—Review—

Recent Advances in Interventional Radiology for Acute Massive Pulmonary Thromboembolism

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Abstract

Acute massive pulmonary thromboembolism is life-threatening and requires vigorous treatment. Anticoagulation is the most traditional treatment for pulmonary thromboembolism, but may not be sufficient for massive thromboemboli. Systemic thrombolytic therapy and surgical thrombectomy are the traditional therapeutic options in this situation. Catheter-directed thrombolysis, percutaneous embolectomy and, more recently, percutaneous thrombus fragmentation techniques using specialized devices are now available to treat the most severe cases of massive pulmonary thromboembolism. The success of these techniques depends on a thorough understanding of the mechanism of action of each of the devices and familiarity with the relevant catheterization techniques. We present a review of currently available equipment and techniques, and describe our work with hybrid treatment using a combination of mechanical fragmentation, localized fibrinolysis and clot aspiration.
(J Nippon Med Sch 2005; 72: 74–84)

Key words: pulmonary embolism, interventional procedure, thrombolysis, thrombectomy, catheters and catheterization

Introduction

Pulmonary thromboembolism is the third most common cardiovascular condition and a leading cause of death in the United States[1]. Although it was previously believed to be rare in Japan, the number of Japanese patients treated for pulmonary thromboembolism has increased markedly over recent years because of increasing recognition of the condition and advances in diagnostic tools. The true incidence of pulmonary thromboembolism is not known, but it is estimated that there are more than 600,000 cases each year in the United States[1]. No statistical reports have been published in Japan.

Death in patients with acute massive pulmonary thromboembolism is caused by sudden circulatory collapse as a consequence of obstructed pulmonary blood flow. The immediate mortality rate is approximately 10%. Of the survivors, 70% fail to have the diagnosis made and the mortality rate in this group may approach 30%[2]. Initial therapy must therefore be directed toward rapid restoration of the pulmonary circulation[3]. Traditional therapeutic options are anticoagulation, systemic thrombolysis and surgical thrombectomy.

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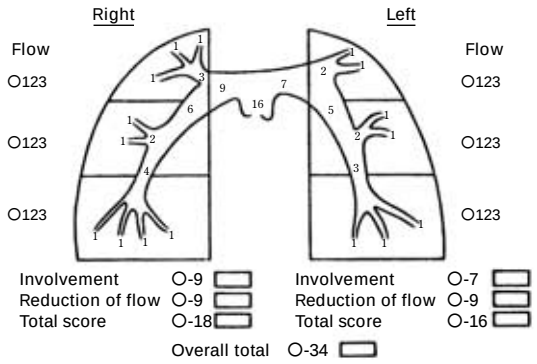

Fig. 1 Miller score[6].
In this system, the right and left main pulmonary arteries are considered to have nine and seven major branches, respectively, and an embolus in any of these branches gives a score of 1 point. Each lung is considered to have an upper, middle and lower zone, and for each of these three zones absence of pulmonary artery flow scores 3 points, severely reduced flow scores 2 points, mildly reduced flow scores 1 point and normal flow scores 0 points. The Miller score can thus range from 0 to 34.

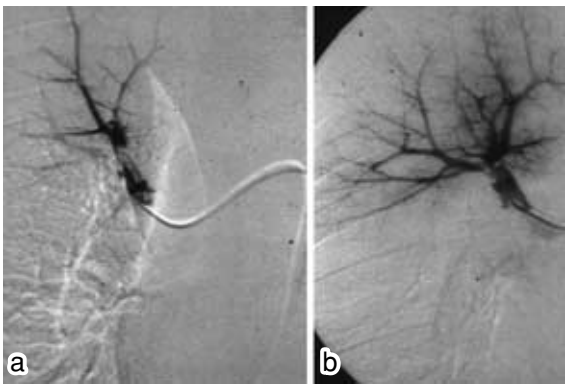

Fig. 2 Superselective thrombolysis with t-PA[11].
(a) The pulmonary angiogram shows emboli in the right superior trunks. (b) Improvement of perfusion is seen after superselective infusion of t-PA (800,000 unit/8 min).

Recently, multiple minimally invasive procedures have been introduced, including catheter-directed thrombolysis, percutaneous embolectomy, and thrombus fragmentation[2,4]. The aim of these procedures is to prevent death due to right heart failure by prompt peripheral dispersal of the central thrombus, resulting in reduced pulmonary vascular resistance and increased pulmonary flow.

This review describes the principles behind and techniques for using these interventional procedures in managing patients with life-threatening pulmonary thromboembolism. We also outline our work with a hybrid technique using a combination of mechanical fragmentation, localized fibrinolysis and clot aspiration[5].

Indications

The indications for aggressive interventional therapy to treat acute massive pulmonary thromboembolism are as follows[2]:

1. Circulatory collapse with need for cardiopulmonary resuscitation (shock index [heart rate/systolic blood pressure] > 1)

2. Right ventricular afterload stress and/or pulmonary hypertension (mean pulmonary arterial pressure > 25 mmHg)

3. Angiographic findings:

Miller score > 20/34 (**Fig. 1**)[6,7].

The equipment and techniques used for aggressive interventional therapy are considered in the following sections.

Catheter-directed Thrombolysis

Catheter-directed thrombolysis with intrapulmonary infusion of thrombolytic drugs is a technique advocated by many authors, which aims to accelerate clot lysis and achieve rapid reperfusion of the pulmonary circulation. In 1988, Verstraete et al published a prospective, randomized, multicenter comparative study of intravenous versus intrapulmonary treatment with 100 mg recombinant human-tissue plasminogen activator (rt-PA) over 7 h, which showed that intrapulmonary infusion offered no significant benefit over intravenous administration[8]. However, their study did not apply the specialized techniques that are currently used.

The superiority of rt-PA over urokinase for treatment of massive pulmonary thromboembolism has yet to be confirmed[9]. In multicenter studies using acute dosing regimens, recanalization rates achieved by thrombolysis alone were reported as reductions in the angiographic score after 2 h by 17.8% (intravenous urokinase) and 22.4% (intravenous rt-PA), and by 12.0% (intrapulmonary

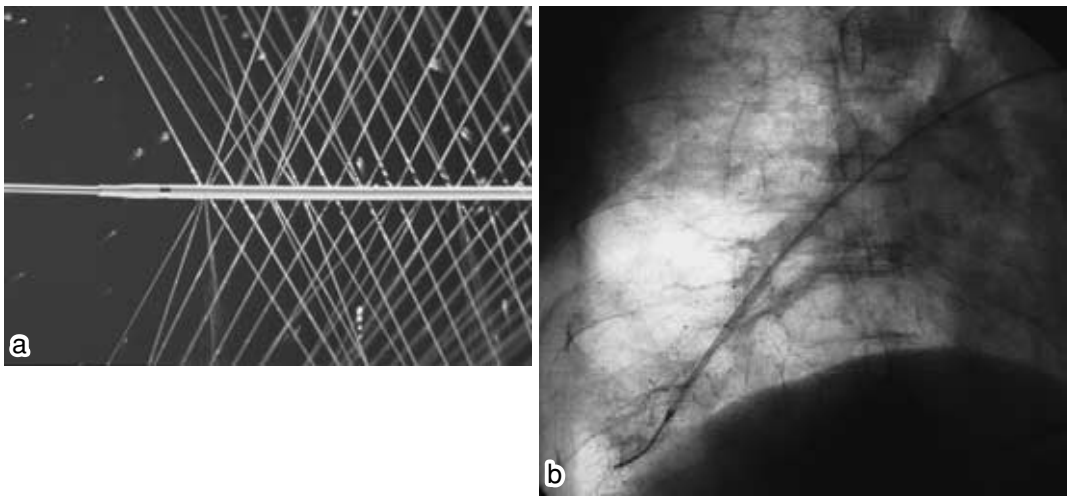

Fig. 3 Pulse-spray thrombolysis[12].
(a) Pulse-spray infusion catheter system. Mechanical action of the injected fluid is very important. (b) Pulse-spray system in the right pulmonary vascular tree. Radiopaque markers show the location of the infusion holls.

Table 1 Results of percutaneous embolectomy[7, 13, 16, 18]

Authors	No of cases	Device used	Technical success	30-Days survival	Complications
Greenfield et al	46	Greenfield percutaneous embolectomy catheter	35/46 (76%)	32/46 (70%)	Pulmonary hemorrhage (1), Ventricular perforation (1)
Timsit et al	18	Greenfield percutaneous embolectomy catheter	11/18 (61%)	13/18 (72%)	Ventricular arrythmia (1), Renal failure (2)
Lang et al	3	Lang device	3/3 (100%)	2/3 (66%)	none
Tajima et al	15	PTCA guiding catheter	15/15 (100%)	15/15 (100%)	none

rt-PA) and 15.4% (intravenous rt-PA)[8,10].

Superselective Thrombolysis

Superselective thrombolysis with the catheter wedged into the peripheral segment/subsegmental arteries has been described, and prompt thrombolysis is reported (**Fig. 2**)[11].

Pulse-spray Thrombolysis

Pulse-spray injection of thrombolytic drugs into clots is another specialized technique for the treatment of acute massive pulmonary thromboembolism (**Fig. 3**)[12]. With this method, the mechanical action of the injected fluid is very important for clot lysis.

Drug regimens that have been used for catheter-directed intrapulmonary thrombolysis are as follows[2]:

Urokinase:

Infusion of 250,000 IU/h mixed with 2,000 IU heparin over 2 h, followed by infusion of 100,000 IU/h urokinase over 12～24 h.

rt-PA:

Bolus of 10 mg followed by 20 mg/h over 2 h, or 100 mg over 7 h.

These doses are about 5～10 times larger than those routinely used in Japan.

Percutaneous Embolectomy (Table 1)

The ideal embolectomy catheter should be[2]:

1. Easy to use and position within the clots in the pulmonary artery.

2. Adequately steerable during the procedure.

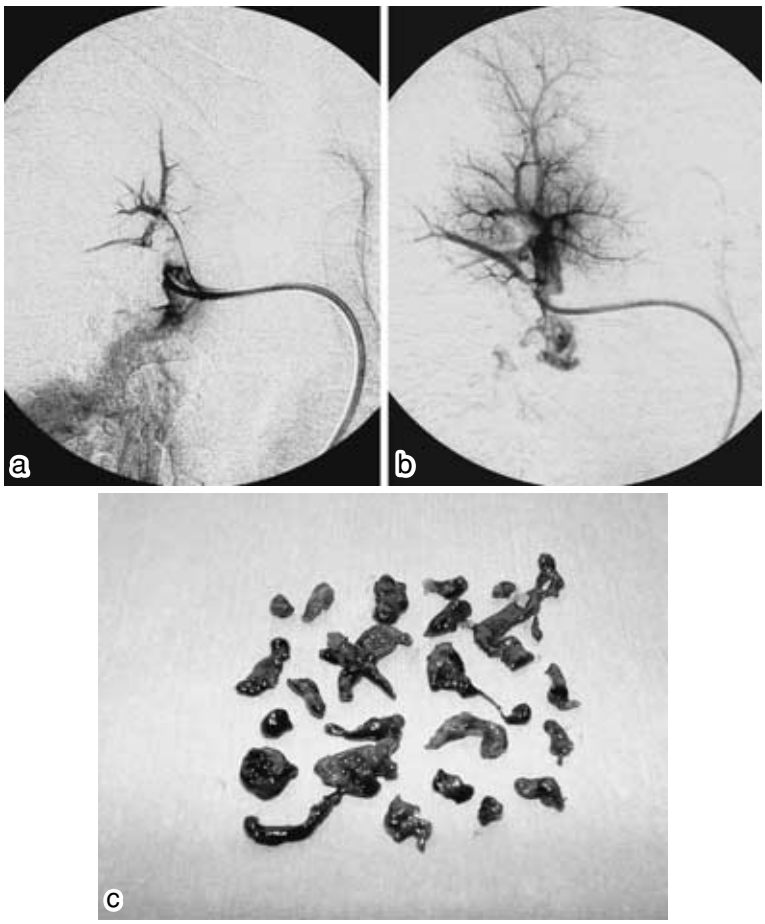

Fig. 4 Manual aspiration thrombectomy with a PTCA guiding catheter[18]. (a) On pulmonary angiogram, an aspiration catheter is inserted in clots. (b) The pulmonary angiogram (during aspiration). (c) Aspirated thrombi (another patient).

3. Able to promote complete removal of clots or fragmentation to very small particles.

4. Low profile and low cost.

Percutaneous pulmonary embolectomy has not achieved widespread use. Possible reasons include the need for a venotomy or a large introducer sheath (16～24 Fr), special skills for steering and pulmonary placement, and only partial removal of the embolus, necessitating repositioning and subsequent passes[2,13,14]. In contrast, percutaneous clot aspiration with an 8 Fr Percutaneous Transluminal Coronary Angioplasty (PTCA) guiding catheter has begun to be used in Japan because of the small size of the catheter.

The equipment and techniques used for percutaneous embolectomy are described below.

1. Greenfield Embolectomy Device

The Greenfield embolectomy catheter system consists of a 10 Fr, 100-cm-long, braided, steerable catheter with a 5- or 7-mm plastic cup at the tip, which was designed to be inserted through a venotomy via the femoral or jugular vein. The control handle (joy stick) allows for catheter maneuvrability as it is advanced through the right heart system under fluoroscopic guidance. Once the cup abuts the embolus, suction is applied using an aspirating catheter with a 30-m*l* syringe. If brisk blood flow is not obtained, the suction is maintained while the catheter with the trailing embolus is removed through the venotomy. Multiple passes may be required to complete the treatment. This device was the first tool designed for the treatment of massive pulmonary thromboembolism, and has been available for more than 30 years. Greenfield

Table 2 Results of hydrodynamic thrombectomy[19, 20, 23]

Authors	No of cases	Device used	Technical success	30-Days survival	Complications
Voigtländer et al	5	Angio Jet/ Open embolectomy (2/5)	3/5 (60%)	4/5 (80%)	Hemoptysis (1) Bradycardia (3)
Fava et al	11	Hydrolyser/ Systemic lysis (6/11)	10/11 (90%)	not reported	none
Reekers et al	8	modified Hydrolyser/ Systemic lysis	8/8 (100%)	7/8 (88%)	none

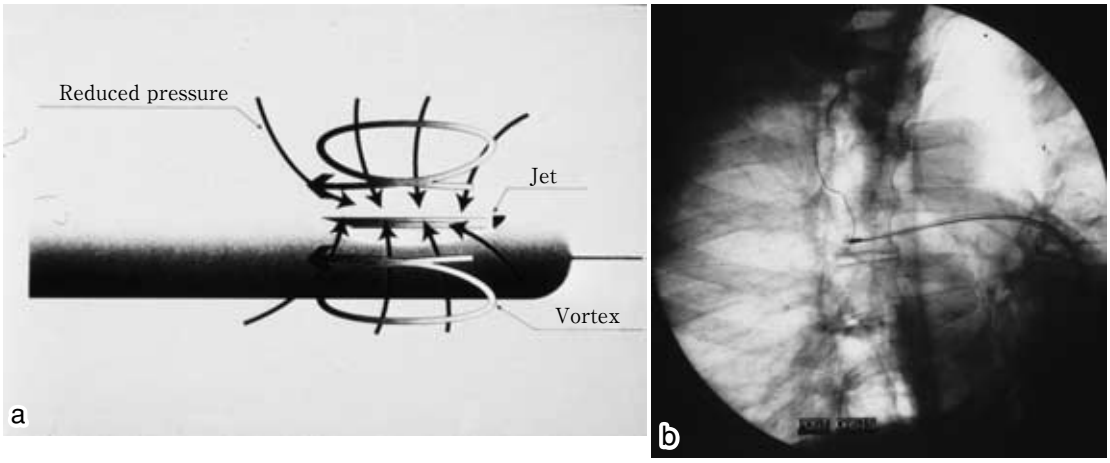

Fig. 5 Hydrodynamic thrombectomy catheter system.
(a) The principle of the Hydrolyser system. (b) The Oasis system is located in the right pulmonary artery.

et al reported it to be successful in extracting pulmonary thrombus in 76% of patients, and to achieve significant reduction of the mean pulmonary arterial pressure and increase in the cardiac output[15,16]; however, this device has been less successful in the hands of other investigators[2,7].

2. Lang Percutaneous Pulmonary Thrombectomy Device

The aspiration catheter system described by Lang et al is a homemade device that uses commercially available catheters of different sizes; a 14 Fr, 90-cm-long Ultratane non-tapered catheter is used for suction through a 16 Fr, 40-cm-long stationary sheath[13]. Improvement in hemodynamic and pulmonary perfusion was rapidly achieved in all three patients assessed in the initial study; however, this technique is no longer used in the hospital in which it was invented.

3. PTCA Guiding Catheter

Percutaneous pulmonary clot aspiration using a large-lumen 8 Fr PTCA guiding catheter has been reported[17,18] (**Fig. 4**). The advantages of this technique are low vessel invasiveness and convenience for use in a standard angiography laboratory, because a small (8 Fr) introducer sheath and a conventional PTCA guiding catheter are employed. There is, however, a risk of blood depletion; we observed a mean decrease of 1～2 g/dl in the hemoglobin level, but no patient required blood transfusion due to this procedure. This technique has proved successful and popular in Japan.

Hydrodynamic Thrombectomy and Clot Aspiration (Table 2)

Hydrodynamic catheters (Hydrolyser (Cordis, Warren, NJ), Oasis (Boston Scientific/Medi-Tech) and AngioJet (Possis, Minneapolis, MN)) work on a Venturi-based principle (**Fig. 5**)[19–21]. Pressurized

Table 3 Results of percutaneous thrombo-fragmentation[3, 5, 28, 30]

Authors	No of cases	Device used	Technical success	30-Days survival	Complications
Schmitz-Rode et al	10	Rotational pigtail/ Systemic lysis (8/10)	8/10 (80%)	8/10 (80%)	None
Fava et al	16	Pigtail & PTA balloon/ local lysis (16/16)	14/16 (88%)	14/16 (88%)	Puncture site hemorrhage (3)
Uflacker et al	5	Amplatz thrombectomy catheter	4/5 (80%)	4/5 (80%)	Hemoptysis (1) Hemolysis (5)
Tajima et al	25	Hybrid treatment	25/25 (100%)	25/25 (100%)	Recovered cardiac arrest (1) Catheter fragmentation (1)

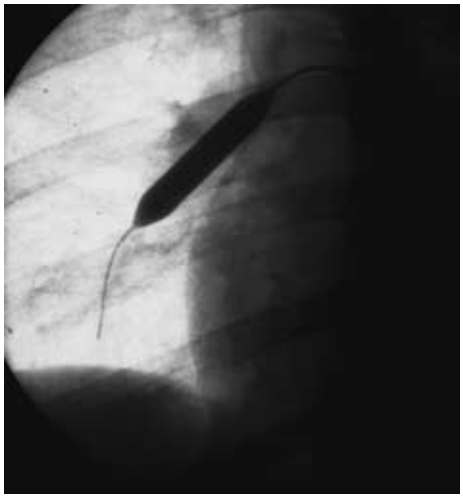

Fig. 6 Balloon PTA system.
The 10 mm diameter balloon is located in the right intermediate artery and inflated.

saline jets are forced from a specialized catheter tip toward the effluent vessel lumen, thereby creating a vacuum around the catheter tip (Venturi effect) that pulls the thrombus into the jet stream (vortex) and into the effluent lumen[2,22]. These systems are very safe because they remove the fragmented clots, and no distal embolization occurred in the concept stages. However, as a result of their design and limited power and size, these devices have limited application in large vessels. They are likely to be more successful in patients with relatively fresh thrombus located in the periphery of the pulmonary vascular tree. Improvements on these devices are currently being developed, including a more powerful hydrodynamic effect and a special pigtail tip for use in the pulmonary artery (7 Fr modified hydrolyser catheter)[2,23]; however, these modifications are not yet commercially available.

Thrombofragmentation Devices (Table 3)

These devices break down a thrombus into smaller fragments, which migrate peripherally in the pulmonary artery, thus opening up the main pulmonary artery and improving perfusion. The rationale for their use in the pulmonary circulation is based on the rapid relief of central obstruction. The knowledge that the cross-sectional area of the distal arterioles is more than four times that of the central circulation, and that the volume of the peripheral circulatory bed is about twice that of the pulmonary arteries, suggests that the redistribution of large central clots as smaller clots in the peripheral pulmonary arteries may acutely improve cardiopulmonary hemodynamics, with significant increases in total pulmonary blood flow and right ventricular function[2-4].

The action of these thrombectomy devices can sometimes be facilitated by softening the thrombotic mass using thrombolytic therapy, which helps speed up the debulking and fragmentation of the occlusive clots. Fragmentation can also be used as a complement to thrombolytic therapy, since fragmentation of a large clot exposes fresh surfaces on which endogenous urokinase and infused thrombolytic drugs can work to further break down the resulting emboli.

The equipment and techniques used for fragmentation are outlined below.

1. Balloon Angioplasty for Clot Fragmentation

Balloon angioplasty has been used for the fragmentation of pulmonary emboli for several

years. This technique attempts to produce rapid restoration of the pulmonary blood flow and promote improvement in the cardiac output and reduction of pulmonary pressure (**Fig. 6**). An 88% recovery rate has been reported with pharmacological thrombolysis[3].

2. Kensey Dynamic Device

The Kensey Device was the first available flexible rotating-tip catheter and the predecessor of several generations of rotational catheters[24]. At the distal tip, there was a high-speed rotating cam which was driven at speeds of 5,000～10,000 rpm by a bedside direct current motor. This device was approved by the Food and Drug Administration for atherectomy, but is not currently available even in the United States. It was used quite successfully in an animal model; however, its use for the treatment of pulmonary thromboembolism in humans has never been reported in the literature[2].

3. Impeller Basket Device

The Impeller Basket Device consists of a flexible wire shaft inside a 7 Fr catheter, with a small impeller mounted on the wire and in the center of a self-expandable metallic basket[25]. The impeller is connected to an external electric motor, which may produce up to 100,000 rpm. The impeller creates a vortex inside the basket, causing fragmentation of the clots. The device is relatively stiff, and has been used in a limited but unreported number of human cases[2].

4. Thrombolizer

The Thrombolizer is a coaxial catheter system with a self-expandable plastic basket[26]. This in turn contains a small rotatory basket that creates a vortex, leading to thrombus fragmentation. It has been tried experimentally in animal models and was relatively successful in promoting fragmentation of pulmonary emboli. However, histopathological examinations showed periarterial and peribronchial hemorrhage in some cases. There have been no reports of the use of this tool in humans.

5. Rotatable Pigtail Catheter

The Rotatable Pigtail Catheter (William Cook Europe, Denmark) is a custom-made device that employs a modified high-torque, 5 Fr, 115-cm-long pigtail catheter. It has an oval hole in the side of the outer curvature of the pigtail loop, allowing passage of a guidewire. Clots are fragmentated by the mechanical action of the rotating pigtail tip. The guidewire allows the catheter to be advanced or withdrawn over it[27]. In a clinical study, this device showed a 80% success rate in 10 patients, producing clinical improvement and reduction of pulmonary arterial pressure, although hemodynamic stabilization was completed in combination with 48 h of thrombolysis[28].

6. Arrow-Trerotola Percutaneous Thrombolytic Device

The Arrow-Trerotola Percutaneous Thrombolytic Device is a low-speed (3,000 rpm) rotational basket used for thrombectomy in dialysis patients who have received grafts. Clinical experience with this device in massive pulmonary thromboembolism is limited[29]. Although clinical improvement was observed, the device was difficult to direct into some of the vessels being treated, and there was no improvement in pulmonary arterial pressure.

7. Amplatz Thrombectomy Device

The Amplatz Thombectomy Device is an 8 Fr reinforced polyurethane catheter with a metal tip housing an impeller mounted on a drive shaft[30]. The high speed of the impeller creates a vortex inside the vessels and macerates the thrombus. Access into the pulmonary artery is achieved through a long, 10 Fr guiding catheter. Initial experience showed clinical improvement in a limited number of patients, but there were significant difficulties with steerability.

8. Rotarex Catheter

The Rotarex Catheter is a relatively new device for the percutaneous mechanical removal of fresh and organized thrombus[31]. Experimental data support the use of this catheter for the treatment of obstructed vessels with diameters as large as 8 mm.

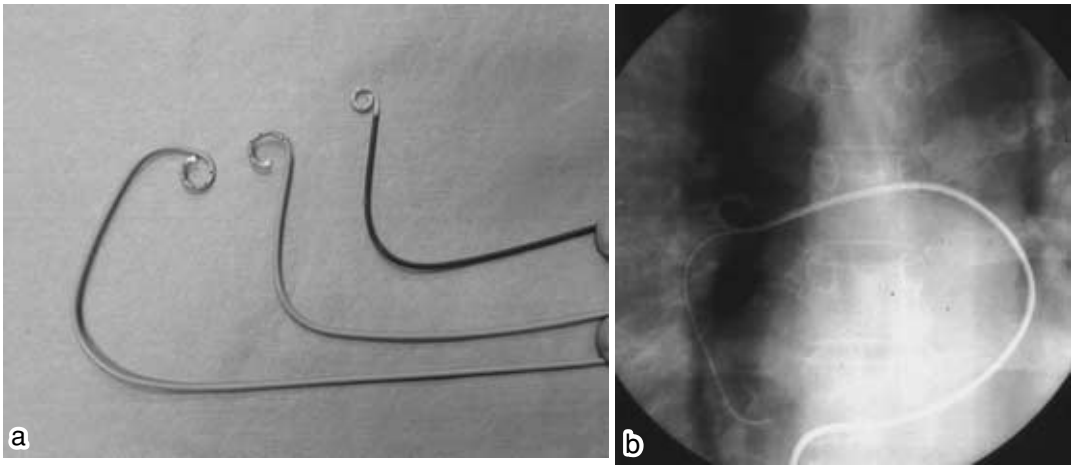

Fig. 7 Fragmentation catheter system.
(a) Pigtail catheters with different shape and pigtail diameter. (b) The modified pigtail catheter is rotated manually about the axis of the stationary guidewire, and advanced or withdrawn over the guidewire as required.

Hybrid Treatment

We have used a combined approach to thrombolysis using mechanical fragmentation, localized fibrinolysis and clot aspiration with good results[5]. This section briefly describes our work.

Procedures

A 5～6 Fr conventional curved pigtail catheter for pulmonary angiography (K-PA catheter, Medi-kit Co. Ltd., Japan) was used as the fragmentation catheter system (**Fig. 7, a**). The long guidewire was left in a peripheral site in the pulmonary artery (PA), and the proximal tip of the guidewire was inserted into the most proximal side hole of the curved pigtail catheter. The catheter was then inserted over the guidewire and through the 8 Fr PA sheath. This modified technique is easy to implement and requires no greater skill than that needed for right heart catheterization.

The emboli were fragmented by the mechanical action of the rotating pigtail catheter (**Fig. 7, b**). The catheter was rotated manually about the axis of the stationary guidewire, and advanced or withdrawn over the guidewire as required.

After fragmentation, all patients received an intrapulmonary injection of rt-PA (640×10^4IU, equivalent to 12.8 mg/64 min), followed by manual clot aspiration using a large-lumen PTCA guide catheter (8 Fr Guider-Softip, Boston Scientific, Scimed, USA). Strong manual aspiration was created by drawing back the plunger of a regular Luer-Lok 20-m*l* syringe while slowly withdrawing the catheter through the introducer sheath. During thrombolysis, all patients received heparin sodium (initial dose: 5,000 IU, maintenance dose: sufficient to maintain an activated partial thromboplastin time ratio of 2). After this treatment, additional systemic urokinase was infused on the intensive care unit to remove residual thrombi, depending on the patient's condition. The original dosing regimen was $24～48 \times 10^4$IU/day for 3 days.

Results

All 25 patients survived the procedure and their clinical status improved. Angiography in all patients after treatment demonstrated improved pulmonary perfusion (mean Miller score before treatment; 22.2; after treatment: 13.6; $p < 0.01$) (**Fig. 8**). Mean pulmonary arterial pressure decreased from 32.6 to 23.4 mmHg ($p < 0.01$). No patient had an increase in their Miller score or pulmonary arterial pressure after treatment. Mean treatment time was 124.6 min. There was no recurrent pulmonary thromboembolism after the procedure, and 23 patients were discharged after a mean of 58.5 days; 2 patients died of ovarian/lung cancers.

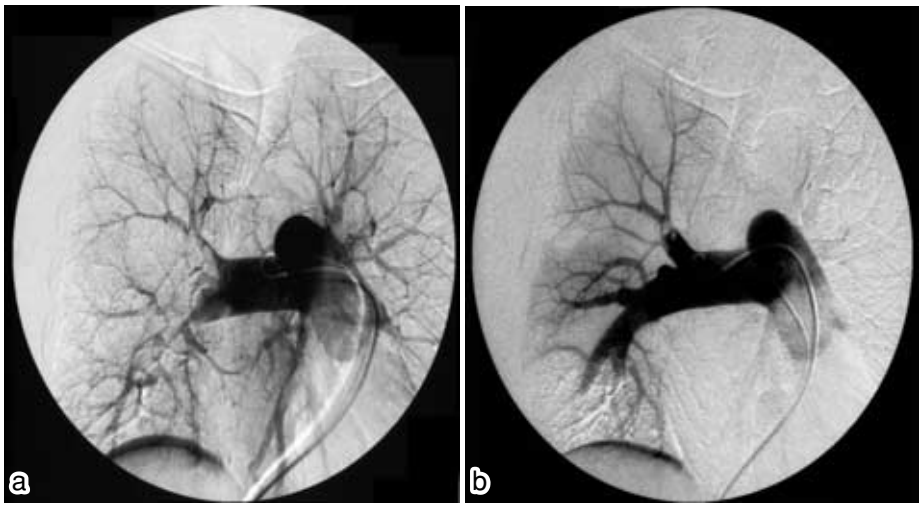

Fig. 8 Hybrid treatment of acute massive pulmonary thromboembolism.
(a) Pulmonary angiogram shows massive emboli in the right main pulmonary artery. Pulmonary arterial pressure is 58/20 (36) mmHg. (b) Improvement of perfusion is seen after the hybrid interventions. Post treatment pulmonary arterial pressure is 38/3 (20) mmHg. Total treatment time was 101 min.

Complications

Major: We experienced one case of cardiac arrest during pigtail catheter rotation. The patient was quickly intubated, and received cardiopulmonary resuscitation and catheter thrombolysis/thrombectomy. The heart was restarted 30 min after the event, and the PA pressure decreased. The patient was discharged from hospital 70 days after the procedure without further complications.

Minor: The catheter shaft broke within the sheath during catheter rotation in one patient, and was easily pulled out.

No other complications were encountered during or after the procedure.

Short Discussion

The present technique offers the possibility of a synergistic effect between mechanical fragmentation and pharmacological thrombolytic therapy because the fragmented clots provide a greater surface area on which the thrombolytic agent can work, thus improving the results of lytic activity and allowing a reduction in the total dose and infusion time[4]. There have been several previous reports of mechanical fragmentation combined with thrombolytic therapy for the treatment of massive pulmonary thromboembolism, all of which indicated rapid hemodynamic improvement[3,9,32,33]. However, the mean infusion time was reported to be 18～48 h, and the infusion had to be continued in the intensive care unit.

The aim of this hybrid procedure was to improve the patient's hemodynamic situation, and this was successfully accomplished in all cases. With an average total procedure time of 124.6 min, a high recanalization rate was rapidly achieved. Post-treatment angiography in all patients demonstrated improved pulmonary perfusion, with the mean Miller score decreasing from 22.2 to 13.6 ($p<0.01$). The results were significantly superior to those of multicenter studies using thrombolysis alone, whether catheter-directed or peripherally injected[8,10].

In a phase I clinical multicenter study, there was no significant decrease in the mean arterial pulmonary pressure immediately after fragmentation with the pigtail catheter[28]. This was explained by pulmonary vasoconstriction caused by localized release of neurohumoral factors such as endothelin. A subsequent open, prospective, multicenter study of fragmentation using a pigtail rotation catheter showed a significant decrease in the mean PA pressure from 31 mmHg before fragmentation to 28 mmHg afterwards ($n=15$, real fragmentation time 17 min)[34]. As the effect of

fragmentation by a pigtail catheter alone did not appear to be sufficient, we decided to use a hybrid approach. In our series, the mean PA pressure decreased from 32.6 mmHg to 23.4 mmHg ($p<0.01$) immediately after the use of combined mechanical fragmentation, localized fibrinolysis and manual clot aspiration. As the hemodynamic situation of the patients improved significantly, we decided to continue to use systemic urokinase therapy instead of catheter-directed thrombolysis.

In conclusion, fragmentation using a modified rotating pigtail catheter with intrapulmonary fibrinolysis and manual clot aspiration rapidly and safely produces an improvement in the severely compromized hemodynamic situation in patients with acute massive pulmonary thromboembolism. This hybrid treatment appears to be especially useful in patients at high risk of right ventricular failure, and is a minimally invasive alternative to surgical embolectomy.

Management of the patient with massive pulmonary thromboembolism requires a team approach, including the referring physicians, surgeons and interventional radiologists[22]. Expeditious use of the catheter technique for embolectomy or fragmentation immediately after angiography provides the patient with the best chance of surviving the initial impact of this life-threatening condition.

Grants: This work was supported in part by a Research Project Grant-in-Aid for Scientific Research (C) (2) (Project number 12670907), from the Ministry of Education, Culture, Sports, Science and Technology, Japan.

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(Received, October 25, 2004)
(Accepted, November 30, 2004)