### Fragmentation of Massive Pulmonary Embolism Using a Pigtail Rotation Catheter*

**Thomas Schmitz-Rode, MD; Uwe Janssens, MD; Hans H. Schild, MD; Steffen Basche, MD; Peter Hanrath, MD; and Rolf W. Günther, MD**

**Study objectives:** The purpose of this study was the evaluation of the efficacy and safety of mechanical fragmentation of acute massive pulmonary emboli with a rotatable pigtail catheter.

**Material and methods:** Ten patients (4 female, 6 male, age 53.8 ± 9.5 years) with acute massive pulmonary embolism with hemodynamic impairment were included in the study. The fragmentation catheter device (William Cook Europe A/S; Bjaerverskov, Denmark) consisted of a 5F catheter embedded in a flexible 5.5F sheath. Pulmonary emboli were fragmented by mechanical action of the recoiled rotating pigtail, while the guide wire was exiting an oval side hole proximal to the pigtail tip. In eight cases, an additional thrombolysis was performed.

**Results:** Fragmentation was successful in 7 of 10 patients. Average percentage of recanalization by fragmentation was 29.2 ± 14.0%, and 36.0 ± 10.0% exclusively of the seven successful cases. Average shock index decreased significantly prefragmentation to postfragmentation from 1.52 to 1.22 (p = 0.03) and to 0.81 48 h later (p < 0.001). Decrease of the average mean arterial pulmonary pressure prefragmentation to postfragmentation was insignificant (from 33 to 31 mm Hg, p = 0.14); further decrease within the 48 h follow-up was highly significant (from 31 to 21 mm Hg, p < 0.001) due to a synergy of fragmentation and thrombolysis (average dose 63 ± 25 mg plasminogen activator). There were no procedure-related complications. Overall mortality rate was 20%.

**Conclusion:** Fragmentation of massive pulmonary emboli with the pigtail rotation catheter achieved rapid partial recanalization in most cases, with ease of instrumentation, and without complications. Hemodynamic stabilization was completed in synergy with thrombolysis.

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**Key words:** catheters and catheterization, technology; embolism, pulmonary; fragmentation; interventional procedures; pulmonary arteries, stenosis or obstruction; thrombolysis, mechanical

**Abbreviations:** rt-PA = plasminogen activator

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Despite diagnostic improvements and advances in medical therapy, acute massive pulmonary embolism accounts for approximately 50,000 deaths per year in the United States.\(^1\) During the past three decades, the mortality rate did not decline.\(^1-3\) Patients are at highest risk of death within the first hours of onset due to right ventricular failure.\(^4-8\) Survival depends on rapid recanalization of the pulmonary arterial obstruction and reduction of the right ventricular afterload. In a number of cases, thrombolytic therapy may fail to achieve this therapeutic goal in time.

Percutaneous catheter treatment may represent an additional option for high-risk patients, in terms of a synergistic adjunct to thrombolysis as well as an alternative to surgical embolectomy. Different concepts of percutaneous treatment include catheter
embolectomy\textsuperscript{9-11} and embolus breakup with standard diagnostic and balloon catheters.\textsuperscript{12-15}

In the present study, a new percutaneous technique was evaluated, based on a rotatable pigtail catheter that can be used for pulmonary angiography and mechanical embolus fragmentation. Following experimental assessment\textsuperscript{16} and a successful first clinical application,\textsuperscript{17} the results of a phase I clinical multicenter study are presented.

Materials and Methods

Fragmentation Catheter System

The fragmentation catheter device (Schmitz-Rode T, Günther RW. Apparatus for fragmentation of a lung embolus. German patent DE G 9409863.8, US patent 5,630,823, PCT WO 95/35066) (William Cook Europe A/S; Bjaerverskov, Denmark) consisted of a coaxial combination of catheter and sheath. The nylon catheter with a 5F high-torque shaft had a radiopaque pigtail tip with an outer diameter of not more than 8 mm. In the outer curvature of the pigtail loop an oval side hole was arranged in straight projection to the axis of the catheter shaft, allowing passage of a guide wire (Fig 1, top). In the distal shaft portion, six small standard sideholes were arranged for delivery of contrast medium or thrombolytic agent. Four centimeters of the distal shaft of the catheter were curved 90°, with upturned pigtail for femoral and downturned pigtail for jugular access, hence facilitating improved probing of the right ventricle. The femoral version had a length of 115 cm, the jugular 105 cm, respectively.

The pigtail catheter was embedded in a flexible 5.5F sheath (length 90 cm for the femoral version, 80 cm for the jugular version) with a radiopaque tip marker. A y-fitting proximal to the sheath allowed adjustable tightening and sheath flushing with the catheter inserted (Fig 1, bottom).

The catheter-sheath system was used either with a 0.035-inch teflon-coated guide wire with movable core and curved tip (tip radius 1.5 mm, Cook TCMT) or with a 0.035-inch hydrophilically coated guide wire with curved tip (Cook Roadrunner PC). Both wires allowed either to exit the end hole or the oval side hole of the pigtail catheter under fluoroscopic control. End hole exit of the wire straightened the pigtail for catheter introduction, probing, and removal. Side hole exit of the wire was essential for embolus fragmentation (Fig 1, top). Since the embolic occlusion of the pulmonary artery was passed with the wire, it worked as a fixed, central axis. The pigtail catheter was rotated bimanually within the fixed sheath and over the wire axis by twisting a rough shrink tube at the very proximal end of the catheter between thumb and index finger (Fig 1, bottom). The sheath reduced friction during rotation and stabilized the access route. The rotating pigtail may be advanced or withdrawn over the wire as a guide rail as often as necessary for fragmentation of the embolus.

Study Design and Selection of Patients

This study was conducted as an open, noncomparative, prospective trial in three German centers, according to the European Standard for Clinical Investigation of Medical Devices EN 540\textsuperscript{9} and under observation of the Declaration of Helsinki II (sponsor: William Cook Europe A/S, Denmark). Approval was obtained from the local university ethics committee for each center and from an EN540-certified European institutional review board. The local government (notified body) responsible for each center was informed.

Depending on the patient's condition, written or verbally informed consent was obtained. The ethics committee was notified about the inclusion of any mechanically ventilated and sedated patient and consent was obtained as soon as possible in the clinical course.

Ten patients (4 female, 6 male, age 53.8 ± 9.5 years) from three centers were included in the study. The demographic and clinical data are given in Table 1.

Inclusion criteria were angiographically confirmed acute massive pulmonary embolism with hemodynamic impairment (pulmonary arterial occlusion > 50%, mean pulmonary artery pressure > 23 mm Hg, shock index = heart rate/systolic systemic BP > 1) and involvement of the central (main and/or lobar) pulmonary arteries. Hemodynamically stable patients and patients with exclusive involvement of peripheral (segmental/subsegmental) pulmonary arteries were excluded.

All examinations, including pulmonary angiography and the fragmentation procedure, were carried out in an ICU. Patients who showed a rapid deterioration of their cardiopulmonary condition were intubated, sedated, and put on respiratory therapy with oxygen supplementation. Positive inotropic and vasoactive support with catecholamines was supplemented according to the patient's hemodynamic condition. Prior to pulmonary angiography, bedside transthoracic or transesophageal echocardiography was performed to confirm the suspicion of pulmonary embolism and to exclude right atrial or ventricular floating thrombi. In case of thrombi-in-transit, right heart catheterization was waived. For catheter access, the protocol allowed jugular or femoral puncture, according to the preference of the examiner. However, transfemoral access was considered contraindicated in case of ilio caval or ipsilateral femoral venous thrombosis, as documented by vascular ultrasound and subsequent ilioangiography. To avoid inadvertent arterial puncture, jugular cannulation was usually performed by ultrasound guidance.

Pulmonary angiography was accomplished at a cardiologic angiography unit (Siemens Coroskop HIP; Siemens Medical Systems; Erlangen, Germany) using cine mode with a frame rate of 25/s. Initial angiography was done either with the fragmentation catheter at a flow rate of 15 mL/s or with a 7F standard pigtail catheter at a flow rate of 14 to 18 mL/s and an injected volume of 30 to 40 mL. Additional intrapulmonary checks during and after fragmentation were performed with the fragmentation catheter.

After initial bilateral angiography and confirmation of the diagnosis, the fragmentation catheter was positioned with the wire exiting the side hole. The side of predominant occlusion was treated, in one case both sides. The central part of the embolus was fragmented first, and subsequently the more peripherally located portions. After the fragmentation procedure, a Swan-Ganz catheter (Baxter Healthcare; Irvine, CA) was exchanged allowing subsequent hemodynamic monitoring. Clinical follow-up at an ICU lasted for at least 48 h.

The application of thrombolytic therapy as the gold standard 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 to the operator's decision according to the particular circumstances (cardiopulmonary status, consideration of possible contraindications) of each individual case.

Quantitative angiographic assessment of prefragmentation and postfragmentation angiograms was performed by three examiners independently using the "angiographic severity index for pulmonary embolism" defined by Walsh et al.\textsuperscript{10,12} The occluded area (expressed as a percentage) was calculated before and after treatment by the individual occlusion score for each lung related to the maximum score of 9.
Recanalization of occluded area (expressed as a percentage) was calculated as the difference between pretreatment and posttreatment occlusion, related to the pretreatment occlusion. Fragmentation success was defined as a recanalization of occluded area of ≥25%. The 48-h treatment success (including thrombolysis, if performed) was defined as circulatory stabilization 48 h after fragmentation with a shock index < 1, a mean pulmonary arterial pressure < 25 mm Hg, and a systemic arterial BP returned to normal values.

Overall treatment success was defined as the final clinical outcome of the patient (at the day of discharge from hospital), under consideration of all adverse events, which happened before or after fragmentation.

The paired Wilcoxon signed rank test was used for statistical analysis of prefragmentation and postfragmentation and 48-h follow-up data.

Results

One patient was not included in the study due to a large embolus-in-transit in the right side of the heart detected by transesophageal echocardiography. In 10 patients, catheter fragmentation of pulmonary emboli was performed (Fig 2). The right
pulmonary artery was treated in four cases, the left pulmonary artery in five cases, in one patient both sides were treated.

Seven of the 10 patients were receiving mechanical ventilation with a high fraction of inspired oxygen (0.8 ± 0.15) prior to fragmentation therapy (Table 1). Unstable hemodynamics required positive inotropic support with medium- to high-dose catecholamines in this group. Three patients underwent cardiopulmonary resuscitation (Table 1). In one patient (No. 3), a shock index >1 at the time of inclusion decreased below the level of 1 immediately prior to fragmentation, due to inotropic support. The study results are given in Tables 2–5.

Average shock index decreased significantly prefragmentation to postfragmentation from 1.52 to 1.22 (p = 0.03, Table 2) and to 0.81 48 h later (p < 0.001). The increase in systolic and diastolic systemic BP prefragmentation to postfragmentation was just beyond the level of significance (p = 0.06). Further development within the 48-h follow-up was clearly insignificant.

Systolic and diastolic pulmonary artery pressure decreased significantly prefragmentation to postfragmentation (p = 0.03 and 0.01). Within the 48-h follow-up, significant decrease continued (p = 0.02 and 0.01). However, the decrease of the average mean arterial pulmonary pressure prefragmentation to postfragmentation was insignificant (p = 0.14), whereas it was highly significant within the 48-h follow-up (p < 0.001). Development of the blood gases (PaO₂ and PaCO₂) showed no significance at all.

The catheter approach used was three times the right jugular vein and five times the right femoral vein (Table 3). In one case, the left femoral vein was chosen in a patient with right deep vein thrombosis who was wearing a stiff-neck bandage. In another patient with an obliterated right jugular vein, the left one was cannulated. The different approaches did not impair placement and handling of the fragmentation catheter.

Mean total procedure time was 41 min, with a range of 8 to 70 min (Table 3). Mean real fragmentation time was 17 min, with a range of 4 to 35 min. In 6 of 10 cases, there were no technical problems with catheter handling and fragmentation function. In three cases, there was an obvious mismatch between the fragmentation pigtail with a diameter of 8 mm and a large embolus (diameter, 28 to 33 mm) in a dilated main artery (Fig 3). Fragmentation achieved only marginal improvement in these cases (Table 3, No. 3,6,10). According to observation under fluoroscopy, the rotating pigtail tended to displace to the circumference of the large emboli without reaching out to the center. Small improvements were due to recanalization at the margin of the emboli and of obstructed lobar arteries, where the pigtail size was adequate.

In one case the catheter was wedged in the sheath, which made catheter advancement impossible. Exchange with a new catheter set allowed fragmentation as planned.

The results of quantitative evaluation of the angiograms according to the angiographic severity index are given in Table 3. Its decrease prefragmentation to postfragmentation was highly significant (p < 0.001). According to the definition of fragmentation success, three cases were refractory to this therapy (No. 3,6,10), which is equal to a success rate of 70%. The overall mean percentage of recanalization...
Figure 2. A 36-year-old male patient with traumatic fractures of the first cervical vertebra, right upper and lower leg, and thrombosis of the right femoral vein. **Top left:** Prefragmentation complete occlusion of the left pulmonary artery. **Top right:** Pigtail rotation catheter in place, from left femoral approach (right femoral thrombi, jugular approach not possible, because patient was wearing a “stiff-neck” bandage). **Bottom left:** After embolus fragmentation: partial recanalization and intraluminal fragments (arrows). **Bottom right:** Final control angiography 3 days later (central venous digital subtraction angiography) after additional thrombolysis with 70 mg of plasminogen activator.

Fractionation by fragmentation was 29.2 ± 14.0% (range, 11 to 57%). The mean percentage exclusively of the seven successful cases accounted for 36.0 ± 10.0% (range, 25 to 57%).

In 2 of 10 patients, thrombolytic therapy was absolutely contraindicated (Table 4). Additional thrombolysis with plasminogen activator (rt-PA, Actilyse; Thomaes; Biberach/Riss, Germany) was performed in the remaining eight cases (five relative contraindications, three without contraindications, Table 4). The eight patients received a mean dose of 63 ± 25 mg. Only in two of eight patients was the approved maximum dose (100 mg) administered. Bleeding complications did not occur. In a patient with heparin-induced thrombocytopenia syndrome and a large, consistent central embolus (No. 3), thrombolysis with 60 mg rt-PA failed to achieve any improvement. After subsequent fragmentation, which showed only marginal improvement, thrombolysis was continued with urokinase (Rheotromb; Curasan; Kleinostheim, Germany) for 3 days.

There were no complications related to angiography or to the fragmentation procedure. One patient (No. 9), who underwent repeated cardiopulmonary resuscitation, died from right heart failure 1 h after fragmentation, despite a successful partial recanalization. This was classified as a medical adverse event. In the other nine patients, no adverse events happened within the 48-h follow-up interval (Table 5). Circulatory restitution at 48 h was achieved in five patients, and in a further patient (No. 1), considering that the pulmonary hypertension was chronic (Table 5). This is equal
to a 48-h treatment success rate of 60%. The remaining cases did not fulfill the criteria of shock index < 1 (No. 7, 9, 10), mean pulmonary arterial pressure < 25 mm Hg (No. 3, 7, 9), and normalized systemic arterial BP (No. 9, 10). Patient 1 died from sepsis and multiorgan failure after the 48-h interval. A direct relation to residues of pulmonary embolism seemed unlikely, as a control angiography 6 days after fragmentation demonstrated completion of recanalization. Overall mortality was 20% (48-h mortality, 10%), overall treatment success accounted for 80%, including a patient with brain death (due to a cardiac arrest of unknown duration) who became an organ donor later.

### Discussion

Several approaches have been made to establish a percutaneous catheter procedure. The first dedicated device was the Greenfield embolectomy catheter, introduced in 1969.9 Despite encouraging results, the catheter device did not achieve widespread use. Possible reasons include the need of a venotomy or a large (24F) introductory sheath, special skills in steering and pulmonary placement, and part removal of embolus, with the need of repositioning and subsequent passes.10,11,14,21 In a recent study, also employing the removal-by-suction technique, similar shortcomings were observed, as clot break-off during

### Table 2—Circulatory Data

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Before</th>
<th>After</th>
<th>48 h</th>
<th>Before</th>
<th>After</th>
<th>48 h</th>
<th>Before</th>
<th>After</th>
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<td>31</td>
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<td>±0.58</td>
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<td>45</td>
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<td>25</td>
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<tr>
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<td>36</td>
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<td>29</td>
<td>27</td>
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<td>16</td>
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<td>47</td>
<td>43</td>
<td>*</td>
<td>32</td>
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<td>21</td>
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Mean ± SD: 1.52 ± 0.56 1.22 ± 0.38 0.81 ± 0.38 52 ± 8 47 ± 8 31 ± 12 33 ± 4 31 ± 5 21 ± 8 25 ± 7 21 ± 6 14 ± 7

*Death of patient.

### Table 3—Fragmentation Procedure and Angiographic Outcome Data

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Approach*</th>
<th>Procedure Time, min</th>
<th>Real Fragmentation Time, min</th>
<th>Technical Problems With Catheter</th>
<th>Angiographic Severity Index (According to Walsh et al19)</th>
<th>Recanalization in Percent of Occluded Area</th>
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</thead>
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<tr>
<td></td>
<td>Jug Fem</td>
<td></td>
<td></td>
<td></td>
<td>Prefragmentation/Postfragmentation Right Left</td>
<td>Right Left</td>
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<tr>
<td>1</td>
<td>R jug</td>
<td>60</td>
<td>15</td>
<td>No</td>
<td>7/3†</td>
<td>57</td>
</tr>
<tr>
<td>2</td>
<td>R jug</td>
<td>60</td>
<td>30</td>
<td>1. setECH 7</td>
<td>8/5†</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>R jug</td>
<td></td>
<td></td>
<td>2. set no</td>
<td></td>
<td>38</td>
</tr>
<tr>
<td>3</td>
<td>R jug</td>
<td>40</td>
<td>25</td>
<td>Mismatch§</td>
<td>9/8†</td>
<td>(11)</td>
</tr>
<tr>
<td>4</td>
<td>L fem</td>
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<td>2/4</td>
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<tr>
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<td>4</td>
<td>No</td>
<td>8/6†</td>
<td>–</td>
</tr>
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<td>R fem</td>
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<tr>
<td>9</td>
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<td>6/8</td>
<td>–</td>
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<tr>
<td>10</td>
<td>R fem</td>
<td>70</td>
<td>35</td>
<td>Mismatch§</td>
<td>9/8†</td>
<td>(11)</td>
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</table>

Mean ± SD: 41 ± 20 17 ± 9

*Jug = jugular; fem = femoral.
†Fragmentation was performed.
‡Catheter was wedged in sheath, advancement impossible.
§Pigtail too small for large embolus in dilated main artery (but adequate for lobar arteries).
||Exclusively the seven successful cases: recanalization, 36.0 ± 10.0%.
removal, especially during valve passage, and the need of several repeated passes.\textsuperscript{22}

There are a few studies describing patients with cardiogenic shock, which could be saved by perforating central emboli with guide wire and standard catheters.\textsuperscript{12–14,23} In another report, central emboli were compressed by balloon dilatation.\textsuperscript{15} Both techniques comprise fragmentation of central emboli with dispersal of the fragments to the periphery and led to partial hemodynamic improvement.

What are the possible advantages of a fragmentation therapy of central pulmonary emboli? Fragmentation of centrally located, large pulmonary emboli may lead to a partial recanalization of a complete occlusion. In comparison to the central main pulmonary arteries, the peripheral arteries at a level of 1 mm in diameter have approximately the twofold total cross-sectional area.\textsuperscript{24} In central emboli, which do not occlude completely, the dislocation of the ensuing fragments to the periphery may result in a relative gain of nonobstructed cross-sectional area.

In patients threatened by right ventricular failure, even a small hemodynamic improvement may be life-saving and enlarges the critical time frame for further recanalization by medical thrombolysis. Besides the “plug removal” and the “dislocation-to-periphery” effects, there is the effect of increased total surface area of the resulting fragments, which may cause an increased efficacy of an accompanying thrombolysis or of spontaneous intrinsic lytic activity, if thrombolysis is contraindicated.

However, the standard catheters used in the above-mentioned studies were not tailored for pulmonary arterial recanalization. A dedicated system may deliver better results.

Following these considerations, we and others have spent a great deal of effort in the development of a pulmonary fragmentation catheter, favoring technically sophisticated solutions with high-speed rotating catheter tips, especially encaged or encapsulated impellers.\textsuperscript{25–29} Animal experimental testing of these devices revealed complex handling, difficulties in pulmonary placement and steerability, technical failures, eg, breakage of the rotation axis, and histologic evidence of pulmonary arterial wall damage.\textsuperscript{25,28,29} Nevertheless, there is one report of a partially successful clinical employment of such a high-speed rotating catheter.\textsuperscript{26}

The ideal catheter system for treatment of acute massive pulmonary embolism should be rapidly placed and well steerable in all parts of the pulmonary artery system. Ease of handling is an important feature, saving time and avoiding complications in an emergency procedure.

The pigtail rotation catheter concept was chosen under the consideration that the pigtail tip is the safest configuration for probing of the pulmonary arteries.\textsuperscript{30,31} The pigtail tip avoids perforation and allows easy manipulation 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.\textsuperscript{16}

Experimental testing of the pigtail rotation catheter in dogs confirmed ease of handling and pulmonary steerability. Clot fragmentation was coarse compared with the pulverization achievable by impeller catheter treatment,\textsuperscript{16,27} but this seemed acceptable in consideration of the clinical goal to accomplish a partial but rapid recanalization for reduction of the right ventricular load.

Average degree of experimental recanalization of the pulmonary arteries was 53 ± 21%.\textsuperscript{16} In comparison, quantitative evaluation of the angiograms of the present clinical study showed an overall average percentage of recanalization prefragmentation to postfragmentation of 29.2 ± 14.0%, with exclusion of the three “unsuccessful” cases 36.0 ± 10.0%, respectively. While experimental results were obtained by fragmentation of nonorganized “fresh” thrombus, clinical procedures had to deal with partly or completely organized emboli, less prone to fragmentation. This explains the lower recanalization rate observed.

In comparison, Timsit et al\textsuperscript{11} reported a recanalization rate of 15.4% (decrease in Miller index from 26/34 to 22/34) for the catheter embolectomy procedure in 11 of 18 patients (“success group,” excluding the unsuccessful cases).

With an average total procedure time of 41 min and an average real fragmentation time of 17 min, the recanalization rate achieved by pigtail fragmentation was rapidly accomplished and compares well with the results given in the 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% (rt-PA),\textsuperscript{32} after 12 to 18 h by 30 ± 25% (urokinase) and 24 ± 18% (rt-PA),\textsuperscript{33} and after 24 to 48 h by 33 ± 15% (rt-PA) and 43 ± 13% (streptokinase).\textsuperscript{34}

Hemodynamic response of partial recanalization is expressed by the significant decrease in average shock index prefragmentation to postfragmentation. A further decrease within the 48-h interval has to be attributed to the synergy of fragmentation and thrombolytic therapy in 8 of the 10 cases. The average dose administered was below the approved maximum dose and bleeding complications did not occur. Although this should not be overinterpreted with regard to the small number of cases, it might indicate the possibility of dose reduction and reduction of complications in a combined synergistic therapy scheme of fragmentation and thrombolysis.
### Table 4—Medical Therapy Data

<table>
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<th>Patient No.</th>
<th>Heparin Dose, IU, Initial + Maintenance/d</th>
<th>Contraindication to Thrombolysis Treatment</th>
<th>Thrombolytic Agent Used</th>
<th>Thrombolysis Total Dose, mg</th>
<th>Time Relation to Fragmentation</th>
<th>Mode of Application</th>
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<tr>
<td>1</td>
<td>15,000 + 25,000</td>
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<td>rt-PA</td>
<td>100</td>
<td>55 min before</td>
<td>IV</td>
</tr>
<tr>
<td>2</td>
<td>5,000 + 25,000</td>
<td>Relative: recent abdominal surgery (5 d ago)</td>
<td>rt-PA</td>
<td>40</td>
<td>13 h after</td>
<td>IV</td>
</tr>
<tr>
<td>3</td>
<td>—*</td>
<td>Relative: fractures</td>
<td>rt-PA/urokinase</td>
<td>60/170,000 U/h</td>
<td>1 d before/3 h before (3 d)</td>
<td>IV</td>
</tr>
<tr>
<td>4</td>
<td>—*</td>
<td>Relative: fractures</td>
<td>rt-PA</td>
<td>70</td>
<td>Following fragmentation</td>
<td>IV</td>
</tr>
<tr>
<td>5</td>
<td>0 + 24,000</td>
<td>No</td>
<td>rt-PA</td>
<td>60</td>
<td>5 min after</td>
<td>Catheter</td>
</tr>
<tr>
<td>6</td>
<td>3,000 + 19,200†</td>
<td>No (surgery 2 wk ago)</td>
<td>rt-PA</td>
<td>22.5</td>
<td>90 min after</td>
<td>Catheter</td>
</tr>
<tr>
<td>7</td>
<td>7,500 + 21,600</td>
<td>Absolute: cranial surgery 1 d before</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>8</td>
<td>0 + 25,000</td>
<td>Absolute: fresh cranial trauma</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>9</td>
<td>5,000 + 0</td>
<td>Relative: cranial surgery (10 d ago)</td>
<td>rt-PA</td>
<td>100</td>
<td>10 min before</td>
<td>IV</td>
</tr>
<tr>
<td>10</td>
<td>5,000 + 25,000</td>
<td>Relative: infarction medial cerebral artery</td>
<td>rt-PA</td>
<td>50</td>
<td>Following fragmentation</td>
<td>Catheter</td>
</tr>
</tbody>
</table>

*Confirmed HIT.
†HIT on third day after fragmentation.

Systolic and diastolic pulmonary artery pressure decreased slightly but significantly prefragmentation to postfragmentation. However, in average, there was no significant decrease of the mean arterial pulmonary pressure. This was mainly due to a case with only marginal angiographic improvement after fragmentation and two other cases with angiographically proven recanalization and decrease of shock index, but unchanged or slightly increased pulmonary arterial pressure values. Enhanced right cardiac output might be responsible. Another explanation may be pulmonary vasoconstriction.

### Table 5—Clinical Outcome Data

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>Preexisting Cardiopulmonary/eurologic Deficits</th>
<th>Deficits Acquired Within 48-h-Interval</th>
<th>Circulatory Restitution at 48 h*</th>
<th>Deficits Acquired After 48-h Interval</th>
<th>Final Restitution/ Clinical Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pulmonary hypertension</td>
<td>—</td>
<td>Complete, (except pulmonary hypertension)</td>
<td>Sepsis + multi-organ failure (14 d after fragmentation)†</td>
<td>Death</td>
</tr>
<tr>
<td>2</td>
<td>—</td>
<td>—</td>
<td>Complete</td>
<td>—</td>
<td>Complete</td>
</tr>
<tr>
<td>3</td>
<td>—</td>
<td>—</td>
<td>Incomplete, elevated pulmonary pressure, thrombolysis continued</td>
<td>—</td>
<td>Complete</td>
</tr>
<tr>
<td>4</td>
<td>—</td>
<td>—</td>
<td>Complete</td>
<td>—</td>
<td>Complete</td>
</tr>
<tr>
<td>5</td>
<td>—</td>
<td>—</td>
<td>Complete</td>
<td>—</td>
<td>Complete</td>
</tr>
<tr>
<td>6</td>
<td>Right bundle block</td>
<td>—</td>
<td>Complete</td>
<td>—</td>
<td>Complete</td>
</tr>
<tr>
<td>7</td>
<td>Brain death (cardiac arrest of unknown duration)</td>
<td>—</td>
<td>Incomplete, circulation stable, but elevated pulmonary pressure</td>
<td>—</td>
<td>Circulation stable organ donor</td>
</tr>
<tr>
<td>8</td>
<td>Right heart insufficiency</td>
<td>—</td>
<td>Complete</td>
<td>—</td>
<td>Complete</td>
</tr>
<tr>
<td>9</td>
<td>Death (1 h postfragmentation)</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Death</td>
</tr>
<tr>
<td>10</td>
<td>Left hemiparesis</td>
<td>—</td>
<td>Incomplete, shock index elevated, catecholamines continued</td>
<td>—</td>
<td>Complete (except neurologic deficit)</td>
</tr>
</tbody>
</table>

*According to the criteria: systemic BP normalized, shock index < 1, mean pulmonary artery pressure < 25 mm Hg.
†Control angiography 6 days after fragmentation showed complete recanalization.
caused by a local release of neurohumoral factors such as endothelin. In comparison to our result, a multicenter study of thrombolytic therapy found a zero reduction of pulmonary pressure 2 h after start of infusion. However, Uflacker et al. reported a considerable increase in pulmonary artery pressure after mechanical thrombectomy with the Amplatz catheter in three of four cases, which may support the theory of local vasoconstriction.

Within the 48-h follow-up interval, mean pulmonary artery pressure showed a significant decrease, which is again an effect of fragmentation in concert with medical (or intrinsic) thrombolysis.

Development of PaO₂ and PaCO₂ were insignificant during fragmentation as well as in the 48-h follow-up, which might in part be due to different degrees of O₂ respirator concentrations used.

The different venous approaches did not impair placement and rotation function of the fragmentation catheter. Manual rotation proved to be sufficient for embolus break-up and obviated the need of the motor unit used in experimental testing, with the advantages of a direct tactile response and better visual correlation of the pigtail movement under fluoroscopic observation. The technical problems that occurred in this study were considered for design improvements for a new catheter version for the phase II study. An important feature is the increase in pigtail diameter and shaft size, which seems to be necessary for mechanical destabilization of large emboli in enlarged central arteries, and might improve the fragmentation results of the present study.

Our success and mortality rates compare favorably with those of surgical pulmonary embolectomy, indicating that fragmentation therapy may serve as an alternative to surgery, if thrombolysis threatens to fail. They are also comparable with similar percutaneous procedures reported in the literature. For the catheter embolectomy procedure, Greenfield et al. reported a 30-day survival rate of 70% and Timsit et al. reported an overall long-term survival rate of 72%.

CONCLUSIONS

This preliminary clinical study suggests that percutaneous treatment of acute massive pulmonary embolism with the pigtail rotation catheter may represent a new option, especially in emergency patients threatened by right ventricular failure, as an adjunct to thrombolysis and as an alternative to surgical embolectomy. The procedure may be also useful outside the ICU. The concept is simple, does not require special skills, can be rapidly accomplished, joins closely with diagnostic angiography, without the need for a catheter exchange, and did not show any device- or procedure-related complications. Central pluglike occlusions seem to be most suitable for fragmentation. However, our results
clearly demonstrate that fragmentation recanalizes only parts of the occlusion.

Possible drawbacks of the fragmentation concept include cases with complete embolic “cast,” including the periphery of the pulmonary arteries,36 emboli in dilated central arteries with a relative small periphery in chronic pulmonary arterial hypertension, consistent organized emboli, not prone to fragmentation, and pulmonary vasoconstriction, probably due to mechanically induced neurohumoral mediator release, which is still subject of investigation.

A phase II study including additional centers and with an improved catheter design (increased shaft diameter, different pigtail sizes for main and lobar pulmonary arteries, and an improved rotation technique) is underway.

REFERENCES