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A Pressure and Volume-Limited Inflation Syringe

Peter Thorburn Walling, B.Sc, MB.BS., F.F.A.R.C.S.,* A. William Paulsen, MMSc., Ph.D. CCE,†
Denise Rorech-Maleck, M.D.‡

Excessive pressures generated in balloon-tipped pulmonary artery (PA) catheters, which have migrated distally, contribute to the morbidity and mortality associated with their use. A simple syringe modification is described by which additional dead space is added to the inflation syringe. The volume of injected gas is also increased to compensate for the dead space, thus ensuring correct balloon inflation. The added dead space acts as a compression chamber should normal balloon inflation be restricted (Safety Syringe). An additional modification is described in which the syringe nozzle is reduced to a pinhole, thus decreasing the rate of gas escape and lessening the possibility of rapid lateral impact of the balloon on the PA wall (Super Safety Syringe). The syringes were compared with a standard volume-limited syringe. Pressures were recorded at the intraluminal site of balloon contact in rigid tubes, live porcine PA, and human cadaver PA. The Safety Syringe consistently generated pressures of less than 975 mmHg, the lowest pressure at which human PA rupture has been demonstrated, under the most adverse simulated clinical conditions. The currently used volume-limited syringe generated a pressure of approximately 1500 mmHg when balloon inflation was restricted, and in one human cadaver PA, produced rupture. The pinhole modification of the Super Safety Syringe increased the time to generate maximum pressure from less than 0.25 s to about 1.5 s. (Key words: Equipment, catheters: pulmonary artery. Equipment, syringes: pressure-limited; rate-limited; volume-limited. Monitoring, vascular: pulmonary artery catheters.)

PULMONARY ARTERY (PA) damage caused by balloon-tipped catheters is a source of morbidity and mortality, with clinical signs ranging from an asymptomatic pulmonary infiltrate to an exsanguinating hemoptysis.[1–8] Causative factors include distal migration of the catheter tip, balloon overinflation resulting in direct PA rupture, rapid lateral impact of the balloon, and asymetric hyperinflation, propelling the catheter tip peripherally to spear the PA wall.[9–11]

The incidence of PA damage is approximately one in 500–1000 catheter insertions[1,8]§ and is usually related to balloon overinflation in the mid to distal PA.[9] Over 80% of PA ruptures occur in patients over 60 yr of age,[12,13] and approximately 50% of overt ruptures are fatal.[5,13]

A significant safety feature in the use of the PA catheter would be a mechanism to automatically limit balloon inflation pressure in the event of peripheral migration of the catheter tip into a small branch of the PA.[2] Hardy[9] has reported that an increase in dead space in a balloon catheter system reduces the intraballoon pressure for a given volume of injected gas, but at the cost of a reduced balloon volume. If the volume of injected gas is increased to ensure correct balloon inflation, the deliberate addition of appropriate dead space would act as a safety chamber into which compressed gas could be accomodated should normal balloon inflation be restricted. A second safety feature would be to reduce the size of the syringe nozzle to a pinhole to reduce the rate of gas escape from the syringe, and thus lessen the possibility of rapid lateral impact of the balloon onto the arterial wall.[10]

The maximum allowable intracatheter pressure must be significantly greater than that required to initiate balloon inflation, 500 mmHg above atmospheric, so that the operator may be confident that inflation has occurred.[10] However, it should be limited to produce a PA intraluminal pressure of less than 975 mmHg, the lowest pressure at which PA rupture has been demonstrated.[9]

To construct a dead-space syringe we used materials easily available in a hospital and that involved no moving parts. We tested the syringe with the most commonly used PA catheter in situations as close to the clinical setting as possible.

Materials and Methods

The PA catheter studied was the Swan-Ganz® (TD Cath 1.5 cc CAP, 93A-131-7F, American-Edwards Laboratories). The kit is supplied with a 1.5-cc volume-limited syringe (Monoject) which produces balloon inflation to 13 mm diameter.

The syringe modification was designed, by trial and error, using easily obtainable disposable materials.

It was found that if the syringe dead space was increased by 1.1 cc, and the injected volume of gas was increased from 1.5 cc to 2.0 cc, correct balloon inflation was achieved.

To construct a pressure-and volume-limited inflation device (Safety Syringe), a 5-cc plastic syringe is used (Becton-Dickenson Co.). The volume of injected gas is limited by puncturing a side hole into the barrel centered at the 3.4-cc mark using a 15-g needle (Monoject).

* Staff Anesthesiologist, Baylor University Medical Center, The University of Texas Southwestern Medical School, Dallas, Texas.

† Director of Biomedical Engineering for Anesthesia and Surgery, Director of Anesthesia Research, Baylor University Medical Center, Assistant Professor, Department of Anesthesiology, The University of Texas Southwestern Medical Center.

‡ Resident, Parkland Memorial and Affiliated Hospitals, Dallas, Texas.

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Address reprint requests to Dr. Walling: Suite 860 Wadley Tower, 3600 Gaston Avenue, Dallas, Texas 75246.

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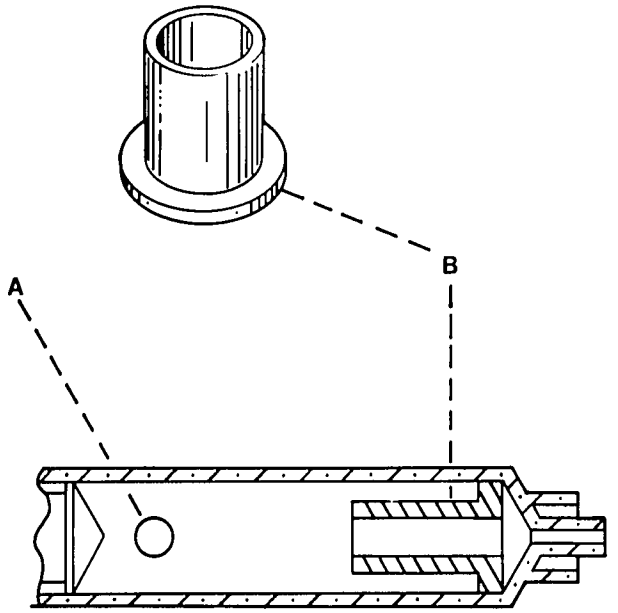

FIG. 1. Diagram of pressure-and volume-limited syringe showing: *A.* side hole, which limits volume of compressible gas; and *B.* hollow spacer, to increase syringe dead space, and thus form safety chamber. The flange ensures a snug fit in the 5-cc syringe barrel.

Gas compression will not occur until this hole has been passed by the leading surface of the syringe plunger.

The dead space is increased by pushing a hollow spacer into the syringe barrel to reach the 1.4-cc mark. In the prototype described, an iv tube protector cover is cut in half, and the hollow flanged part is used as it fits tightly into the syringe barrel (Pharmaseal® K50L, fig. 1). It has been found that this method provides a reproducible dead space increase of 1.1 cc. If alternative materials are used as a spacer, it is important to check the volume of dead space by air displacement so that the correct allowance may be made for the volume of the spacer itself.

A modified dead-space syringe (Super Safety Syringe) was constructed in which the male leur was reduced to a pinhole by sealing a 5-mm section of a 30-g needle shaft with a drop of epoxy resin, in this way the maximum pressure and inflation rates were limited.

The syringes are used clinically in the same way as the Monoject volume-limited syringe, the plunger being depressed only long enough for the PA catheter to float into position or for a few respiratory cycles when reading a PA capillary wedge pressure.

PHYSICAL STUDIES

The same PA Catheter was inflated with Monoject, Safety Syringe, and Super Safety Syringe, and the fully inflated balloon was measured using a caliper to ensure correct expansion to 13 mm.

To simulate distal migration in the PA and possible maximum intraluminal pressures generated by forceful overinflation of the PA balloon, the catheter was inserted into a series of endotracheal tubes of known internal diameter (3.5–10.0 mm). A side-looking catheter tip pressure transducer (MPC-500®, Millar Instruments, Houston, TX) was attached to the PA catheter, the sensor facing the balloon at midballoon level. The catheter shaft and transducer wire were held together with a 1 in tube of heat-shrunk plastic, situated proximally to allow free expansion of the balloon while the transducer remained in intimate contact with the balloon equator. The PA catheter and attached transducer measured 3.5 mm across. Pressures were recorded using a Hewlett Packard 8805D Carrier Amplifier and a chart recorder. Calibration of the catheter tip pressure transducer, amplifier, and chart recorder were checked at three points (0, 1000, 2000 mmHg) using Bio-Tek® (Winooski, VT) model DPM II universal pressure meter, and the Bio-Tek® model DPM I pneumatic transducer tester. The catheter tip and attached transducer were covered with water-soluble lubricating jelly before insertion into each tube. Within each tube, and in the same position, the PA balloon was forceably inflated by hand, disregarding any resistance that was felt, in an attempt to reproduce the most dangerous clinical scenario. The Monoject and Safety Syringe were each used twice until a steady pressure was attained, then the balloon was deflated by withdrawal of the syringe plunger. Each inflation lasted approximately 5 s. Data were digitized from the chart recording using a Hewlett Packard® model 17623A high resolution digitizing tablet and a Hewlett Packard® model A900 computer system.

IN VIVO STUDIES

Dynamic studies to compare syringes were conducted using the same measuring equipment. In mongrel pigs weighing between 20 kg and 25 kg, anesthesia was induced with ketamine and maintained using enflurane in oxygen. Median sternotomy was performed and a double purse-string suture placed in the proximal PA. The PA catheter and attached transducer were inserted into the PA through a small incision and the sutures tightened enough to provide hemostasis. The catheter and attached transducer were advanced randomly into a distal branch of the PA. Each of the syringes (Safety, Super Safety, Monoject) were used in turn to hyperinflate the PA catheter balloon until a steady PA intraluminal pressure was attained. In the first animal only, the Monoject and Safety Syringe were compared. The PA intraluminal pressures were unexpectedly low and a reproducible pressure spike was observed during inflation with Safety Syringe (fig. 2). The pressure spike could only be obtained from one position in the PA, and only in the first animal. Although it

is thought that the catheter was actually in the mid PA and not the distal PA, this study is included because the unexplained spike in pressure together with the concern regarding rapid lateral impact on the PA wall previously mentioned led to the pinhole modification, resulting in the Super Safety Syringe. Studies in the second two pigs compared the Monoject, Safety Syringe, and Super Safety Syringe. Four readings were taken with each syringe in each pig.

In Vitro Human Studies

Human cadaver lung tissue was removed at autopsy and immersed in saline to which antibiotics has been added. The bottled specimens were stored overnight at 4° C and measurements made the next day.

Using the same measuring equipment, the catheter and attached transducer were advanced into various distal branches of the pulmonary artery. After vigorous balloon inflation, steady-state pressures were measured three times each for the Super Safety, Safety, and Monoject syringes. The catheter was then withdrawn into a larger branch and pressure recordings made as before. Some mid PA readings were discounted because pressures were not reproducible. This was probably due to the balloon sliding into different positions upon inflation.

To obtain an approximate idea of the PA diameters at some of the inflation sites, castings of the PA were made from the second and third autopsy specimens, a right middle lobe and left upper lobe, respectively (Batson's® No. 17 Plastic replica and corrosion kit, Polysciences Inc., Warrington, PA).

Results

Physical Studies

Pressures generated increased with decreasing tube size. The maximum pressure generated in the smallest tube (3.5 mm) was 1565 mmHg using the Monoject syringe. The Safety Syringe generated 830 mmHg in the same tube. The Monoject Syringe consistently generated pressures above 1000 mmHg in tubes 5.0 mm and smaller (fig. 3).

In Vivo Studies

The Monoject syringe produced a peak pressure of 1545 mmHg (range: 1521–1569 mmHg) in pig 2, and 1455 mmHg (range: 1427–1488 mmHg) in pig 3. The plateau pressure was 1475 mmHg (range: 1463–1495 mmHg) in pig 2, and 1375 mmHg (range: 1343–1398 mmHg) in pig 3.

The Safety Syringe produced a peak pressure of 955 mmHg (range: 906–1021 mmHg) in pig 2, and 810 mmHg (range: 800–832 mmHg) in pig 3. The plateau pressure was 870 mmHg (range: 860–884 mmHg) in pig 2, and 773 mmHg (range: 768–778 mmHg) in pig 3.

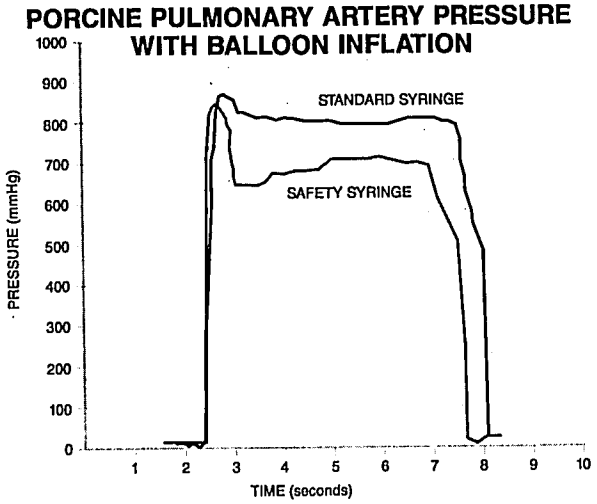

FIG. 2. Porcine mid PA intraluminal pressures with balloon inflation. The unexpected spike seen when Safety Syringe was used let to the addition of the pin hole nozzle (pig 1).

Using the Super Safety Syringe, no initial peaks were seen; the maximum pressure in pig 2 was 795 mmHg (range: 750–853 mmHg), and 775 mmHg (range: 752–794 mmHg) in pig 3.

The Monoject and Safety Syringe generated maximum pressures in less than 0.25 s. The Super Safety Syringe generated maximum pressure in about 1.5 s. No signs of PA rupture occured in any of the pigs (fig. 4).

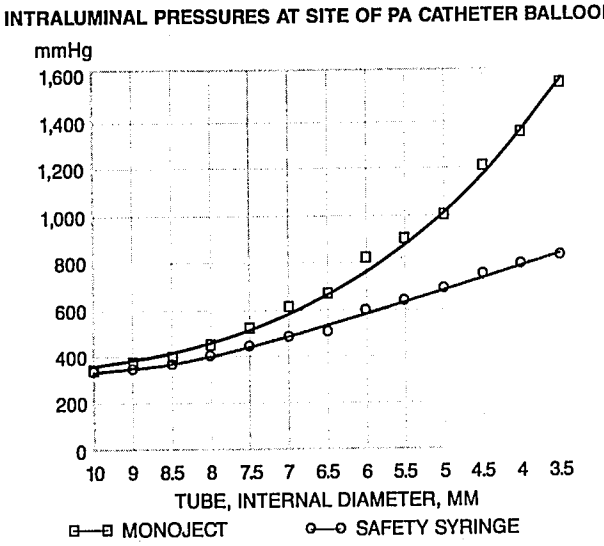

FIG. 3. Maximum intraluminal pressures using the Monoject and Safety Syringe. Distal migration in the PA in simulated by inflating the balloon in cylindrical tubes of decreasing size.

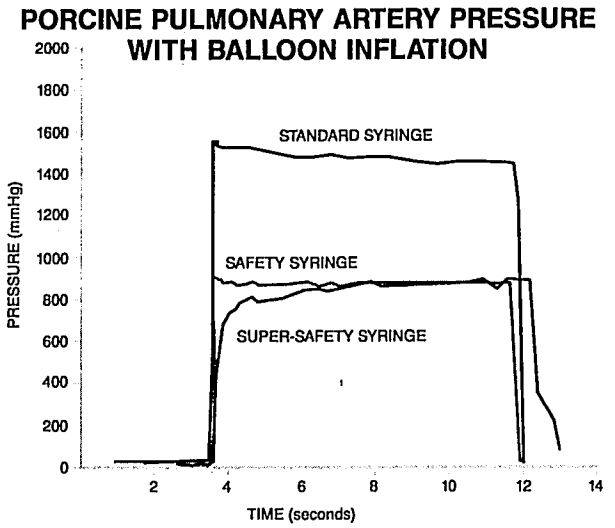

FIG. 4. Typical porcine distal PA intraluminal pressures with balloon inflation. Monoject, Safety Syringe, and Super Safety Syringe compared (pig 2).

HUMAN STUDIES

The first PA we studied had been partly skeletonized by the pathologist, but the distal branches were still surrounded by lung tissue. After six inflations with the Safety Syringes, the Monoject syringe was used, and at a pressure of 1500 mmHg, the balloon caused rupture of the PA and broke through the thin layer of overlying lung tissue (fig. 6). The rupture happened abruptly, with no apparent stretching of the vessel. The transducer was on the opposite side of the catheter to the rupture and therefore cannot be seen in the figure. The distal 3 mm of the catheter remained within the lumen of the PA. After the specimen had been photographed, it was very difficult to deflate the balloon. The inflation orifice within the balloon was occluded by the undamaged part of the PA lumen. The balloon had to be squeezed to remove the air. When the catheter was removed, the hole in the PA measured 3 mm × 3 mm round.

The remainder of the pressure studies were made using the intact right middle and left upper lobes. Balloon expansion could be observed by watching the swelling of the overlying lung tissue. Although the setting was not physiological, two observations are pertinent. First, expansion was obviously slower with the Super Safety Syringe than with either the Safety or the Monoject syringes. Second, when balloon expansion was accompanied by catheter movement in the larger branches of the PA, the movement was always seen to be backwards or proximal, causing withdrawal of the catheter tip, not advancement.

The greatest pressure generated by the Monoject syringe was 1560 mmHg, and the highest pressure generated by either of the Safety syringes in over 80 inflations was 940 mmHg (fig. 5).

Discussion

The pressures recorded from the rigid tubes, while a poor substitute for a branching, moving PA subjected to complex intrathoracic pressure changes, at least indicate the important effect of added dead space in the inflating syringe. Although allowance must be made for the small bulk and possible distorting effect of the transducer itself, it would appear that by increasing balloon restriction, the benefit of added dead space increases substantially at 6 mm diameter and below.

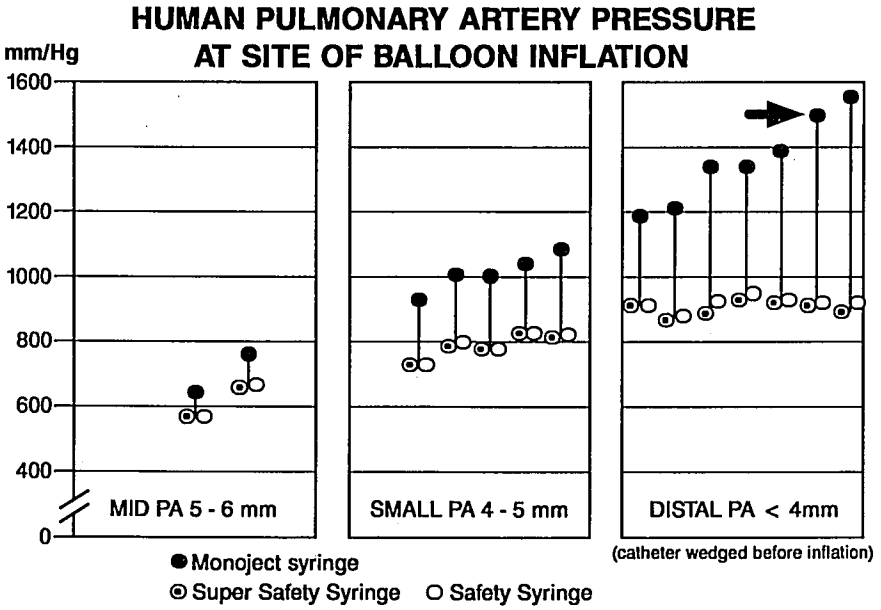

FIG. 5. Maximum sustained intraluminal PA pressures at site of balloon inflation *versus* approximate PA diameter. Readings from same location joined by vertical line. Pooled results from three human cadaver lungs. Each point is the mean of three readings, largest variation 5% from the mean. Arrowed result did not attain sustained pressure, but PA burst at 1500 mmHg.

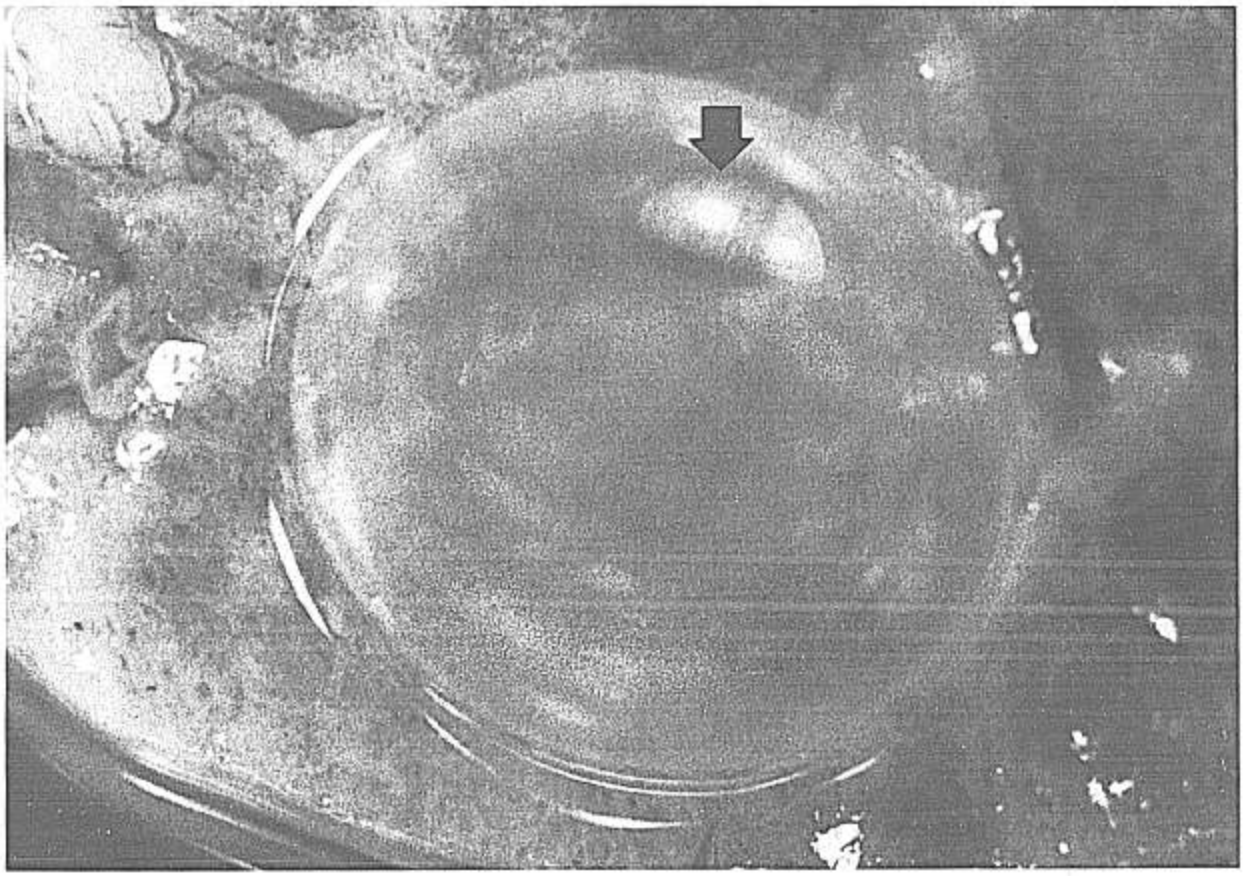

FIG. 6. Pulmonary artery rupture in human cadaver. The balloon has burst through the artery wall and lung tissue. The arrow points to the catheter still within the lumen of the PA. The catheter tip is 3 mm to the left of the edge of the hole.

In the PA of the live pig, an initial pressure spike was always seen, except when the pinhole modification was used. In pig 1 (fig. 2.), the large pressure spike produced by the Safety Syringe closely resembles the normal pattern of intraballoon pressure change in unrestricted balloon inflation demonstrated by McDonald,[10] in which he showed that when the critical opening pressure of about 500 mmHg was achieved, the balloon popped open rapidly, and that shortly thereafter, the intraballoon pressure settled to a plateau of about 300 mmHg. The large pressure spike (fig. 2) probably reflects the result of rapid lateral impact and is almost certainly from the mid PA where significant and rapid balloon expansion occurred. It prompted the pinhole modification, and although we never saw such a large spike again in hundreds of pressure readings from both live pig or human autopsy PA studies, we feel that the pinhole modification is worthwhile. The relative contribution from rapid rate of pressure increase, causing rapid lateral impact, and maximum intraluminal pressure increasing wall tension in the production of PA damage, is unknown. Therefore, it would seem prudent to reduce both the rate of increase and maximum pressures to levels which are clinically acceptable.

The pressures recorded from the distal PA in the latter two pigs were similar and highly reproducible. With the most vigorous inflation, neither type of Safety Syringe produced a sustained PA intraluminal pressure greater than 975 mmHg, while the Monoject syringe repeatedly generated pressures 400 mmHg higher than 975 mmHg, the lowest pressure shown to cause rupture in the human PA. It must be appreciated that with the slower balloon inflation produced by the Super Safety Syringe, the subtle loss of resistance felt through the thumb is diminished as well. We felt that this is a small price to pay for the increased safety in the operation of PA catheters, and that balloon inflation should be regulated by feedback from the patient monitor and not by touch.

The autopsy studies must be viewed with caution, as the specimens were at least 24 h old. Also, the vessel that ruptured may have been weakened by the six previous inflations using the Safety syringes. However, we feel we have shown that the addition of dead space to a syringe predictably and reliably reduces the pressure to which the human PA may be subjected during balloon inflation.

Neither the Safety Syringe nor the Super Safety Syringe is intended to replace detailed instruction and skilled use

of the pulmonary artery catheter. Also, the danger of PA damage from a cold, stiff catheter during open-heart surgery remains, unless the catheter is pulled back at the appropriate time.¶

The principle of adding known amounts of extra dead space to a syringe may also be useful in other systems where balloon catheters are used and pressures may be limited accurately, *e.g.*, urinary and biliary catheters.

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