IN-VITRO STUDY OF FILTERING EFFICIENCY IN VENA CAVA FILTERS

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Abstract. *Inferior vena cava filters are used in order to avoid pulmonary embolism. Three commercial vena cava filters were evaluated for their clot trapping efficiency and pressure loss due to insertion of blood clots. An in vitro flow circulation system was built with a simulated inferior vena cava. Blood thrombi were made from fresh bovine blood and cut into different lengths. Blood clots were inserted in the system and the clot trapping efficiency was measured by computing the clots trapped by the filters. Pressure loss was measured with an open manometer as clots were inserted in the system. Results indicate a notable increase in efficiency as longer clots are used in the experiments. For a larger number of blood clots (>30) a strong decrease in filter efficiency is observed. There was no difference in the pressure loss measured for the first ten clots among the filters tested and a higher pressure was measured for larger number of captured thrombi. In conclusion, we have found no significant difference in the clot trapping efficiency among the filters but different values for the pressure loss and clot trapping efficiency for larger numbers of captured thrombi.*

Keywords*: pulmonary embolism, inferior vena cava filters, clot trapping efficiency, pressure loss.*

1. INTRODUCTION

Pulmonary embolism (PE) is a potential deadly disorder caused by migration of blood clots and subsequent occlusion of a pulmonary artery. In the USA, over 200,000 fatal cases of PE are registered every year (Horlander, 2003). Inferior vena cava (IVC) filters have been used to prevent PE by mechanical trapping of dislodged thrombi in cases of failed or contra-indicated anticoagulation treatments for patients with deep venous thrombosis (Kaufman, 2009; Hammond, 2009; Aziz, 2010). Several characteristics have been recognized for an ideal IVC filter as: high filtering efficacy with no impedance of flow, non thrombogenic and retrievable (Kinney, 2003). Despite the presence of several inferior vena cava filters in the market it is stated that the ideal filter has not yet been developed (Kinney, 2003; Lorch, 2002). Thus, a crucial factor in selecting a vena cava filter is how efficiently a filter can capture risky thrombi.

Clinical trials are usually the last stage in the medical product development process, however, these studies have limitations, especially for the numerous different clinical variables encountered among patients, which makes results comparison difficult (Becker, 1992). In order to have a more stable condition, we have developed an experimental set-up for the evaluation of inferior vena cava filters. In this experiment the clot trapping efficiency of three commercial filters was studied. The filters are: Günther Tulip (Cook Medical Inc., Bloomington, IN, USA), Optease (Cordis Corporation, Bridgewater, NJ, USA) and Braile (Braile Biomédica, Ribeirão Preto, Brazil).

2. MATERIAL AND METHODS

2.1 In vitro model

The in vitro model consists of four components: 1) circulation system, 2) IVC model, 3) thrombi insertion section and 4) manometer (Fig. 1). The circulation system is driven by a physiologic flow simulator pump (PhysioPulse 100, Shelley Medical Imaging Technologies). The pump is computer controlled and allows precise flow regulation. The simulated IVC model is made of round, transparent Tygon® tubing (Saint Gobain, Les Miroirs, Courbevoie, France). Its inlet is connected to the insertion section, that is a glass bifurcation simulating the confluence of the iliac veins having a side-port for thrombi insertion without interruption of flow.

An open manometer is used to measure pressure immediately before and after the test section. Static pressure at location is maintained at 10-15 cmH2O by adjusting the height of outflow port.

The blood is simulated by a 32 % (mass) solution of glycerin. The density of this working fluid is 1,07 g/cm3 and its viscosity is 2,51 Pa.s which corresponds to that of blood (Waite and Fine, 2007, p. 15).

Thrombi were made from fresh bovine blood inserted in 3 and 5 mm round glass tubes and allowed to coagulate within 24 hours. The filled glass tubes were refrigerated at 4 ºC prior to use.

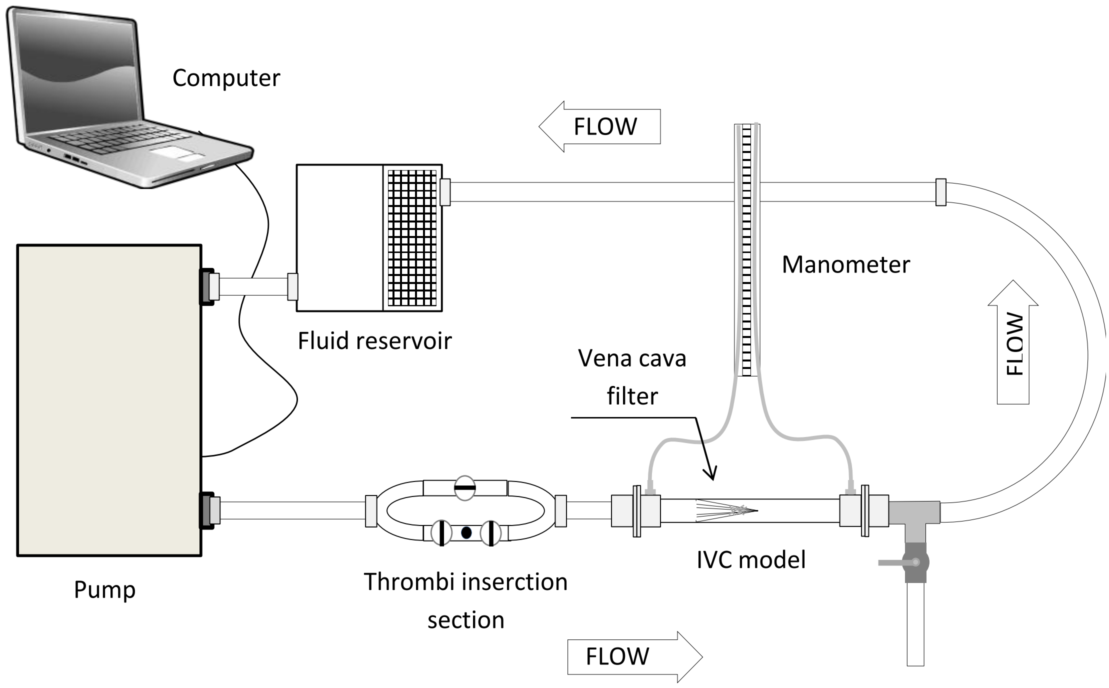

Figure 1. In vitro model for inferior vena cava filter testing.

2.2 Experimental parameters

All three vena cava filters were tested in an ideal nontilted horizontal position of the flow model in a 28 mm IVC tube. A constant fluid flow of 2 lpm is used during the efficiency and pressure tests. The 3 mm diameter thrombi were cut in length of 6, 11, 16 and 21 mm and used for the efficiency tests. The 5 mm diameter thrombi were cut in 35 mm length for the efficiency and pressure tests.

2.3 Testing protocols

2.3.2 Filter efficiency

Ten clots of the same size were serially introduced into the system and their progress was observed. A clot was considered captured when it was retained in the filter for at least one minute. Capture was recorded independently for each clot in a sequence and the total of clots retained in the filter after each run was computed. The test was repeated 10 times for every combination of filter and clot size (3x6; 3x11; 3x16; 3x21 mm).

2.3.1 Pressure loss and sequential test

Up to fifty clots were sequentially introduced into the system as the pressure change was computed for every captured clot. The test was interrupted when one of the situations occurred: fifty clots were introduced; the pressure loss was higher than 20 cmH2O; the filter did not capture any clot in a sequence of ten clots; the filter migrates until the end of the test section. The test was repeated three times for every filter.

The sequential test is the efficiency for the first ten introduced clots compared to the total number of clots introduced during the pressure loss protocol.

3. RESULTS AND DISCUSSION

3.1 Efficiency measurements

The in vitro clot trapping efficiency of the three vena cava filters are presented in Fig. 2 and Fig. 3.

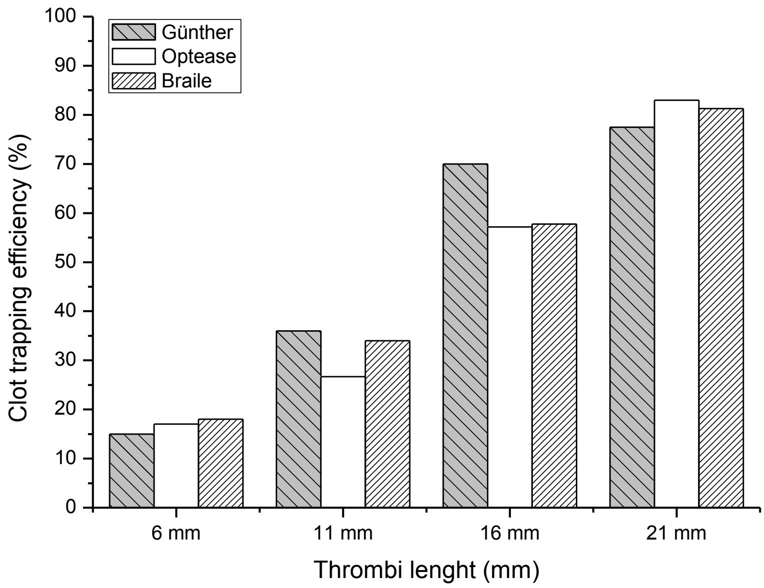

Figure 2. Filter efficiency of the tested vena cava filters.

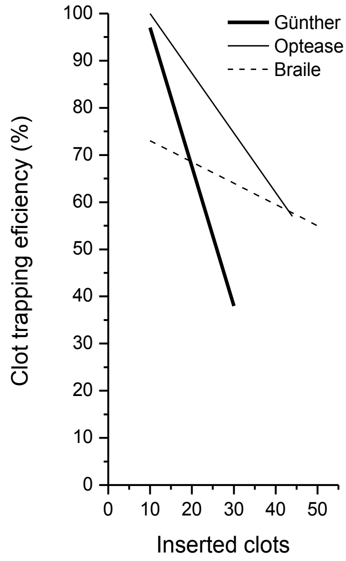

Figure 3. Sequential filter efficiency for the tested vena cava filters.

There is notable difference of efficiency according to the length of the blood clots as shown in Fig. 1. Braile filter was most effective (18%) when tested with 6 mm thrombi. For 11, 16 and 21 mm efficiency was 34, 58 and 81% respectively. Optease had the best efficiency for the longest clots (83%) and 57, 27, 17% efficiency as thrombi decreased in length. Günther had the best performance for 11 and 16 mm clots (36 and 70% respectively) and efficiency of 78 and 15% for 21 and 6 mm clots. It is observed a variation of efficiency according to blood clot length. However results don't indicate important difference of efficiency when filters are compared for the same test conditions.

The length of the clots directly affects the filter efficiency since clot hydrodynamics is altered as its length increases. There is a tendency of clots to drape more easily around the filter structures because of a possible transverse clot orientation at the moment of the impact with the filter. It was observed that clots that reach the filter in a parallel orientation to the flow tend not to be captured by the filter.

Several experimental studies have been conducted to evaluate the vena cava filters mentioned in this study (Xian, 1995; Lorch, 2002; Stoneham, 1995; Braile, 2005). However, results cannot be compared or extrapolated from one study to another since a standardized experimental protocol has not yet been defined.

Although the exact number and size of thrombi proved to be human lethal is not identified, it is known that large thrombi (> 7 mm) are easily captured by vena cava filters. In order to perform a comparative study we used the 3 mm thrombi, which associated with a large size of vena cava (28 mm) and low flow velocity (2 L/min.) simulate a critical condition for clot capture. A good filter performance in these conditions indicates better results with more favorable parameters.

Figure 3 shows clot trapping efficiency for the first ten and for all clots inserted (5 mm thrombi). All filters had a great decrease in clot trapping ability as efficiency was computed from all inserted clots. Günther and Optease had a high efficiency for the first ten clots (100 and 97%, respectively) while Braile was 73% efficient. As efficiency was calculated for all inserted thrombi, efficiencies decreased to 38% (Günther), 55% (Braile) and 57% (Optease). These findings indicate poor filter efficiency in the presence of a large thrombic load. The same pattern was noted by Xian et al (1995). We observed that as the capture section was being fulfilled a high velocity flow channel was created where the subsequent thrombi were preferentially passing through. As early this channel was created the steepest was the slope of the curves which indicate the inability of the filter to capture high volumes of thrombi.

3.1 Pressure measurements

Figure 3 shows pressure loss measured for the vena cava filters.

As expected, pressure loss was higher as more thrombi were captured. For all filters there is no significant difference in pressure loss until ten or less thrombus were captured. However, a significant difference was noted as filters were able to capture more than ten clots. Higher pressure measurements were registered for Optease filter as the maximum pressure was 15.3 cmH2O for 22 captured clots. Braile filter reached a pressure of 9.1 cmH2O maximum for 27 captured clots. Günther was able to capture only 11 clots as ten sequential inserted clots were not captured. Maximum pressure in this condition was 2.0 cmH2O. An influence of the filter in pressure measurements was noted for the test.

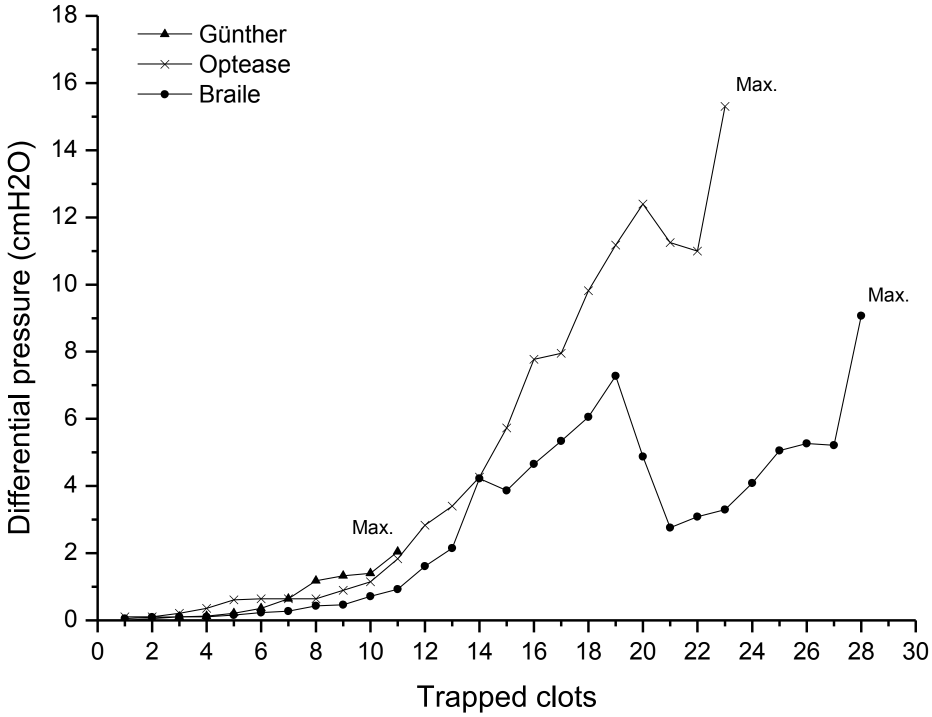

Figure 4. Differential pressure caused by clot insertion for the tested vena cava filters.

It is notable that no significant difference was observed for the clot trapping efficacy of the vena cava filters. However as blood clots volume increased (>30) there was a difference in efficiency and pressure loss measured for all three tested vena cava filters.

4. CONCLUSION

The efficiency of all tested vena cava filters decreased as shorter clots were used. As length of thrombi influences efficiency of vena cava filters, filters might not be efficient to prevent pulmonary embolism caused by numerous small clots. Filters also showed a drastically decrease in efficacy when a large embolic load was used, and differential pressure increased as clots were inserted in the test section, which restricts the use of these vena cava filters in patients in advanced stages of deep venous thrombosis.

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6. RESPONSIBILITY NOTICE

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