

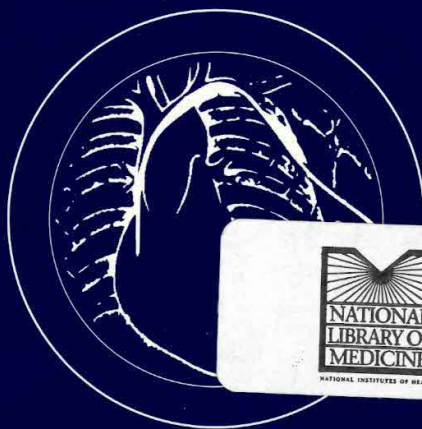
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VOLUME 46, NUMBER 1, JANUARY 1999

Catheterization and Cardiovascular Interventions

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Volume 46, Issue 1 was mailed the week of December 21, 1998.



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Catheterization and Cardiovascular Interventions (ISSN 1522-1946) is published monthly by Wiley-Liss, Inc., a division of John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012. **Send subscription inquiries to:** John Wiley & Sons, Inc., Subscription Department, 9th floor, 605 Third Avenue, New York, NY 10158.

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Subscription price: Volumes 46–48, 1999, twelve issues, \$1,470 in the U.S., \$1,590 in Canada and Mexico, \$1,692 outside North America. **Special Personal Rate:** Volumes 46–48, 1999, within North America \$295, \$367 outside North America. **NOTE:** Subscriptions at the personal rate **MUST** be paid by personal check, credit card, bank draft or money order. **Special "Physicians in Training" Rate:** \$99 for 1999 within North America. **ALL** orders at the Special Physicians in Training rate **MUST** be accompanied by a signature certifying participation in the program (Director of Program). All subscriptions outside North America will be sent by air. Payment must be made in U.S. dollars drawn on a U.S. bank. **Members of the Society for Cardiac Angiography and Interventions** receive the journal as part of their dues. **Offprint sales and inquiries** should be directed to the Reprint Billing Department, John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158-0012, (212) 850-8776; all other inquiries should be directed to the Customer Service Department (212) 850-6645. **Change of Address:** Please forward to the subscriptions address listed above 6 weeks prior to move; enclose present mailing label with change of address. **Claims** for undelivered copies will be accepted only after the following issue has been received. Please enclose a copy of the mailing label or cite your subscriber reference number in order to expedite handling. Missing copies will be supplied when losses have been sustained in transit and where reserve stock permits. Send claims to John Wiley & Sons, Inc., Customer Service, 605 Third Avenue, New York, NY 10158. If claims are not resolved satisfactorily, please write to Caroline Rothaug, Subscription Fulfillment and Sales, John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158. **Cancellations:** Subscription cancellations will not be accepted after the first issue has been mailed. Periodicals postage paid at N.Y., N.Y., and at an additional mailing office. **POSTMASTER:** Send change of address to Catheterization and Cardiovascular Interventions, Subscription Systems and Distribution, John Wiley & Sons, Inc., 605 Third Avenue, New York, NY 10158.

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A New Technique for Sizing of Atrial Septal Defects

Xiaoping Gu, MD, Young-Min Han, MD, James Berry, RDMS, Myra Urness, and Kurt Amplatz,* MD

This article evaluates a new compliant balloon catheter for sizing of Atrial Septal Defects (ASDs) in vitro and in vivo using X-ray and echo measurements. A phantom consisting of a plastic plate with 17 circular holes varying from 8 to 30 mm was used to determine the accuracy of the measurements. The catheter has a 7 Fr shaft with a double lumen. The balloon is made from a 0.002" plastic membrane. Four platinum marker bands on the shaft of the catheter allow radiographic measurements. The balloon catheter was placed through various holes of the phantom and inflated with 38% contrast medium. X-ray measurement by video and cine recording were performed and compared with the true measurement of the model. The study was carried out in a double blind fashion. For echo measurements, the plastic model was immersed in a water bath. The balloon was inflated with water and measured in a long-axis view. The actual diameters were compared with the measurements obtained by video, cine, and echo recordings. One young pig with a surgically created ASD was used for in vivo measurement. The balloon catheter was passed through the ASD over an exchange wire, inflated with diluted contrast medium until a waist was observed, which was measured by video and cine techniques. The animal was euthanized, and the defect was measured by a tapered measuring probe. The difference between the actual size and measurements obtained by video recordings was 0.54 ± 0.30 mm, by cine 0.62 ± 0.20 mm, and by echo measurements 0.60 ± 0.43 mm. All measurements were less than 1 mm in error except for four measurements (< 1.5 mm). A strong correlation was present between each two groups ($r = 0.99$, $P < 0.0001$). In the in vivo study, the size of the video and cine recordings (14.2 and 13.9 mm, respectively) were very closer to the actual size (14 mm) as measured by a probe in the postmortem specimen. The new balloon catheter provides a more rapid and precise determination of the stretched diameter of atrial septal defects. It eliminates the error of pulling a catheter through the communication. This new technique should be of benefit to all investigators using septal occlusion devices and will facilitate the selection of the properly sized Amplatzer septal occluder. *Cathet. Cardiovasc. Intervent.* 46:51–57, 1999. © 1999 Wiley-Liss, Inc.

Key words: balloon catheter; balloon measurement; stretched diameter; atrial septal defect

INTRODUCTION

Transcatheter closure of secundum atrial septal defect (ASD) has been well described and is a well-established technique [1–11]. For all devices determination of the so called stretched diameter of the communication is required. Recently, a stenting device was described where exact sizing is of paramount importance for success [12]. The standard technique of sizing is by an inflated latex balloon, which is pulled through the communication as originally described by King et al. [13]. This technique, however, is not very reliable and leads to the design of a new balloon catheter that does not have to be pulled through the communication. It is the purpose of this study to evaluate its accuracy in an in vitro and in vivo study using X-ray and echo measurement techniques.

METHODS

The Catheter

The catheter (AGA Medical, Golden Valley, MN) is 7F, made from radiopaque nylon (20% barium sulfate). It has a double lumen and end hole allowing for passage of a 0.035" guidewire. The balloon is compliant and made from a very thin stretchable polyurethane membrane

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Received 16 March 1998; Revision accepted 23 July 1998

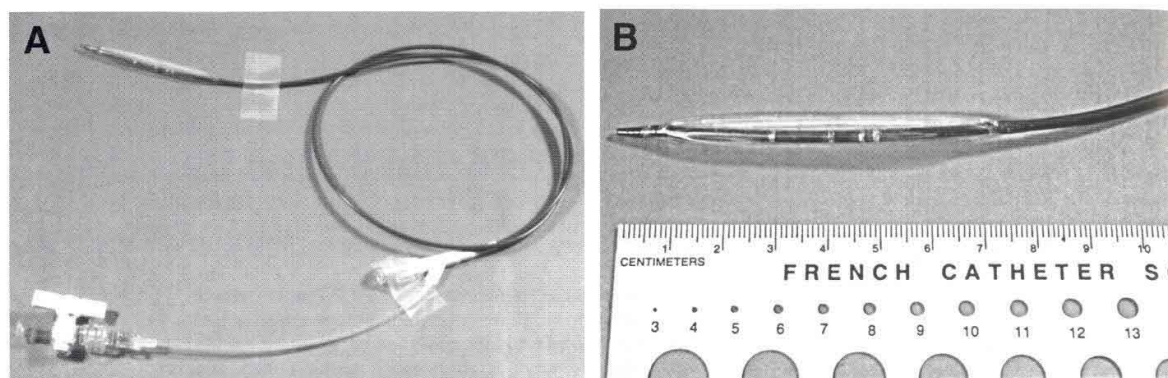


Fig. 1. A: Overview of the catheter. B: Close-up view of the catheter tip showing balloon and platinum marker bands.

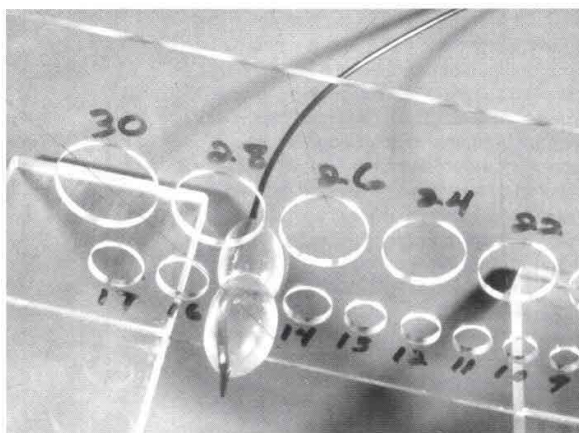


Fig. 2. Close up view of plastic model with holes of various sizes. Balloon catheter deployed showing pronounced waist.

(0.002" in thickness). The balloon-carrying segment is angled 45° to the shaft, providing a more or less right-angled position in relation to the atrial septum. Inflation of the balloon is accomplished by a side port (Fig. 1A).

Twenty side holes, arranged in spiral fashion in the balloon segment, allow rapid inflation and deflation. Four radiopaque markers made from small, 1-mm-wide platinum bands are attached at 10-mm, 5-mm, and 2-mm intervals on the shaft of the catheter. (Fig. 1B).

In Vitro Test

A phantom consisting of a 3-mm plexiglass plastic plate was used to determine the accuracy of various balloon measurements (Fig. 2). Seventeen circular holes have been drilled in the test object varying from 7.79 mm to 30.28 mm. The size of the holes did not correspond to full metric numbers to eliminate bias in a double blind

study. The balloon catheter was inserted through various holes and the radiopaque markers were imaged by video tape and recorded on 35-mm cine film in the 4" magnification mode. Without changing the tube-to-object distance, the balloon was inflated with 38% Diatrizoate solution using a 60 cc syringe. Inflation was continued until a slight waist was observed, which was measured by video and cine recording representing the stretched diameter (Fig. 3). The balloon pressure was measured by a strain gauge and the amount of contrast medium injected was recorded.

All ultrasound measurements were made with a Hewlett Packard 2000 imaging system employing a 7.5/5.5 MHz transducer. The same plastic model was immersed in a degassed water bath. The balloon was placed through various holes and inflated with degassed water. Great care was taken to eliminate all air from the balloon to avoid acoustic artifacts. The balloon was imaged along its long axis. The balloon waist diameter was measured on line from a freeze-frame image using electronic calipers (Fig. 4).

The actual diameters of each hole in the plastic plate was measured by a digital electric ruler and compared with the measurements obtained by video, cine, and echo recordings. The Pearson correlation coefficients were calculated. A *P* value smaller than 0.01 was considered statistically significant.

The balloon catheter was placed across 10 atrial septal defects in human postmortem specimens and a distinct waist could be observed (Fig. 5).

In Vivo Test

One young domestic pig, weighing 30 kg, was used for the in vivo study. The ASD was surgically created as previously described [12]. Two weeks after the surgery, the right femoral vein was surgically exposed and an 8F

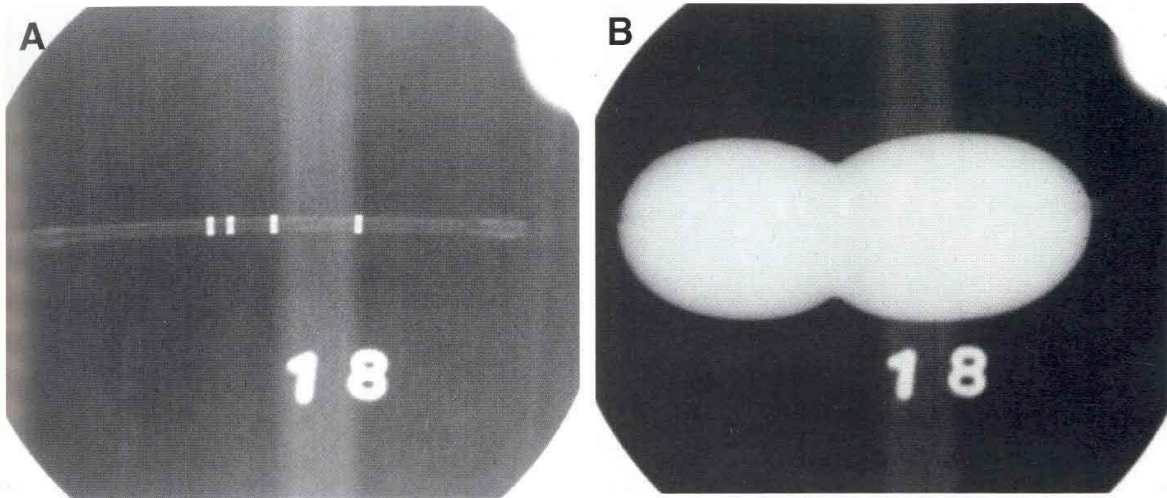


Fig. 3. A: Visualization of the radiopaque markers by cine to correct for X-ray magnification errors. B: Cine image of inflated balloon showing the waist in the middle of the balloon. Sizing the waist is used to determine the stretched diameter

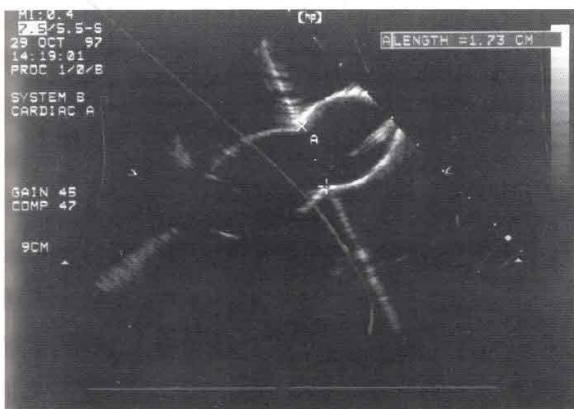


Fig. 4. Echo scan of inflated balloon. The waist is measured to determine the stretched diameter

sheath was inserted. The ASD was crossed by a curved catheter, an exchange guidewire was introduced, the catheter was removed, and the balloon catheter was passed over the exchange wire into the left atrium under fluoroscopic guidance. The balloon was inflated with 20% Diatrizoate solution until a waist was observed and video and cine measurements were obtained (Fig. 6A).

Transesophageal echocardiography was attempted but was not successful because of the artifacts produced by the tracheal air column. This is well known because of the unusual porcine anatomy. The animal was euthanized, the heart was explanted, and the defect was measured by a tapered measuring probe (Fig. 6B).

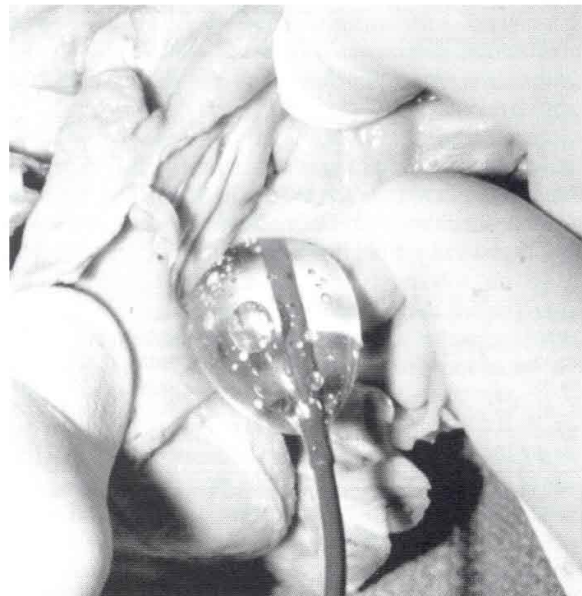


Fig. 5. Close-up view of the catheter placed across the atrial septal defect in a human specimen of the heart. Air bubbles can be avoided by purging the catheter first with carbon dioxide.

RESULTS

All measurements of the 17 holes are listed in Table I. The stretched diameter obtained by video and cine recordings were calculated by two independent observers and were averaged. The statistical significance of the interobserver measurements was determined and no sig-

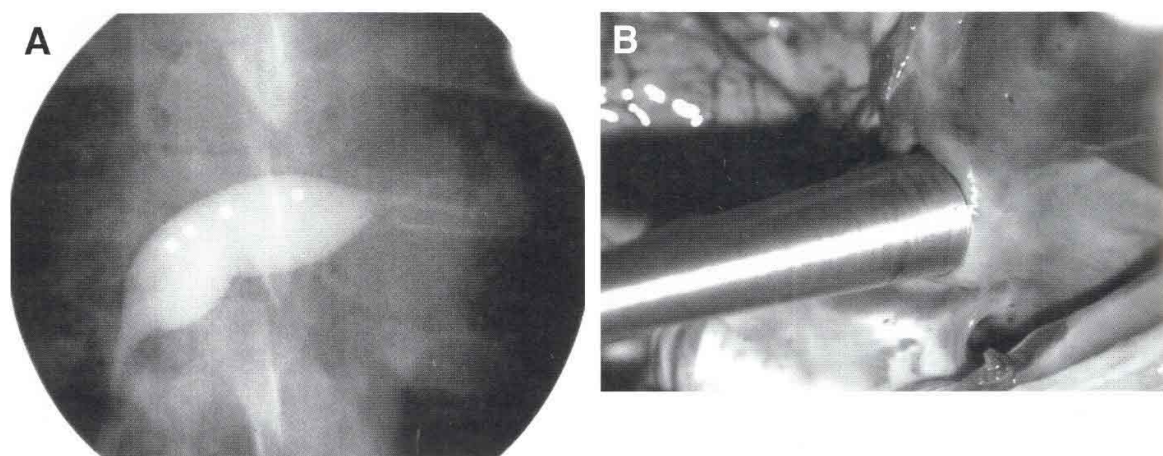


Fig. 6. A: Cine angiogram of deployed balloon catheter within the surgically created atrial septal defect (13.9 mm). B: Probe measurement of the ASD in the postmortem specimen revealing a communication of 14 mm.

TABLE I. Measured Diameters of Balloon Catheter In Vitro

Actual diameter (mm)	Balloon-stretched diameter (mm) ^a		
	Video	Cine	Echo
7.79	7.35 (0.44)	7.74 (0.06)	7.91 (0.12)
9.09	8.53 (0.56)	8.41 (0.69)	8.94 (0.15)
9.93	9.41 (0.52)	9.24 (0.69)	9.45 (0.48)
11.22	10.59 (0.63)	10.46 (0.77)	10.8 (0.42)
11.92	11.47 (0.45)	11.52 (0.40)	11.5 (0.42)
12.72	12.06 (0.66)	12.20 (0.53)	13.6 (0.88)
14.65	14.12 (0.53)	13.94 (0.71)	14.5 (0.15)
15.17	15.00 (0.17)	14.47 (0.70)	16.5 (1.33)
16.03	15.88 (0.15)	15.45 (0.58)	16.9 (0.87)
16.80	16.47 (0.33)	16.21 (0.59)	18.0 (1.20)
18.28	18.71 (0.43)	17.74 (0.54)	17.3 (0.98)
19.88	20.00 (0.12)	19.35 (0.53)	19.7 (0.18)
22.30	22.90 (0.60)	21.86 (0.45)	22.1 (0.20)
24.05	24.52 (0.47)	23.31 (0.74)	23.6 (0.45)
25.65	26.45 (0.80)	24.84 (0.81)	25.9 (0.25)
27.06	28.06 (1.00)	26.13 (0.93)	26.2 (0.86)
30.28	31.61 (1.33)	29.52 (0.77)	29.0 (1.28)

^aAll numbers in parentheses represent the differences between measured and actual values.

nificant difference was found ($P > 0.05$). The difference between the actual size and measurements obtained by video recording was 0.54 ± 0.30 mm (mean $\pm$ SD, range from 0.12–1.33 mm). By cine measurements it was 0.62 ± 0.20 mm (range from 0.6–0.93 mm); by echo it was 0.60 ± 0.43 mm (range from 0.12–1.33 mm). With all three techniques, all measurements (Table I) were less than 1 mm in error except for four measurements (<1.5 mm).

The relationship of the actual diameters and the stretched diameter measured by video, cine, and echo are shown in Figures 7 to 9. A strong correlation was presented between each two groups ($r = 0.999$, $P <$

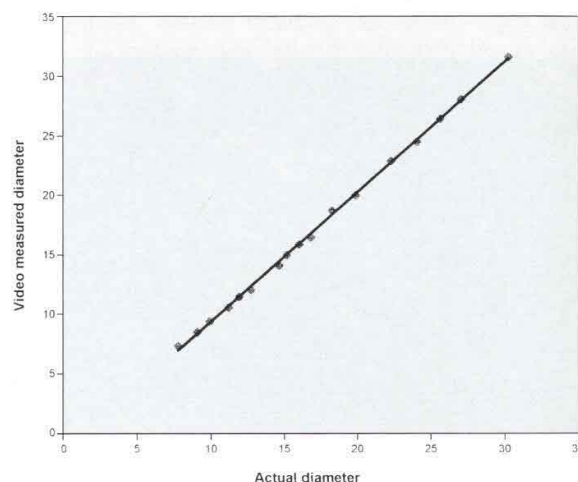


Fig. 7. Correlation between actual diameter and video measured diameters $r = 0.9996$, $P < 0.0001$.

0.0001). The recorded pressures in the balloon and the amount of contrast medium are listed in Table II.

In the in vivo test, the stretched diameter of the ASD was measured to be 14.2 mm by video and 13.9 mm by cine measurements (Fig. 6). These results were almost the same as the probe measurement (14 mm) in the postmortem specimen.

Bench Testing

A 76% ionic contrast medium was diluted 50/50 with saline and the balloon was inflated with this solution using a 12-cc syringe. Inflation times and deflation times were recorded. The balloon could be inflated to a diameter of 24 mm in 10 sec and deflated in 15 sec. Using

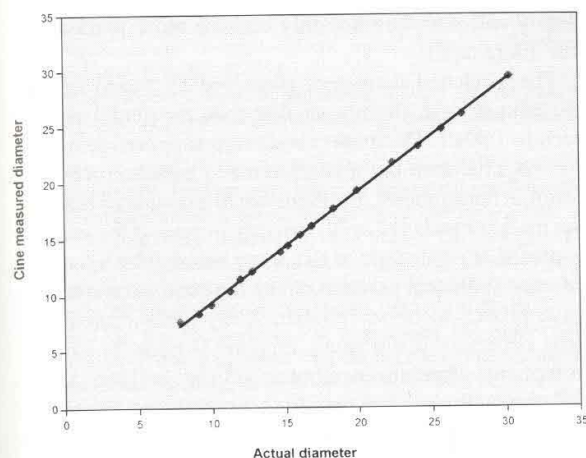


Fig. 8. Correlation between actual diameter and cine measured diameters $r = 0.9997$, $P < 0.0001$.

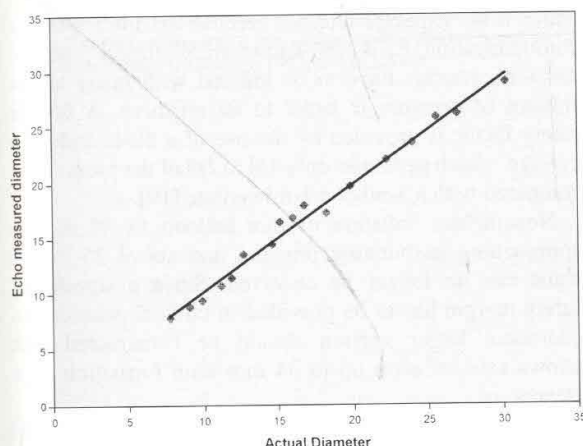


Fig. 9. Correlation between actual diameter and echo measured diameters $r = 0.9994$, $P < 0.0001$.

the same diluted contrast medium and a 60-cc syringe, it was found that the bursting diameter of the balloon was 34, 35, and 36 mm in three test samples.

DISCUSSION

Determination of the stretched diameter of atrial communications has remained the gold standard for all transcatheter occlusion devices, although echocardiography has been used as well [14–16]. Echo measurements are always significantly smaller than the stretched diameter. The differences between echo measurements and stretched diameters have been reported to be between 2 to 10.5 mm [17].

TABLE II. Balloon Pressure, Diameter, and Volume of Dye

Volume of dye (ml)	Pressure (mmHg)	Diameter of ASD model (mm)
6	8	8
7	10	9
8	15	10
9	25	11
11	40	12
12	55	13
13	65	14
15	80	15
16	85	16
17	90	17
19	100	18
23	120	20
26	140	22
30	170	24
36	200	26
44	260	28
55	325	30

Rao et al. [18] suggested that the stretched diameter can be estimated by echo measurements applying a formula: 1.05 times the echo measurement in mm plus 5.49 mm. Based on their previous study [18], using two-dimensional echocardiography, a good correlation could be achieved ($r = 0.9$, $P < 0.001$). The differences between predicted and measured stretched diameter were within 2 mm in most of the 21 patients, but differences up to 4.5 mm were also observed [17]. From this study it is clear that echo measurements and the application of this formula are not reliable. In clinical practice, errors as much as 100% have been reported (data not shown).

The errors in echo measurements can be explained by the fact that most communications are not perfectly round, whereas the balloon transforms the oval communication into a round structure. However, for most commercial devices, echo measurements would be adequate, since devices are only available in relatively few sizes. With the Amplatzer, however, it is of paramount importance to obtain a precise measurement of the communication because stenting is the principal of this new prosthesis [12]. Consequently, devices are available in 1-mm increments. If a device is selected that is too small, the risk of embolization and residual shunting increases significantly. On the other hand, if the device is too large, the two retention disks may balloon into the right and left atria, resulting in a bulky appearance that does, however, improve with time.

The catheter is made from radiopaque nylon with a small central lumen allowing for passage over a 0.035" guidewire, which leaves ample room for a large second lumen for rapid inflation and deflation of the balloon. The very short inflation time of 10 sec should significantly decrease procedural and fluoroscopy times in clinical

practice. An angulation of 45° of the balloon in relation to its shaft was selected because the average atrial septum of the human heart has a 45° inclination. A more or less right-angled position through the communication can, therefore, be expected. An ultrathin expandable tough plastic material (0.002") was selected rather than latex, which is a plant product subject to aging, particularly if exposed to light. The thickness of the latex balloon membrane (Meditech, Watertown, MA) was found to be six times greater than the polyurethane membrane of the AGA catheter.

Due to the extreme thinness of the plastic material, the catheter can be readily passed percutaneously directly through the skin or through a 9 F sheath. Breakage of the balloon which was observed with latex materials should not occur (data not shown). The proposed technique in clinical use would be the prior inflation of the balloon with carbon dioxide and aspiration of all gas because complete purging of air is difficult and time-consuming. To facilitate percutaneous entry, an assistant is applying forceful negative pressure by an attached syringe. Under fluoroscopic and echocardiographic guidance, the balloon catheter is passed over an exchange wire across the defect and inflated with diluted contrast medium until a waist can be observed or the left-to-right shunt ceases as observed by Doppler echocardiography. Based on our in vitro results, echo measurements are reliable enough to determine the stretched diameter but X-ray measurements can be added. After removal, the balloon can be reinflated with the same known amount of contrast medium and passed through a sizing plate to obtain an additional measurement. As experience is gained probably only one measuring technique will be used in clinical practice.

The previously used technique of pulling a balloon catheter through the communication is fairly unreliable for two reasons. The first is that sizing depends on the tension applied and on the anatomy of the septum. By pulling the balloon catheter more forcefully, even very much oversized balloons may slip through the communication, particularly with a floppy septum. The second is that the balloon catheter may just be spreading the two flaps because it cannot be pulled at right angle through the communication. This fact is well known from clinical practice where sizing of a patent-foramen-type communication may result in completely different measurements by pulling the balloon or pushing it from the right atrial side (data not shown). The pulling technique therefore depends largely on anatomy.

The described new technique places a stationary measuring balloon more or less at right angle to the atrial septum, which may well yield more reliable results since the pulling factor is excluded. Contrary to the established technique, one single measurement will suffice, whereas typically balloon sizing is carried out several times.

Sizing will therefore not only become more precise, but also more rapid.

The stretched diameters measured by video or cine recordings were slightly smaller than the actual size, as seen in Table I. The marker bands are supposed to correct for magnification but a slight error in measurement may result in inaccuracies. Furthermore, the distances between the marker bands are only correctly imaged if the catheter is placed at right angle to the X-ray beam, which may not be easy in clinical practice. Since the echo measurements have proven to be so reliable, X-ray measurements are only necessary if ultrasonic imaging is poor. The highly compliant ultrathin membrane of the balloon allows inflation with very low pressures. For the measurement of the holes ranging from 8 to 20 mm, the required pressure was only in the neighborhood of 120 mm of mercury. It increased to 325 mm of mercury for 22- to 30-mm holes (Table II). The pressure of 325 mm of mercury is less than 1/2 atmosphere (1 atmosphere is 760 mm of mercury), which is not expected to cause mechanical dilation of the communication. As is well known from clinical practice, dilation catheters have to be inflated with many atmospheres of pressure in order to be effective. A further safety factor is provided by the use of a 60-cc inflation syringe, which generates only 1/4 to 1/8 of the pressure as compared with a 3-ml or a 1-ml syringe [19].

Nonetheless, inflation of this balloon to 30 mm is approaching its bursting pressure and above 25 mm a waist can no longer be observed. Since a significant safety margin has to be provided in clinical practice, an additional larger version should be constructed that allows safe inflation up to 34 mm with formation of a clear waist.

In conclusion, the new catheter and measuring technique provide a more rapid and precise determination of the stretched diameter in an in vitro as well as in an in vivo experiment. It may be of benefit to all investigators using septal occlusion devices and above all it will facilitate the selection of the properly sized Amplatzer septal occluder.

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