Journal of the American College of Cardiology
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Published by Elsevier Science Inc.

Vol. 33, No. 3, 1999
ISSN 0735-1097/99/$20.00
PII S0735-1097(98)00610-X

Pediatric Cardiology

Follow-Up Results of Transvenous Occlusion of Patent Ductus Arteriosus with the Buttoned Device

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OBJECTIVES The purpose of this presentation is to document results of buttoned device (BD) occlusion of patent ductus arteriosus (PDA) in a large number of patients with particular emphasis on long-term follow-up in an attempt to provide evidence for feasibility, safety and effectiveness of this method of PDA closure.

BACKGROUND Immediate and short-term results of BD occlusion of PDA have been documented in a limited number of children.

METHODS During a six-year period ending August 1996, transcatheter BD closure of PDA was attempted in 284 patients, ages 0.3 to 92 years (median 7) under a protocol approved by the local institutional review boards and FDA with an investigational device exemption in U.S. cases.

RESULTS The PDAs measured 1 to 15 mm (median 4) at the narrowest diameter; 20 were larger than 8 mm and 10 larger than 10 mm. They were occluded with devices measuring from 15 to 35 mm delivered via 7F (N = 140) or 8F (N = 144) sheaths. Successful implantation of the device was accomplished in 278 (98%) of 284 patients. The Qp:Qs decreased from 1.8 ± 0.6 (mean ± SD) to 1.09 ± 0.19 ($p < 0.001$). Effective occlusion defined as no (N = 167 [60%]) or trivial (N = 79 [28%]) residual shunt was achieved in 246 (88%) patients. All types of PDAs, irrespective of the shape (conical, tubular or short), size (small or large) or length (short or long) of the PDA and previously implanted Rashkind devices, could be occluded. Follow-up data, 1 to 60 months (median 24) after device implantation, were available in 234 (84%) patients. Seven (3%) patients required reintervention to treat residual shunt with (N = 2) or without (N = 5) hemolysis. Actuarial reintervention-free rates were 95% at 1 and 5 years. There was gradual reduction of actuarial residual shunts and were 40%, 28%, 21%, 14%, 11%, 10%, 6% and 0% respectively at 1 day, 1, 6, 12, 24, 36, 48 and 60 months after device implantation. Incorporation of folding plug over the button loop in 10 additional patients produced immediate and complete occlusion of PDA.

CONCLUSIONS This large multiinstitutional experience confirms the feasibility, safety and effectiveness of buttoned device closure of PDAs. All types of PDAs irrespective of the shape, length and diameter can be effectively occluded. Incorporation of folding plug over the button loop produces complete PDA occlusion at the time of device implantation. (J Am Coll Cardiol 1999;33:820–6) © 1999 by the American College of Cardiology

Immediate and short-term results of transvenous occlusion of patent ductus arteriosus (PDA) with the buttoned device (BD) have, in a limited number of patients, demonstrated feasibility, safety and effectiveness of this method (1–3). However, long-term results have not been documented. The purpose of this study is: 1) to present the data on larger number of patients than that in our preliminary study (2), 2) to document long-term follow-up results of PDA occlusion with the BD in an attempt to assess long-term efficacy and safety of this procedure, and 3) to evaluate efficacy of folding plug modification of the BD in producing complete closure of large PDAs.

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Manuscript received June 4, 1998; revised manuscript received August 14, 1998, accepted November 2, 1998.

PATIENTS AND METHODS

During a six-year period from September 1990 to August 1996, 284 patients were taken to the catheterization laboratory with the intent to occlude PDA with BD.

Abbreviations and Acronyms
BD = buttoned device
PDA = patent ductus arteriosus

Protocol. The procedure was performed under a protocol approved by the Institutional Review Board at each institution, as per local regulations and FDA approval for clinical trials with investigational device exemption in U.S. cases.

Inclusion/exclusion criteria. Patients with clinical and echo-Doppler features of PDA that are ordinarily candidates for surgical closure are included. The so-called "silent ductus" cases (4,5) are excluded. Otherwise, ductal size and shape are not the bases for exclusion. Ten patients with persistent shunt following previous Rashkind device (6,7) implantation for PDA closure were also included. Ducti associated with complex cyanotic heart defects and those with pulmonary vascular obstructive disease are excluded.

Device. The buttoned device (Custom Medical Devices, Amarillo, Texas and Athens, Greece) consists of three components: 1) occluder, 2) counter-occluder and 3) delivery system and has been described in detail previously (2). During the last one-half of cases, however, the device was modified such that both the knots (buttons) attached to occluder were made radiopaque with spring buttons. The devices are produced in several sizes, from 15 mm through 40 mm, in 5 mm increments.

Procedure. After clinical and echocardiographic diagnosis and informed consent, cardiac catheterization and aortography percutaneously via femoral vein and artery were performed to confirm the clinical diagnosis and to delineate the ductal size and shape. Minimal ductal diameter was measured in the lateral view, corrected for magnification, compared with the diameter of the angiographic catheter. Heparin (100 units/kg) was administered intravenously and a 7-F (for 15 mm devices) or an 8F (for devices larger than 15 mm) long sheath (Cordis, Miami, Florida or Cook, Bloomington, Indiana) was introduced transvenously and its tip positioned in the descending aorta across the ductus. Again, the method of device implantation has been described in detail previously (2) and will only be outlined here. The occluder component of the device was folded and introduced into the sheath and advanced with a 7F pusher catheter and delivered into the descending aorta. The sheath and the occluder were withdrawn such that the occluder lies against the aortic end of the ductus and the sheath tip is in the main pulmonary artery. The counter-occluder was threaded over the delivery wire, but within the sheath and delivered into the main pulmonary artery. By gently pulling the delivery wire and the occluder simultaneously with advancing the counter-occluder with the tip of the sheath, the occluder and counter-occluder were buttoned across the ductus. Verification that buttoning has occurred was made by fluoroscopic demonstration of the passage of radiopaque wire of the counter-occluder beyond the radiopaque button(s). If the ductus was short, buttoning across both buttons was performed. If the ductus was long, buttoning across the proximal button (farthest from the occluder) was considered adequate. The delivery wire was cut and removed, followed by withdrawal of the nylon thread, thus disconnecting the device from the delivery wire.

Following device implantation, oximetry and aortography were performed to evaluate the residual shunt. Three doses of Cefazolin (25 mg/kg/dose) were administered intravenously. Aspirin (5 to 10 mg/kg/day) administered orally was given for a six-week period.

Follow-up. Clinical evaluation, chest X-ray and echocardiography-Doppler studies were performed 1 day, 1, 6 and 12 months after the device implantation and yearly thereafter. These were performed by the interventional cardiologist, radiologist and echocardiographer respectively, at the participating medical center. Clinical evaluation scrutinized for physical findings indicative of residual shunt and need for reintervention. Chest roentgenograms were reviewed for device position and to exclude wire fractures. Echocardiography-Doppler studies were performed to detect and quantitate residual shunt (Table 1) and to exclude

Table 1. Quantitation of Residual Ductal Shunt

None	—	No residual shunt
Trivial	—	Color Doppler jet width ≤1 mm at the origin of the shunt No left ventricular volume overload*
Small	—	Color Doppler jet width of residual shunt between 1 to 2 mm No left ventricular volume overload*
Medium	—	Color Doppler jet width of residual shunt 2 to 4 mm Left ventricular volume overload* may be present
Large	—	Color Doppler jet width of residual shunt >4 mm Left ventricular volume overload* is present

*Left ventricular volume overload is defined as left atrium to aortic root ratio >1.2 and enlargement of the left atrium and left ventricle (>95 percentile for age).

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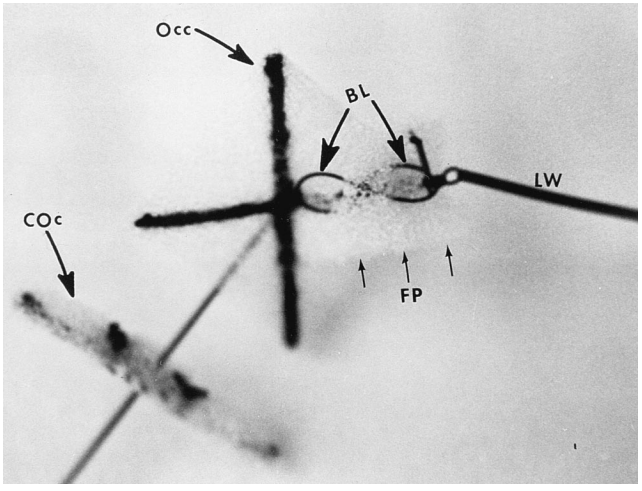

Figure 1. Photograph of the modified buttoned device showing the occluder **(Occ),** counter-occluder **(COc)** and polyurethane folding plug **(FP)** covering **(arrows)** the button loop **(BL).** LW = loading wire.

obstruction in the left pulmonary artery and descending aorta.

Definitions. Complete occlusion is defined as having no residual shunt whatsoever by the modality of the evaluation whether it be aortography or Doppler evaluation. Effective occlusion is deemed to have been achieved if there was complete occlusion (no residual shunt) or trivial residual shunt (see Table 1 for definition) on echocardiography-Doppler studies. Residual shunt by echocardiography-Doppler studies was quantitated as per the guidelines listed in Table 1.

Folding plug buttoned device. Following preliminary analysis of the results (8) with high incidence of residual shunt, the device was modified such that a polyurethane foam plug was incorporated over the button loop (Fig. 1). Ten patients underwent PDA closure with this modified device.

Statistical methods. The data are expressed as mean ± SD for normally distributed variables. Median and ranges are given for data that are not normally distributed. Paired *t* tests were used to compare pre- versus post-closure values. Categorical data were compared using chi-square tests. Actuarial evaluation of event-free rates and residual shunts was performed by Kaplan-Meier method. The level of statistical significance was set at $p < 0.05$.

RESULTS

Study subjects. Two hundred and eighty four patients ages 4 months to 92 years (median 7 years) were taken to the catheterization laboratory with the intent to perform transcatheter BD occlusion of their PDA during a six-year period ending August 1996 at 21 institutions around the world (Appendix). The number of patients undergoing the procedure at these institutions varied between 3 and 79 (median 6). Their weights ranged between 5 and 90 kg with a median of 19 kg. Fourteen children (1,2) and one adult (3) have been included in our previous reports.

PDAs and devices. The size of the PDA, measured at its narrowest diameter on a lateral view cineangiogram varied between 1 and 15 mm with a median of 4 mm. Twenty PDAs measured 8 or more mm in diameter; ten were larger than 10 mm. Data on pulmonary-to-systemic flow ratio (Qp:Qs) were available in 169 patients and was 1.8 ± 0.6 (mean ± SD) with a range of 1.2 to 4.8. The PDA was conical in shape in 164 patients, tubular in 56, short in 29 (some are aortopulmonary window type), miscellaneous types in 25 and previous Rashkind device implantation in 10.

The PDAs were occluded with 15 mm devices in 140 patients, delivered via a 7F sheath. Twenty mm devices were used in 115 patients, 25 mm devices in 15 patients, 30 mm devices in six patients, and 35 mm devices in two patients. Six patients received miscellaneous size devices. The latter 144 devices were implanted via 8F sheaths.

Immediate results. The device was successfully implanted in 278 (98%) of 284 patients. In six (2%) patients, the device pulled through the PDA. Transcatheter retrieval was undertaken in three patients. In two of these patients a larger device was implanted and the third patient was sent to elective surgery. In the remaining three patients, surgical retrieval of the device along with PDA ligation was undertaken. No other complications were encountered.

The Qp:Qs (in the 169 subjects in whom it was measured) decreased from 1.8 ± 0.6 to 1.09 ± 0.19 ($p < 0.001$). Complete occlusion by aortography was observed in 167 (60%) of 280 patients in whom the device was implanted, including all 10 patients with residual shunts following Rashkind device placement. Effective occlusion, defined as trivial (n = 79) or no (n = 167) residual shunt on echo-Doppler study (Table 1) within 24 hours after device implantation, was achieved in 246 (88%) of 280 patients. All types of PDAs including conical, tubular and short could be occluded. There is no relationship between the length or diameter of the PDA and the presence or absence of effective occlusion. Continuous murmur disappeared in all but four (1.4%) of 280 patients.

Small (n = 34) or trivial (n = 79) residual shunts were present in 113 (40%) of 280 patients. Ductal shape did not influence the percent residual shunt ($p > 0.1$) (Fig. 2A). However, ductal size does influence the residual shunts; the larger the ductal diameter, the greater was the prevalence of residual shunt ($p < 0.01$) (Fig. 2B). This is in contradistinction to effective occlusion (as defined in the preceding paragraph) which is not influenced by the size of the PDA.

Follow-up results. Clinical, chest X-ray and echocardiography-Doppler follow-up data were available for review in 234 (84%) of 280 patients 1 to 60 months

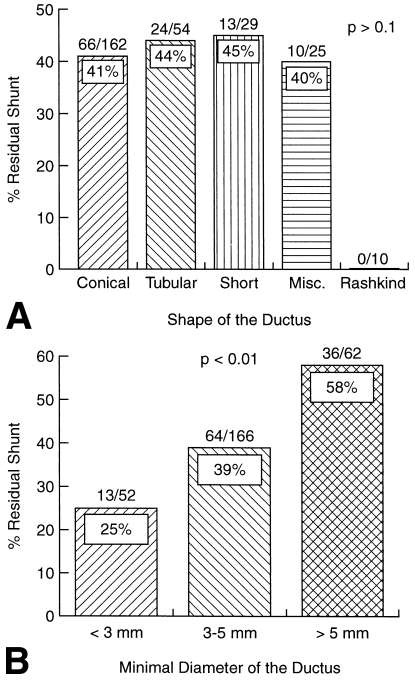

Figure 2. (A) Relationship of residual shunt (by echo-Doppler within 24 hours of device implantation) with shape of the ductus; note that there is no significant ($p > 0.1$) relationship. **(B)** Relationship of residual shunt (within 24 hours of procedure by echo-Doppler) to the size of ductus is shown; note higher incidence of residual shunts with larger ducts.

(median 24) after device implantation. Seven (2.5%) patients required reintervention during follow-up. Two patients underwent surgical ligation for residual shunt. Two patients with hemolysis secondary to trivial residual shunt also underwent surgical ligation. The remaining three patients were treated by coil (n = 2) or a second buttoned device (n = 1) implantation for occluding residual shunts. Actuarial event-free rates are shown in Figure 3.

The device was in position on chest x-ray and there was no breakage of the radiopaque wire components of the device seen. No endocarditis was observed during follow-up.

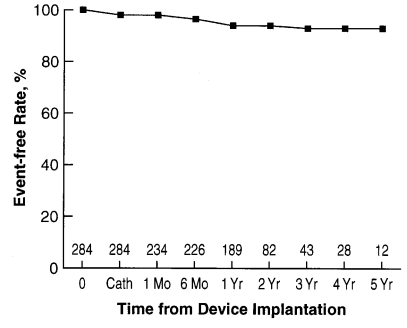

Figure 3. Transcatheter closure of PDA. Graph showing actuarial event-free rates after transvenous buttoned device occlusion of patent ductus arteriosus.

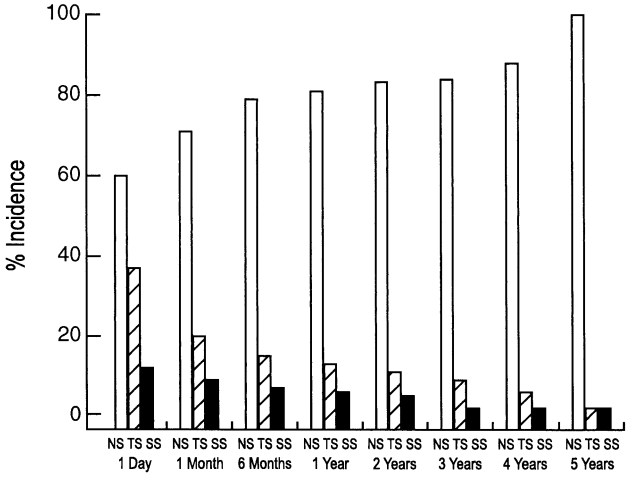

Figure 4. Prevalence of residual shunts following buttoned device occlusion of patent ductus arteriosus. Note that there was gradual increase in the number of subjects without residual shunts while the number of patients with residual shunt decreased gradually. McNemar's pairwise comparison of data was used and Bonferroni correction was applied. The rate of change is statistically significant ($p < 0.05$ to <0.01). NS = no residual shunt; SS = small residual shunt; TS = trivial residual shunt.

There was no clinical or echocardiographic evidence for thrombus formation. No late embolization of the device components nor device detachment were observed. Echocardiography-Doppler studies revealed gradual increase ($p < 0.05$ to <0.01) in the number of subjects without residual shunts (Fig. 4). Rates of resolution of residual shunts are depicted in Figure 5. There have been no instances of recanalization, i.e., no reappearance of the shunt after it had been demonstrated closed by color Doppler. No evidence for obstruction in the descending aorta or in the left pulmonary artery was observed.

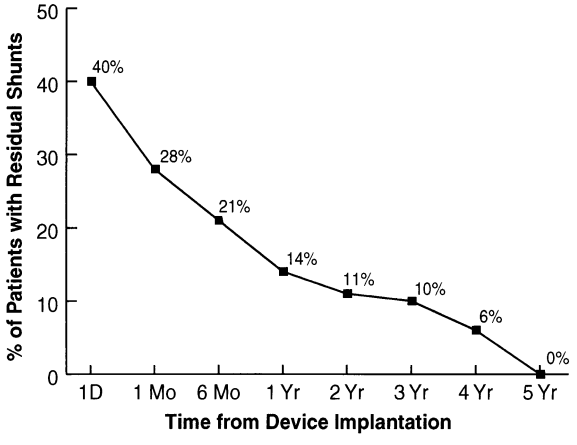

Figure 5. Actuarial resolution ($p < 0.01$) of residual shunts following buttoned device closure of patent ductus arteriosus. Reinterventions are not included in the calculation of resolution of residual shunts.

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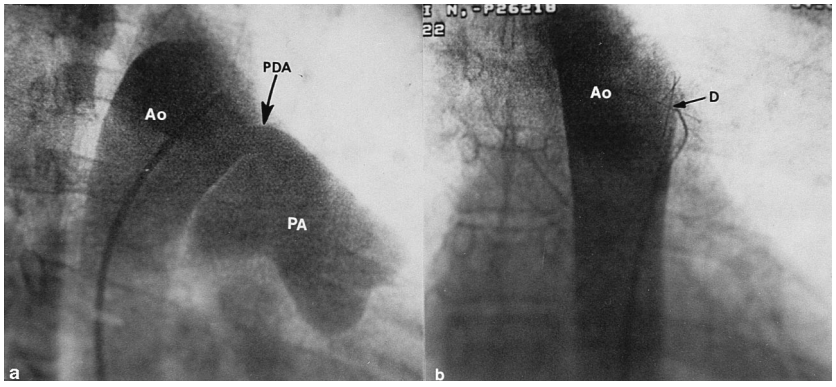

Figure 6. Selected cineangiographic frames from aortograms in right anterior oblique view prior to **(a)** and 15 minutes following **(b)** transvenous implantation of buttoned device with a folding plug demonstrating a large patent ductus arteriosus (PDA) in **a,** which is completely occluded following device (D) implantation **(b).** Ao = aorta; PA = pulmonary artery.

Folding plug device. Ten patients, ages 3 to 39 years, weighing 9 to 70 (median 12) kg underwent transcatheter occlusion with the folding plug BD delivered via 8F sheaths. The PDAs measured 4 to 11 mm (median 8) at their narrowest diameter. This device with the occluder at the aortic end of the ductus, folding plug in the ductal lumen and counter-occluder in the pulmonary artery, produced complete occlusion in all 10 patients, demonstrated by aortography 15 minutes following device implantation (Fig. 6) and by color Doppler echocardiography on the morning following device placement. There was no evidence for obstruction either in the aorta or in the left pulmonary artery. Follow-up was available one to three months following the procedure. The ductus remains closed by color Doppler studies.

DISCUSSION

In a preliminary study of 14 children reported in 1993 (2), feasibility, safety and effectiveness of the buttoned device in transcatheter occlusion of PDA was demonstrated. However, because of the limited number of patients studied, no definitive conclusions could be drawn. Furthermore, the follow-up duration was short. In the current study involving a large group of children and adults, feasibility, safety and effectiveness of the buttoned device closure of PDA is reconfirmed. Effective occlusion was accomplished irrespective of the size (diameter) and shape (conical, tubular or short) of the ductus, although complete occlusion rate was lower with larger PDAs (Fig. 2B). Both short and long PDAs could be occluded because of adjustable button design of the button loop.

Whereas effective occlusion rates, defined as trivial or no shunt, are high (88%), residual shunts were observed in 40% patients. These residual shunts, however, diminished and resolved with time (Fig. 5). The indications for closure in many of these patients are prevention of bacterial endocarditis. Therefore, these patients are potentially at risk for development of subacute bacterial endocarditis prior to disappearance of the residual shunt. For this reason, it would be better if the device or method could be modified such that complete closure would occur at the time of device implantation. Because of this, the device was modified by incorporating polyurethane foam over the button loop, the folding plug. With this modified device, complete occlusion at the time of implantation was achieved in all patients. Future clinical trials will utilize this modified device.

Patients with residual shunts at follow-up beyond one year after device implantation may need reocclusion because the rate of spontaneous closure decreases after the first year (Fig. 5). Of the surgical, second buttoned device and coil options, we prefer coil occlusion (9,10) for small residual shunts and a second buttoned device for moderate to large residual PDAs.

Since the description of the first transcatheter method of closure of PDA by Porstmann et al. (11,12), a variety of devices have been described (6,7,9,13–19) which are tabulated (Table 2). Most of the devices require large delivery sheath and some require transarterial delivery of the occluding device (Table 2). Long-term follow-up results for most of the devices are scant (17–19). Longer follow-up results with Rashkind device show significant incidence of residual shunts (20,21), especially with large PDAs.

At the present time surgical (22), video-assisted thoracoscopic (23) and several transcatheter (6,7,9,11–19) methods are available for closure of PDA. In the absence of prospective, randomized clinical trials, it is difficult to accurately compare relative risks and benefits of these procedures. But the morbidity and length of hospitalization associated with most transcatheter methods appears less than that experienced with surgical (24) and video-assisted thoracoscopic (23) procedures. Residual shunt appears to be present with all types of PDA closure (20,21,24–26) and may be dependent upon sensitivity of the method used (for example, auscultatory vs. color Doppler) for detection of residual shunt.

Table 2. Clinically Used Devices for Transcatheter Occlusion of Patent Ductus Arteriosus

Device	Size of Sheath Used for Device Delivery	Device Implantation Route
Porstmann's Ivalon plug	18F	Arterial
Rashkind's hooked umbrella device	6F	Arterial
Rashkind's double-disc device	8F or 11F	Venous
Clamshell device	11F	Venous
Buttoned device	7F or 8F	Venous
Botallo-occluder	10F to 16F	Venous
Gianturco coils	4F or 5F	Arterial or Venous
Gianturco-Grifka sac	10F	Venous
Duct Occlud pfm	4F	Venous or Arterial
Amplatzer duct occluder	6F	Venous
Folding plug buttoned device	8F	Venous

Recently, Cambier et al. (9) have described transcatheter closure of PDA using Gianturco coils (27). Because of small-sized catheters needed to deliver the coil, ease with which the technique can be learned and to incur less expense several groups of workers, referenced extensively elsewhere (28), have adopted this method. Further modification of the method by introducing detachable version (29), antegrade and multiple coil approach (30), snare-assisted coil delivery (31), temporary balloon occlusion during coil placement (32), double-disk shaped diabolo configuration design (18), increasing the wire diameter to 0.052-in (33) and five-loop coil design (10) have been undertaken with success. Based on extensive review of this subject (28,34), we concluded that coil occlusion is appropriate for the ductus measuring ≤3.5 mm. Larger PDAs (>3.5 mm) may be best closed by other methods. The buttoned device presented in this study appears suitable in occluding such PDAs. Effective occlusion can be accomplished even in large PDAs with the regular buttoned device. Incorporation of folding plug appears to achieve complete occlusion at the time of device implantation.

Limitations. This is a retrospective review of multiinstitutional experience with PDA closure and has limitations associated with any retrospective multiinstitutional study. The follow-up echocardiographic data pertaining to residual shunts was analyzed at the investigators' institution and may introduce a bias. Analysis of these data at a core laboratory as has recently been advocated in coronary interventional studies may help reduce such a bias. Lack of follow-up data in 16% of the patients is another limitation of this study.

In conclusion, feasibility, safety and efficacy of transvenous occlusion of PDA with buttoned device is demonstrated and confirmed in this study. Although it is feasible to use this device for small PDAs, coil occlusion is probably more appropriate for such PDAs. Modified buttoned device with folding plug may be an optimal choice for moderate and large PDAs.

APPENDIX

The following institutions and investigators participated in the international buttoned device trial for transcatheter closure of patent ductus arteriosus: *All India Institute of Medical Sciences,* U. Kaul, MD; *Anzhen Hospital,* Beijing, China, C. Han, MD; *Batra Hospital and Medical Research Center,* New Delhi, India, R. Lochan, MD; *East Hospital,* Gothenberg, Sweden, L. Solymar, MD; *G. B. Pant Hospital,* New Delhi, India, R. Arora, MD; *German Heart Center,* Berlin, Germany, F. Berger, MD; *Guandong Cardiovascular Institute,* Guandong, China, C. Chen, MD; *Hospital do Coracão de Ribeirão Preto,* Ribeirão Preto, Brazil, J. Haddad, MD; *Hospital Reina Sofia,* Cardoba, Spain, J. Suarez de Lezo, MD; *King Edward Memorial Hospital,* Mumbai, India, H. Kulkarni, MD; *Nizam Institute of Medical Sciences,* Hyderabad, India, S. Jai Shankar, MD and B. Somaraju, MD; *Ospedale Clinicizzata San Donato,* San Donato Milanese, Italy, E. Onorato, MD; *Royal Liverpool Children's NHS Trust,* Alder Hey, Liverpool, England, K. Walsch, MD; *Saint Louis University Health Sciences Center,* St. Louis, MO, R. Bach, MD and P. S. Rao, MD; *Sejong General Hospital,* Puchon, Korea, S. H. Kim, MD; *Sri Venkateswara University Hospital,* Tirupathi, India, S. Agarwal, MD; *Université de Lille,* Lille, France, C. Rey, MD; *Université de Nancy,* Nancy, France, F. Marcon, MD and A. M. Worms; *University of Wisconsin Children's Hospital,* Madison, WI, P. S. Rao, MD and A. W. Wilson, MD; *Wonju Christian Hospital,* Wonju, Korea, H. Y. Lee, MD and J. H. Yoon, MD; *Yonsei University Hospital,* Seoul, Korea, J. Y. Choi, MD.

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