

Basic Science Review

Large Tube Section Is the Key to Successful Coronary Thrombus Aspiration: Findings of a Standardized Bench Test

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Thrombus removal by aspiration is one of the adjunctive techniques used to avoid embolization during PCI for acute myocardial infarction. Numerous devices are now available, but little is known about the mechanical rationale used in comparing them. The aim of the present study was to determine parameters to obtain optimal thrombus aspiration (TA). Heparin- and antiplatelet-free blood samples were aspirated into 3 mm diameter standardized glass tubes to create a 30 mm long thrombus. Thrombus formation took place at room temperature over a period of 6 or 12 hr. Various catheters were tested using a variable vacuum device: three with right-angle distal tip (0.038", 0.067", and 0.070") and one with a beveled distal (length of the beveled, 0.054"; inner diameter catheter, 0.040"). The single endpoint was complete thrombus aspiration. A total of 103 TAs were presented for the four catheters. For 6- or 12-hr-old thrombus for a given catheter, there was no significant difference in vacuum pressure required to succeed TA ($P = 0.47$). For 6- or 12-hr-old thrombus, the larger the contact area is, the lower the pressure needed to aspirate the thrombus. Moreover, a beveled distal tip length (0.054") does not make it possible to succeed TA at a lower pressure. The main factor for successful TA for thrombi ≥ 6 hr is inner diameter and not immediate thrombus contact area. © 2006 Wiley-Liss, Inc.

Key words: embolism; aspiration; thrombus; catheter; device

INTRODUCTION

Restoring flow in the culprit coronary artery must be the main objective in the treatment of patients with acute myocardial infarction (MI) [1,2]. However, the objective must also include reperfusion of the myocardium at risk. A major complication of percutaneous intervention at the acute phase of MI is the no-reflow phenomenon. This is inadequate flow in cardiac tissue despite reopening of the epicardial artery and is due to a number of factors, including microvascular disruption, endothelial dysfunction, myocardial edema, and plugging or embolization by thrombotic or atheromatous debris [3,4]. In 15% of cases, angiograms reveal distal embolization following successful primary angioplasty performed at the acute phase of MI [5]. This macroscopic phenomenon is associated with a worse long-term prognosis [5].

The clinician has two principal weapons in his therapeutic arsenal to prevent embolization: pharmacological therapy and/or aspiration techniques, and lesion-

specific intervention techniques with direct stenting and single inflation [6]. Many aspiration devices are now available, but little is known about the mechanical rationale used in comparing them. A number of technical characteristics, namely, the length between the ostium and the distal tip, the distal inner lumen, the shape of distal tip, the value of negative pressure, and the aspiration time, influence the quality of aspiration. The aim of the present study was to determine parameters to obtain optimal thrombus aspiration (TA).

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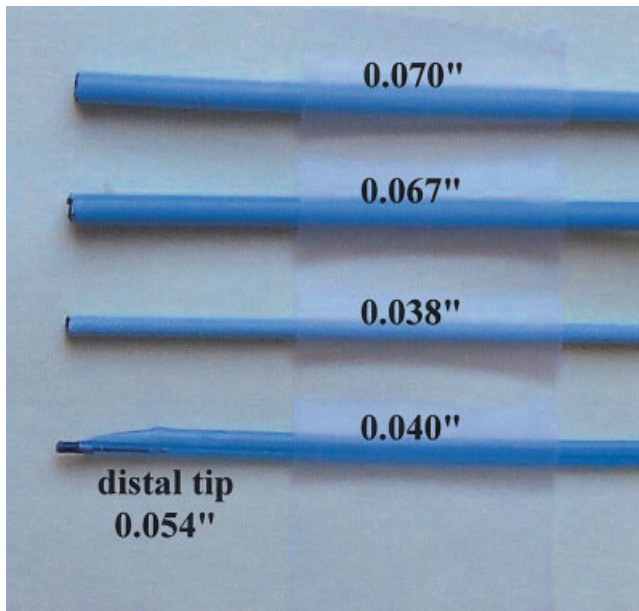


Fig. 1. Photographs of the four distinct catheters tested in our study. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com].

MATERIALS AND METHODS

Samples of blood (10 cc) were taken from fasting healthy subjects who were not following any treatment and had specifically not taken aspirin or NSAIDS during the previous month. The untreated blood samples were put into 3 mm diameter glass tubes to create 30 mm long thrombi. Six and 12-hr-old thrombi that had formed at room temperature were used. The aspiration system was controlled by a manual manometer (range, 0–500 mbar) linked to an air-tight flask into which the thrombus was aspirated.

The catheter was connected to the aspiration system and the tip placed in direct contact with the thrombus by visual assessment. The catheter was connected to the aspiration system and the tip placed against the thrombi. The vacuum was set at 20 mbar and then increased in increments of 20 mbar every 30 sec. Complete aspiration of the thrombus into the flask was the primary endpoint. The thrombus was considered blocked in the catheter when the vacuum needed to evacuate it was increased by five increments (100 mbar).

The catheters were tested in random order. To avoid any bias in measurement, the tests were conducted by operators who were blinded to both the vacuum pressure employed and to the age of the thrombus.

Various commercially available diagnosis or guiding catheters (Cordis) with bores ranging from 0.038" to 0.070" were tested: three (0.038", 0.067", and 0.070" diameter) with right-angle distal tips and one (0.04"

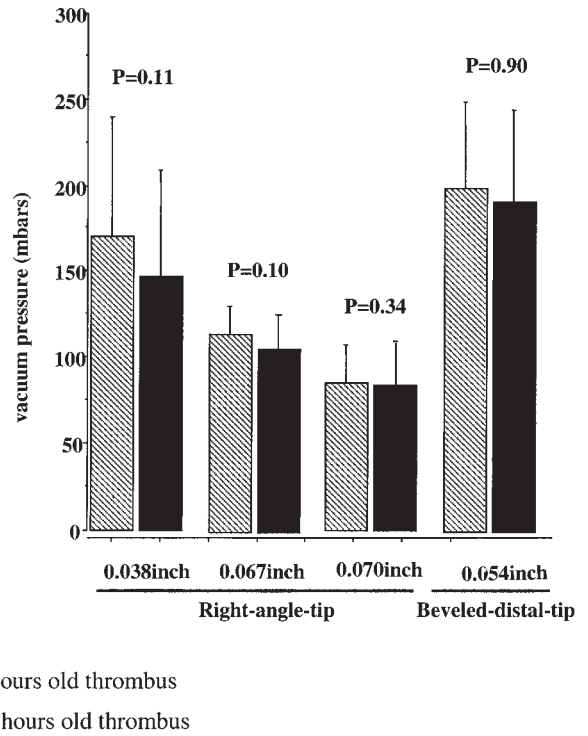


Fig. 2. Comparison of aspiration pressures for thrombi of 6 or 12 hr old. For a given catheter, there was no significant difference between 6- and 12-hr thrombi.

diameter) with a beveled distal tip specifically designed for TA giving a contact diameter of 0.054" (Export, Medtronic; Fig. 1).

The results are presented as mean values with standard deviations. The student's *t*-test was used to compare aspiration pressure between the catheters. Numerical variables are expressed as percentages, and comparisons between catheters use the chi-square test. A value of $P < 0.05$ was considered significant.

RESULTS

A total of 103 TA were performed (13 ± 2 per catheter). Complete aspiration was achieved in every test with pressures ranging from 60 to 320 mbar (mean, 141 ± 62 mbar); for a given catheter, there was no significant difference in the vacuum pressure required to aspirate 6- or 12-hr thrombi (144 ± 63 mbar for 6-hr thrombi vs. 137 ± 62 mbar for 12-hr thrombi; $P = 0.47$; Fig. 2).

However, for right-angle-tip catheters, the vacuum pressure required to achieve complete TA depended on the bore: the greater the bore, the lower the pressure (Fig. 3). By linear regression analysis, a strong association appears between catheter lumen size and vacuum

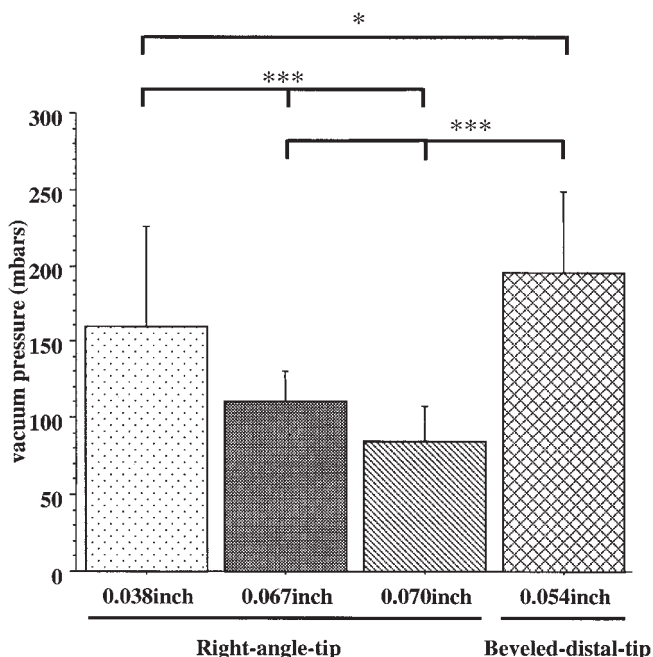


Fig. 3. Comparison of aspiration pressures required to achieve complete thrombus aspiration for catheters of different diameters. *, $P < 0.05$; ***, $P < 0.001$.

aspiration pressure for 6- and 12-hr-old thrombi as well as for the entire sample as a whole ($P < 0.0001$, $P < 0.01$, and $P < 0.0001$, respectively). If data for the beveled-tip catheter are excluded, the correlation coefficient substantially increases (from $r = 0.24$ to 0.59). The beveled-tip catheter required a relatively greater vacuum pressure to achieve TA. Moreover, the thrombus blocked in this catheter (0.04") more frequently than in a smaller-bore (0.038") right-angle-tip catheter (8/28 vs. 0/27; $P < 0.01$).

DISCUSSION

Our test showed that the bore of the catheter has an inverse relationship with the vacuum pressure required to achieve complete TA, and that the beveled-tip catheter we tested required a relatively greater vacuum pressure.

Test-Bench Performance of TA Catheters

Sakurada et al. [6] compared the aspiration, ease of positioning, and lateral-branch accessibility of a new design of thrombus vacuum catheter with those of two other branded systems (Percuturge and Rescue). They used a 1.4 mm diameter gelatin cylinder to mimic the behavior of a thrombus [6]. However, the chosen diameter was smaller than that of the epicardic arteries, which are generally treated by PCI (even more

so for TA) [7,8]. Moreover, the biomechanical properties of gelatin do not correspond to those of thrombi, which are the result of a dynamic process [9]. The impact of these choices was to limit the clinical relevance of the results. By using 3 mm diameter thrombi created in vitro, we created conditions that are closer to those found in clinical practice [9].

Our tests showed that for a given catheter, the vacuum pressures required to aspirate a 6- or 12-hr thrombus were similar, the difference lying in the fact that 12-hr thrombi are partially organized, as necroscopic studies have shown [9]. As the intervention takes place between 6 and 12 hr after MI onset, our findings are clinically valid.

Relationship Between Aspiration Pressure, Diameter, and Tip Type

Like other authors, we have shown the mechanical relationship between the bore of the TA catheter and aspiration pressure [6]. We have also shown that the use of a beveled-tip catheter does not make it possible to reduce this pressure. This observation is partly explained by the fact that the beveled tip of a 0.04" bore catheter has a contact diameter of 0.054". Thus, the aspirated thrombus tends to block in the catheter, and greater vacuum pressure is required to evacuate it. This occurred in 8 out of 28 tests in our study.

Clinical Applications

Thromboaspiration is a promising technique in the treatment of atherothrombosis [8,10,11]. Several systems are already available and decisions to use them will be based on effectiveness, ease of use, and cost [6]. Our study has contributed a certain number of elements that will help clinicians in their choice of catheter [12] and would help to avoid the need for excessively high aspiration pressures, especially if contact with the thrombus is less than optimal, in which case there is a risk of exceeding the vacuum capacity of the equipment [8]; obtain complete TA (today, a residual thrombus is found in more than a quarter of procedures) [8,13]; and prevent blockage of the thrombus in the catheter and the subsequent risk of repeat embolization. In addition, a large lumen size may go against the current trend for smaller catheters, and a compromise should be found for the management of thrombus-containing lesions. Even though optimal thrombus contact is necessary for effective thromboaspiration, the flexibility and trackability of the catheter must also be taken into account to avoid the risk of collapse during aspiration.

In TA, the best results are obtained when the bore of the catheter is as large as possible. These findings should lead to the development of more effective aspi-

ration devices. The main factor to consider in TA for thrombi ≥ 6 hr is inner diameter and not thrombus contact area.

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