Plaque Abrasion and Intra-aortic Balloon Leak*

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Study objective: To determine and correct cause of high incidence of intra-aortic balloon leaks (ruptures). Design: Epidemiologic investigation of factors associated with intra-aortic balloon leak, and sequential application of corrective measures evaluated by continued concurrent data collection. Setting: Thirty-four-bed ICU in 598-bed tertiary care medical center. Interventions: Procedure changed to place smaller balloons (34 mL instead of 40 mL) in patients less than 163 cm in height. Measurements and results: Demographic and clinical data on all patients showed no change after initial interventions, followed by significant drop (8 to 2%) in incidence of balloon leak when smaller, shorter balloons were placed in shorter patients. Conclusions: Placement of larger, longer balloons in patients increases risk of perforation of balloon by calcific plaque in the distal thoracic and abdominal aorta. (CHEST 1995; 108:1495-98)

IAB=intra-aortic balloon

Key words: complications; intra-aortic balloon; rupture, leak

Plaque abrasion and resultant leak of the intra-aortic balloon (IAB) is a well-recognized but rare complication of IAB counterpulsation.\(^1,2\) We describe an outbreak of unusually high incidence of IAB leak, and discuss its apparent etiology and resolution after institution of appropriate measures.

METHODS

Maine Medical Center is a 600-bed tertiary care referral hospital in which 1,200 open-heart surgery cases and 4,000 cardiac catheterizations (including 1,300 percutaneous transluminal coronary angioplasties) are performed yearly. In calendar year 1990, we became aware of a high number of IAB leaks (8/163, 5%) compared with our accepted norm of 1 to 2%.

Demographic data were obtained for all patients in whom IABs were placed in 1990. Charts and chest radiographs of the patients in whom IAB leaks occurred were reviewed. Particular attention was paid to the technique of insertion and appropriateness of the position of the IAB.

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Hospitals using the same brand and volume of IAB (Datascopc Corp; Fairfield, NJ) were surveyed to determine if they were encountering similar problems. The reports of IAB "ruptures" to the Food and Drug Administration were obtained and reviewed and rates were compared with our own. Microscopic studies of each of our failed balloons was carried out by the manufacturer. Clinical evaluation of the insertion techniques and management practices of each physician inserting balloons was reviewed. Every physician who had inserted an IAB in the operating room, ICU, or cardiac catheterization laboratory during the preceding year was required to rereview an instructional videotape. Despite these interventions, a high rate of leak continued and the epidemiologic evaluation was intensified. As a result of these findings, an additional intervention was initiated; 34-mL (14 mm diameter x 21.5 cm long) balloons were inserted in all patients shorter than 163 cm (64 inches) instead of the usual 40-mL (15 mm diameter x 26 cm long) balloon.

Prospective studies of IAB insertions continue to the present time.

RESULTS

Comparison of our data to that from the Food and Drug Administration and the manufacturers confirmed that we were continuing to have an inordinately high rate of leaks (7% vs 1 to 2%) during the period September 1990 through February 1991. Radiographic review revealed no apparent technical problems and that balloon positioning was appropriate. No other hospitals surveyed had high rates such as ours. Epi...
miologic data are seen in Table 1. Prior to June 1991, there were no leaks in IABs placed by cardiologists and there was a questionably high rate of leak in two surgeons’ patients. Review of their techniques showed no obvious cause for this discrepancy and, because of the relatively small numbers, no statistical or clinical significance could be inferred.

Patients in whom leaks developed tended to have the following characteristics. Although only 84 of 231 (37.4%) of the IAB patients at Maine Medical Center were female, female patients accounted for 8 of 11 (72.7%) of the failed IAB population. On the average, patients with failed IABs were 6 years older, 3 cm shorter, and weighed 6 kg less than those who did not develop leaks. More impressive was the difference in the rates of those patients more than 170 cm tall compared with those less than 170 cm tall; 7% of patients shorter than 170 cm developed IAB leak and less than 2% of patients taller than 170 cm developed a leak (χ² 3.92; p<0.05) (Fig 1). Duration of insertion prior to recognition of IAB leak was not related to frequency; in fact, most of the leaks were recognized within 24 h of insertion. None of the other demographic characteristics (Table 1) were associated with increased incidence of leaks.

Morphologic examination of failed IABs revealed microscopic pinhole leaks. These were usually in the proximal portion of the balloon—the portion that is usually distal in the patient in the abdominal aorta (Figs 2 and 3). Representative pictures of aortas (Figs 4 and 5) show typical areas of calcific plaque.

In June 1991, a new policy was instituted that encouraged the use of smaller balloons (34 mL) in shorter patients (<163 cm). Between June 1991 and September 1992 there were five reported IAB leaks. During this time, 186 balloons were in place for a rate of 2.7%. Of the five balloons that developed leaks, three were placed by cardiologists and two by cardiovascular surgeons. From October 1992 through September 1994, 239 balloons were inserted; three developed leaks for a rate of 1.3%. Of the patients who developed a leak, the first was a 65-year-old man who

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<td>Totals</td>
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<tr>
<td>All</td>
<td>231</td>
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<td>Mean age, yr</td>
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<td>Mean height, cm</td>
<td>166.1</td>
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<tr>
<td>By surgeons</td>
<td>141</td>
<td>87</td>
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<td>By cardiologists</td>
<td>73</td>
<td>77</td>
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<tr>
<th>% IAB Leak</th>
<th>}&lt;170</th>
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<td>11/164</td>
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<td>3/154</td>
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Figure 1. Patient height vs IAB leak.

Figure 2. Typical plaque abrasion and penetration on proximal portion of a balloon.

Figure 3. Microscopic (×40) appearance of plaque abrasion and a pinhole leak in an IAB.
infection.\textsuperscript{1,3–5} Aortic dissection perhaps is more common than is recognized clinically.\textsuperscript{5} Other balloon complications include bleeding, infectious complications, and balloon rupture. Although balloon rupture has been reported, it appears to be very infrequent and in the review of complications in 733 patients by Kantrovitz et al.,\textsuperscript{1} balloon rupture was not mentioned. In another large study, two balloon ruptures were reported among 202 patients. It was not apparent from the study that this complication resulted in any adverse effect other than the need to replace the balloon.\textsuperscript{1} Kvillevik et al.\textsuperscript{2} also did not note any balloon ruptures among 153 IAB pump insertions. Ruptures of the IAB device with subsequent neurologic dysfunction, presumed secondary to helium embolism, have been reported.\textsuperscript{6,7} However, these seem to be a very small minority of reported balloon ruptures. Sutter et al.\textsuperscript{2} reviewed 19 incidents of balloon leak among 454 patients, a rate of 4.2%. This article appears to be the only one in which rates of balloon leak approached the rate we found during the initial 18 months of this study. Among these 19 cases, the leak was recognized by observing blood in the catheter or safety chamber in 11 patients, activation of the console alarm in 3 cases, and both events were noted in the remaining 5 cases. In two cases, instead of removing the balloon, the consoles were changed and counterpulsation continued for periods of 12 and 24 h. Both these patients had neurologic sequelae.\textsuperscript{2} One other case of helium embolization due to a leak in an IAB appears to have been related to an inadvertent tear of the IAB by a needle used in an attempt to inject intra-aortic protamine intraoperatively.\textsuperscript{7}

The use of the term rupture in this and other articles is probably inappropriate since in all reported cases of helium embolization, the hole in the balloon has been described as pinhole in size. With a pinhole leak and the characteristics of the pressures in and around the balloon, blood is probably more likely to enter the balloon than helium is to leak out. Helium loss at most is limited to the 40 mL (or 34 mL in the smaller balloon) volume of the balloon; the driving pressure gas is separated from the balloon gas in the safety chamber. Perhaps more importantly, the difference between aortic BP and intraballoon gas pressure is relatively low, +15 to +25 mm Hg during balloon inflation (patient early and mid diastole) and is a large negative number, −80 to −170 mm Hg during balloon deflation (patient late diastole and systole). This results in a net pressure difference in favor of blood entering the balloon rather than helium escaping. Finally, with small pinhole leaks, the small bubble of gas that might escape during diastole will be opposed by relatively large surface tension forces.

We postulate that balloon entrapment also is a common complication of IAB leaks. Instead of helium

**Discussion**

The IAB has been a major advance in the treatment of cardiogenic shock and myocardial ischemia. As it is one of the more invasive procedures done in critical care medicine, it is not surprising that the complication rates are high.\textsuperscript{3} Despite this, the clinical impression is that the benefits of IAB pumping in properly selected patients clearly outweigh potential complications and the procedure has continued to be widely employed.

Vascular complications have included perforation, thrombi, emboli, limb ischemia, and local wound

**Figure 4.** Aortic plaque immediately distal to the subclavian artery ostium.

**Figure 5.** Deendothelialized plaque in distal abdominal aorta.

weighed 61 kg and was 155 cm tall and the second was a 65-year-old man who weighed 116 kg and was 172 cm tall; both of these patients had 40-mL balloons inserted. The final leak was in a 72-year-old woman who weighed 45 kg and was 150 cm tall; she had a 34-mL balloon inserted.
caused by repeated abrasion against the heart and aorta. Since the abdominal aorta has a smaller diameter and more plaque than the thoracic aorta, one would expect to find more abrasion in the portion of the balloon more distal from the heart and to find a higher incidence of balloon leak in shorter patients. This was the case in our patients. Of our patients who developed leaks in their IABs, the vast majority were female and tended to be older, shorter, and weigh less than the patients whose balloons did not develop a leak. These observations all support this concept, and although an epidemiologic study such as this cannot prove a cause-and-effect relationship, the circumstantial evidence strongly supports our hypothesis. Random clustering of events, giving a false impression of increased incidence, could explain the apparent high rate of leak during the first 18 months of this study. However, it would not explain the statistically and clinically significant difference between shorter and taller patients.

We believe we are the first to report significantly higher incidence of balloon leak in shorter patients. More importantly, changing our practice to provide shorter balloons in shorter patients resulted in substantial reduction in the incidence of leaks.

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REFERENCES