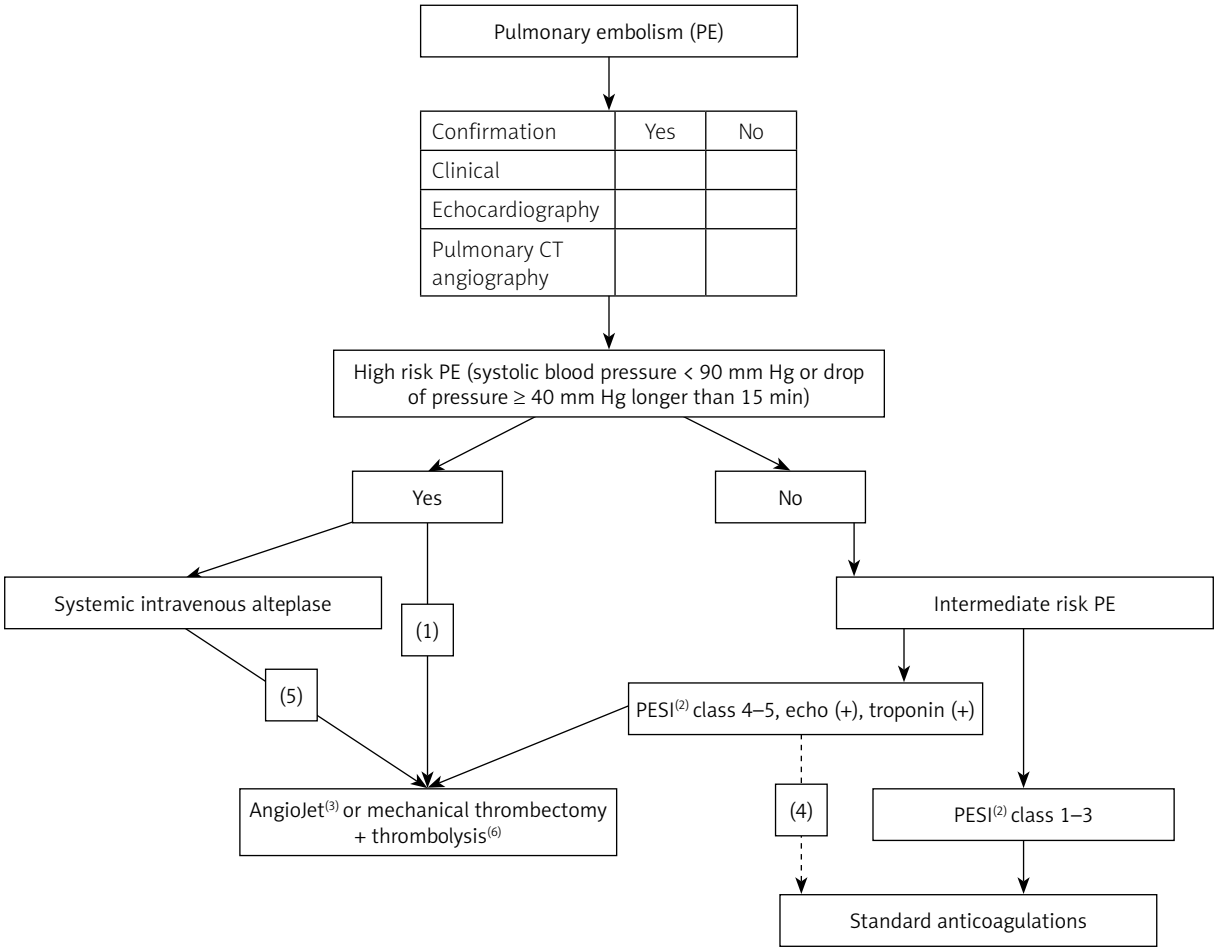
Aim

This open-label study was aimed at assessing the feasibility of management of severe PE using PMPT in a Polish hospital. We also evaluated the safety and efficacy of such treatment, with reference to the results of this treatment in other countries [6, 10, 12–18].

Material and methods

In 2015 the University Hospital in Krakow initiated a pilot programme of the management of patients presenting with high- and intermediate-risk PE, 4 or 5 class of PESI, dysfunction of the right ventricle, elevated troponin and contraindications for fibrinolytic therapy. Absolute contraindications for fibrinolysis comprised head trauma, brain surgery and other major surgical procedures. Relative contraindications regarded patients with traumatic and surgical injuries associated with a high risk of uncontrollable bleeding, such as recent fracture or patients after cardiopulmonary resuscitation with injuries of the ribs and sternum, and patients with neurological pathologies that potentially could be exacerbated by bleeding to the nervous tissue, such as polyneuropathy. Although several endovascular techniques can be used for the purpose of mechanical thrombectomy of the pulmonary arteries, considering the fact that our team has expertise in the use of the AngioJet (Boston Scientific, Natick, MA, USA) rheolytic thrombectomy system, we decided to use this endovascular device. For the purpose of this programme and also for everyday practice, we created an algorithm – how to diagnose and manage PE patients, and which patients should be qualified for PMPT (Figure 1). The study protocol has been approved by the Bioethical Committee of the Regional Board of Physicians in Krakow (approval Nº138/KBL/OIL/2015).

We primarily focused at the feasibility of PMPT, which was defined as the rate of technically successful procedures, and at safety of such management measured by in-hospital mortality and prevalence of severe adverse events. We also performed an analysis of how PMPT improved haemodynamic, angiographic and clinical parameters in these patients.



1 – primary or absolute/relative contraindications for fibrinolysis, [2] – PESI – Pulmonary Embolism Severity Index, [3] – AngioJet™ rheolitic thrombectomy, 4 – no patients consent, no vascular access, 5 – no clinical improvement: hypotension, hypoxemia, [6] – AngioJet™ rheolitic thrombectomy + local administration of alteplase.

Figure 1. Algorithm of management of patients with pulmonary embolism in our hospital

Analysed clinical criteria comprised improvement of function of the right ventricle, postprocedural adverse events and in-hospital mortality. Haemodynamic and laboratory parameters, such as systolic blood pressure, heart rate and blood gases parameters (pH and O_2 saturation) were evaluated before and after the procedure (Table I). Echocardiography was performed before endovascular thrombectomy, 6–12 h after completion of PMPT and on the 2nd–4th postprocedural day.

We prospectively evaluated results of the treatment in 7 patients (4 women and 3 men) who were managed from December 2015 to April 2017. Patients were aged 52.7 ±16.6 years. All of them presented with high or intermediate risk PE, and the diagnosis was confirmed by computed tomography (CT) angiography (Tables II and III). There were also 4 patients who met the above-described criteria but for different reasons were not managed with PMPT (Figure 2). Out of these patients, 3 of them improved clinically during preparation for the procedure and no longer presented with a high risk class according to the PESI. Another patient, with a long history of PE and haemodynamic instability, was managed with thrombolysis instead of PMPT, since considering the duration of the embolism and poor clinical status of this individual, the endovascular approach seemed technically challenging and very risky.

According to our protocol (Figure 1), patients presenting with high- or intermediate-risk PE, 4 and 5 classes PESI, with occlusion of at least 2 lobar arteries and contraindications for thrombolysis were managed with PMPT. Other patients received standard treatment using thrombolysis or antithrom-

Table I. Pre- and postprocedural findings

Patient	Localisation of emboli	Miller index before/after the procedure	HR/min before/after the procedure	SBP mm Hg before/after the procedure	pH before/after the procedure	PaO_2 [mm Hg] before/after the procedure	Duration of endovascular treatment [min]	Final outcome
1	Lobar arteries of superior, middle and inferior lobes of right lung	18/5	130/100	100/120	7.3/7.4	67/ 89	30	Clinical success
2	Lobar arteries of superior, middle and inferior lobes of right lung	27/15	135/100	100/110	7.3/7.4	62/84	25	Clinical success
3	Lobar arteries of superior, middle and inferior lobes of right lung	18/11	130/110	100/100 (on dopamine)	7.26/7.42	69/86	30	Death 7 days after procedure due to pneumonia
4	Both pulmonary arteries	33/32	140/0	80/0 (on dopamine)	7.2/6.9	40/41	70	Intraprocedural death
5	Lobar arteries of superior, middle and inferior lobes of right lung	21/8	130/99	100/110	7.23/7.4	63/85	20	Clinical success
6	Lobar arteries of middle and inferior of right lung; lobar arteries of inferior lobe of right lung	16/5	130/100	110/110	7.35/7.45	67/85	30	Clinical success
7	Lobar arteries of superior, middle and inferior lobes of right lung; lobar arteries of superior and inferior lobes of left lung	26/10	131/95	85/110 (on dopamine)	7.2/7.45	55/82	70	Clinical success

botic agents. Out of these 7 patients managed with PMPT, there was one presenting with PESI class 4 and 4 patients with PESI class 5. Four patients provided their written informed consent to undergo the procedure, while the remaining 3 patients were unconscious and thrombectomy was performed as a life-saving intervention. Three patients required mechanical ventilation before and during the endovascular procedure. There were cardiac arrests in 2 patients before the procedure and in 1 patient during the procedure.

All patients managed with PMPT were administered therapeutic doses of low-molecular-weight heparin once PE has been suspected. In the case of relative contraindications for anticoagulation (there was 1 patient after head trauma and 2 patients after abdominal surgery) patients received subtherapeutic doses of heparin. In addition, in 2 patients with contraindications for therapeutic anticoagulation we implanted retrievable cava filters. After PMPT patients were managed in the intensive care unit. Once their clinical status became stable, which occurred on the 3rd–13th postprocedural day, they were transferred to the internal medicine ward and after further stabilisation of their status they were discharged home, with the recommendation of long-term oral anticoagulation.

Endovascular technique

In this group of patients we did not use mechanical thrombectomy augmented by local fibrinolysis, which was an option in our protocol (Figure 1). Endovascular thrombectomy was performed 3–20 h from the onset of symptoms of PE (Table III). Femoral access was the preferred route for this intervention. This vein was cannulated with a 5 Fr or 6 Fr introducer sheath. Then, over a standard (such as InQwire Guide Wire, Merit Medical Systems) or hydrophilic (for example, AqWire, Covidien, ev3 Endovascular, Inc., Plymouth, MN, USA) guide wire, a pigtail diagnostic catheter was positioned in the pulmonary trunk. This diagnostic catheter was then advanced into each pulmonary artery and angiography was performed. Routinely we used 10 ml of contrast on each side, or 30 ml in the case of injection of contrast at the level of the pulmonary trunk. This volume was adjusted depending on the clinical status of the patient and the value of the pulmonary pressure. In the case of poor clinical status of the patient

and/or echocardiographic features of right ventricle overload, we tried to reduce the volume of contrast to 8–10 ml. After confirmation of embolisation, the above-described introducer sheath was replaced with a bigger one (6 Fr or 7 Fr). We suggest using the SiteSeer Judkins Right catheter (Medtronic, Minneapolis, MN, USA) or a long sheath with a special tip, such as the 6 Fr 90 cm length Destination Guiding Sheath (Terumo, Tokyo, Japan). Then the AngioJet system was introduced. Using this device emboli were subsequently aspired from all occluded pulmonary branches. Initially we performed 2–5 passages of the thrombectomy device in the occluded artery, with simultaneous assessment of the tolerance of the intervention by the patient. Then we evaluated the degree of residual stenosis in angiography. Of note, we did not perform embolectomy of small branches of the pulmonary artery, since navigation through these tiny vessels is associated with very high risk of haemorrhage. We also avoided aspirations of embolic material lasting longer than 7–10 s, since such manoeuvres can result in dyspnoea and cardiac decompensation. Thrombectomy was continued until all major branches of the pulmonary arteries became recanalised, or the patient significantly improved clinically in terms of haemodynam-

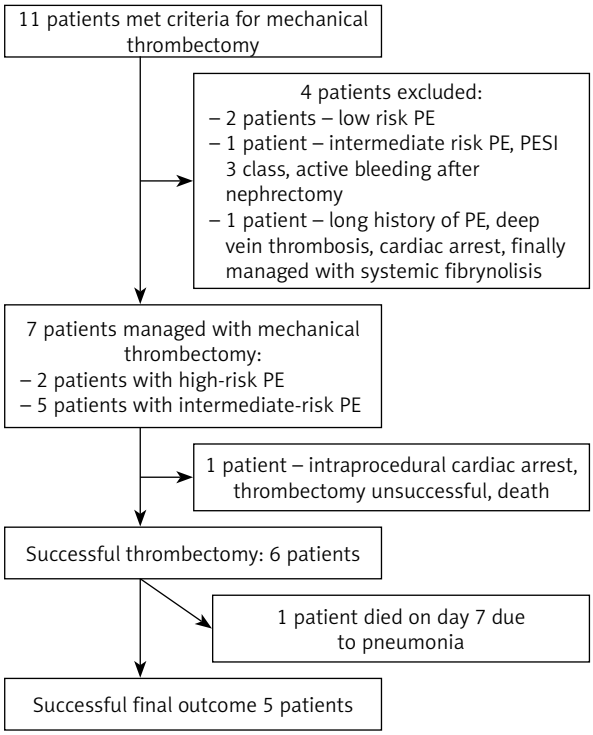


Figure 2. Flow chart of patients

Table II. Demographic, clinical and diagnostic data of all treated patients (n = 7)

Parameter	Value
Gender:	
Males	3 (43%)
Females	4 (57%)
Age, mean ± SD [years]	52.7 ±16.6
Risk factors for PE:	
Immobilisation	2 (29%)
Recent surgery	2 (29%)
Malignancy	1 (14%)
Recent trauma	1 (14%)
Obesity	1 (14%)
Contraindications for thrombolysis	7 (100%)
Symptoms:	
Dyspnoea	7 (100%)
Chest pain	4 (57%)
Presyncope/syncope	3 (43%)
Cardiac arrest	2 (29%)
Palpitations	2 (29%)
Clinical presentation:	
Intermediate-risk pulmonary embolism:	5 (71%)
PESI class 5	4 (57%)
PESI class 4	1 (14%)
High-risk pulmonary embolism + shock	2 (43%)
Hypoxia	7 (100%)
Tachycardia (heart rate > 130/min)	7 (100%)
Diagnostic modalities:	
Right heart strain	7 (100%)
Right ventricular dilatation	6 (86%)
Troponin I > 0.01 ng/ml	6 (86%)
Right ventricle failure (echocardiography)	7 (100%)
Paradoxical motion of interventricular septum	2 (29%)
Embolism of both pulmonary arteries in CT angiography	1 (14%)
More than 2 lobar arteries occluded in CT angiography	7 (100%)
Deep vein thrombosis of the lower extremities demonstrated by sonographic examination	2 (29%)

Table III. Clinical characteristics of patients

Patient	Sex	Age [years]	Relevant comorbidities	Risk factors of thrombo-embolism	Severity of PE	Informed consent	Cardiopulmonary resuscitation	Troponin T	Time from onset of symptoms to the procedure [h]	Contraindications for fibrinolysis
1	Male	31	No	Fracture of lower leg	Intermediate-risk PE; PESI 4	Yes	No	Positive	10	Relative contraindications
2	Female	55	Lung cancer	Malignancy, recent history (< 10 days) of pulmonectomy	Intermediate-risk PE; PESI 5	Yes	No	Positive	20	Absolute – patient after major surgery
3	Female	66	Coronary artery disease, fracture of the ribs after resuscitation	Immobilisation	Intermediate-risk PE; PESI 5	Patient unconscious, life-saving procedure	Before procedure	Positive	3	Relative contraindications
4	Male	42	Intracranial bleeding	Immobilisation	High-risk PE	Patient unconscious, life-saving procedure	During procedure	Not done	4	Absolute – intracranial bleeding
5	Male	59	Polyneuropathy	Immobilisation	Intermediate-risk PE; PESI 5	Yes	No	Positive	3	Relative contraindications
6	Female	38	No	General surgery, obesity	Intermediate-risk PE; PESI 5	Yes	No	Positive	10	Absolute – patient after major surgery
7	Female	78	Acute myocardial infarction, fracture of the ribs after resuscitation	Immobilisation	High-risk PE	Patient unconscious, life-saving procedure	Before procedure	Positive	5	Relative contraindications

ic stability and blood gas parameters, even if the angiographic result was suboptimal. We regarded a 30% residual stenosis as acceptable on condition that there was good inflow to peripheral branches of the pulmonary arteries. Also 30–50% stenosis with significant improvement of clinical status (normalisation of heart rate and blood gas parameters) and good inflow to peripheral branches was interpreted as a good result. Residual stenosis more than 50% or no clinical improvement represented an indication for more passages of the thrombectomy system with subsequent angiographic control. In this patient series in each individual we performed 3–6 aspirations with the AngioJet system. Duration of the procedure ranged from 30 to 70 min and the total volume of contrast injected ranged from 50 to 100 ml.

Statistical analysis

Statistical analysis was performed using the SigmaStat for Mac, Version 7.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as medians, categorical data as numbers and percentages.

Results

Diagnosis of PE was made based on the results of pulmonary CT angiography. CT angiography in 1 patient revealed an occlusion of both pulmonary arteries, in 5 patients occlusion of three lobar arteries and in 1 patient occlusion of five lobar arteries (Table I). The Miller index (an angiographic measure of pulmonary occlusion, which is calculated as the sum of obstruction and perfusion indexes, ranging from 0 = best to 34 = worst) scored 16–33 (Table I). In addition, in all patients echocardiography demonstrated signs of right ventricle overload, such as dilatation of the right ventricle (7 patients) and abnormal mobility of the interventricular septum (3 patients).

In total, 2 patients died during the hospital stay, 1 patient with intraprocedural cardiac arrest and unsuccessful thrombectomy (mentioned above), and another patient who died 7 days after the procedure due to pneumonia. Thus, the in-hospital mortality was 28.6%. Except for 1 case of intraprocedural death and 1 case of fatal pneumonia, there were no serious adverse events directly associated with PMPT, such as perforation of the pulmonary artery or another blood vessel, distal embolisation or bleeding from the access site. In 3 individuals, who were our first patients managed with PMPT, there were bradyarrhythmias during a longer aspiration of embolic material. These symptoms ceased spontaneously with discontinuation of aspiration; thus we consider these adverse events as moderate ones. Based on these experiences we limited the time of aspiration to 7–10 s, and bradyarrhythmias were not seen in subsequent patients.

It was possible to introduce the AngioJet system to pulmonary arteries in all patients. Mechanical thrombectomy with this device was successful in 6 patients (technical success rate – 85.7%). The only patient with unsuccessful thrombectomy died during the procedure.

Five PMPT procedures were successful (example results of thrombectomy – Photos 1 and 2). In these patients normalisation of heart rate took place during the first 2 h after the procedure, while the improvement of respiratory function manifesting with disappearance of dyspnoea and normalisation of blood gas parameters occurred 2–6 h after thrombectomy. Only 1 patient, with a recent history of myocardial infarction, required a 3-days long infusion of dopamine. The remaining 4 patients were haemodynamically stable just after the procedure. Control echocardiography in all survivors demonstrated normalised function of the right ventricle.

Duration of hospital stay in survivors was 6–20 days. There were no recurrent thromboembolic events during 3–14 months of follow-up. Changes of angiographic and laboratory parameters after thrombectomy are summarised in Table I.

Discussion

The results of our case series suggest that PMPT can be seen as an alternative to standard management, especially in patients with contraindications for fibrinolysis or surgical embolectomy. A small sample size, single-centre study and no control group are the main limitations of this survey. On the other hand, a standardised protocol for PMPT seems to be a strong point of our report.

Early aggressive treatment restoring patency of occluded pulmonary arteries represents the principal factor affecting mortality in severe PE [2]. According to the guidelines of the European Society of Cardiology, shock or systemic hypotension is an accepted indication for urgent thrombolysis in patients with acute PE [2, 7]. Surgical or endovascular

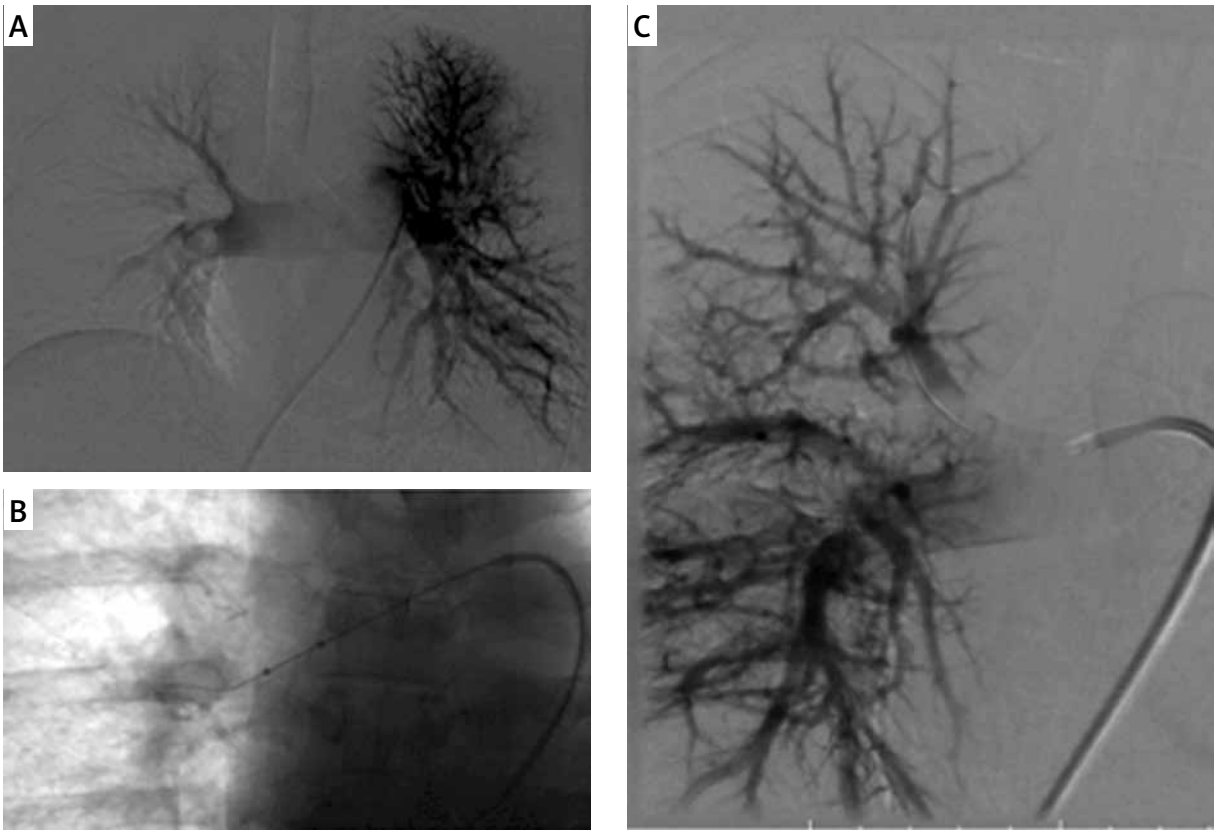


Photo 1. Result of thrombectomy in patient with right-sided pulmonary embolism: **A** – initial image – occlusion of the middle and inferior lobar arteries, and also partial occlusion of the superior lobar artery, **B** – AngioJet system introduced to the pulmonary artery, **C** – final result

thrombectomy can be an option in selected cases [10, 12–17]. Although intravenous systemic thrombolysis is recommended as a life-saving treatment in severe PE, the clinical benefit of such management is not obvious. According to the ICOPER registry, systemic fibrinolysis did not affect mortality in patients presenting with high-risk PE [3]. The American College of Chest Physicians recommends an endovascular intervention only in patients with contraindications for fibrinolysis, primarily those with a high risk of bleeding [19], while the European Society of Cardiology suggests the endovascular approach as an alternative for surgical embolectomy in patients with unsuccessful thrombolysis [7]. Still, a number of single-centre studies, as well as meta-analyses of such trials, have demonstrated that PMPT in high- or intermediate risk-PE can be safe and effective, and that the risk of serious adverse events is comparable or even lower than that after fibrinolytic therapy [6, 10, 12–17]. This relatively high efficacy of PMPT is related to the fact that mechanical fragmentation of the embolus increases the chance of recanalisation of the pulmonary artery. In addition, the dose of fibrinolytic agent that is directly administered to the pulmonary arteries is reduced and therefore bleeding complications are less frequent [3, 6, 14–16]. Consequently, in some highly experienced centres PMPT is regarded as the procedure of choice, even if systemic thrombolysis and surgical embolectomy still play important roles [6, 10, 13–17]. It has been emphasized that clinical success of PMPT is primarily associated with recanalisation of pulmonary and/or lobar arteries. This in line with our observations. In our material intraprocedural death occurred in a patient with unsuccessful thrombectomy of the pulmonary arteries. Also, following observations of other researchers who demonstrated that the decision upon completion of the procedure should be based on the clinical and not angiographic outcome, we finished PMPT once the patient clinically improved, irrespective of the angiographic picture of the pulmonary circulation. Such a strategy is due

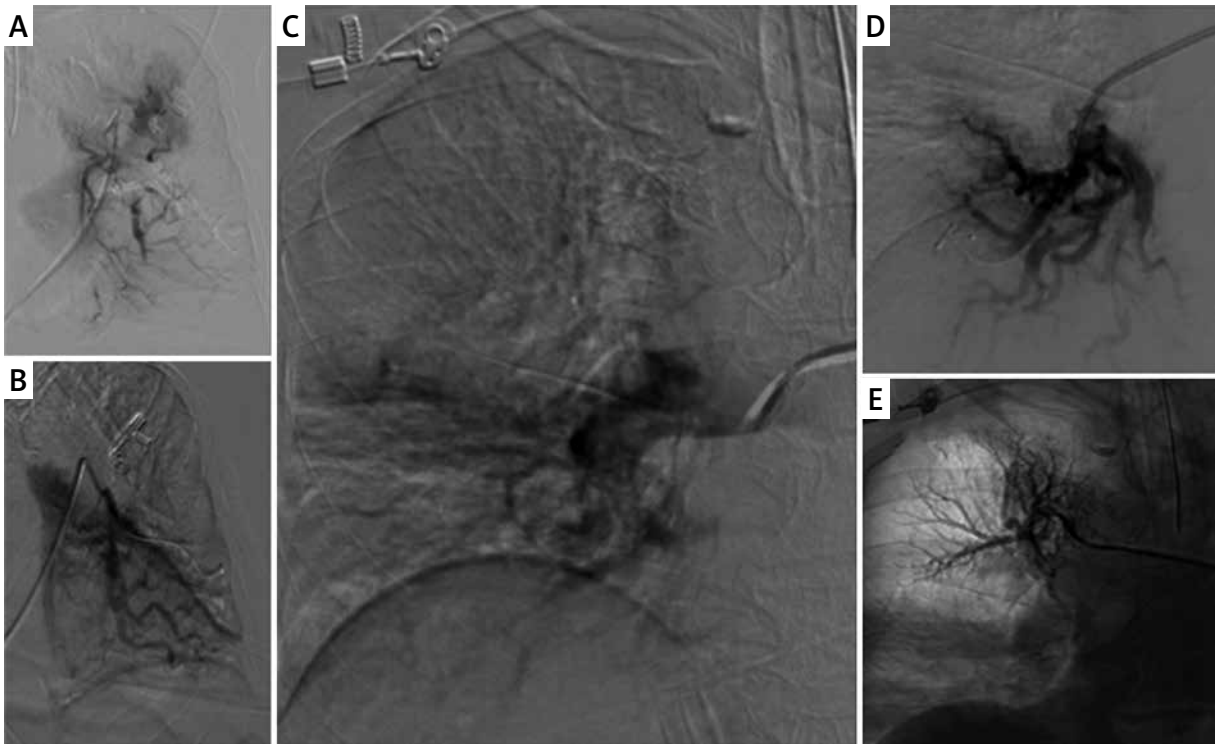


Photo 2. Result of thrombectomy in patient with bilateral occlusion of pulmonary arteries: **A** – initial image: occlusion of the left superior and inferior lobar arteries, **B** – after thrombectomy of the inferior lobar arteries of the left lung, **C** – occlusion of the superior, middle and inferior lobar arteries of the right lung, **D** – recanalisation of the inferior, **E** – superior lobar arteries

to the fact that thrombectomy of distal pulmonary vessels is associated with especially high risk of life-threatening technical failures [6, 10, 15].

The question whether PMPT should be followed by local pharmacological thrombolysis is also under debate. Lee *et al.* reported the results of such management in 91 patients presenting with intermediate risk PE. They administered alteplase, with mean time of drug infusion 18 h, and observed clinical improvements in all patients [20]. This observation suggests that low-dose local thrombolysis can be an effective additional treatment in patients without contraindications for fibrinolytics. There were published two studies assessing long-term local fibrinolysis using the EkoSonic Endovascular System [21, 22]. The system has been found effective in patients presenting with intermediate-risk acute PE and the results were superior to standard anticoagulation with heparin. In the first study the authors used 10–20 mg of alteplase, while in the other the total dose of alteplase was 24 mg. Consequently, there were significantly different rates of hemorrhagic adverse events (0% vs. 10%). It should also be emphasized that in the first study [21] 84% of patients did not meet the inclusion criteria; thus the group assessed was very highly selected.

Bradyarrhythmia associated with longer aspirations of embolic material is a well-known problem. This complication was seen in 15% of patients managed by some authors [23–25], while others did not report these adverse events [6, 10]. Short aspirations seem to be the best measure to avoid these complications. In is not clear which factors trigger bradyarrhythmias. Some authors blamed haemolysis-related hyperkalaemia, adenosine or a spasm of arteries caused by nitric oxide sequestrated in the pulmonary circulation [24, 25]. We did not use prophylaxis with aminophylline, which was recommended by some authors [25]. Also, in our patients management of bradyarrhythmias with endocavitary stimulation was not needed.

Some authors reported quite a high rate of serious adverse events associated with the use of the AngioJet system, such as haemoptysis, renal failure, peripheral embolisation and bradyarrhythmias [23]. Still others

found this endovascular device to be rather safe [6, 10]. In our patients, except for bradyarrhythmias, there were no serious complications, and even those could be avoided after modification of the procedure.

Conclusions

The results of treatment of our patient series, even respecting the fact that this was a small group, demonstrates that in the Polish context PMPT of high- or intermediate-risk PE is technically feasible, and such management is relatively safe and effective.

Conflict of interest

The authors declare no conflict of interest.

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