Angioplasty Balloon Inflation Pressures during Treatment of Hemodialysis Graft–related Stenoses

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PURPOSE: This two-part prospective investigation was designed to determine the balloon inflation pressures required to dilate stenoses associated with hemodialysis grafts and evaluate the burst pressures of five different angioplasty balloons.

MATERIALS AND METHODS: Eighty-nine patients with dysfunctional hemodialysis grafts were enrolled and underwent fistulography. The diagnostic studies revealed 104 stenoses, which were treated with balloon angioplasty. The characteristics of these stenoses and the balloon inflation pressures required to dilate the lesions were recorded. In part two of this investigation, the burst pressures of five different angioplasty balloons were evaluated immediately after their use during angioplasty procedures. Twenty-five balloons of each type were inflated until the balloon burst or 30 atm of pressure was achieved. Several different statistical tests were used to analyze the data set.

RESULTS: The mean balloon inflation pressure required to dilate all 104 stenoses was 17.2 atm. Subgroup analysis revealed that the mean balloon inflation pressure required to dilate 75 venous anastomotic stenoses was 17.9 atm and that a mean pressure of 15.6 atm was required to dilate 29 stenoses located within the native outflow veins. The angioplasty balloon burst pressure experiments revealed that the majority of the tested balloons can be inflated to pressures 5–6 atm greater than the manufacturers’ rated burst pressures. However, the margin of safety for overinflation was variable among the balloons tested, and angioplasty balloons experience fatigue with repeated inflations.

CONCLUSION: The majority of stenoses associated with hemodialysis grafts can be successfully dilated with use of available high-pressure angioplasty balloons.

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Abbreviation: PTFE = polytetrafluoroethylene

BALLOON angioplasty is the most common therapeutic endovascular procedure. The traditional use of balloon angioplasty has been for the treatment of arterial atherosclerotic stenoses. In the majority of patients, these lesions can be easily dilated with use of conventional angioplasty balloons. However, in many interventional radiology practices, a more common indication for balloon angioplasty is for treatment of neointimal hyperplastic stenoses associated with hemodialysis grafts and fistulas. Unlike atherosclerotic stenoses, these neointimal hyperplastic lesions can be difficult to dilate and may require the use of high-pressure angioplasty balloons. Occasionally, even high-pressure angioplasty balloons must be inflated beyond their rated burst pressures for effective treatment of resistant stenoses.

Despite the frequent use of angioplasty for treatment of hemodialysis access–related stenoses, few published studies have reported the balloon inflation pressures required to dilate these lesions (1–4). This two-part prospective investigation was performed to (a) document the angioplasty balloon inflation pressures necessary to dilate stenoses associated with polytetrafluoroethylene (PTFE) hemodialysis grafts and (b) determine the burst pressures of five different angioplasty balloons.

MATERIALS AND METHODS

Before patients were enrolled, this investigation was approved by our institutional human studies committee. The first part of this prospective study involved patients with patent but dysfunctional upper-extremity PTFE hemodialysis grafts who were
referred to the interventional radiology department between March 2003 and September 2004. Hemodialysis graft dysfunction included low intra-graft blood flow rates (<600 mL/min), increased venous pressures during hemodialysis treatment, or prolonged bleeding after removal of the hemodilysis needles. Patients with native fistulas or thrombosed hemodialysis grafts were excluded from this investigation. In addition, patients who underwent angioplasty of central venous stenoses, intragraft stenoses, or stenoses within endovascular stents were excluded from study enrollment.

During the first 9 months of this investigation, only data related to balloon angioplasty of venous anastomotic stenoses were collected. During the second half of this study, data collection was expanded to include angioplasty of venous anastomotic stenoses and native vein stenoses associated with PTFE hemodialysis grafts.

**Patient Demographics**

This study included 89 patients who underwent balloon angioplasty of 104 stenoses; 64 of the patients were female, and the mean patient age was 63.8 years (range, 31–90 y). Eighty-two patients had loop-configuration hemodialysis grafts, 63 of which were in the forearm and 19 of which were in the upper arm. Seven patients had straight grafts, four in the forearm and three in the upper arm. The mean graft age at the time of the angioplasty procedure was 827 days (range, 42–2,219 d).

**Diagnostic Fistulography**

For loop-configuration grafts, an 18-gauge needle was used to enter the apex of the graft, and a guide wire was inserted into the arterial limb. Subsequently, a 5-F angiographic catheter was advanced along the guide wire and positioned with its tip in the brachial artery adjacent to the arterial anastomosis. For straight grafts, an 18-gauge needle was used to enter the graft near the arterial anastomosis in an antegrade direction. A guide wire was inserted, followed by a 5-F angiographic catheter positioned with its tip in the middle of the graft. The diagnostic fistulogram was obtained by injecting contrast material through the angiographic catheter. Multiple digital subtraction images of the graft and native veins were obtained. Suspected stenoses were imaged in at least two orthogonal planes.

In patients with straight grafts, the arterial anastomosis was visualized by injection of contrast medium during simultaneous occlusion of the outflow vein by manual compression. Each stenosis was characterized by anatomic location, length of stenosis, and degree of stenosis before and after the angioplasty procedure. Measurements were performed with use of the calibrated software within the digital imaging system. The reference diameter was a normal segment of vein adjacent to the stenosis. A significant stenosis was defined as causing greater than 50% diameter reduction compared with the adjacent normal segment. Stenoses with less than 50% diameter reduction were not treated.

**Angioplasty Procedure**

An angiographic catheter was used to advance a guide wire across the lesion to be treated with balloon angioplasty. An 8-F vascular sheath (DialEase; Mallinkrodt Medical, St. Louis, MO) was typically inserted into the graft. Heparin was not administered for these angioplasty procedures.

In the study group of 89 patients, 104 stenoses were treated with angioplasty. The selection of an appropriate angioplasty balloon diameter was at the physician’s discretion. A total of 111 angioplasty balloons were used to treat the 104 stenoses. A Centurion angioplasty balloon catheter (Bard Peripheral Vascular, Tempe, AZ) was used for 83 angioplasty procedures, a Conquest angioplasty balloon catheter (Bard Peripheral Vascular) was used for 21 procedures, and a PowerFlex Extreme angioplasty balloon catheter (Cordis Endovascular, Warren, NJ) was used for seven procedures. An 8-mm-diameter balloon was used for 58 stenoses, a 7-mm-diameter balloon for 40 stenoses, and a 6-mm-diameter balloon for six stenoses. All angioplasty balloons were 4 cm long.

The angioplasty balloon was inflated with a Max 30 inflation device (Bard Peripheral Vascular). This inflation device consists of a manometer mounted to a 20-mm-capacity syringe with a high-pressure connector tube for attachment of the inflation device to an angioplasty balloon catheter. The manometer is marked in 1-atm increments from zero to 30 atm of pressure. According to the manufacturer’s instructions for use, the accuracy of the manometer has been determined to be within 1 atm throughout that range of pressures.

Before use, the syringe of the inflation device was filled with a mixture consisting of approximately 50% saline solution and 50% contrast media. Under fluoroscopic observation, the balloon was slowly inflated while the balloon inflation pressure was monitored simultaneously. The angioplasty balloon was inflated until it was fully expanded with no residual waist or until a pressure of 30 atm was reached. The pressure at which the balloon was completely inflated was recorded. Despite a balloon inflation pressure of 30 atm, three stenoses could not be fully dilated. The inability to completely inflate the balloon was documented in these three patients, and the balloon inflation pressure was recorded as 30 atm. The balloon inflation time was 60 seconds.

A final fistulogram was obtained to assess the success of angioplasty. The residual degree of stenosis was measured with the calibrated software and recorded. All angioplasty-related complications were documented. At the end of the procedure, the vascular sheath was removed, and hemostasis was obtained with a purse-string suture.

**Angioplasty Balloon Burst Pressures**

The angioplasty balloon burst pressure experiments constituting the second part of this study were conducted by three physicians at three medical centers in the United States. All three investigators followed the identical testing protocol for all experiments. These balloon burst pressure experiments were not performed in conjunction with the first part of this investigation, the measurement of inflation pressure to dilate neointimal hyperplastic stenoses.

Five different angioplasty balloons were tested to determine their burst pressures. These angioplasty balloons included (a) Centurion, (b) PowerFlex Extreme, (c) Conquest, (d) Workhorse.
II (Angiodynamics, Queensbury, NY), and (e) Blue Max 20 (Boston Scientific, Natick, MA) balloons. Twenty-five balloons of each type were tested, for a total of 125 angioplasty balloons. The manufacturers’ rated burst pressures for these angioplasty balloons are provided in Table 1.

The balloon burst pressure experiments were performed immediately after routine hemodialysis graft-related angioplasty procedures. Each angioplasty balloon was used to treat at least one neointimal hyperplastic stenosis that was associated with a hemodialysis graft. During the angioplasty procedures, the number of inflations of each balloon was documented (Table 2). After completion of the angioplasty procedure, the balloon catheter was positioned so the distal balloon was within a trash receptacle. The balloon was slowly inflated with a Max 30 inflation device until the balloon burst or the inflation pressure reached 30 atm, the upper limit of the inflation device. The balloon burst pressure was documented. If the balloon did not burst at 30 atm, the pressure was recorded as being greater than 30 atm. All three study sites used the Max 30 inflation device for the balloon burst pressure experiments. To minimize variability, only balloons 7 and 8 mm in diameter were used for these balloon burst pressure experiments (Table 2). These two balloon diameters were chosen because these sizes are commonly used for angioplasty of venous anastomotic stenoses (1).

### Statistical Analysis

Categoric variables were initially examined with use of contingency tables, and patterns were tested for statistical significance with $\chi^2$ tests. When the overall pattern was statistically significant, the subpatterns were also tested with $\chi^2$ tests.

Continuous variables were examined by calculation and comparison of mean values. Patterns were tested for statistical significance with analyses of variance. When the overall pattern was statistically significant, the differences between each subgroup were compared on a pair-wise basis with use of the Tukey honestly significant difference test. Associations between continuous variables were examined with correlation analysis. Associations between categoric and continuous variables were examined with logistic regression. All these analyses were performed with JMP 5.0 (SAS Institute, Cary, NC).

### RESULTS

#### Lesion Characteristics

A total of 104 stenoses were treated with balloon angioplasty. Seventy-five stenoses were located at the venous anastomosis, and 29 stenoses were located in native veins. Twenty-one of these native vein stenoses were located in the basilic vein, and eight were in the cephalic vein. The mean length of all 104 stenoses was 21.6 ± 18.2 mm (range, 3–82 mm). The mean degree of stenosis before balloon angioplasty was 64.0% ± 8.9% (range, 50%–86%). The mean degree of stenosis after angioplasty was 21.3% ± 11.6% (range, 0–58%).

#### Balloon Inflation Pressures

When the data from all 104 stenoses are combined, the mean inflation pressure required to dilate these lesions is 17.2 atm ± 5.6 (range, 7–30 atm) (Fig 1). An inflation pressure of 20 atm or greater was necessary to dilate 35 stenoses.

The mean inflation pressure required to dilate the 75 stenoses located at venous anastomoses was 17.9 ± 5.2 atm (range, 8–30 atm). The mean inflation pressure required to dilate the 29 stenoses located within the native veins was 15.6 ± 6.1 atm (range, 7–26 atm). The difference between the mean inflation pressures needed in the dilation of stenoses at venous anastomoses versus native veins approached statistical significance but fell short of it ($t$ test, $P = .052$).

#### Technical Success

Thirteen angioplasty procedures (12.5%) were initially unsuccessful, with greater than 30% residual stenosis (mean residual stenosis, 41%; range, 32%–58%). As previously described, in three patients, the stenosis could not be fully dilated despite balloon inflation pressures of 30 atm. In the other 10 patients, the stenosis was fully dilated, but as a result of immediate elastic recoil, there was greater than 30% residual stenosis. In seven of the 13 patients with greater than 30% residual stenosis, the lesion was dilated again with a larger-diameter (1-mm) balloon. Three of these procedures remained unsuccessful, with more than 30% persistent stenosis. Nine angioplasty procedures (8.6%) were ultimately unsuccessful, yielding a technical success rate of 91%. Two of these nine residual stenoses were treated with stents, and three were treated with stent-grafts. No additional treatment was performed on four of the residual stenoses.

#### Complications

Two of the angioplasty balloons (1.9%) ruptured during inflation; one balloon burst at 24 atm of pressure and another burst at 26 atm. Both these ruptured balloons were Centurion angioplasty balloons, and these inflation pressures exceeded the manufacturer’s rated burst pressure (20 atm). In both patients, the acute balloon rupture caused an intimal tear in the adjacent vein. Both patients were immediately treated with stents, with good results.

There were three additional angioplasty-induced complications (2.9%).

### Table 1

<table>
<thead>
<tr>
<th>Balloon Type</th>
<th>7 mm Diameter</th>
<th>8 mm Diameter</th>
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</thead>
<tbody>
<tr>
<td>Workhorse II</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Centurion</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>PowerFlex Extreme</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Blue Max</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Conquest</td>
<td>30</td>
<td>27</td>
</tr>
</tbody>
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The mean inflation pressure required to dilate the 75 stenoses located at venous anastomoses was 17.9 ± 5.2 atm (range, 8–30 atm). The mean inflation pressure required to dilate the 29 stenoses located within the native veins was 15.6 ± 6.1 atm (range, 7–26 atm). The difference between the mean inflation pressures needed in the dilation of stenoses at venous anastomoses versus native veins approached statistical significance but fell short of it ($t$ test, $P = .052$).
In one patient, the angioplasty procedure caused the acute development of a small (5-mm) pseudoaneurysm. This injury was self limited, and no further treatment was required. In one patient, the angioplasty procedure caused an extensive venous dissection, and in another patient, the angioplasty caused an acute venous occlusion. Both these patients were immediately treated with stent-grafts, with good results.

**Angioplasty Balloon Burst Pressures**

Table 2 provides the results of the angioplasty balloon bursting experiments. These data reveal two distinct groups: one group in which the majority of balloons burst (Workhorse II, Centurion, and PowerFlex balloons) and a second group in which none of the balloons burst (Blue Max and Conquest balloons). This pattern was statistically significant ($\chi^2$ test, $P < .0001$).

**Figure 2** is a graphic presentation of the data from the subgroup of balloons that burst (Workhorse II, Centurion, PowerFlex). When a pair-wise analysis was performed to compare the Centurion balloon with the PowerFlex balloon, the difference in mean burst pressures was not statistically significant (Tukey test, $P > .05$). However, the mean burst pressures of the Centurion and PowerFlex balloons were statistically higher than the mean burst pressure of the Workhorse II balloon (Tukey test, $P < .05$).

There was no statistical difference when the proportion of 7- and 8-mm-diameter balloons were compared among the five types of balloon catheters ($\chi^2$ test, $P = .17$). When only the 64 balloons that burst were considered, a higher percentage of 7-mm balloons burst (57%) compared with 8-mm balloons (46%), but this difference was not significant ($\chi^2$ test, $P = .23$). However, the 8-mm-diameter balloons had a significantly lower mean burst pressure (26.6 atm) than did the 7-mm balloons (27.9 atm; $t$ test, $P = .006$).

As previously described, the angioplasty balloons tested had been used for hemodialysis graft–related angioplasty procedures immediately before these burst pressure experiments. Each angioplasty balloon tested underwent a variable number of inflations during the angioplasty procedures (mean, three inflations; range, 1–10 inflations). An analysis of the number of inflations per balloon revealed two distinct groups: those with an average of two inflations per balloon (Centurion, Conquest, and PowerFlex balloons) and those with an average of four inflations per balloon (Blue Max and Workhorse II balloons). This pattern was statistically significant (analysis of variance, $P < .0001$). When only the subgroup of 64 balloons that burst were analyzed, there was an inverse correlation between the number of balloon inflations and burst pressure ($r = -0.54; P = .0001$), indicating that a greater number of inflations led to lower burst pressures.

**DISCUSSION**

The routine use of high-pressure or ultra–high-pressure angioplasty balloons for treatment of hemodialysis access–related stenoses continues to be debatable. Many interventionalists believe that neointimal hyperplastic stenoses require high inflation pressures (>20 atm) for effective dilation. Therefore, they always select a high-pressure or ultra–high-pressure angioplasty balloon for these procedures. Alternatively, other interventionalists would argue that many of these stenoses can be successfully treated with less expensive standard angioplasty balloons. They would also contend that, when necessary, a standard angioplasty balloon can be inflated beyond the manufacturer’s rated burst pressure. These interventionalists reserve the use of high-pressure or ultra–high-pressure balloons for stenoses that cannot be effectively dilated with a standard angioplasty balloon. When this practice is followed, the use of more costly angioplasty balloons can be limited.

Several previously published studies (2–4) have described the balloon inflation pressures required to dilate stenoses associated with hemodialysis grafts and fistulas. Trerotola et al (2) described a series of 87 angioplasty procedures performed in 75 patients; 70 in patients with PTFE hemodialysis grafts and 17 in patients with native fistulas. In this series of 87 angioplasty procedures, seven stenoses (8%) required balloon inflation pressures greater than 27 atm. These investigators used an ultra–high-pressure angioplasty balloon for dilation of these seven lesions and reported a mean inflation pressure of 34 atm.

Rajan et al (3) reported their observations during angioplasty of venous stenoses located within the cephalic arch in patients with native fistulas. Fifty balloon inflations were required to treat 26 stenoses in 24 patients. Inflation pressures greater than 15 atm were required to efface the lesions in 29 of 50 dilation procedures.

Trerotola et al (4) recently reported the balloon inflation pressures required to dilate 138 stenoses associated with 61 PTFE hemodialysis grafts. In this study group, the mean balloon inflation pressure required to efface the stenosis was 15.4 atm, and only 9% of lesions required inflation pressures greater than 20 atm.

Our results differ from those reported by Trerotola et al (2,4). In our study, the mean inflation pressure required to dilate 104 stenoses was 17.2 atm. One third of these stenoses (34%)...
required balloon inflation pressures of 20 atm or greater. When compared with the results reported by Trerotola et al (2,4), our mean inflation pressure was higher, and substantially more lesions required greater than 20 atm of inflation pressure. One factor that may have contributed to our high mean inflation pressure is the large number of venous anastomotic stenoses. In our study, 72% of the stenoses were located at the venous anastomosis and 28% of lesions were located within the native veins of the upper extremity. Analysis of these two subgroups revealed mean inflation pressures of 17.9 atm for the venous anastomotic stenoses and 15.6 atm for the native vein stenoses. Although this difference in mean inflation pressures did not achieve statistical significance, our results suggest that venous anastomotic stenoses require higher inflation pressures than do stenoses located within the native outflow veins. As previously suggested, the large number of venous anastomotic stenoses included in our study may have contributed to the overall high mean inflation pressure. Another factor that may have affected our findings is the age of hemodialysis grafts. In our study group of 89 patients, the mean graft age was 2.3 years (827 days). The venous anastomotic stenoses associated with these older hemodialysis grafts may have been more resistant to dilation than were “virgin” stenoses in younger PTFE hemodialysis grafts.

Our overall complication rate was 4.8%. Two of these complications (1.9%) were caused by rupture of the angioplasty balloon. In both instances, the balloon had been inflated to a pressure greater than the rated burst pressure. The acute balloon rupture caused substantial damage to the adjacent vein, so both patients were immediately treated with stents. An angioplasty-induced vascular injury occurred in three additional patients (2.9%); two patients incurred venous ruptures, and one patient had the acute development of a pseudoaneurysm. Our complication rate is similar to those previously reported; however, it is higher than the threshold values established by the Society of Interventional Radiology Standards of Practice guidelines (5,6).

The term “rated burst pressure” is defined by the United States Food and Drug Administration as the highest pressure at which the manufacturer has 95% confidence that 99.9% of balloons will not burst with a single inflation (7). It is important to note that the labeled rated burst pressure value is established by the balloon manufacturer, not the Food and Drug Administration. It is possible that a manufacturer may choose to label an angioplasty balloon with a low rated burst pressure value to decrease the likelihood of balloon rupture during clinical use.

Three of the tested angioplasty balloons (Centurion, PowerFlex, Blue Max) have rated burst pressures of 20 atm (Table 1). However, in this study, the mean burst pressures for these three balloons were 27.6 atm, 28.6 atm, and greater than 30 atm. Although these mean burst pressures exceed the manufacturers’ rated burst pressure values, there are differences in the amount that each balloon can be inflated beyond the rated burst pressure. A comparison of Table 1 and Figure 2 suggests that the Workhorse II, Centurion, PowerFlex Extreme, and Blue Max balloons can be inflated to pressures 5–6 atm greater than the manufacturers’ rated balloon pressures with a reasonable expectation that the balloon will not burst. The Conquest balloon has a rated burst pressure of 30 atm. With the Max 30 inflation device, we were unable to accurately measure inflation pressures greater than 30 atm to assess the margin of safety for inflation of the Conquest balloon to pressures greater than its rated burst pressure.

The mean burst pressures of the Blue Max and Conquest angioplasty balloons are both greater than 30 atm. Although the Max 30 inflation device can be used to inflate an angioplasty balloon to greater than 30 atm of pressure, the gauge is not accurate in this pressure range. For this reason, we did not attempt to estimate balloon inflation pressures greater than 30 atm. If the balloon inflation pressure reached 30 atm without bursting the balloon, the burst pressure was documented as greater than 30 atm.
As previously described, the angioplasty balloons evaluated during the burst pressure experiments had been used for routine angioplasty procedures immediately before the burst testing procedure. The number of times each balloon was inflated during the angioplasty procedure was variable, ranging from one to 10 inflations. Our analysis showed an inverse correlation between the number of balloon inflations and burst pressure ($r = -0.54$), suggesting that angioplasty balloons experience fatigue with repeated inflation. However, even after multiple inflations of the angioplasty balloon, the mean burst pressure remained greater than the manufacturer’s rated burst pressure.

Our analysis of the 64 balloons that burst revealed that 8-mm-diameter balloons had a significantly lower mean burst pressure (26.6 atm) than did 7-mm balloons (27.9 atm; $P = .006$). This finding is consistent with the Law of LaPlace, which states that increasing the radius of an angioplasty balloon will increase the tension exerted on the balloon wall. When constructed of the same balloon material, larger-diameter angioplasty balloons will have lower mean burst pressures than will smaller-diameter balloons.

The costs of the angioplasty balloons tested are variable and depend on the manufacturer, the number of balloons purchased, and rebate programs. Therefore, an accurate cost analysis to optimize the use of expensive high-pressure angioplasty balloons is confounded by the variable costs of these products. Our study has demonstrated that all five balloons tested are capable of dilating the majority of stenoses associated with PTFE hemodialysis grafts.

CONCLUSION

As shown in the first part of this investigation, 34% of the 104 stenoses required balloon inflation pressures of at least 20 atm, matching or exceeding the manufacturers’ rated burst pressures for four of the five balloons tested. However, in the second part of our investigation, we demonstrated that the Workhorse II, Centurion, PowerFlex Extreme, and Blue Max angioplasty balloons can be inflated to pressures 5–6 atm greater than the manufacturers’ rated burst pressures, with a reasonable expectation that the balloon will not burst. The fifth balloon tested, the ultra-high-pressure Conquest balloon, has a rated burst pressure of 30 atm, which provides a greater margin of confidence for the dilation of highly resistant stenoses.

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References

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