Surgically placed radiopaque markers: Proof-of-concept of a novel technique to facilitate percutaneous interventions in neonates and infants

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Abstract

Objectives: Aim of this study was to evaluate feasibility and benefit of self-designed, radiopaque markers as a novel technique in neonates and infants with shunt- or duct-dependent lesions.

Background: Surgically placed radiopaque markers have the potential to facilitate postoperative percutaneous interventions.

Methods: All consecutive children with surgically placed radiopaque markers involving systemic-to-pulmonary artery connections or arterial ducts in the context of hybrid palliation and subsequent cardiac catheterization between January 2013 and March 2019 were included in this analysis. Our primary endpoint was our concept’s feasibility, which we defined as a combination of surgical feasibility and the percutaneous intervention’s success. Secondary endpoint was the rate of complications resulting from the surgical procedure or during catheterization.

Results: Radiopaque markers that reveal the proximal entry of a surgical shunt or the arterial duct proved to be a feasible and beneficial approach in 25 postoperative catheterizations. The markers’ high accuracy enabled easy probing and proper stent positioning in 13 neonates with a median age and weight of 121 days (range 9–356) and 4.7 kg (1.6–9.4) at the intervention. No procedural complications or unanticipated events associated with the radiopaque marker occurred. The markers were never lost, never migrated, and caused no local obstructive lesion. Surgical removal was straightforward in all patients.

Conclusions: Radiopaque markers are a promising and refined technique to substantially facilitate target vessel access and enabling the accurate positioning of stents during postoperative percutaneous procedures.

KEYWORDS
congenital heart disease, pediatrics, pediatric intervention, stenting technique, surgery, congenital heart disease
1 | INTRODUCTION

Angiographic diagnostics and percutaneous interventions following surgery are important tools in treating patients with complex congenital heart defects.

Especially in neonates and infants who undergo palliative or hybrid strategies as the first step to achieve weight gain or pulmonary artery growth, postoperative interventions are frequently performed to delay subsequent complex heart surgery. Stenting the arterial duct during hybrid palliation, interventions in the pulmonary arteries through a systemic-to-pulmonary artery shunt, or stenting the shunt itself are examples of such procedures.1-4

Since these procedures involve small shunts with diameters usually between 3.0 and 4.5 mm (which often branch off at a sharp angle from the aorta), probing can be difficult, especially when done in urgent situations.5-9 In the context of hybrid palliation, bilateral pulmonary artery bandings are applied followed by stenting the arterial duct to ensure systemic circulation in congenital cardiac lesions with severe stenosis or an interrupted aorta.10,11 Of utmost importance are the implanted stent's accurate positioning and length so as to avoid both a stenosis of the duct and impairment of the pulmonary arteries or posterior aortic wall—factors difficult to achieve in certain scenarios.12

The use of surgically placed radiopaque markers to depict key anatomical structures for probing and stenting might prove to be a simple yet effective method to facilitate these interventions. This technique has delivered beneficial results in adult patients when used as coronary bypass markers to simplify post-bypass coronary angiography, but it has not been described in a pediatric population so far.13-16 Aim of this study was to evaluate the feasibility and benefit of surgically placed, self-designed, radiopaque markers as a novel technique to facilitate postoperative cardiac catheterization in neonates and infants with shunt- or duct-dependent lesions.

2 | MATERIALS AND METHODS

This study was designed as a retrospective proof-of-concept analysis to evaluate the feasibility of a novel technique to facilitate postoperative cardiac catheterization in infants with congenital heart disease (CHD).

Neonates and infants requiring either the implantation of a systemic-to-pulmonary artery connection (artificial PTFE tubes for central aorto-pulmonary shunts, modified Blalock–Taussig shunts, or right ventricular-to-pulmonary artery shunts) or hybrid palliation (banding of both pulmonary arteries and arterial-duct stenting) were suitable to undergo the implantation of radiopaque markers. Selecting patients to undergo radiopaque-marker application was at the surgeon’s discretion. Two cardiac surgeons were involved in applying the markers.

All consecutive children with radiopaque markers who needed cardiac catheterization at our center since the introduction of this new method were subsequently included in this analysis between January 2013 and March 2019. Procedural data were obtained from the patients’ in-hospital records and institution’s database for cardiology

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**Table 1a**: Patients and procedural characteristics of patients with duct-dependent systemic blood flow

| Cath no | Patient Age (days) | Weight (kg) | Underlying anatomy | Marker position | Marker accuracy | Amount of contrast (ml/kg) | Fluoroscopy time (min) | Additional intervention | Amount of contrast (ml/kg) | Fluoroscopy time (min) | Additional intervention |
|---------|-------------------|-------------|--------------------|-----------------|----------------|--------------------------|-----------------------|------------------------|--------------------------|-----------------------|------------------------|
| 1       | 1                 | 19          | 2.1                | HLH, TAPVC, s/p bPAB | Arterial duct, pulmonary origin | Stenting | 32 | 8.6 | Yes |
| 2       | 2                 | 42          | 1.6                | TAC, IAA, s/p bPAB | Arterial duct, pulmonary origin | Stenting | 13 | 3.8 | Yes |
| 3       | 9                 | 99          | 2.8                | Re-stenting | BAP RPA + LPA | 60 | 12.9 | Yes |
| 4       | 3                 | 9           | 2.4                | DORV, TGA, LVO TO, s/p bPAB | Arterial duct, pulmonary origin | Stenting | 22 | 10.8 | Yes |
| 5       | 6                 | 49          | 3.6                | DORV, TGA, LVO TO, s/p bPAB | Arterial duct, pulmonary origin | Stenting | 36 | 7.5 | Yes |
| 6       | 4                 | 10          | 4.4                | AS, IAA, VSD, s/p bPAB | Arterial duct, pulmonary origin | Stenting | 35 | 6.8 | Yes |
| 7       | 9                 | 95          | 6.7                | Re-stenting | BAP RPA + LPA | 38 | 9.0 | Yes |
| 8       | 5                 | 22          | 2.9                | Stent redilation | BAP RPA | 44 | 7.5 | Yes |
| 9       | 87                | 2.9         | 1.6                | AS, IAA, VSD, s/p bPAB | Arterial duct, pulmonary origin | Stenting | 22 | 1.4 | Yes |
| 10      | 156               | 3.7         | 1.6                | Re-stenting | BAP RPA | 44 | 3.7 | Yes |

Abbreviations: BW, body weight; kg, kilogram; mm, millimeter; ml, milliliter; DORV, double outlet right ventricle; PA, pulmonary atresia; MAPCA, major aortopulmonary collateral artery; BAP, balloon angioplasty; cPAB, central pulmonary artery banding; ccTGA, congenital corrected transposition of the great arteries; TAC, truncus arteriosus communis; IAA, interrupted aortic arch; DI fellow left ventricle; AS, aortic stenosis; VSD, ventricular septal defect; MTS, modified Blalock-Taussig shunt; central shunt; central aorto-pulmonary shunt.
imaging and reporting (McKesson Cardiology, Holon, Israel). Written informed consent of the parents or legal guardians was obtained as usual. The study was approved by the Ethics Committee of the local university. All data obtained in this study comply with the 1975 Helsinki declaration.

We aimed to prove this concept’s feasibility, defined as a combination of surgical feasibility and the percutaneous intervention’s procedural success. We defined surgical feasibility as the correct application of the radiopaque marker, accuracy of the markers’ position on fluoroscopy, and easy removal during the next surgical step. Secondary endpoint was the rate of complications suspected to be associated with the radiopaque marker.

To evaluate the radiopaque marker’s accuracy, we measured the distance between its actual position and the branch-off point of the shunt or branch pulmonary artery on angiography. Markers’ position was defined as accurate if the distance was ≤ 2 mm (Table 1a and 1b).

Of note, we apply the term central shunt to refer to an aorto-pulmonary shunt originating from the ascending aorta supporting the pulmonary blood flow (Table 1b).

### Technique

All operations were performed via median thoracotomy under general anesthesia. For this first feasibility study, radiopaque markers were surgically applied either near the proximal anastomosis of a PTFE shunt or at the level of the arterial duct’s pulmonary orifice. The marker used is an in-house production: as the radiopaque marker, we pulled out the marking strip out of a standard sterile swap (Figure 1a). The thin band made of a multifilament yarn (polypropylene/polyethylene) with minimum 55% barium sulfate was then placed in a circle as proximally as possible around the origin of the shunt or arterial duct (Figure 1b) and gently sealed with a small surgical metal clip to prevent it from opening and slipping (Figure 1c,d).

Postoperative catheterizations were done with the patients under conscious sedation or general anesthesia. Access vessel and sheath size were chosen according to the material required for the intended intervention. Systemic-to-pulmonary artery shunts were usually performed antegradely using four Fr Judkins Right catheters and one or two 0.014 in. coronary guidewires. Coronary bare metal stents from the PRO-Kinetic system (Biotronik, Berlin, Germany) were used for stenting, which were delivered via long 4F sheaths (Flexor Introducer 45 cm, Cook Medical, Bloomington, IN).

In order to stent the arterial duct according to the hybrid approach, a 4F Berman wedge catheter and a 0.018 in. standard wire were used for probing. We favored a transvenous approach to the intervention using four Fr Judkins Right catheters and one or two 0.014 in. coronary guidewires. Coronary bare metal stents from the PRO-Kinetic system (Biotronik, Berlin, Germany) were used for the intervention. Systemic-to-pulmonary artery shunts were usually performed antegradely using four Fr Judkins Right catheters and one or two 0.014 in. coronary guidewires. Coronary bare metal stents from the PRO-Kinetic system (Biotronik, Berlin, Germany) were used for stenting, which were delivered via long 4F sheaths (Flexor Introducer 45 cm, Cook Medical, Bloomington, IN).

The location of the radiopaque marker was detected by standard postero-anterior and lateral projection followed by further angulations in selected cases, when necessary. Two interventionalists carried out the interventions.

### Table 1b

| Cath no | Patient | Age (days) | Weight (kg) | Underlying anatomy | Marker position | Marked vessel intervention | Additional intervention | Fluoroscopy time (min) | Amount of contrast (ml/kg) | Marker accuracy |
|---------|---------|------------|-------------|--------------------|-----------------|---------------------------|------------------------|------------------------|-----------------------------|----------------|
| 11      | 6       | 79         | 31          | DORV, PA, MAPCA    | RV-PA conduit, proximal | Stenting | BAP LPA | 34 | 6.5 | No |
| 12      | 126     | 36         | 71          | BAP, re-stenting    | BAP LPA | 71 | 13.9 |
| 13      | 178     | 40         | 34          | BAP                 | BAP LPA | 34 | 6.5 |
| 14      | 311     | 62         | 79          | Stenting            | BAP LPA | 79 | 9.7 |
| 15      | 7       | 101        | 69          | ccTGA, RV hypoplasia, PA, VSD | Central shunt, proximal | None | 8 | 4.9 | Yes |
| 16      | 276     | 94         | 13          | Stenting            | BAP LPA | 26 | 6.7 | Yes |
| 17      | 8       | 83         | 45          | DILV, TGA, PA      | Central shunt, proximal | Stenting | BAP LPA | 41 | 5.6 |
| 18      | 138     | 5.5        | 13          | Stenting            | BAP LPA | 13 | 4.5 | Yes |
| 19      | 9       | 122        | 6.6         | Ebstein anomaly, PA | Central shunt, proximal | None | 28 | 7.0 | Yes |
| 20      | 10      | 101        | 9.4         | AVSD, DORV, TGA, PS, TAPVC | Central shunt, proximal | None | 25 | 6.7 | Yes |
| 21      | 11      | 97         | 34          | DILV, PA, MAPCA    | Central shunt, proximal | Stenting | BAP RPA + LPA | 47 | 7.7 | Yes |
| 22      | 209     | 60         | 60          | Stent re-dilation   | BAP RPA + LPA | 53 | 5.7 |
| 23      | 356     | 69         | 10.6        | Stent re-dilation   | BAP RPA + LPA | 55 | 10.6 |
| 24      | 12      | 107        | 63          | DORV, MA, PS       | Central shunt, proximal | Stenting | 29 | 9.5 | Yes |
| 25      | 16      | 120        | 63          | TGA, PS, VSD       | mBTS, proximal | None | 26 | 8.1 | No |

Abbreviations: BW, body weight; kg, kilogram; min, minutes; ml, milliliter; DORV, double outlet right ventricle; PA, pulmonary atresia; MAPCA, major aortopulmonary collateral artery; BAP, balloon angioplasty; LPA, left pulmonary artery; RPA, right pulmonary artery; HLH, hypoplastic left heart; TAPVC, total anomalous pulmonary venous connection; s/p, status post; bPAB, bilateral pulmonary artery banding; ccTGA, congenital corrected transposition of the great arteries; TAC, truncus arteriosus communis; IAA, interrupted aortic arch; DILV, double inlet left ventricle; AVSD, atrioventricular septal defect; PS, pulmonary valve stenosis; LVOTO, left ventricular outflow tract obstruction; MA, mitral atresia; VSD, ventricular septal defect; mBTS, modified Blalock-Taussig shunt; central shunt, central aorto-pulmonary shunt.
2.2 | Statistics

Data are presented as median values with ranges.

3 | RESULTS

From January 2013 until March 2018, radiopaque markers were present during 25 cardiac catheterizations of 13 patients with a median age and body weight of 121 days (range 9–356) and 4.7 kg (1.6–9.4). Table 1a and 1b summarizes further patient characteristics, and provides an overview of all interventions. At the time of marker placement, patient’s median age and weight were 14 days (4–46) and 3.1 kg (1.6–4.4). Placement of the markers was rapid and straightforward, taking <3 min in all patients. The time interval between surgical placement and catheterization varied from a few hours in four of five patients undergoing hybrid palliation on the same day to a maximum of 311 days in shunt-palliated patients (median 99 days). The markers’ positions were mostly at the aortal origin of a central shunt (10/25 interventions) or the duct’s pulmonary origin (10/25), and more rarely the proximal entry of a RV-PA shunt (4/25) or the offspring of a modified Blalock–Taussig shunt from the brachiocephalic trunk (1/25). 16% of the catheterizations were done for diagnostic purposes.

The radiopaque markers were surgically applied and removed easily in all 13 patients. The marker’s position was inaccurate according to our definition in two patients. However, the patient with the maximum distance of 4.9 mm between branch-off point and radiopaque marker was the only patient whose marker was at the proximal entry of a RV-PA shunt in which this rather large distance reflected the diameter of the right ventricle’s myocardium (Table 1b, patient 6). In this case, the marker’s position could not have been closer to the entry of the RV-PA conduit. The other patient with a distance between marker and branch-off point >2 mm was the patient whose marker was at the proximal entry of a modified Blalock–Taussig shunt (Table 1b, patient 13). Overall accuracy of the radiopaque markers was high (11/13 patients; 85%). All 25 interventions were completed successfully. This new technique’s feasibility according to this study’s criteria was thus assured in 85%. Median fluoroscopy time for all procedures was 35 min (range 8–79). The median amount of contrast media used was 8.2 ml/kg (3.8–13.9). No surgical or procedural complications or unanticipated events associated with the radiopaque marker occurred.

One patient (Table 1b, patient 6) with pulmonary atresia (PA) in double outlet right ventricle (DORV) had a RV-to-PA shunt near the RV apex due to an atypical coronary artery course. Subsequent probing of the shunt was essentially simplified by the proximal radiopaque marker, as this shunt was subtotally closed (Figure 2a). The entire shunt was then stented, with the marker now facilitating a very accurate position of the most proximal stent (Figure 2b).

In four patients with a 3.5-mm central shunt (Table 1b), the shunt had to be stented as the flow through the shunt had subsided, or to
adjust the shunt size to the patient’s somatic growth. The shunt’s proximal origin was accurately tagged by the radiopaque marker on angiography (Figure 2c) which enabled easy probing without the need for special catheters or co-axial systems. Shunt augmentation by stenting (Figure 2d) was done properly using a single stent in all cases. The shunts’ diameters were expanded by overdilation from 3.5 up to 4.2–4.3 mm, which proved to be beneficial as the consecutive follow-up operations could be postponed by a median 216 days (range 74–422). Median time to successful probing of the target vessel (time interval from the first overview angiography detecting the shunt’s origin until successful coronary guidewire probing) was 6.5 min (range 1–23) in those patients requiring shunt interventions. We used long 4F Flexor sheaths for delivery in all of them.

Five patients underwent stenting of the systemic duct in a hybrid palliation setting, with the radiopaque marker displaying the ducts’ pulmonary origin (Table 1a, Figure 2e,f). After transvenous probing and angiography to visualize the arterial duct with its junction to the descending aorta, the stent was implanted via the same route. Of note, the marker technique enabled us to use a short four Fr sheath for stent delivery without needing an aortic catheter for stent positioning: control angiographies prior to stent implantation were unnecessary as the duct’s pulmonary origin was radiopaquely marked, while a nasogastric tube was used as a reliable landmark for the aortic end in lateral projection (Figures 2e,f, Videos S1–S4). Arterial sheaths were not needed, and we were able to avoid using long sheaths in all but one of these infants. Two infants required a second stent to cover the
entire duct: in one of them (Table 1a, patient 4), the second stent was placed in the same way, without using a long sheath (sinus SuperFlex-DS 7/15 + 7/12 mm). In the second (patient 5), however, we feared a dislocation of the first stent, thus we chose to use a long 5F Flexor sheath secondarily to facilitate stent-in-stent implantation (sinus SuperFlex-DS 8/15 mm + 414 Formula 7/16 mm).

On follow-up, ductal re-stenting was required in two patients after 57 and 134 days, respectively, due to outgrowth and neo-intimal proliferation, but not due to stent malpositioning. The marker and clip never became dislocated or lost, the ring formation remained unchanged, and caused no local obstructive lesion or any other untoward effect. Of note, the postoperative echocardiograms' quality was unaffected by any artifacts caused by the marker. Surgical removal of the radiopaque marker was straightforward in all patients after a maximum 499 days (median 215). One patient (Table 1a, patient 5) underwent total explantation of a stented duct to enable histopathological examination of the marker band. No significant tissue reaction around the marker was detected macroscopically or histologically (Figure 3).

4 | DISCUSSION

Over recent decades, neonates and infants have increasingly been undergoing catheterizations after surgery for congenital heart defects for therapeutic purposes in elective and urgent clinical settings. This non-controlled proof-of-concept analysis demonstrates that surgically placed radiopaque markers that reveal the proximal entry of a systemic-to-pulmonary artery shunt or the arterial duct proved to be feasible and a beneficial method to facilitate postoperative percutaneous procedures in 25 cardiac catheterizations at our center. The strategy we describe is easy to implement surgically and would be similarly helpful for interventionalists at other pediatric-cardiology centers. As implantation requires no additional materials or equipment due to the marker's in-house production, the technique is very inexpensive. Although this report demonstrates convincing intervention results, the absence of a control group precludes any statistical evaluation of specific clinical and technical endpoints (e.g., procedural time, radiation exposure, amount of contrast agent).

In this study, we gave priority to marking central shunts on hypoplastic pulmonary arteries that would be recruited through repeated interventions, or shunts that will necessitate adapting to somatic growth to lengthen palliation and delay the time to corrective surgery, respectively. Catheterizations of infants with marked shunts were characterized by easy access to the pulmonary arteries—reflected in all cases by the brief probing times and accurate stent positioning. In the hybrid setting, stenting of the systemic duct was facilitated by the marker at its pulmonary origin, which allowed use of a short 4F sheath for transvenous antegrade delivery, followed by proper stent placement. The only exception to not employing long sheaths can arise when stent-in-stent implantation is required to cover the entire duct, which occurred twice in this series and actually resulted in using a long sheath once. In two infants, subsequent stenting was necessary due to ductal stenosis, but not due to a malpositioned stent or local marker obstruction. Avoiding long sheaths for stent delivery is particularly beneficial for transvenous access via the heart of young infants because that is usually better tolerated hemodynamically. In addition, our marker strategy also enabled us to dispense with the use of arterial sheaths and aortic catheters that would otherwise be used for control angiographies during stent placement, thus avoiding the vascular complications that are so common in early childhood. Neonates and infants of low body weight are at particular risk for periprocedural complications during cardiac catheterization. Any measure to shorten or simplify interventions in this highly vulnerable patient population should be taken. However, a marker that is imprecisely placed or whose position is not entirely clear to the examiner can lead to wrong decisions. It is therefore crucial that the examiner identify its anatomical position in relation to the vessels' origin or branch-off.

We encountered no procedural complications in this study, and the surgical removal of the markers was straightforward in all patients.

Few other methods have been published to date that facilitate catheterization in children. Cools et al. described a central Laks-type shunt with end-to-side pulmonary and side-to-side aortic anastomosis, and found that this shunt type was easily accessible for percutaneous procedures. Radiopaque markers can further simplify such interventions in addition to that surgical technique. Another innovation could be to apply a radiopaque strip while manufacturing the PTFE tubes used as shunts—which would then depict the shunt's position and length. This could also be considered in the hybrid setting when using surgically applied bands around large systemic ducts to facilitate subsequent stenting, as suggested by Trezzi et al. An additional radiopaque marking of these bands could actually provide further assistance.

4.1 | Study limitations

This is a proof-of-concept analysis with few patients, and the typical limitations of a retrospective single-center study. The risk of confounding is given due to the lack of a control group. Thus, the inferiority of radiopaque markers is unlikely. As the vessels' probing time was short, additional interventions were performed during the same procedure. A control group with neonates and infants without marked shunts or vessels who had not undergone additional interventions was therefore not available. In an analysis of 1,378 adult patients in whom the impact of radiopaque coronary bypass graft markers on postoperative coronary angiography was investigated, bypass graft markers were found to be a significant predictor for less radiation time and reduced use of contrast agent. In a larger pediatric patient series, these positive effects would most likely also be noticeable. There are no radiopaque markers approved for pediatric patients commercially available, thus implying their off-label use or this in-house production, respectively.

5 | CONCLUSION

We conclude that radiopaque markers that reveal the proximal entry of a surgical shunt or the arterial duct are a promising and refined
technique to substantially facilitate target vessel access and enable the accurate positioning of stents during postoperative percutaneous procedures in neonates and infants. Since this was a proof-of-concept analysis of a selected small pediatric cohort, there is no statistical evidence for the potential benefit so far.

ACKNOWLEDGEMENTS

We thank Carole Cürten for language editing, and Stefan Heinz for graphic design.

CONFLICT OF INTEREST

The authors state that they have nothing to disclose.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Hummel J, Kubicki R, Pingpoh C, et al. Surgically placed radiopaque markers: Proof-of-concept of a novel technique to facilitate percutaneous interventions in neonates and infants. Catheter Cardiovasc Interv. 2020;96:E303–E309. https://doi.org/10.1002/ccd.28891