Laboratory Investigations

In Vitro Evaluation of a Rheolytic Thrombectomy System for Clot Removal from Five Different Temporary Vena Cava Filters

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Abstract

Purpose: To evaluate the feasibility of thrombus removal from temporary vena cava filters using a rheolytic thrombectomy device and to assess the embolization rate of this procedure.

Methods: Five temporary vena cava filters together with porcine thrombi were placed in a vena cava flow model (semitranslucent silicone tube of 23 mm diameter, pulsatile flow at a mean flow rate of 4 L/min). A rheolytic thrombectomy system (Hydrolyser) was used with a 9 Fr guiding catheter to remove the clots. The effluent was passed through filters of different size and the amount of embolized particles as well as the remaining thrombus were measured.

Results: Thrombus removal rates ranged from 85% to 100%. Embolization rates between 47% and 60% were calculated for the different filters.

Conclusion: The Hydrolyser is able to remove sufficiently high amounts of thrombus from temporary vena cava filters. However, the amount of embolized particles makes it impossible to utilize this method without special precautions against embolization.

Key words: Vena cava filters, temporary — Thrombectomy, rheolytic — Embolism, pulmonary — Vena cava filters, retrieval of

Temporary vena cava filters have proved to be an effective prophylaxis for pulmonary embolism, performing as well as or even better than permanent filters [1–7]. The concept of retrievable vena cava filters is very appealing, since in a considerable number of the 18% of patients receiving permanent filters prophylactically [8], permanent filter placement might be spared. Except for the Günther Tulip filter all temporary filters we tested have to be removed [9]. For these cases even partial thrombosis of the temporary filter represents a problem [10–12] which has to be solved before removal. If thrombus is demonstrated within the filter, lysis, aspiration thrombectomy, placement of a permanent filter above the temporary one, and surgery have been performed in order to prevent embolization during filter retrieval [2, 13].

The first in vitro experiments have proved that rheolytic thrombectomy devices can be used for thrombolysis in large-diameter vessels, if they are steered via a guiding catheter [14]. On that basis, this method may have potential as a treatment modality for thrombosed temporary vena cava filters. The objective of this study was to test the feasibility of removing thrombus material from temporary filters using a rheolytic thrombectomy device, and to assess the embolization rate of this procedure.

Materials and Methods

The Hydrolyser (Cordis Europe, Roden, The Netherlands), a 7 Fr double-lumen catheter with an oval side-hole 6 mm in diameter, was used as the rheolytic thrombectomy device (Fig. 1) (available in Europe, FDA approval pending). Saline solution is injected into the main lumen of the catheter via a coaxial channel 0.6 mm in diameter. Exploiting the Venturi effect a negative pressure gradient is created around the oval side-hole. This pressure is directed into the exhaust lumen of the catheter thereby sucking the fragmented thrombus material into the exhaust lumen and removing it from the circulation. A conventional angiographic injector (Mark V; Medrad, Maastricht, The Netherlands) supplied the pressurized saline solution. The recommended injection parameters were used: 4 ml/sec flow rate, 750 psi maximum pressure. Steering of the Hydrolyser was accomplished by a 9 Fr multipurpose guiding catheter (Cordis). This guiding catheter was used instead of the usual 0.025-inch guidewire because it has been shown that clot removal from large-diameter vessels is possible applying this method [14]. So far the standard indication for the Hydrolyser is limited to vessel diameters of 8 mm or less.

The following temporary vena cava filters were tested: Temporary Günther (Cook Europe, Bjaeverskov, Denmark), Günther Tulip (Cook), LGT (Braun, Melsungen, Germany), RF02 (Cordis), Anthéor
Table 1. Amount of saline solution used for thrombectomy, clot removal rate, and amount of embolized particles above 1000 \( \mu \text{m} \) and 100 \( \mu \text{m} \) for the different temporary vena cava filters (standard deviations in brackets)

<table>
<thead>
<tr>
<th>Filter type</th>
<th>Saline solution (ml)</th>
<th>Clot removal rate (%)</th>
<th>Embolus &gt; 1000 ( \mu \text{m} ) (%)</th>
<th>Embolus &gt; 100 ( \mu \text{m} ) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary Günther</td>
<td>340 (80)</td>
<td>93 (5)</td>
<td>20 (9)</td>
<td>18 (10)</td>
</tr>
<tr>
<td>Günther Tulip</td>
<td>220 (65)</td>
<td>100</td>
<td>38 (13)</td>
<td>9 (4)</td>
</tr>
<tr>
<td>LGT</td>
<td>350 (85)</td>
<td>85 (9)</td>
<td>38 (21)</td>
<td>14 (10)</td>
</tr>
<tr>
<td>RF02</td>
<td>230 (77)</td>
<td>100</td>
<td>29 (7)</td>
<td>12 (3)</td>
</tr>
<tr>
<td>Anthéor TC</td>
<td>300 (85)</td>
<td>100</td>
<td>37 (10)</td>
<td>17 (6)</td>
</tr>
</tbody>
</table>

TC (Boston Scientific, Watertown, MA, USA) (Fig. 2). All filters are commercially available in Europe.

The different filters were placed in a flow model, in which a semitranslucent silicone tube with an inner diameter of 23 mm served as model for the inferior vena cava. A centrifugal pump supplied a flow rate of 4 L/min. Using a roller pump with a frequency of 70 cycles/min this constant flow was modified to a pulsatile pattern, resulting in pressure deviations of 4–10 mmHg.

Cylindrically shaped clots (ranging from 2 to 3.5 cm \( \times \) 1 cm) were cut out of a solid block of thrombosed porcine blood that had been stored at 4°C for 5–7 days. For each experiment three single clots were introduced into the flow model and captured by the filters. The average weight of these three clots was 2.66 g (range 2.2–3.1 g).

Downstream of the vena cava filters two polyethylene filters (Schweizer Seidengarne, Zürich, Switzerland) with a mesh width of 100 \( \mu \text{m} \) and 1000 \( \mu \text{m} \) were installed to catch the particles that were embolized during the thrombectomy.

For each vena cava filter 10 rheolytic thrombectomies were performed under visual control. A maximum of 400 ml saline solution was used per rheolytic procedure. Knowing the weight of the inserted thrombus, of the empty vena cava model, and of the polyethylene filters, it was possible to calculate the clot removal rate by measuring the weight of the vena cava filters and the polyethylene filters together with the thrombus material after thrombectomy.

The amount of embolized particles and the thrombus removal rate of the different filters were compared by calculating \( p \) values with a Wilcoxon test for paired samples. The initial thrombus weight was tested for differences by a chi-squared test.

Results

Efficiency of Thrombus Removal

The average clot removal rate ranged from 85% for the LGT filter and 93% for the Temporary Günther filter to 100% for the other three filters (Table 1). Applying the Wilcoxon test for paired samples there was a statistically significant \( (p < 0.05) \) difference between the clot removal rate of the LGT and the Temporary Günther filter. The differences in clot removal rates between the LGT and Temporary Günther filter on the one hand and the Günther Tulip, Anthéor TC, and RF02 filters on the other were also statistically significant \( (p < 0.05) \).

Embolized Particles

Table 1 gives the amount of particle embolization as a percentage of the initial thrombus weight for emboli above 1000 \( \mu \text{m} \) and 100 \( \mu \text{m} \). These data are shown graphically in Figure 3. Applying the Wilcoxon test for paired samples for all combinations of different filters,