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Risk Factors Leading to Cerebral Arterial Rupture by Intravascular Balloon

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PURPOSE: To clarify what is safe use of balloons in interventional neuroradiologic procedures. **METHODS:** Critical parameter values of balloon inflation and cerebral artery dilatation and rupture were determined. Dimensions and internal pressure were measured for a variety of latex and silicone balloons during inflation in both unconstrained and constrained environments including glass tubes, cadaveric human cerebral arteries, and canine basilar arteries. **RESULTS:** For unconstrained inflation, pressures within balloons inflated to the recommended maximum volume ranged from 200 to 650 mm Hg. When constrained, pressures became much higher for the same injected fluid volume. Balloon dilatation until artery rupture occurred only for balloons with diameters greater than 2.5 times the unstretched vessel diameter. Balloon pressures at vessel rupture ranged from 1000 to 2000 mm Hg. **CONCLUSION:** Pressures within inflated balloons vary with balloon type, material, degree of inflation, and constraint. Constrained balloons have markedly higher internal pressures, which may lead to vessel rupture if balloons are much larger than the vessel diameter.

Index terms: Catheters and catheterization, balloons; Interventional instrumentation, embolizing systems; Interventional neuroradiology, complications of; Arteries, cerebral; Animal studies

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Balloons have become important instruments for endovascular work in neurointerventional procedures. Principal indications for their use include temporary and permanent vessel occlusions and dilatation of vascular narrowings such as vasospasm or atherosclerotic stenosis. Several reported cases of intracranial arterial rupture during balloon inflation (1–3) (Brothers MF et al, paper presented at the annual meeting of the American Society of Neuroradiology, Washington, DC, June 1991) have prompted us to investigate critical parameters of intravascular balloon and cerebral artery rupture. Similar reports have been published for balloons used in peripheral and coronary vessel angioplasty (4–8). These polyvinyl chloride, polyethylene, or polyurethane balloons are, however, noncompliant in nature in contrast to the compliant latex or silicone balloons used in neurovascular procedures. In addition, the unique situation of cerebral arteries being surrounded primarily by cerebrospinal fluid, not by soft tissue, and the particular construction of the cerebral arterial wall make it necessary to evaluate specifically the behavior of these arteries when exposed to balloon dilatation.

In this study, compliant balloon inflation in both unconstrained and constrained environments was investigated by measuring internal pressure, injection volume, and balloon size. Properties of balloon inflation in air were studied in order to evaluate and compare properties of latex and silicone balloons. To simulate constrained inflation in vessels more closely, balloons were inflated while constrained in glass tubes. Finally, cerebral artery rupture was studied by inflating balloons of various sizes within cadaveric human cerebral arteries and canine basilar arteries.

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Materials and Methods

Unconstrained Balloon Inflation

Balloon pressure, diameter, and length were recorded for unconstrained inflation to the manufacturer's recommended maximum volume (RMV) and at the time of balloon burst. Fifteen balloon types from two manufacturers were studied, including nine latex balloons (Nycomed-Ingenor, Paris, France) and six silicone balloons (Interventional Therapeutics, South San Francisco, Calif). The inflated diameters of the balloons tested ranged in size from 3.5 to 15 mm. The RMV and size of each balloon tested is listed in Table 1. Balloons were fixed on a 2-F catheter (approximately 15 cm in length) and inflated with water in small-volume increments with the simultaneous recording of pressure, diameter, and length. A syringe with a threaded screw plunger was used for precise volume injections. After each inflation increment, the system was allowed to stabilize for 15–30 seconds, and then pressure measurements obtained from a pressure transducer connected to the balloon-catheter-syringe system were recorded. Balloon dimensions were measured for each inflation increment using a vernier caliper.

The effect of multiple balloon inflations was tested by recording pressure and balloon dimensions on first inflation to the RMV and then deflating the balloon and repeating the cycle for 10 total inflations. In addition, balloon parameters were determined for inflation to the RMV and the bursting volume.

Constrained Balloon Inflation

Glass Tubes. To limit the radial expansion during inflation, balloons were inflated within glass tubes lubricated with liquid silicone. Several of the smaller balloon types were tested, including four latex and two silicone balloons. Tube inner diameters were chosen to constrain expansion to between 0% and 100% of the balloons' RMV diameters. Simultaneous measurements of internal balloon pressure, volume, and length were recorded during incremental fluid injection until the balloons burst in the same manner as described for unconstrained balloon inflation.

Cadaveric Human Cerebral Arteries. Dilatation of cerebral arteries was studied by inflating balloons within unfixed vessel segments. Depending on balloon size relative to vessel diameter, vessels were either ruptured or dilated to a high pressure. Normal circle of Willis specimens were removed at autopsy from patients with no known vascular disease. To reduce degradation of the specimens, vessels were kept moist in a saline solution and analyzed within 24 hours of death. Dilatations were performed on all segments of the circle of Willis, including middle (M1 and M2), anterior (A1 and A2), posterior (P1 and P2), basilar, and vertebral arteries. During injection in small-volume increments, simultaneous measurements of balloon pressure, injected volume, and dimensions were obtained. To measure balloon length and vessel outer diameter, a video-tape recording of the dilatation was made with a scale to determine the magnification factor. Dyed fluid was used for injection to facilitate visualization of balloon length within the artery. Four specimens were studied in this manner for a total of more than 50 dilated vessel segments. Several types of small latex and silicone balloons were used for this portion of the study including latex B15, B19, B17, and B16, and silicone SP8502, DSB1503, DSB1804, and DSB1509 balloons.

Canine Basilar Arteries. In vivo measurements were made by inflating balloons within basilar arteries of anesthetized dogs until vessel rupture. The original arterial lumen size was measured on an angiogram before dilatation. Balloons were inflated in small-volume increments with radiographic contrast under fluoroscopic observation. Balloon pressure measurements were recorded and correlated with balloon dimensions obtained from spot films or video-tape recording of the fluoroscopic image with a scale. Five animals were studied in this manner, using latex B15

TABLE 1: RMV, diameter (D), length (L), and bursting parameters of balloons inflated in an unconstrained environment

Balloon Material	Catalog Number	RMV (ml)	D (mm)	L (mm)	Bursting V/ RMV	Bursting D/ RMV D	Bursting D/ Uninflated D	RMV Pressure (mm Hg)	Bursting Pressure (mm Hg)
Latex	B15	0.12	4.5	8.9	6.9	1.6	8.0	600	1550
	B19	0.3	6.0	10.5	3.3	1.7	8.3	600	1250
	B17	0.5	7.8	14.7	2.4	1.4	7.2	650	1200
	B16	0.6	7.0	18.9	3.6	1.3	7.5	400	950
	B7	1.0	13.0	12.6	3.3	1.4	7.2	350	650
	B9	1.0	10.0	21.0	3.4	1.2	6.9	300	650
	B12	2.2	14.0	26.2	2.6	1.3	8.2	350	600
	B26	4.0	15	30	2.9	1.3	9.2	200	450
	B25	15.0	15	89	1.7	1.1	8.3	380	550
Silicone	SP8502	0.1	3.5	12.0	5.5	1.6	6.6	200	600
	DSB1503	0.3	6.5	9.5	3.1	1.4	6.0	400	900
	DSB1804	0.4	6.0	10.0	3.0	1.8	6.1	250	600
	DSB1509	0.9	8.5	21.0	2.1	1.1	6.3	300	600
	DSB1810	1.0	9.0	18.0	2.2	1.3	6.7	300	550
	DSB1815	1.5	10.0	23.0	2.1	1.2	6.7	250	600

and B16 and silicone SP8502 along with two prototype silicone balloons.

Results

Unconstrained Balloon Inflation

Multiple balloon inflations resulted in reduced internal pressure, particularly for latex balloons. Figure 1 shows the pressure-volume curves for a latex and a silicone balloon of similar size. When first inflated, the latex balloon exhibited a very large pressure spike before it yielded and began to enlarge. However, after 10 inflations to the RMV, the yield-point pressure was greatly reduced, and the pressure at the RMV was lowered by almost a factor of two. Most of this relaxation occurred in the first few inflations with stable pressures after approximately five repetitions. The silicone balloon initially inflated at a much lower pressure and was only slightly affected by training. For both latex and silicone balloons, the inflated size was also altered slightly after repeated inflations with a 5% to 10% increase in both length and width between the first and 10th inflation. To reduce the variability in pressure and size measurements with multiple inflations, balloons were inflated five times before use in further tests.

Columns 6–8 of Table 1 list values of critical parameters for balloons inflated in an unconstrained environment until bursting. Included are ratios of the final balloon volume relative to the RMV, the final diameter relative to the RMV diameter, and the final diameter relative to the unstretched diameter. Both latex and silicone balloons must be inflated to greater than twice their RMV to cause bursting (with the exception of latex B25, which is slightly lower). Note that the smallest balloons, latex B15 and silicone SP8502, could withstand injected volumes 5.5 to 7 times larger than the RMV before bursting. The diameter of the balloons increased to as much as 80% larger than the RMV diameter. When compared with the uninflated size, latex balloons exhibited a greater maximum distension (bursting diameter 6.9 to 9.2 times larger than the uninflated diameter) as compared with silicone (bursting diameter 6 to 6.7 times larger than the uninflated diameter).

Balloon pressures at RMV and bursting are listed in the last two columns of Table 1. Pressures at RMV ranged from 200 to 650 mm Hg (760 mm Hg = 14.7 psi = 101.3 kPa = 1 atm). Pressures just before balloon bursting were a factor of 1.5 to 3 times higher than RMV pressures (450 to 1550 mm Hg). Results indicated that latex balloons had a higher internal pressure than silicone balloons of comparable size. Note that smaller balloons burst at higher pressures than larger balloons (with the exception of silicone SP8502). Values in Table 1 were measured for only one balloon of each type. In order to test the consistency of balloon pressures and dimensions with different balloons of the same type, three latex B16 balloons were inflated to bursting in the same manner. Bursting volumes of the three were within 0.2 mL, bursting diameters within 0.2 mm, and bursting pressures within 100 mm

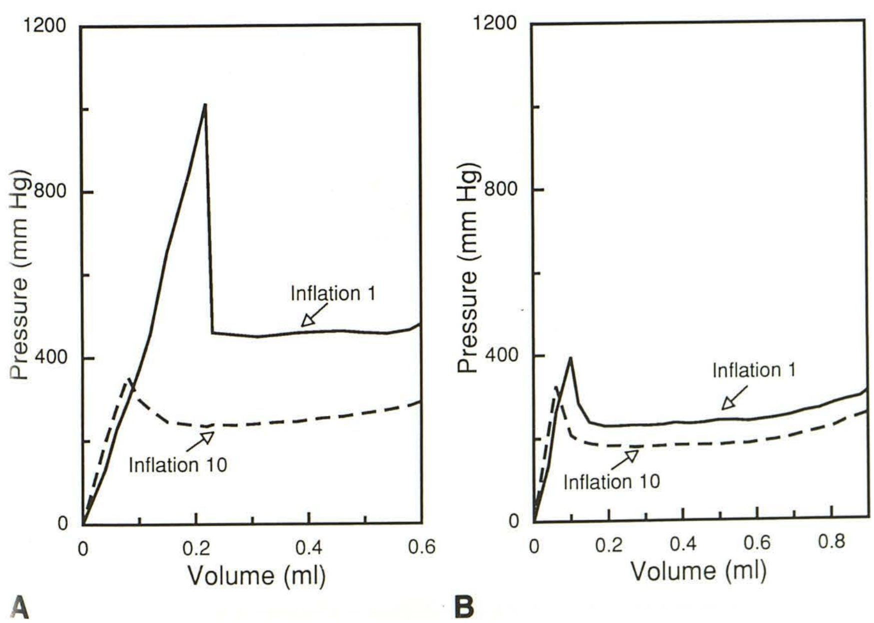


Fig. 1. Pressure-volume curves for first and 10th inflation to RMV for a latex B16 balloon (*A*) and a silicone DSB1509 balloon (*B*).

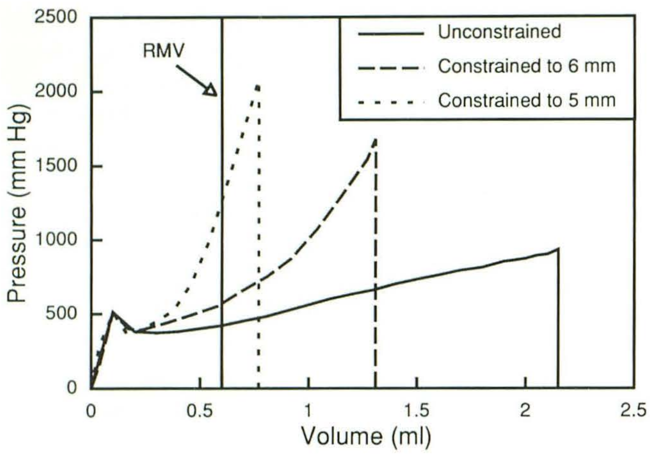


Fig. 2. Pressure-volume curves for latex B16 balloons inflated to rupture in glass tubes of various inner diameters. The RMV balloon diameter is 7 mm.

Hg. In general, the accuracy of tabulated pressure values is approximately 50 mm Hg.

Constrained Balloon Inflation

Glass Tubes. When the balloon radial expansion was limited, balloon length increased, and internal pressure became significantly higher depending on the degree of constraint. Lubrication of the inner surface of the glass tube was essential to allow for proper elongation and prevent premature bursting. Figure 2 shows pressure-volume curves comparing unconstrained and constrained inflation until balloon bursting for a representative balloon type. As the constraining diameter was decreased, balloon pressures became larger for the same injected volume, and balloon bursting occurred at a lower volume.

Table 2 lists constrained pressures at RMV and pressures and volumes at bursting for four latex balloons and two silicone balloons. Data are grouped into three constraint ranges, which correspond to the balloon RMV diameter larger than the constraining diameter by 0% to 20%, 40% to 60%, and 80% to 100%. Note that inflation pressures and bursting pressures increased as the degree of constraint increased. Pressures in excess of 2600 mm Hg were obtained when small latex balloons were constrained by 80% to 100%.

Cadaveric Human Cerebral Arteries. A cadaveric cerebral artery segment dilatation with artery rupture is shown in Figure 3. In all cases of vessel rupture, a longitudinal tear was formed in the vessel wall, which extended along the length of the inflated balloon (see Fig 3C). Graphs of injected volume versus vessel outer diameter, balloon length, and pressure are shown for a representative dilatation in Figure 4. The balloon used for this dilatation of an M1 segment (unstretched diameter 2.5 mm) was an oversized latex B19 balloon (6 mm RMV diameter). As the balloon was inflated, it first expanded to meet the vessel

TABLE 2: RMV pressure and bursting parameters for balloons inflated in glass tubes

Balloon Material	Catalog Number	RMV (ml)	RMV Diameter/ Constraining Diameter	RMV Pressure (mm Hg)	Bursting Pressure (mm Hg)	Bursting Volume (ml)
Latex	B15	0.12	Unconstrained	600	1550	0.8
			1.0–1.2	600	2050	0.8
			1.4–1.6	700	2250	0.4
	B19	0.3	Unconstrained	600	1250	1.0
			1.0–1.2	800	2350	0.6
			1.4–1.6	2000	2400	0.4
			1.8–2.0	2600	>2600	>0.3
	B17	0.5	Unconstrained	650	1200	1.2
			1.0–1.2	800	1500	0.8
			1.4–1.6	2100	2100	0.5
			1.8–2.0		>2600	>0.4
	B16	0.6	Unconstrained	400	950	2.2
			1.0–1.2	550	1700	1.3
			1.4–1.6	1300	2100	0.8
			1.8–2.0	2200	>2600	>0.7
Silicone	SP8502	0.1	Unconstrained	200	600	0.6
			1.0–1.2	260	850	0.2
			1.4–1.6	600	1050	0.13
	DSB1509	0.9	Unconstrained	300	600	1.9
			1.0–1.2	400	600	1.3
			1.4–1.6		1000	0.8

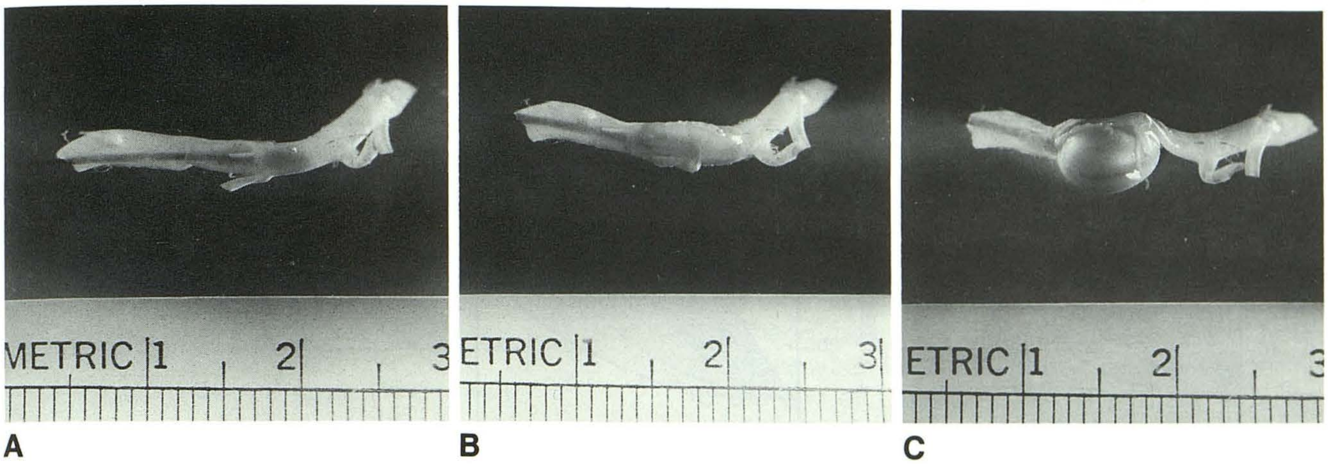


Fig. 3. Latex B16 balloon within a cadaveric human vertebral artery segment. Uninflated (*A*) and partially inflated balloon (*B*) and ruptured vessel with balloon protruding (*C*) are shown.

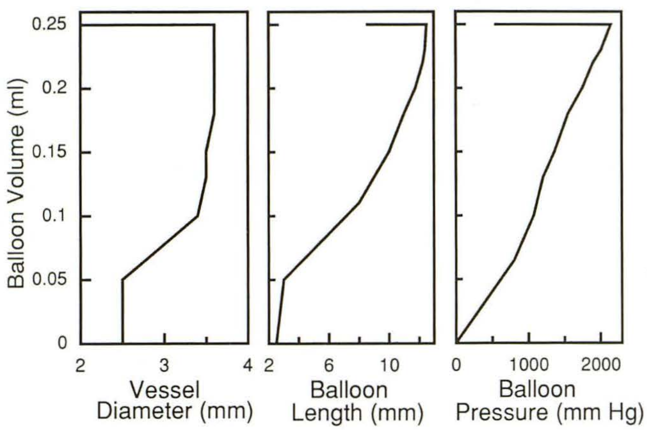


Fig. 4. Dilatation of a middle cerebral artery segment until vessel rupture using a latex B19 balloon. Graphs show injected volume versus vessel outer diameter, balloon length, and pressure.

wall; then the artery increased in diameter. With further injection of fluid, the vessel reached its maximum expansion of 3.5 mm. The balloon continued to lengthen, and the pressure rose markedly until eventually the artery ruptured. In this instance, the vessel ruptured at a pressure of 2150 mm Hg and an injected volume of 0.25 mL, which is below the balloon's RMV of 0.3 mL.

Balloon pressures within dilated arteries are shown in relation to balloon volume in Figures 5A and 5B. Figure 5A summarizes pressure and volume measurements for dilatation of 19 vessel segments ranging from 1.0 to 5.0 mm in initial diameter with an SP8502 balloon. Figure 5B represents 15 vessel segment dilatations with a B15 balloon. As was previously indicated by balloon inflation within glass tubes, pressures increased as the constraining diameter was decreased. Note that dilatation of smaller arteries resulted in a sharp rise in pressure with increasing volume. Pressures rose more slowly when balloons were less severely constrained.

In Figures 6A–6D, balloon pressures are shown in relation to balloon dimensions. The dimension parameter plotted is the balloon aspect ratio, which is equal to the inflated balloon length divided by the balloon diameter within the dilated vessel. In each graph several curves are plotted, each representing a single vessel dilatation with simultaneous pressure and dimension measurements. SP8502 balloon pressures are shown in Figure 6A for three vessel dilatations with initial diameters of 1.25, 2.5, and 3.0 mm. Note that the pressure versus the aspect ratio is consistent over this wide range of initial vessel diameters. Figure 6B represents pressures for B15 balloon dilatations of 2.2-, 3.0-, and 3.5-mm vessels. The curve extending to the upper right of the graph represents pressures within a vessel dilated until arterial rupture. Similar graphs are shown for silicone DSB1804 (2.5- to 3.0-mm vessels) and latex B19 (2.0- to 2.5-mm vessels) in Figures 6C and 6D. All three curves representing vessel dilatation with the B19 balloon in Figure 6D were inflated until the vessel ruptured.

Vessel ruptures occurred only for balloons with RMV diameters greater than 2.5 times the unstretched vessel diameter. Figure 7 shows the relationship between the degree of inflation at the time of vessel rupture and the balloon diameter relative to the initial vessel diameter. The figure includes 19 vessel segments that were inflated until rupture with either small latex or silicone balloons. For balloons with RMV diameters 2.5 to 3 times the initial vessel diameter, vessel rup-

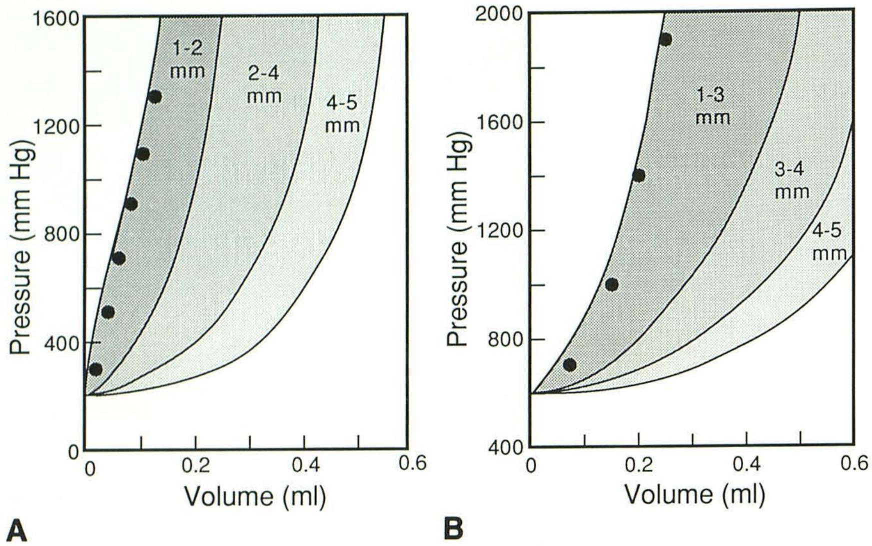
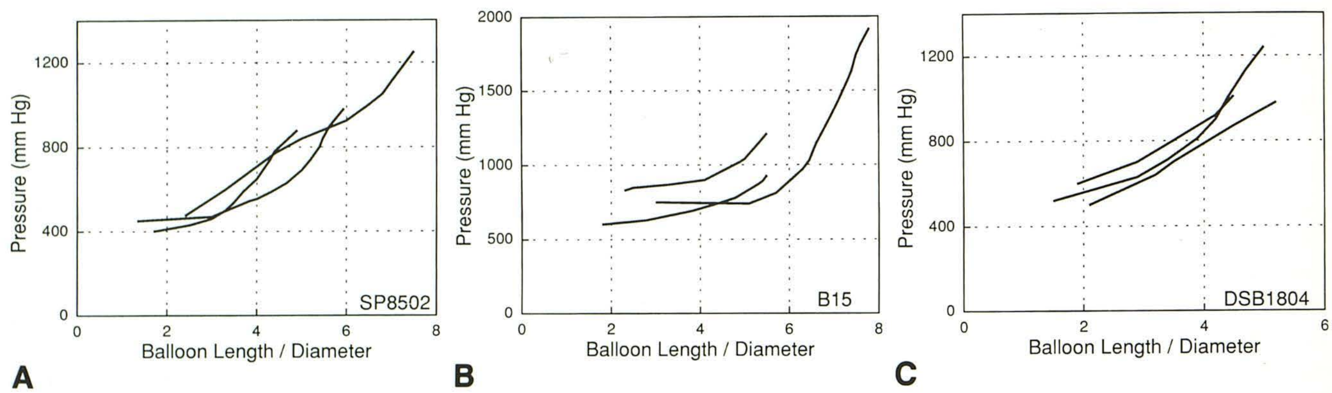


Fig. 5. Balloon pressure as a function of injected volume and initial vessel size for cerebral artery dilatation with a silicone SP8502 balloon (*A*) and a latex B15 balloon (*B*). Pressure-volume curves for dilatation of multiple human cerebral artery segments are represented by *shaded regions* divided into several unstretched-diameter ranges. Data points (●) show pressure-volume measurements for dilatation of a canine basilar artery with an initial diameter of 1.5 mm.



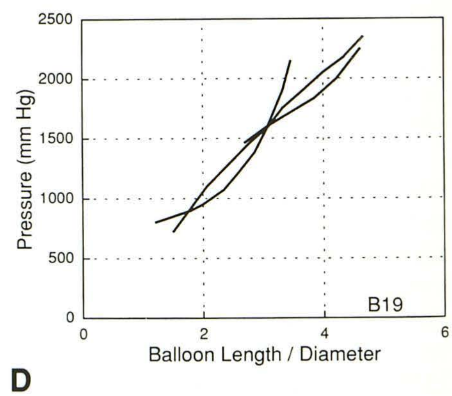


Fig. 6. Balloon pressure versus aspect ratio (balloon length divided by diameter) for cadaveric human cerebral artery dilatations with SP8502 (*A*), B15 (*B*), DSB1804 (*C*), and B19 (*D*) balloons.

ture generally occurred only for injected volumes above the RMV. However, when balloons were greatly oversized, vessel ruptures occurred at volumes lower than the RMV. Average balloon pressures at vessel rupture are in the range of 1000 to 2000 mm Hg depending on balloon type and degree of constraint. Ruptured vessels were dilated to a diameter as low as 20% and as high as 200% of the initial unstretched diameter just before rupture. Histology (Parisi JE, personal communication) of vessels which were dilated but not ruptured did not reveal any obvious damage in light microscopy. When vessels were ruptured, tears occurred in a longitudinal, slit-like fashion and with fracture of the different wall layers in a single area of the vessel circumference (Fig 8).

Canine Basilar Arteries. Spot films of a canine basilar artery before and during dilatation and after arterial rupture are shown in Figure 9. The initial size of the dilated vessel in each of the five studies was 1.5 mm. The five balloons studied

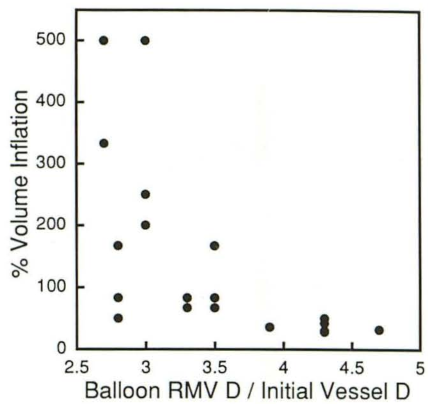


Fig. 7. Cadaveric human cerebral artery ruptures. The degree of balloon inflation at vessel rupture (expressed as a percent of balloon RMV) is plotted against the ratio of the balloon RMV diameter to the initial vessel diameter.

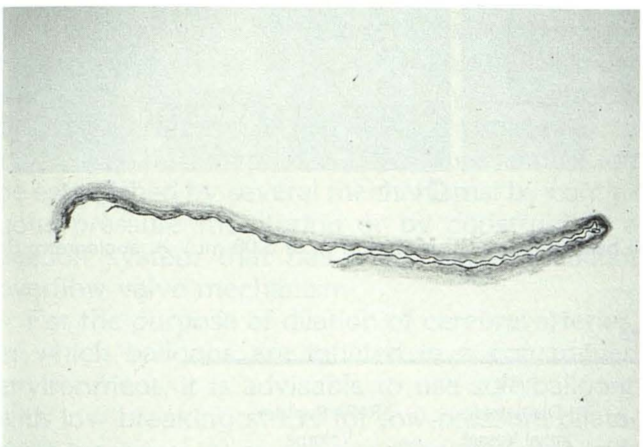


Fig. 8. Cross-section of a middle cerebral artery dilated until rupture. Note that all layers of the arterial wall have ruptured in one area only.

are listed in Table 3 along with pressure, diameter, and volume at vessel rupture. Balloons labeled SP-PT1 and SP-PT2 are prototype silicone balloons, constructed of the same material as the SP8502 balloon but with smaller diameters. SP-PT1 is 2.2 × 18 mm at an RMV of 0.1 mL; SP-PT2 is 3.0 × 12 mm at an RMV of 0.08 mL. Balloon pressures at vessel rupture ranged from 1300 to 1800 mm Hg (except for B15 dilatation), which are comparable to those measured in cadaveric human cerebral arteries. The large pressure obtained for the vessel rupture with the latex B15 balloon was likely due to bending or crimping, which prevented full expansion of the balloon. Note that the greatly oversized latex B16 balloon caused vessel rupture at a fraction of the balloon's RMV, whereas smaller balloons required volumes greater than their RMVs. Pressure-volume curves for the SP8502 and B15 balloon canine artery dilatations are shown in Figures 5 and 6, respectively. In both cases, balloon pressures are similar to those measured in like-sized human cerebral artery specimens.

Discussion

The tension in the wall of a balloon indicates the magnitude of the dilating force the balloon provides when inflated within a vessel. According to the law of Laplace, $T \propto PR$, where T is the tension in the balloon wall, P is the internal pressure, and R is the balloon radius. The measurement of decreasing pressure with multiple balloon inflations indicates that the balloon wall tension and dilating force can be reduced, especially for latex. However, even after multiple inflations, latex balloons provide a larger dilating force than silicone balloons of the same size, as indicated by their higher internal pressures (Table 1).

A balloon constructed of a certain material ruptures when the stress on the wall of the balloon exceeds the breaking stress of that material. The wall stress, σ, is a function of wall tension and thickness, t: $\sigma = T/t \propto PR/t$. For balloons constructed of the same material with similar wall thickness, a balloon with a smaller radius requires a higher internal pressure to produce the same tension and wall stress as a larger balloon. Therefore, pressures within smaller balloons will be higher than larger balloons before bursting as data in Table 1 illustrate, with the exception of the silicone SP8502 balloon. The softer SP8502 balloon has a lower RMV pressure and bursting pressure in relation to the other silicone balloons because it is produced from a softer silicone elastomer.

In an unconstrained environment, balloon pressures are a function of the balloon material and size and degree of balloon inflation. In a constrained environment, the balloon pressure obtained with a constant inflation volume is dependent on the degree of constraint. As shown by the pressures measured within balloons constrained in glass tubes and cerebral arteries, the higher the degree of constraint, the higher the internal pressure. The pressure increase in a balloon due to a constraining force can be so dramatic that balloon bursting pressures can be obtained below recommended maximum volumes.

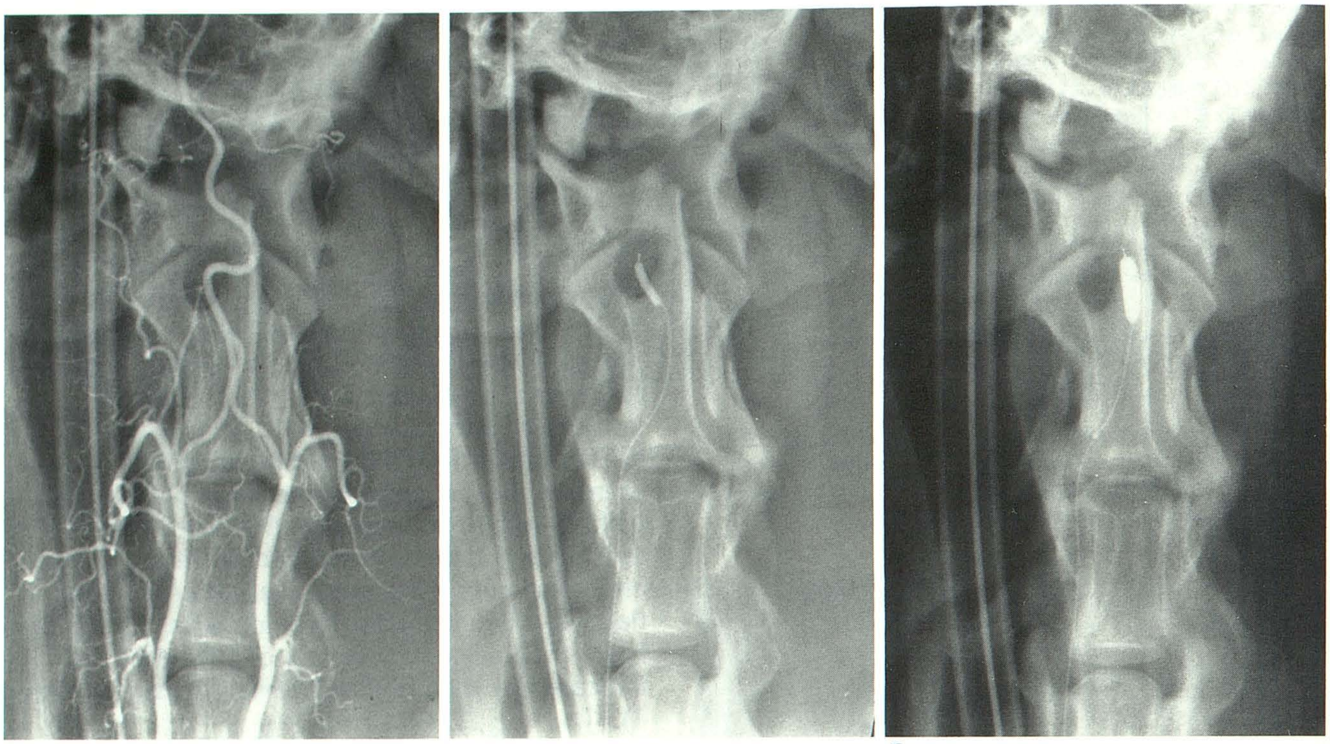


Fig. 9. Dilatation of a canine basilar artery with a prototype silicone balloon (3.0 × 12 mm at RMV of 0.08 mL). *A*, angiogram; *B*, balloon partially inflated; and *C*, vessel ruptured.

TABLE 3: Dilatation and rupture of canine basilar arteries

Catalog Number	RMV Diameter (mm)	Pressure at Vessel Rupture (mm Hg)	RMV Diameter/ Initial Vessel Diameter	RMV/Rupture Volume
SP8502	3.5	1300	2.3	0.8
SP-PT1	2.2	1500	1.5	0.5
SP-PT2	3.0	1500	2.0	0.5
B15	6.0	>2600	4.0	0.3
B16	8.0	1800	5.3	3.0

The balloon dilatations of human cadaveric arteries and canine basilar arteries seem to have similar effects on the vessel wall, with initial elasticity of the vessel and comparable rupture pressures. The event of vessel dilatation and rupture occurred for both vessel types in a similar manner, with an initial dilation and subsequent pressure increase at a constant vessel diameter to the point of vessel rupture. The likelihood of vessel rupture is dependent on several variables, including the dilating force provided by the inflated balloon, the size of the balloon relative to the unstretched vessel size, and the maximum distention of the dilated vessel wall. Vessel rupture occurred in a longitudinal pattern with extensive slit-like fissuration of the vessel wall. No obvious wall damage could be observed in vessels with dilatation only, although high pressures were used. In living tissue, however, endothelial or vessel wall damage might occur secondarily to such dilatation, and our observations suggest that it could be difficult to demonstrate acute structural injury.

Cerebral artery fracture may occur under many different circumstances (3). If balloons are involved, the likely mechanism is rupture of the vessel wall in a longitudinal pattern secondary to overinflation of the balloon at a high pressure. To prevent such an overinflation of a balloon in a cerebral artery, several factors must be considered. Although unconstrained balloons inflate to a lower pressure at a given diameter, the pressure may rise dramatically as soon as a balloon is constrained by the arterial lumen. The ratio of length to diameter (aspect ratio) of a constrained balloon, which is easily controlled by observation during fluoroscopy, is a helpful indicator of balloon pressure, because the pressure increases as the aspect ratio increases (see Fig. 6A–6D). An oversized balloon inflated in a constrained environment may lead to arterial rupture as soon as critical pressure values are reached. For the purpose of vessel dilatation, it seems thus safe to use balloons of maximal inflated diameter not exceeding the unstretched vessel lumen for more than approximately 20%.

The choice of a balloon with a low breaking stress should be favored if the balloon shell is compliant and potentially may overinflate the arterial lumen. For dilatation of vasospasm, for which in general only low dilatation forces are required, a soft silicon shell seems to be most appropriate. Another method to avoid overinflation and arterial and/or balloon rupture is to control the balloon pressure. Pressure control can be established by several mechanisms: by continuous pressure monitoring or by constructing a balloon system that has a pressure-dependent overflow valve mechanism.

For the purpose of dilation of cerebral arteries, in which balloons are inflated in a constrained environment, it is advisable to use soft balloons with low breaking stress for low-pressure dilatations (vasospasm) or noncompliant balloons with limited volume and pressure control for high-pressure dilatations (atherosclerotic stenosis).

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