DOI:10.11817/j.issn.1672-7347.2018.09.011
www.csumed.org/xbwk/fileup/PDF/2018091000.pdf

Echocardiography-guided percutaneous closure of patent ductus arteriosus without arterial access: Feasibility and safety for a new strategy

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ABSTRACT

Objective: To evaluate the feasibility and safety of device closure of patent ductus arteriosus (PDA) using only venous access under echocardiography guidance alone.

Methods: A total of 102 consecutive pediatric patients underwent transcatheter PDA closure without arterial access, under the guidance of only echocardiography. The patients were followed up by clinical examination, electrocardiogram, and echocardiogram at 1, 3, 6 12, and 24 months.

Results: Transvenous PDA closure under echocardiographic guidance was successful in 99 (97.1%) patients. There were no acute procedural complications or severe adverse events. The duration ranged from 10 to 65 minutes (median, 21 minutes). Immediate complete closure of PDA was achieved in 87 patients (87.9%), and 100% of the patients were completely closed after 24 h. There were no severe adverse events in the period of 1–24 months (median, 12 months) follow up.

Conclusion: Transvenous PDA closure without fluoroscopy avoids radiation exposure, contrast agent usage and potential arterial complications. It can be used as an alternative procedure, especially for children.

KEY WORDS patent ductus arteriosus; vascular access; imaging modalities; transesophageal echocardiography; radiation protection

超声引导下股静脉路径动脉导管经皮封堵术：一种治疗新策略的可行性和安全性研究

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Date of reception: 2017-09-16

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[摘要] 目的：评估超声引导下股静脉路径动脉导管经皮封堵术的可行性和安全性。**方法：**选择2014年6月至2016年5月在中南大学湘雅二医院就诊的连续102例动脉导管未闭(patent ductus arteriosus，PDA)患儿。所有患儿在单纯超声引导下，经股静脉路径行动脉导管经皮封堵术。术后1，3，6，12，24个月定期随访，随访内容包括临床评估、心电图和超声心动图。**结果：**99例(97.1%)患儿成功实施超声引导下经股静脉路径动脉导管经皮封堵术。全组病例无急性手术并发症或严重不良事件。手术时间10~65(中位数21) min。87例(87.9%)患儿实现PDA即刻完全闭合，其余12例患儿均在24 h后达到完全闭合。随访时间1~24个月，随访期间无严重并发症发生。**结论：**超声引导下经股静脉路径动脉导管经皮封堵术避免了放射性暴露，无需造影剂，消除了动脉并发症的潜在风险，是治疗PDA患儿安全且有效的方法。

[关键词] 动脉导管未闭；血管路径；显像模式；经食道超声心动图；放射保护

As an isolated lesion, patent ductus arteriosus (PDA) is a common congenital heart disease and represents 8%–10% of all congenital heart defects. Since the first surgical PDA closure in 1939 and the later transcatheter PDA closure in 1967, there have been many significant developments in the devices used to close PDA[1]. In the past 20 years, transcatheter PDA closure has become the leading approach because both efficacy and safety have been confirmed by numerous studies[2-5]. The standard method in transcatheter closure of PDA with Amplatzer duct occluder-I (ADO-I) is transvenous procedure through the femoral vein under the fluoroscopy guidance of aortic catheter accessed from femoral artery route[6]. However, a few important concerns about the standard procedure remain. Firstly, the transcatheter closure of PDA, as well as other more complex pediatric interventions, has raised concerns regarding radiation exposure, which is particularly relevant when treating children[7-8]. Secondly, though it is not common, the use of iodinated contrast media may result in contrast-induced acute kidney injury[9-10]. And thirdly, femoral artery access for angiography will increase the procedural time and potential risks of vascular complications[11-13]. Recently, respective efforts have been made to either reduce the radiation exposure or contrast agent usage[14-17], or to avoid arterial access[18-19]. However, there is no reported strategy set targeting all of these issues simultaneously. In this study, we established a new method for transcatheter PDA closure through femoral venous route under the guidance of transesophageal echocardiography (TEE), without access to femoral artery or the employment of fluoroscopy. This single-centered study aims to access the feasibility and safety of this new strategy.

1 Patients and methods

1.1 Patients

From June 2014 to May 2016, 102 Chinese patients (38 males and 64 females) with PDA underwent attempted echocardiography-guided transvenous device closure. The median age of the 102 patients was 2.3 years (range 1 to 14 years) and the median weight was 11.6 kg (range 6 to 46 kg) (Table 1). Thirty patients had symptoms of failure to thrive and/or heart failure. All patients had echocardiographic evidence of significant left-to-right shunting through the PDA with left atrial enlargement and ventricular volume overload. Patients with additional congenital cardiac anomalies that would require cardiac surgery, body weighted less than 5 kg, and PDA diameter smaller than 3 mm were excluded from the study.

Table 1 Baseline characteristics of the study population (*n*=102)

Characteristics	Media (range) or number
Male/Female	38/64
Age/years	2.3(1–14)
Weight/ kg	11.6(6–46)
PDA type A/B/C/E	76/7/15/4
PDA minimal diameter/mm	4.2(3.1–7.5)
PDA length/mm	5.6(3.2–10.7)

1.2 Ethics

All procedures were in accordance with institutional guidelines and were approved by the institutional review board. Study approval was obtained from the Committee on Clinical Applications at the Second Xiangya Hospital

of Central South University, and informed consent was obtained from the patients' parents.

1.3 Device and delivery system

The PDA occluder (provided by Shanghai Shape Memory Alloy Co. Ltd., Shanghai, China) was described in previous report[20]. In brief, this occluder is a cone-shaped device made of nickel titanium alloy, and its aortic flange is 3 mm wider than the connecting waist (Figure 1A and 1B). Prostheses are currently available in sizes ranging from 4-6 to 14-16 mm at increments of 2 mm. The smaller diameter is at the pulmonary end and the larger measurement is at the aortic side. The occluder size is selected according to the PDA diameter measured by TEE, with its smaller diameter 1 to 3 mm larger than the minimal diameter of the ductus.

The device is attached by a recessed microscrew to a delivery cable made of stainless steel. It is delivered through a 6F-8F long sheath. For introduction into the delivery sheath, the device is pulled into a special loader. The delivery system is also manufactured by Shanghai Shape Memory Alloy Co. Ltd., Shanghai, China.

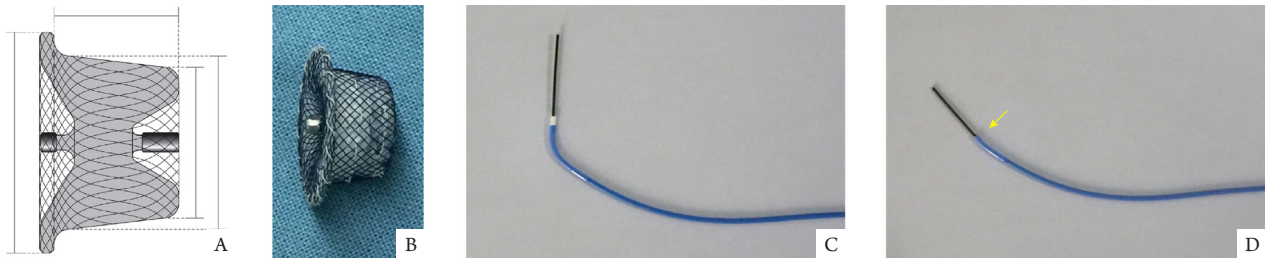

Figure 1 Devices used in study

A, B: Self-centering PDA occluder made of nickel titanium alloy; C: Original J curved Cobra catheter with guidewire inside; D: Trimmed Cobra catheter with guidewire inside. Arrow indicates that the curved segment of the catheter is cut off

1.4 Procedures

All procedures were carried out in a routine operating room under the guidance of echocardiography (Vivid E9 Dimension, bought from General Electric Company, Horten, Norway). There was no backup fluoroscopy, but a cardiopulmonary bypass unit was on standby. All patients underwent general anesthesia with intubation. After intubation, TEE probe bought from General Electric Company, Horten, Norway. 9T for patients less than 15 kg, 6T for patients more than 15 kg. TEE was inserted into the middle esophagus. We firstly showed the short axis view of ascending aorta, and then rotated the probe slightly to the upper-left to detect the PDA. Both transthoracic echocardiography (TTE) (Figure 2A) and TEE (Figure 2B) were applied to comprehensively study all aspects of the PDA anatomy (shape, length and minimum diameter) (Table 1). Then the distance between the right femoral venous puncture site and the left second intercostal parasternal space of the patient (hereinafter referred to as "safe distance") was measured by operator and then marked on the catheter and delivery sheath as described before[21]. Vascular access was obtained through right femoral vein. Heparin at a dose of 100 U/kg and antibiotic prophylaxis were administered. A 0.038-inch straight stiff guidewire (provided by Terumo Medical Corporation, Somerset, New Jersey, USA) was advanced into the right atrium (RA) under TEE guidance using bicaval view plane. A 5Fr JR 4 diagnostic catheter (provided by Cordis Corporation, Miami Lakes, Florida, USA, Figure 1C) was subsequently advanced into RA over the wire. Then the guidewire was withdrawn progressively and the tip of catheter was tracked by the TEE. It may be necessary to adjust the direction of the catheter tip to advance through the tricuspid valve towards right ventricle (RV). The guidewire was then advanced into RV through the catheter (Figure 2C). Guided by TEE, along with the wire, the catheter's direction was adjusted again to go through the outflow tract of RV and pulmonary valve towards main pulmonary artery (Figure 2D). The guidewire was withdrawn progressively, and with the guidance of TEE, the catheter was adjusted to make its tip point to the PDA's pulmonary end, and the guidewire was then advanced

through the PDA into the descending aorta (DAO) (Figure 2E). In some cases, the curved segment of the catheter was trimmed off (Figure 1D) so that its tip was prone to pointing to the PDA's pulmonary end. The TEE probe was then repositioned to exam the DAO to confirm that the guide wire was in the DAO. The catheter was exchanged with a 6F-9F delivery sheath. Under TEE guidance, the sheath was advanced through the PDA into the DAO over the guidewire (Figure 2F). Upon removal of the guide wire and dilator, a loading sheath with an appropriately sized PDA cclude was introduced into the delivery sheath. Under TEE guidance, the device is delivered by initially deploying only the retention disk in DAO and pulling it firmly against the orifice of the ductus and embedding it into the ductal ampulla (Figure 2G). The rest of the device is then uncovered within the PDA (Figure 2H). Before the device was unscrewed, the appropriate and stable position was confirmed by TEE, demonstrating no residual left to right shunting and no significant blood flow acceleration at the pulmonary artery and aortic arch. Aspirin [3 mg/(kg·d)] was routinely administered for 6 months. The patients were followed up by clinical examination, electrocardiograph, and TTE at discharge, 1, 3, 6, 12, and 24 months after the operation.

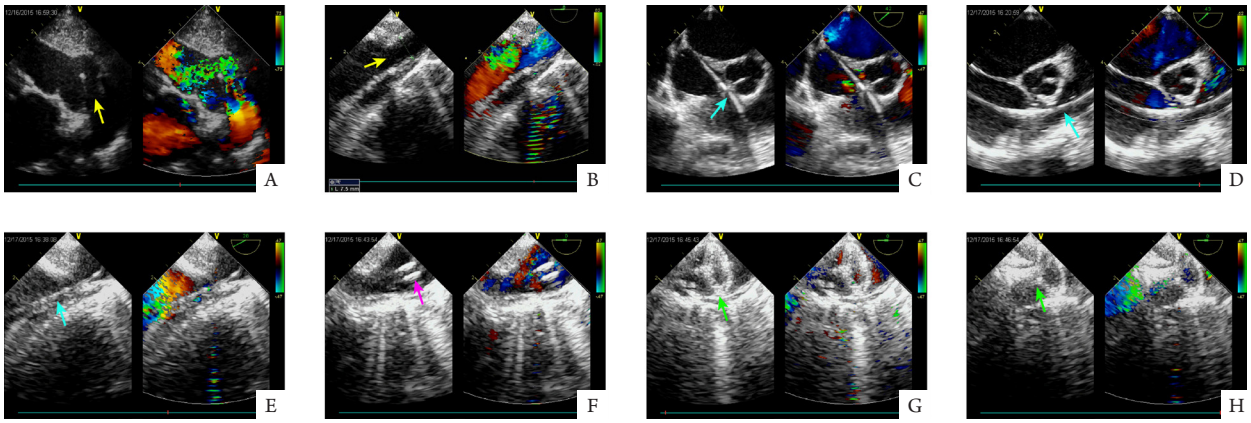

Figure 2 Procedural steps

PDA was comprehensively studied by TTE (A) and TEE (B) preoperatively. Yellow arrows indicate PDA. Under the guidance of TEE, cooperating with the catheter, the guidewire (light blue arrows) advances through the tricuspid valve (C), right ventricle outflow tract (D) and pulmonary valve, and crossed PDA (E) into DAO. The delivery sheath (purple arrow) then advanced into DAO over the guidewire (F). Deployed the retention disk of occluder (green arrow) in DAO (G). Uncovered the rest of the device (green arrow) within PDA (H)

2 Results

A total of 102 consecutive Chinese pediatric patients with isolated PDA underwent attempted transcatheter device closures under TEE guidance only, without arterial access. The Baseline Characteristics of the Study Population are shown in Table 1. According to the classification of Krichenko, 76 patients had type A (conical), 7 had type B (window), 15 had type C (tubular), and 7 had type E (elongated) PDA. The median PDA minimal (pulmonary end) diameter determined by TTE was 4.2 (range 3.1 to 7.5) mm. The median PDA length was 5.6 (range 3.2 to 10.7) mm. The transcatheter occlusion procedure under TEE guidance was successful in 99 (97.1%) patients. During early stage of this study, attempts of transcatheter closure were failed in three patients due to failure of passing guide wire through PDA. All these 3 patients were converted to minimally invasive percardiac device closure as described before[20]. There were no acute procedural complications or severe adverse events (e.g., death, arterial rupture, valve injury, device drop-off, or embolism). The procedure time ranged from 10 to 65 minutes (median, 21 minutes). Immediate complete closure of PDA was achieved in 87 patients (87.9%). In the other 12 cases (12.1%), there were traces of residual shunt immediately after the procedure, which resolved after 24 hours. A transient, well-tolerated episode of junctional rhythm was observed in 5 patients

(5.1%) during the operation. All patients had uneventful postoperative recovery, and were followed by clinical examination, electrocardiography, and transthoracic echocardiography. No severe adverse events (e.g. death, cclude migration, hemolysis, pericardial effusion, or pulmonary branch or aortic stenosis) were noted during the period of 1–24 (median 12) months.

To estimate a number that may be defined as the required case volume to achieve proficiency in the echo-guided PDA device closure procedure, operative times were analyzed. The patients were divided into 4 groups: the initial 25 patients, the 26th–50th patients, the 51st–75th patients and the final 24 patients (Figure 3). Statistical analysis (ANOVA-test) revealed that the mean operative times of the third group (patients 51–75) was significantly shorter than the initial 25 patients (P<0.05, Figure 3). And, when the last 24 patients were compared to the first 25 patients, the mean operative time was further shorter (P<0.01, Figure 3).

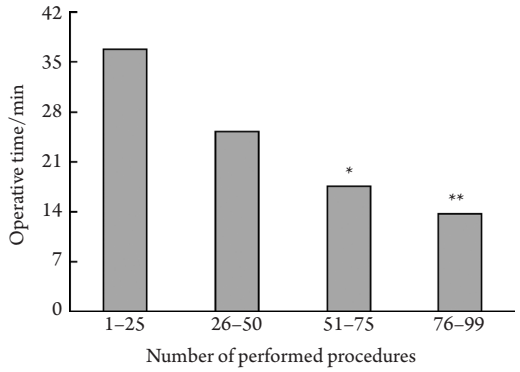

Figure 3 Learning curve

*P<0.05, **P<0.01 vs the first 25 procedures

3 Discussion

PDA is the first congenital heart disease that could be treated by the transcatheter closure[22]. As catheterization techniques develop and spread, transcatheter occlusion has become the most common treatment for PDA. The well-accepted guidance for transcatheter PDA closure has been X-ray aorta angiography[2-6, 11-13]. Two major concerns remain with the conventional techniques. One is X-ray radiation and contrast agent toxicity, especially for pediatric patients[7-10, 23]. The other one is the increased potential risks of vascular complications caused by femoral artery puncturing for angiography[11-13]. Despite separate solutions have been proposed to either reduce radiation exposure and contrast agent usage[14-15, 17, 24], or to avoid arterial access[18-19], there is no reported method that deals with these two problems at the same time. We are the first to report that echocardiography can be used as the only guidance for transcatheter PDA closure without arterial access. Our study firstly shows that transcatheter closure of PDA intravenously only without fluoroscopy is technically feasible and safe, suggesting that echocardiography alone could not only serve as the alternative guidance for transcatheter duct closure but also help avoid radiation exposure and potential arterial complication.

In an effort to reduce injury related to fluoroscopy and angiography, TTE has been used as major guidance during transcatheter occlusion of PDA[14-15, 24]. However, radiation and contrast agents could not be avoided completely in these studies. In the current study, we use echocardiographic guidance alone during transcatheter closure of PDA. In most cases, TEE alone is competent for guidance during the whole procedure, though in some cases TTE may be helpful for "double-check" at some point. Compared to fluoroscopic guidance, the biggest challenge of echocardiographic guidance is to track the guidewire, catheter and delivery sheath with two-dimensional echo view plane, which is significantly associated with procedure time and safety. This might be the major reason why the previous studies preferred to build up the device delivery track under fluoroscopy rather than echocardiography, when the later was only used to monitor the occluder deployment[15, 24]. To conquer this challenge, we firstly employed the method of "safe distance" which refers the distance between the left second intercostal parasternal space and the right femoral vein puncture site. The "safe distance" is measured before procedure and marked on the catheter and delivery sheath. When the "safe distance" of catheter is reached, rotate the catheter to facilitate the detection of its position in the pulmonary artery by TEE, which could significantly reduce the procedure time. If the "safe distance" is reached but the delivery sheath can't be detected, any blind performance should be prohibited to avoid arterial rupture, which is key to procedure safety. It is also important in our opinion to choose and trim a catheter appropriately. We used JR 4 diagnostic catheter, of which the J cured tip is

very helpful to adjust the direction of the guidewire for advancing through tricuspid valve and right ventricle outflow tract. Whereas trimming of the J tip of the catheter could remarkably facilitate the advancement of guidewire through ductus. During the early stage of this study, there were 3 patients failed in transcatheter closure due to failure of passing guidewire through PDA. But after we started trimming the catheter, no more failed delivery track building up happened again. Visualization of deployment is also important for the safety and efficacy of device closure of PDA. In the current study, the device placement process is clearly visible using TEE guidance and well-timed placements can be precisely controlled by the operators. Dislocation or residual shunting can be easily found and appropriately adjusted immediately. Complications such as interfering with the blood flow of aorta or pulmonary branches can be also detected simultaneously. Using these strategies, satisfactory outcome has been achieved in our current study. There were no acute procedural complications or severe adverse events. Though operating time may be prolonged in certain cases, especially in the few early cases, the procedure time remarkably decreased as operators gain experience. The learning curve is very short for operators, especially when they are cooperating closely with experienced sonographer.

Traditional transcatheter PDA device closure involves arterial access for angiography before, during, and after deployment of the device. The incidence of femoral artery related complications remain concerned, especially among children[25]. Arterial access in children is reported to cause a high rate of complication ranging between 3.7% and 16%, of which a significant proportion requires intervention[25-26]. Moreover, complications such as arterial disruption, or acute occlusion, may be even limb-threatening[27]. There are several reported studies[18-19] in which transcatheter PDA device closure was performed without arterial access, but fluoroscopy was routinely used for guidance, and the successful rate was relatively low. In the current study, we were able to close PDAs in 99 out of 102 consecutive patients with venous access alone, under echocardiography guidance only, with satisfying feasibility and safety. Interestingly, Pan and colleagues[17] recently reported that a group of 63 consecutive PDA patients underwent transthoracic echocardiography-guided PDA occlusion with femoral arterial access only. Despite the risk of femoral artery related complications, there was more limitation for patient inclusion criteria, because ADO II occluder is unsuitable for PDAs with diameter more than 5.5 mm. In the current study, patient selection criteria are similar to the traditional practice and similar success ratio has been achieved[4, 28].

The main limitations of this study were its retrospective observational nature and the absence of a control group for comparison. Moreover, the data were from a single-centered study, the outcome and the superiority of this new strategy should be validated by prospective multi-centered randomized controlled trials.

The current study demonstrates the feasibility, safety and advantages of device closure of PDA using only venous access under echocardiography guidance alone. This new strategy avoids radiation exposure, contrast agent usage and potential arterial complications, which can be applied as an alternative, especially for children.

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(Edited by GUO Zheng)

本文引用：张伟志, 高雷, 金万存, 吴勤, 胡世军, 杨一峰, 赵天力. 超声引导下股静脉路径动脉导管经皮封堵术：一种治疗新策略的可行性和安全性研究[J]. 中南大学学报(医学版), 2018, 43(9): 1000-1006. DOI:10.11817/j.issn.1672-7347.2018.09.011

Cite this article as: ZHANG Weizhi, GAO Lei, JIN Wancun, WU Qin, HU Shijun, YANG Yifeng, ZHAO Tianli. Echocardiography-guided percutaneous closure of patent ductus arteriosus without arterial access: Feasibility and safety of a new strategy[J]. Journal of Central South University. Medical Science, 2018, 43(9): 1000-1006. DOI:10.11817/j.issn.1672-7347.2018.09.011