Initial experience with the 3.3 Fr Mongoose® pigtail catheter for aortic angiography during patent ductus arteriosus closure in small patients

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ABSTRACT

Background : **Smaller femoral arterial sheaths may be associated with fewer vascular complications. The 3.3 Fr Mongoose® Pediavascular pigtail catheter is a catheter that allows higher flow rates, potentially resulting in improved angiographic quality. We reviewed our experience with this small catheter during patent ductus arteriosus (PDA) closure.**

Materials and Methods : **Review of patients ≤20 kg in whom the Mongoose® catheter was used during PDA closure from 12/13 to 4/15. Angiographic efficacy and procedural details were compared to ten 4 Fr catheter cases. Comparisons were performed using Mann–Whitney U-test; $P < 0.05$ was statistically significant.**

Results : **Twelve (9 female) patients were catheterized with a 3.3 Fr Mongoose®. Median weight 10.5 kg (range 6.4–18.2), height 81 cm (range 37–111), and body surface area (BSA) 0.47 m² (range 0.33–0.75) were similar to ten patients (3 females) in the 4 Fr control group (P = NS); median weight 9.9 kg (range 6–16.8), height 80 cm (range 64–102), and BSA 0.46 m² (range 0.31–0.74). Angiographic quality was subjectively adequate with both with no difference in the median pixel density between the two techniques (3.3 Fr: 76.7 [range 33.5–90] and 4 Fr: [70; 38–102]; P = NS). Contrast used was similar between the groups (3.3 Fr: median 4.2 ml/kg and 4 Fr: 4.9 ml/kg; P = NS). Median radiation dose was similar in the two groups (3.3 Fr: 28.1 mGy [range 17.2–38] and 4 Fr: 38 mGy [range 20.4–58.5]; P = NS). All ducts were closed at latest follow-up (P = NS). No complications were encountered.**

Conclusions : **The 3.3 Fr Mongoose® allowed similar angiography to the 4 Fr pigtail catheter, allowing safe and effective transcatheter PDA closure in small children.**

Keywords : Angiographic/fluoroscopic, atrial septal defects/patent ductus arteriosus/patent foramen ovale, catheter design, closure, interventional devices/innovation, pediatric intervention

INTRODUCTION

Patent ductus arteriosus (PDA) closure in the catheterization laboratory is now the standard for all nonneonatal PDAs.[1-7] Although a safe intervention, there are potential rare risks including bleeding, infection, arrhythmias, device embolization, and pulse loss.[6,8,9] Although rarely reported to be performed without aortic angiography, performance of an angiogram in the aorta before and after closure of the ductus is most

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common.[10,11] 3 Fr pigtail catheters have historically not allowed adequate injection velocity for angiography of the ductus for anatomical assessment. The 3.3 Fr Mongoose® pigtail catheters from Pediavascular (Pediavascular Cleveland, OH, USA) allow for faster injections and potentially better angiograms. The aim of this study was to retrospectively assess the efficacy and safety of the novel Mongoose® 3.3 Fr pigtail catheter for PDA closure.

MATERIALS AND METHODS

Standard approaches to transcatheter closure of the PDA have been described elsewhere.[6,12-14] To briefly summarize the general technique used in these cases, right and left heart hemodynamic catheterization was performed. Following this, a biplane angiogram of the descending aorta with the tip of the pigtail catheter positioned at the level of the ductal ampulla was obtained using a low-dose fluoroscopic and angiographic technique[15] previously described for endomyocardial biopsy in small children. The magnification used for most angiograms in this study was 16 cm using Siemens Artis zee system (Siemens Medical Solutions, Malvern, PA, USA) and the PA camera was typically positioned 30° RAO and lateral camera straight lateral. Closure of the ductus was then performed using either an MReye 0.038" coil, an Amplatzer ADO device (St. Jude Medical – St. Jude Medical Inc., MN, USA), or a Nit-Occlud PDA device (PFM Medical – PFM Medical Ag, Cologne, Germany). One or two biplane angiograms were performed following device placement to confirm device position and ductal closure before completion of the catheterization.

The 3.3 Fr Mongoose® pigtail catheter is manufactured in three different lengths (40, 60, and 80 cm) and with maximum flow rates (ml/sec) of 13, 11, and 9, respectively, with a listed maximal burst pressures of 1200 PSI, thereby allowing for faster injections and potentially better angiograms. The catheter takes a 0.030" wire and is somewhat stiffer than typical pigtail catheters. In all cases, a 3.3 Fr Pediavascular sheath was placed in the femoral artery and a 3.3 Fr pigtail catheter was used. Most were the two shortest length catheters allowing for the maximal flow rates listed.

This was a single-center, retrospective, descriptive review of all patients in whom this catheter was used for aortic angiography during PDA closure from 12/13 to 4/15. Comparison was made with prior ten cases, in which a more standard 4 Fr angiographic catheter was used from 9/12 to 12/13.

Approval of the Institutional Review Board was obtained before retrospective data collection was performed. Cases were identified by querying the pediatric catheterization database. During the time periods studied, the attending cardiac catheterization laboratory staff has been unchanged and the fluoroscopic equipment utilized as well as PDA closure techniques have also been similar, thus mitigating confounders.

Inclusion criteria

Patients with PDA who underwent transcatheter PDA closure during the above time frame with weight <20 kg were included in this study.

Exclusion Criteria

Patients with other congenital heart problems requiring additional angiography that is not related to the PDA were excluded from this study.

Data collected included demographic as well as procedure-related data. Pixel density (including average, standard deviation, and maximum and minimum pixel values) was assessed using the region of interest oval tool of the General Electric Healthcare (Chicago, Illinois, USA) RA1000 PACS system. Complications, efficacy, and safety data were obtained in follow-up.

Statistical analysis

Variables were reported as median with range. Comparisons were performed using Mann–Whitney U-test, with $P < 0.05$ was considered statistically significant.

RESULTS

Twelve (9 female) patients met inclusion criteria for the study and were catheterized with a 3.3 Fr Mongoose® pigtail catheter. The median age was 23.5 months (range 6–68), median weight was 10.5 kg (range 6.4–18.2), median height was 81 cm (range 37–111), and the median body surface area (BSA) was 0.47 m^2 (range 0.33–0.75). These were not different from the ten patients (3 females) in the 4 Fr control group with median age 17 months (range 8–95), median weight 9.9 kg (range 6–16.8), median height 80 cm (range 64–102), and BSA 0.46 m^2 (range 0.31–0.74). Patient demographic details are summarized in Table 1.

Angiographic quality was subjectively adequate with both catheters in all cases [Figure 1] with no objective difference in average pixel density between the two techniques (3.3 Fr: median 76.7 [range 33.5–90] and 4 Fr: median 70 [range 38–102]; P = NS). The procedure time, defined in this study as the time from gaining vascular access to the time of vascular sheath removal, was slightly longer in the 4 Fr group (3.3 Fr: median 54.5 [range 49–68] and 4 Fr [median: 65.5 range 48–171]; $P = 0.006$). The fluoroscopy time (minutes) was similar between the two groups (3.3 Fr: median: 8.3 [range 4.4–17.7] and 4 Fr: median 7.35 [range 5.5–27.1]; P = NS). Median radiation dose as measured by air Kerma was also similar in the two groups (3.3 Fr: 28.1 mGy [range 17.2–38] and 4 Fr: 38 mGy [range 20.4–58.5]; P = NS).

Median total contrast (ml) was similar in both groups (3.3 Fr: 45 [range 27–90] and 4 Fr: 48 [range 33–95]; *P* = NS). The median contrast dose (ml/kg) used was similar between the two groups (3.3 Fr: 4.2 and 4 Fr: 4.9; *P* = NS). Echocardiography on post operative day 1 (POD) demonstrated PDA closure in 10/12 3.3 Fr patients and 10/10 4 Fr patients (*P* = NS). At a mean follow-up of 2.3 months, all PDAs were closed. Procedural data and complications are summarized in Table 2. Figure 1 shows lateral angiography comparison of PDA before closure.

There were no procedural complications in either group; subjective equal pulses and perfusion were noted on postcath day 1 in all patients.

DISCUSSION

Avoidance of complications is of paramount importance in any interventional procedure, and one of the most common problems encountered following catheterization of small children is pulse loss.[16-22] Although many factors can affect the development of arterial occlusion including inadequate heparinization and vascular access technique, size of the sheath is highly associated with injury to the vascular structure. Thus, most pediatric interventionalists try to perform all procedures with as small a vascular sheath as possible to achieve the interventional goal and minimize risk.[3,12,23]

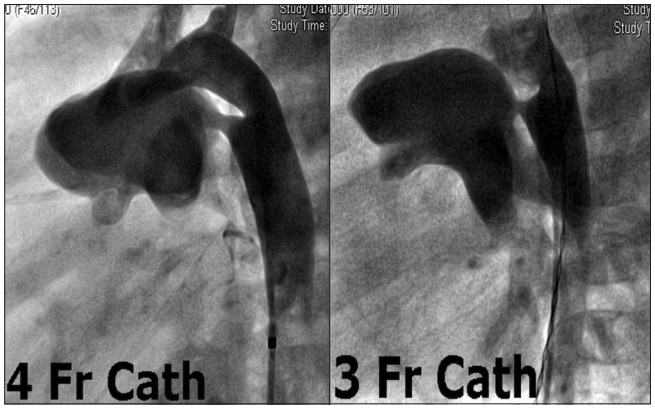

Figure 1: Lateral angiography comparison of patent ductus arteriosus before closure. PDA: Patent ductus arteriosus, 4 Fr Cath: 4 French Catheter, 3.3 Fr Cath: 3.3 French Catheter

Table 1: Demographic data

Catheter	3.3 Fr	4 Fr
Number of patients (*n*)	12	10
Gender (male) (%)	3/12 (25)	7/10 (70)
Median weight (kg, range)	10.5† (6.4-18.2)	9.9† (6-16.8)
Median BSA (m^2, range)	0.47† (0.33-0.75)	0.46† (0.31-0.74)

†*P*: Not significant. BSA: Body surface area

Table 2: Procedural data and complications

Catheter	3.3 Fr	4 Fr
Angiography quality (pixel density, range)	76.7† (33.5-90)	70† (38-102)
Contrast (mL/kg)	4.2†	4.9†
Air kerma dose (mGy, range)	28.1† (17.2-38)	38† (20.4-58.5)
PDA closure on POD# 1	10/12†	10/10†
PDA closure at last follow-up	12/12†	10/10†
Complications	0/12†	0/10†

†*P*: Not significant. PDA: Patent ductus arteriosus, POD: Post operative day

This study demonstrates preliminary findings of the efficacy and safety of the novel Moongoose® 3.3 Fr pigtail catheter for aortic angiography during PDA closure. In our series, this catheter allowed for adequate angiography in comparison to the 4 Fr control group despite its smaller diameter. As the density of contrast and clarity of the image are related directly to the speed of injection, it is clear that because this catheter allows for markedly faster injection rates, this is likely the main reason that it is superior to prior 3 Fr catheters and similar in efficacy to 4 Fr catheters that previously were the smallest to allow flow rates over 10 ml/s. Adequacy of angiographic quality was demonstrated both subjectively and objectively in this small series. Importantly, safety was not compromised in this study with no complications encountered in either group.

Although ductal closure was not universal on POD#1 (10/12 for the 3.3 Fr group), the device utilized in the patients, in which there was not early closure was the Nit-Occlud PDA device. Although this device has been demonstrated to result in a 96.8% complete echocardiographic closure at 12 months, there may be a higher incidence of early ductal patency after its use in comparison with other devices.[14] At present, at latest follow-up, as predicted, all PDAs in our series are closed. With respect to safety, there were no complications in either group; radiation exposure was minimized as was the use of contrast.

Study limitations

This is a small retrospective study performed at a single institution, and these results may not be applicable to all centers. Use of Mann–Whitney test allotted comparison of medians in a nonparametric distribution data set. With a small number of patients, our results only show the 3.3 Fr catheter is comparable to the 4 Fr catheter. Further study with larger numbers would be warranted to achieve statistical significance. The total number of cases included in this work is small due to the volume of this center which makes drawing conclusions difficult; however, we do believe that these data are adequate rationale for a possible larger study. A prospective study comparing the newer 3.3 Fr catheter to more standard 4 Fr angiography catheters would be of interest, but it is unclear if there is adequate equipoise to proceed with such a trial at this juncture. An additional limitation of this study is that the two operators have an average experience level of >10 years in practice and the impact of this experience level of the results and complication rates cannot be easily determined. Finally, unless

laboratories are using the ALARA techniques including air gap technique, it is unlikely that the radiation air Kerma doses described in this work will be achievable in other catheterization laboratories.

CONCLUSIONS

The 3.3 Fr Mongoose® allowed for adequate and similar angiography quality to the more standard 4 Fr pigtail catheter, allowing safe and effective transcatheter PDA closure in small children in this small study. Total contrast, radiation dose, and echocardiographic PDA closure rates were similar between the two catheters. There were no complications in either group, and visualization of the PDA was equal with the use of this novel catheter. These preliminary results suggest noninferiority, but a larger study with more participants would be useful to verify these preliminary data.

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Conflicts of interest

There are no conflicts of interest.

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