Massive Pulmonary Embolism: Percutaneous Emergency Treatment by Pigtail Rotation Catheter

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OBJECTIVES

This study was designed to assess the feasibility, efficacy and safety of mechanical fragmentation of pulmonary emboli using a new rotational pigtail catheter system.

BACKGROUND

Acute massive pulmonary embolism associated with right ventricular dysfunction is frequently lethal, despite high-dose thrombolytic therapy. Adjunctive catheter fragmentation may prevent a fatal outcome.

METHODS

In 20 patients (age 58.9 ± 10.5 years) with severe hemodynamic impairment, massive pulmonary emboli were fragmented by mechanical action of the rotating pigtail. Fifteen patients received thrombolysis after embolus fragmentation or no thrombolysis at all (noninterference group).

RESULTS

Prefragmentation pulmonary arterial occlusion was 68.6 ± 11.3% for both lungs. Pulmonary placement and navigation of the fragmentation catheter was easy and rapid. Fragmentation time was 17 ± 8 min. The noninterference group showed a decrease pre- to postfragmentation of shock index from 1.28 ± 0.53 to 0.95 ± 0.38 (p = 0.011), mean pulmonary artery pressure from 31 ± 5.7 to 28 ± 7.5 mm Hg (p = 0.02) and a recanalization by fragmentation of 32.9 ± 11.8% (mean angiographic score per treated lung from 7.4 to 5.0). Overall mortality was 20%.

CONCLUSIONS

Fragmentation by pigtail rotation catheter provided for a rapid and safe improvement of the hemodynamic situation and an average recanalization of about one-third of the pulmonary embolic occlusion. The method appears useful especially in high-risk patients threatened by right ventricular failure, to accelerate thrombolysis, and as a minimal-invasive alternative to surgical embolectomy. (J Am Coll Cardiol 2000;36:375–80) © 2000 by the American College of Cardiology
Figure 1. Pigtail fragmentation catheter (with underlying rotated pigtail loop indicating a 180° turn) with a special tip configuration for embolus fragmentation; the guide wire is exiting an oval side hole distal to a radiopaque marker and serves as a directing axis crossing the embolic occlusion. During manual catheter rotation, the pigtail tip is slowly advanced and withdrawn within the occlusion over the fixed guide wire. The embolus is fragmented by mechanical action of the rotating pigtail.

was passed with the wire, the pigtail catheter was rotated manually over the fixed wire as a central axis. Under rotation, it was repeatedly advanced and withdrawn, until a sufficient fragmentation of the embolus was achieved.

Two catheter versions were tested. Version I (applied in patients 1–10) had a pigtail tip with an outer diameter of 8 mm and was embedded in a long sheath. Because of technical limitations of the fragmentation procedure in some of the patients, the design was improved. Version II (applied in patients 11–20) consisted of two catheters, one with a 12-mm pigtail for the main pulmonary arteries and one with 8-mm diameter for the lobar arteries.

In all patients, transesophageal or transthoracic echocardiography was performed before angiography to identify right heart strain, to demonstrate indirect signs of pulmonary embolism and to exclude right heart-transit thrombi. Pulmonary angiography and embolus fragmentation were carried out in a catheter laboratory near the intensive care unit (Siemens Coroskop HIP or Siemens Polytron 1000 VR; Siemens Medical Systems, Erlangen, Germany). Before central venous access from the femoral vein, femoral or ilio caval thrombosis was excluded by vascular ultrasound and ilio cavography. Selective angiography was performed pre- and postfragmentation using iopromide at 300 mg/ml (flow rate 12–15 ml/s, injected volume 25–35 ml). Subjects of treatment were emboli of the central pulmonary arteries. It was left to the investigator’s decision if both sides were treated or only the predominant side. After the procedure, a Swan–Ganz-catheter (Baxter Healthcare, Irvine, CA) was exchanged for subsequent hemodynamic monitoring. The patients were kept on intensive care unit for at least 48 h. Systemic blood pressure, heart rate and pulmonary artery pressure were recorded pre-, post-, and 48 h after fragmentation.

In 16 patients, anticoagulation was achieved with high-dose intravenous porcine heparin (Heparin-Sodium Braun; B. Braun Melsungen AG, Melsungen, Germany). Three patients received danaparoid natrium (Orgaran; Organon, Oberschleißheim, Germany) and one patient received lepirudin (Refludan; Hoechst Marion Roussel, Frankfurt, Germany) because heparin-induced thrombocytopenia was suspected and later on confirmed serologically.

Thrombolysis as the gold standard of therapy in acute massive pulmonary embolism was not restricted in any way by the study protocol. Total dose, dose distribution, starting point, and mode of delivery was left at the operator’s discretion according to the particular circumstances (cardio pulmonary status, consideration of possible contraindications) of each individual case. To analyze the influence of thrombolysis and fragmentation on the pre- to postfragmentation recanalization results, the patients were allocated to two groups. 1) Noninterference group: patients who received thrombolysis after embolus fragmentation or no thrombolysis at all. Changes in circulatory parameters and angiographic occlusion scores pre- to postfragmentation were independent of thrombolysis and therefore exclusively attributable to fragmentation. 2) Interference group: patients who received thrombolysis before or during fragmentation. Thrombolysis might have interfered with the fragmentation recanalization results.

Quantitative angiographic assessment of pre- and postfragmentation angiograms was performed by three examiners independently using the angiographic severity index for pulmonary embolism defined by Walsh et al. (10). Unilateral angiograms were graded from 0 (no clot) to 9 (entire lung affected). A synopsis of the score is given by Goldhaber et al. (11). Recanalization of the occlusion (expressed as a percentage) was calculated for each lung treated by fragmentation as follows: \([\text{score pre} − \text{score post}] / \text{score pre} \times 100\).

Circulatory stabilization 48 h after fragmentation was defined as shock index < 1, mean pulmonary arterial pressure < 25 mm Hg and systemic arterial blood pressure returned to normal values.

All statistical tests were two-sided, and a significance level of 0.05 or less was applied unless stated otherwise. Descriptive statistics included mean and SD values. All variables were tested for normal distribution with the Kolmogorov-Smirnov test. Student’s two-tailed t test was used for comparisons of paired samples. Interobserver variability was determined by reliability coefficient. Data were analyzed using SPSS 8.0 (SPSS, Chicago, Illinois).

The study was performed according to the European Standard for Clinical Investigation of Medical Devices EN 540 (13) and under observation of the Declaration of Helsinki. Approval was obtained from the local university ethics committee for each center and from an EN540-certified European institutional review board. The notified body (local government) responsible for each center was informed. Before the catheter procedure, written or verbally informed consent was obtained, if possible. However, the majority of the patients were unconscious and under respi-
rator therapy at the date of inclusion. In these cases, the ethics committee was notified about the inclusion and consent was obtained after recovery.

RESULTS

Baseline characteristics of patients at inclusion. Catheter fragmentation of pulmonary emboli was performed in 20 patients (10 female, 10 male; age 58.9 ± 10.5 years). Quantitative evaluation of the prefragmentation angiograms revealed an average pulmonary arterial occlusion of 68.6 ± 11.3% (range 56 ± 83%). Mechanical ventilation was necessary in 14 patients (70%) to cope with respiratory failure in massive pulmonary embolism. Unstable hemodynamics required medium- to high-dose catecholamines in 17 of 20 patients (85%). A shock index $\geq 1$ (1.47 ± 0.54) was present in 16 of 20 patients (80%). The other 4 of 20 patients (20%) were included with a mean pulmonary artery pressure $> 30$ mm Hg. Seven patients (35%) underwent cardiopulmonary resuscitation before fragmentation.

Fragmentation procedure. The right pulmonary artery was treated in 14 cases, the left one in 10 cases and in four patients both sides were treated (Fig. 2). Central venous access was achieved 10 times via the right femoral vein, 8

Figure 2. Sixty-six-year-old male patient with deep vein thrombosis after coronary angiography. (A and B) Prefragmentation pulmonary angiogram shows emboli in the right intermediate and upper lobe arteries (arrowheads), and in the left intermediate artery (arrowheads) with occlusion of the lower lobe artery. Shock index 1.10, mean pulmonary artery pressure 30 mm Hg. (C and D) After bilateral embolus fragmentation: partial recanalization, more pronounced on the right side. Shock index 0.59, mean pulmonary artery pressure 15 mm Hg. Intraluminal fragment (arrowhead) is in a segmental artery of the left lower lobe.
times via the right jugular vein and 1 time each via the left jugular and left femoral vein. Pulmonary placement and navigation of the fragmentation catheter was easy and rapid from all approaches. Total procedure time was 44 ± 26 min (range 8–120 min). Real fragmentation time was 17 ± 8 min (range 4–35 min).

In 16 of 20 cases, there were no technical problems with catheter handling and rotation for embolus fragmentation. However, there was an obvious mismatch between the fragmenting pigtail loop with a diameter of 8 mm and a large central pulmonary embolus (diameter 28–33 mm) in three cases treated with version I. Fragmentation achieved only marginal improvement in these cases. These problems did not occur in version II providing a 12-mm pigtail for the central arteries. In one case, the catheter (version I) was wedged in the sheath and exchanged with a new one.

In one patient with a subtotal occlusion of the right lung with a large occluding embolus in the intermediate artery protruding into the still perfused upper lobe artery, initial embolus dislocation by the fragmentation catheter produced a total occlusion of the upper lobe. Subsequent fragmentation provided for a recanalization (pre- to postfragmentation) of 38% in this case. Except for this event, there were no further procedural complications.

Pharmacologic thrombolysis. NONINTERFERENCE GROUP (15 OF 20 PATIENTS). Pharmacologic thrombolytic therapy was absolutely contraindicated in three patients with acute central nervous lesions (one cranioencephalic trauma, one cranial tumor and one postneurosurgery). Two of these three patients survived. The remaining 17 patients received thrombolysis, despite relative contraindications in 12 cases (surgery or trauma within 10 days before enrollment in 10 patients, cerebral insult within 10 days in 1 patient, 1 patient after intramuscular injection).

In 12 of 20 patients, thrombolytic therapy was started 100 ± 215 min (range 0–780 min) after the postfragmentation angiographic control and after acquisition of the postfragmentation circulatory data. The thrombolytic agents applied were plasminogen activator (Actilyse; Thomaes, Biberach, Germany) in seven cases (47 ± 15 mg) and urokinase (Urokinase HS medac; Medac, Hamburg, Germany; Rheothromb; Curasan, Kleinostheim, Germany) in five cases (1,140,000 ± 863,000 U).

INTERFERENCE GROUP (5 OF 20 PATIENTS). Five patients received thrombolytic agents 205 ± 171 min (10–480 min) before fragmentation therapy. In all five cases, fragmentation was indicated, because the patients were threatened by right ventricular failure despite thrombolysis, and without showing an angiographic recanalization improvement at inclusion. In four cases, rt-Pa was administered (92.5 ± 13 mg), and in one case, urokinase was administered (1,360,000 U).

Circulatory data. For the noninterference group, hemodynamic data pre- and postfragmentation are displayed in Table 1. Average shock index, and systolic, diastolic and mean pulmonary artery pressure decreased significantly. This positive effect continued at 48 h of follow-up (shock index 0.76 ± 0.36, mean pulmonary artery pressure 18 ± 6 mm Hg). Systemic blood pressure showed an inverse pattern with significant improvement. The heart rate did not significantly decline pre- to postfragmentation, but returned to near normal values 48 h later (88 ± 23 bpm).

Angiographic outcome. Rating of the angiograms according to the angiographic severity index was performed with good interobserver agreement (reliability coefficient 0.98). There was a significant decrease of the mean score pre- to postfragmentation in 20 patients (24 lungs) from 7.4 to 5.0. The overall mean percentage of recanalization by fragmentation was 33.6 ± 12.6%. For the noninterference group (15 patients, 19 lungs), the mean percentage of recanalization was 32.9 ± 11.8%; for the interference group (5 patients, 5 lungs), it was 36.4 ± 15.0%.

Clinical outcome. Three patients, who underwent prolonged cardiopulmonary resuscitation (average duration 57 min), died from right heart failure after fragmentation, despite a successful recanalization of 32.8 ± 8.9%.

No adverse events occurred in the remaining 17 patients within the 48-h follow-up interval. Complete circulatory restitution (systemic blood pressure returned to normal, shock index < 1, mean PAP < 25 mm Hg) at 48 h was achieved in 9 of the 17 cases, whereas pulmonary artery pressure remained elevated in 6 patients (mean 27.8 ± 2.0 mm Hg), including 1 patient with a history of pulmonary hypertension. Elevated shock indices persisted in the other two patients. Brain death was diagnosed in two patients with elevated pulmonary artery pressure 48 h after fragmentation. Cardiopulmonary resuscitation preceded fragmentation in both patients. One patient died from sepsis and multiorgan failure 14 days after intervention. Overall mortality was 20% (4/20 patients).

**DISCUSSION**

Rationale for catheter fragmentation. Reports from the literature (4–7), including our preliminary results (8,9), demonstrate that catheter fragmentation facilitates at least partial recanalization of a central embolic occlusion. Ac-

<table>
<thead>
<tr>
<th>Circulatory Parameters</th>
<th>Prefragmentation (mean ± SD)</th>
<th>Postfragmentation (mean ± SD)</th>
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<tbody>
<tr>
<td>Shock index/ BP systolic</td>
<td>1.28 ± 0.53</td>
<td>0.95 ± 0.38</td>
</tr>
<tr>
<td>Heart rate (beats/min)</td>
<td>124 ± 26*</td>
<td>111 ± 33*</td>
</tr>
<tr>
<td>PAP mean (mm Hg)</td>
<td>31 ± 6</td>
<td>28 ± 8</td>
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<tr>
<td>PAP systolic (mm Hg)</td>
<td>50 ± 13</td>
<td>45 ± 12</td>
</tr>
<tr>
<td>PAP diastolic (mm Hg)</td>
<td>22 ± 6</td>
<td>18 ± 6</td>
</tr>
<tr>
<td>BP mean (mm Hg)</td>
<td>74 ± 16</td>
<td>87 ± 15</td>
</tr>
<tr>
<td>BP systolic (mm Hg)</td>
<td>105 ± 21</td>
<td>122 ± 23</td>
</tr>
<tr>
<td>BP diastolic (mm Hg)</td>
<td>59 ± 15</td>
<td>69 ± 13</td>
</tr>
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All parameters changed significantly (p < 0.05),* except heart rate.

BP = systemic blood pressure; PAP = pulmonary artery pressure.
cording to pathophysiological considerations, fragmentation of central emboli and dislocation of the fragments to the periphery result in a relative gain of nonobstructed cross-sectional area. Peripheral pulmonary arteries at a level of 1 mm in diameter have approximately twofold the total cross-sectional area in comparison with the central pulmonary arteries (14). In patients threatened by right ventricular failure, even a small hemodynamic improvement may be life-saving and extend the critical time frame for further recanalization by thrombolysis. Moreover, the increased total surface area of the fragments may accelerate the efficacy of an accompanying thrombolysis or of spontaneous intrinsic lytic activity.

**Catheter development.** Development of technically sophisticated pulmonary fragmentation catheters with high-speed rotating impellers did not prove to be successful (15–17). Experimental animal trials revealed complex handling of these devices, difficulties in pulmonary placement and steerability, technical failures, and histological evidence of pulmonary arterial wall damage (16,17). The ideal catheter system for treatment of acute massive pulmonary embolism should be rapidly placed and well steerable. Ease of handling is an important feature, saving time and avoiding complications in an emergency procedure (18). The pigtail rotation catheter concept was chosen under the consideration that the pigtail tip is the safest configuration for probing of the pulmonary arteries (19). The pigtail tip avoids perforation and is easy to navigate into and within the pulmonary arteries. Starting out from the standard pigtail catheter design, only slight modifications were made to enable a continuous fragmentation function (8).

**Influence of thrombolysis on recanalization.** Thrombolytic therapy as the gold standard in treatment of massive pulmonary embolism was not restricted by our study protocol for ethical reasons. Therefore, results at 48 h after intervention were influenced by additional thrombolysis in 17 of 20 patients. However, we were able to demonstrate in a subgroup of 15 of our patients (noninterference group) that fragmentation alone led to a significant hemodynamic and angiographic improvement, which was the primary objective of our study. Five patients (interference group) had to be excluded regarding the assessment of recanalization by fragmentation, but were evaluable regarding feasibility and safety of the procedure.

**Comparison of study results with data from the literature.** Recanalization by fragmentation of one-third of the occlusion compares well with the current literature for thrombolysis as the medical standard therapy. Multicenter studies with actual dosing regimens report a reduction of the angiographic score after 2 h by 17.8% (urokinase) and 22.4% (plasminogen activator) (11), after 12–18 h by 30 ± 25% (urokinase) and 24 ± 18% (plasminogen activator) (20) and after 24–48 h by 33 ± 15% (plasminogen activator) and 43 ± 13% (streptokinase) (21).

According to the results of a multicenter registry, overall in-hospital mortality rate ranged from 25% for patients presenting with cardiogenic shock to 65% in patients who underwent cardiopulmonary resuscitation (2). In another study of patients with massive pulmonary embolism, the mortality in the group treated by thrombolysis was 33% (3). Our mortality rate of 20% compares well with these data and also with those of surgical pulmonary embolectomy (22), indicating that fragmentation therapy may serve as an alternative to surgery, if thrombolysis threatens to fail.

**Possible limits and shortcomings of the fragmentation technique.** Despite a successful recanalization, three of our patients died early after intervention due to intractable right heart failure. This demonstrates that fragmentation therapy after prolonged cardiopulmonary resuscitation may fail to prevent a fatal outcome.

In unfavorable situations, catheter fragmentation may initially deteriorate the situation by dislodging pulmonary emboli in still-perfused pulmonary arteries, producing an occlusion there. This event in one of our patients can be viewed as a complication of the fragmentation technique, which could be treated successfully by subsequent fragmentation. Other complications were not observed.

**Conclusions.** In contrast to our preliminary report (9), the data of the present, completed study enable us to show: 1) that the technical shortcomings encountered in our first patients were overcome, using an improved catheter design, and 2) that there is a considerable recanalization potential due to catheter fragmentation without interference of thrombolysis.

Percutaneous treatment of acute massive pulmonary embolism with the pigtail rotation catheter provided for a rapid and safe improvement of the hemodynamic situation and an average recanalization of about one-third of the pulmonary embolic occlusion. We consider this technique as a valuable contribution of the interventionalist in treatment of pulmonary embolism, offering the potential of immediate partial reperfusion. The method appears useful especially in high-risk patients threatened by right ventricular failure, to accelerate thrombolysis and as a minimally invasive alternative to surgical embolectomy.

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