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RESEARCH REPORT

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Anesthesia for bilateral pulmonary banding as part of hybrid stage I approach palliating neonates with hypoplastic left heart syndrome

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Abstract

Background: Neonatal management of patients with hypoplastic left heart syndrome and complex remains a challenging task, whereby the "hybrid" palliation is often reserved for high-risk patients as a "rescue" procedure.

Aim: This study documents the anesthetic challenges and potential complications associated with the Giessen hybrid stage I approach.

Methods: The Giessen hybrid stage I approach is focused on surgical bilateral pulmonary artery banding. Retrospective perioperative data were analyzed. Contrary to a stable group A, inotropic treatment before surgery for treatment of postnatal shock classified patients as unstable (Group B). Clinical outcomes considered were inhospital mortality, duration of postoperative mechanical ventilation, postoperative time at the intensive care unit, perioperative vasoactive medication requirements, and red blood cell transfusion.

Results: From June 1998 to December 2015, 185 patients were allocated to Group A (n = 165) and Group B (n = 20). The inhospital mortality was 2.2% with no difference between the groups. There was also no difference in the postoperative time on mechanical ventilation and the time in the intensive care unit. Vasoactive medication was more often required in Group B (100%) compared to Group A (19%). In Group B, more red blood cells were transfused 6.0 ± 8.3 vs 2.0 ± 5.8 mL/kg in Group A ($P < .05$, 95% CI 0.0 - 2.6).

Conclusion: Considering a learning curve, anesthesia for surgical bilateral pulmonary artery banding palliating patients with hypoplastic left heart syndrome and complex can safely be performed, independent from the preoperative clinical status.

KEYWORDS

bilateral pulmonary artery banding, congenital heart surgery, hybrid procedure, hypoplastic left heart syndrome, pediatric anesthesia

1 | INTRODUCTION

Hypoplastic left heart syndrome (HLHS) and newborns with multiple left heart obstructions, summarized as hypoplastic left heart complex (HLHC), represent a group of rare heart defects with a highly conjoined patient risk profile requiring cardiac surgery during the first days of live. Based on variable hypoplasia of the left ventricle, connected valves, ascending aorta, and aortic arch, the generation of a sufficient perfusion of the systemic circuit is hindered after the physiologic postnatal adaptation process. Surgical treatment for HLHS was expanded from stepwise Norwood-like procedure and cardiac transplant by the hybrid approach in 1998.[1] The hybrid approach in pediatric cardiovascular surgery is a palliative strategy for HLHS/HLHC and related entities, usually performed in the first, latest two weeks after birth.[2] The combined catheter-based and surgical approach includes an open-chest bilateral pulmonary artery banding (bPAB), also as part of cardiac insufficiency therapy, combined with intravenous prostaglandin E1 infusion. Stenting of the ductus arteriosus Botalli (DAB) is performed either via transpulmonary access or using a separate percutaneous approach, both securing systemic perfusion with additional atrial septostomy, if necessary.[3] Despite the fact that hybrid stage I is carried out differently, cardiopulmonary bypass (CPB) and deep hypothermic cardiac arrest (DHCA) can be avoided minimizing surgical trauma during the first days of life and lessening initial operative risks.[4] Nonetheless, a recent Meta-analysis has described inferior early outcomes in patients undergoing hybrid stage I procedure compared to the Norwood procedure,[5] bringing the perioperative management and patient selection into the focus of interest. Cao et al observed a higher risk profile among the patients undergoing the hybrid procedure with an expectable higher incidence of clinically decompensated conditions prior to surgery.[5] It is well known that beside anatomic considerations and comorbidities, the preoperative physiological status has impact on the outcome of patients undergoing stage I Norwood operation or its variants.[6,7] This relationship has not been investigated for patients undergoing a hybrid stage I procedure. The objective of the presented retrospective study was to describe the perioperative anesthetic management and to assess a potential association of the preoperative physiological status (ie, preoperative inotrope requirement) on inhospital mortality, duration of postoperative mechanical ventilation, postoperative time at the intensive care unit, perioperative vasoactive medication requirements, and red blood cell transfusion in patients undergoing bPAB as part of the Giessen stage I hybrid approach (GHA).

What is already known

- The hybrid stage I procedure is an established therapeutic strategy for the initial palliation of neonates with hypoplastic left heart syndrome.
- However, little information is available about the perioperative anesthetic management.

What this article adds

- This article documents anesthetic management and complications of patients undergoing bilateral pulmonary artery banding as part of the hybrid stage I procedure.
- This article further demonstrates that this procedure can safely be performed independent of patients' preoperative physiological status and postnatal comorbidities.

2 | MATERIALS AND METHODS

After positive approval by the local ethics committee (Trial Code Number 127/15), we performed this retrospective data analysis. The examined database contains patient data from all surgeries performed from July 01, 1998, to December 31, 2015, at the Giessen Pediatric Heart Center (GPHC) of the University Hospital Giessen (data warehouse and center for analysis). We extracted and analyzed the pre- and perioperative data of 185 neonates from the in house patient data management system (PDMS; ICUData®, IMESO GmbH), who were treated with a bPAB as a part of the GHA. All data were controlled and analyzed by three independent investigators. Furthermore, the "HLHS database" of the GPHC was used for comorbidities, interventional data, and mortality data. Prematurity was defined as gestational age < 35 weeks, and genetic anomalies were determined by chromosomal microarray analysis, genetic consult, or presence of dysmorphisms.

Patients who came to the operating room (OR) without inotropic support were considered clinically stable and assigned to Group A. In contrast, patients with inotropic support including norepinephrine for treatment of preoperative shock were assigned to the clinically unstable group (Group B).

2.1 | Statistics

Demographic and procedural information were analyzed by SPSS (Statistics Version 23.0.0.2) and subsequently visualized. Categorical variables are presented as number and percentage, and continuous data are presented as mean (standard deviation (SD)) and as median (interquartile range (IQR)). For between-group differences, the chi-square and Fisher exact test were used to compare categorical data. After analyzing continuous data for normal distribution (Shapiro-Wilk test), rmANOVA, *t* tests, or Mann-Whitney *U* test/Wilcoxon rank test were performed to compare the means or medians as appropriate. Values of $P < .05$ were considered significant. However, the relative small number of 4 inhospital deaths precludes a multivariate analysis of the data.

3 | RESULTS

3.1 | Patient characteristics and perioperative data

We identified 185 neonates (77 female, 108 male) that underwent bPAP as a part of GHA between 1998 and 2015. All patients with HLHS/HLHC who were presented at the GPHC were treated with the hybrid approach. Two small pieces of a PTFE tube graft were used for bPAP. In general, the size of the bands placed around the pulmonary arteries is standardized with 3 mm < 3.0 kg, and 3.5 mm ≥ 3.0 kg, however in individual cases, the surgeon decides on the basis of the intraoperative situs. The clinical course of all patients is shown in Figure 1.

A total of 165 patients (89%) were assigned to Group A and 20 to Group B (11%). The biometric and perioperative data are presented in Table 1. No differences between the groups could be observed with regard to the majority of postnatal risk factors, including the number of patients with a birth weight less than 2.5 kg, prematurity, comorbidities, number and timing of atrial septostomy or atrial stenting, the occurrence of aortic atresia, and surgical procedure time.

3.2 | Anesthetic and hemodynamic management

In preoperatively nonsedated patients, anesthesia was induced with 3-5 μg/kg fentanyl, in 42% of the patients midazolam (0.1 mg/kg) or ketamine (1-2 mg/kg) in 18% of the patients was added if necessary followed by the application of cisatracurium (0.2-0.3 mg/kg) before endotracheal intubation. An opioid-based anesthesia (mean total dose of fentanyl equivalent 22 ± 23 μg/kg) and slightly more frequent supplemented with volatile agents in Group A (stable) patients (47% vs 25%) was used to maintain anesthesia while assuring hemodynamic stability with a target minimum mean arterial pressure of 40 mm Hg. To support hemodynamic stability, volume bolus therapy was necessary in 2/3 of all patients with no difference between the groups. However, mean transfused red blood cell volume was higher in Group B patients (6.0 ± 8.3 mL/kg (Group B) vs 2.0 ± 5.8 mL/kg (Group A, $P < .05$, 95% CI 0.0-2.6). 28% (n = 52) of all patients had to be treated with vasopressors and/or positive inotropic drugs throughout the intraoperative period, including all Group B patients. The infusion of vasoactive drugs was continued postoperatively in 44 patients. No patient required extracorporal live support.

Antiarrhythmic therapy (8% of patients) was most frequently necessary due to supraventricular tachycardia during preparation and placement of the band around the left pulmonary artery. Adenosine and esmolol were the most commonly used drugs in this situation. More details about the different intraoperative medications are given in Table 2.

3.3 | Hemodynamic data, lactate, and cerebral near-infrared spectroscopy

The courses of mean arterial pressure, heart rate, central venous oxygen saturation, regional cerebral saturation, and fractional cerebral tissue extraction are shown in Figure 2.

Cerebral near-infrared spectroscopy data were available for the intraoperative period in 49% of patients (Group A: n = 80 (48%), Group B: n = 10 (50%). No differences between the groups and over time could be observed. However, in both groups there was a tendency for NIRS values to decrease over time. This was associated with a trend toward an increase in fractional cerebral tissue extraction. No increase in lactate levels has been observed in both groups; also, preoperative lactate levels were higher in group B patients (Group A: preop. lactate 1.5 ± 1.6 mmol/L, postop. lactate 1.5 ± 1.1 mmol/L; Group B: preop. lactate 2.4 ± 2.9 mmol/L, postop. lactate 2.3 ± 3.1 mmol/L).

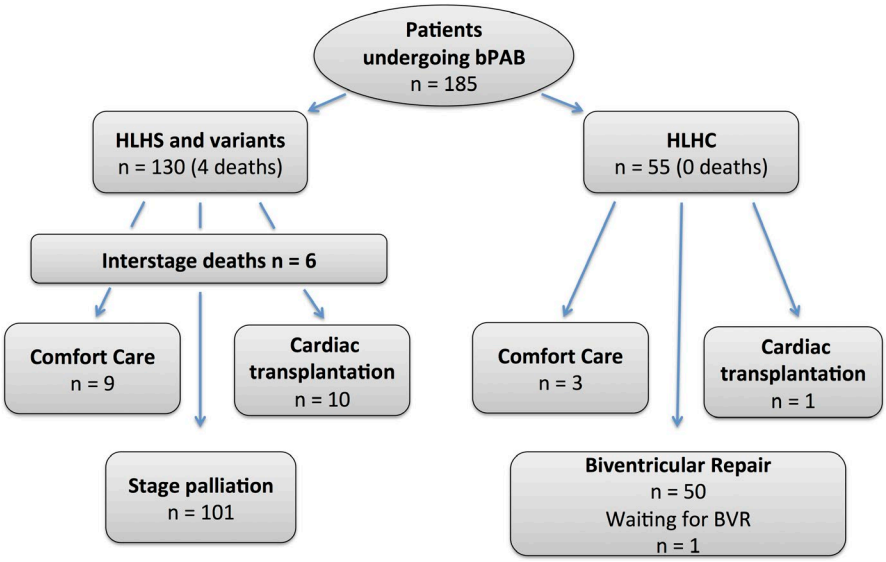

FIGURE 1 Clinical course and outcome of all patients undergoing the Giessen stage I hybrid approach. bPAB, bilateral pulmonary artery banding; HLHS, hypoplastic left heart syndrome; HLHC, hypoplastic left heart complex; BVR, biventricular repair [Colour figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Patients characteristics and process times

Characteristics	Group A (stable) (n = 165)	Group B (unstable) (n = 20)
Median age (IQR)—days	6 (4-10)	6 (3-10)
Mean weight (SD)—kg	3.0 (± 0.7)	3.4 (± 0.6)*
Weight < 2.5 kg—no. (%)	31 (19)	1 (5)
Male sex—no. (%)	95 (58)	13 (65)
Prematurity < 35 wk—no. (%)	23 (14)	3 (15)
Genetic anomalies—no. (%)	36 (22)	6 (30)
HLHS—no. (%)	118 (72)	12 (60)
HLHS with aortic atresia—no. (%)	64 (39)	6 (30)
Atrial septostomy or stenting prior bPAB—no. (%)	18 (11)	4 (20)
Atrial septostomy or stenting after bPAB—no. (%)	38 (23)	1 (5)
Median Aristotle score—(IQR)	17.5 (2.0)	17.5 (5.0)
Mean preop. oxygen saturation—(SD) %	92 (± 8)	92 (± 9)
Mean preop. hemoglobin—(SD) g/dL	13.5 (± 2.5)	12.8 (± 2.4)
Mean preop. lactate—(SD) mmol/L	1.5 (± 1.6)	2.4 (± 2.9)*
Median procedure time (IQR)—minutes	65 (33)	76 (32)
Median postop. ventilation time (IQR)—hours	28 (39)	43 (46)
Median postop. ICU time (IQR)—days	6 (4)	7 (5)
Inhospital mortality—no. (%)	3 (1.8)	1 (5)

Abbreviations: bPAB, bilateral pulmonary artery banding; HLHS, hypoplastic left heart syndrome; IQR, interquartile range; SD, standard deviation.

*P < .05 vs group A (95% CI: 3.0-3.2 for weight, 95% CI 1.2-1.7 for lactate).

TABLE 2 Intraoperative drug therapy

Characteristics	Group A (stable) (n = 165)	Group B (unstable) (n = 20)
Anesthesia		
Opioids—no. (%)	161 (98)	20 (100)
Mean total fentanyl equivalent—(SD) μg/kg	22 (23)	25 (27)
Midazolam—no. (%)	71 (43)	6 (30)
Ketamine—no. (%)	28 (17)	5 (25)
Volatile anesthetics—no. (%)	77 (47)	5 (25)
Total Inotropes/Vasopressor application—no. (%)	32 (19)	20 (100)*
Ephedrine bolus—no. (%)	8 (5)	0 (0)
Noradrenaline—no. (%); continuous—no. (%)	11 (7); 4 (2)	2 (10); 2 (10)
Dopamine continuous—no. (%)	0 (0)	2 (10)*
Dobutamine continuous—no. (%)	6 (4)	6 (30)*
Adrenaline—no. (%); continuous—no. (%)	13 (8); 9 (6)	3 (15); 3 (15)
Milrinone continuous—no. (%)	3 (2)	9 (45)*
Levosimendan continuous—no. (%)	1 (1)	0 (0)
Antiarrhytmics—no. (%)	13 (8)	2 (10)
Bolus volume therapy—no. (%)	111 (67)	12 (60)
Mean total volume bolus infusion—(SD) mL/kg	12.4 (12.3)	14.0 (10.6)
Mean crystalloid bolus infusion—(SD) mL/kg	7.3 (8.8)	7.3 (14.0)
Mean albumin bolus infusion—(SD) mL/kg	2.4 (4.8)	1.4 (3.6)
Mean packed red cells—(SD) mL/kg	2.0 (5.8)	6.0 (8.3)†
Mean fresh-frozen plasma—(SD) mL/kg	0.7 (3.6)	1.0 (3.3)

*P < .05 vs Group A (chi-square test).

†P < .05 vs Group A (Mann-Whitney U test, 95% CI: 1.5-3.6).

3.4 | Postoperative treatment and outcome

All patients were transferred mechanically ventilated to the PICU after the procedure. However, median postoperative ventilation time was 29 hours (IQR 38 hours), and the median postoperative length of stay in the intensive care unit was 6 days (IQR 4 days), respectively, with no difference between the groups. The overall inhospital mortality after Giessen stage I hybrid approach was 2.2% with three patients in Group A and one patient in Group B dying. Detailed information on the four deceased patients can be found in Table 3.

4 | DISCUSSION

To the best of our knowledge, there is only little information on the anesthesiological management in patients undergoing hybrid stage I procedures despite a 30-day mortality rate that should not be underestimated.[8,9] Furthermore, no data at all exist comparing patients presenting under clinically unstable conditions, defined as inotrope therapy prior to surgery to those presenting under clinically stable conditions for the hybrid stage I approach. Our retrospective single-center analysis of the perioperative anesthesiological management has shown that the surgical part of GHA focusing only on bPAB is safe and effective even in patients presenting under unstable clinical conditions. An opioid-based anesthesia with low dosing of supplemented volatiles and intravenous agents was performed to ensure sufficient analgesia/anesthesia with minimal impact on hemodynamics. Over a time period of more than 16 years, there was no intraoperative death and inhospital mortality was 2.2% analyzing 185 HLHS/HLHC patients undergoing GHA. It has to be considered that the data contain a learning curve. A median heart rate of 149/min after induction of anesthesia is acceptable, but in general too high, especially for HLHS/HLHC patients, in which the right ventricle is already pressure and volume stressed. We therefore discontinued the use of dopamine and dobutamine in 2008. In addition, we have also taken a more critical view of the indication for continuous administration of adrenaline.

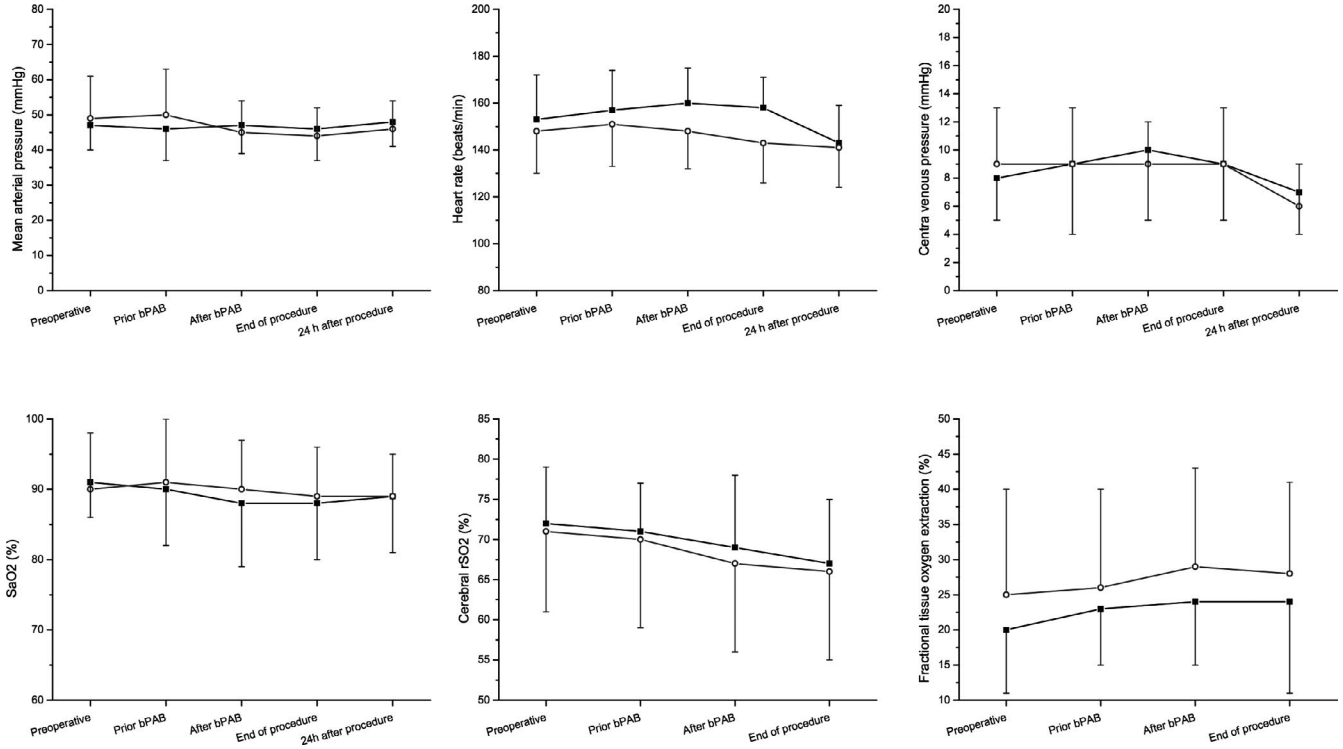

FIGURE 2 Course of mean arterial pressure, heart rate, central venous pressure (upper row from left to right), oxygen saturation, cerebral near-infrared spectroscopy, and fractional cerebral tissue extraction (lower row from left to right). Open circles indicate Group A, and solid squares indicate Group B

TABLE 3 Inhospital mortality after Giessen stage I hybrid approach

Patient No.	Group	Cardiac diagnosis	Hybrid strategy	Time of death (days after surgery)	Cause of death	Extracardiac diseases
4	A	HLHS (MS/AA), PAPVR with stenosis	Atrioseptostomy before bPB, ductal stenting immediately after bPB	Day of surgery	Cardiac shock, suspected myocardial infarction	None
148	B	HLHS (MS/AS)	No atrioseptostomy necessary, emergency ductal stenting before bPB	Day of surgery	Cardiac shock, suspected ductal stent occlusion (aortic end)	None
68	A	HLHS (MA/AA)	No atrioseptostomy necessary, ductal stenting after bPB	26 d	Cardiac shock, myocardial infarction	None
172	A	HLHS (MS/AS)	Atrioseptostomy before bPB, ductal stenting after bPB	10 d	Cardiac shock, re-obstruction of the atrial septal defect, ductal stent occlusion (aortic end)	Status after necrotizing enterocolitis, hypotrophic premature infant (1.35 kg, 36 + 2 wk of pregnancy)

Abbreviations: AA, aortic atresia; AS, aortic stenosis; bPB, bilateral pulmonary artery banding; HLHS, hypoplastic left heart syndrome; MA, mitral atresia; MS, mitral stenosis; PAPVR, partial anomalous pulmonary venous return.

If one looks at the course of the mean arterial blood pressure, no clinically relevant differences are found over the time, and between the two groups. This is certainly also due to the fact that we tried to keep the MAP ≥ 40 mm Hg during anesthesia and surgery. In order to achieve this goal, 66% of the patients received at least one volume bolus and 28% of the patients received inotropes and/or vasopressors, respectively. Not surprisingly, more vasoactive medications were used in group B. However, we also have used more RBC in this group. The more liberal transfusion of RBC in patients of group B aimed at optimizing the oxygen transport capacity in these patients with preexisting inotropic support and preoperative elevated lactate levels. There was no difference in preoperative

hemoglobin between the groups, and surgical-related blood loss during bPAB could be almost excluded because not observed.

The GHA consisting of a sole performed surgical bPAB is completed by percutaneous duct stenting and atrial septostomy, in restrictive ASDs, as separate procedures.[2,3] Elective transcatheter treatment is mostly performed in extubated spontaneous breathing babies utilizing analgosedation and has been described elsewhere.[10] Considering an experienced and well-prepared team, the GHA is an easy surgical-interventional measure despite dealing with complex congenital heart defects also for newborns arriving in the hospital unstable or even in cardiogenic shock, as oftentimes observed in the past. Patients afflicted by single ventricle congenital heart disease generally have an elevated risk profile with reduced myocardial performance, tricuspid valve insufficiency, and the need for inotropic support and mechanical ventilation as additional risk factors.[6,11,12] It remains an open question, why in general survival after the hybrid approach is not superior to the Norwood stage I and only minor outcome parameters may be improved.[5,13,14] Despite the absence of CPB, DHCA, and a more extensive surgical trauma of Norwood surgery, patient selection may be responsible, with risk factors often more prevalent in the hybrid group.[15,16] Additionally, we hypothesize that "hybrid procedures" are worldwide variably utilized, and most centers use it only treating "high-risk patients" with a limited case load at all.[3] The GHA represents a minimal-handling approach, in which surgical bPAB can be performed in a median surgical procedure time of one hour; when reverse Blalock-Taussig-shunt and/or intraoperative transpulmonary DA stenting are avoided, as performed in other centers.[17-19] In our center, all patients with HLHS/HLHC are treated with the hybrid approach regardless of their risk profile; therefore, the perioperative course can be compared between as classified stable or unstable patients. In terms of biometric data, including body weight < 2.5 kg and the distribution of patients with aortic valve atresia and surgical time, there was no difference between the two analyzed groups. Despite elevated preoperative lactate values in patients of Group B, GHA surgery did not further increase the lactate levels, indicating no major oxygen debt during anesthesia and surgery. Contrary, the results of more complex hybrid stage I procedures, including reverse BT shunts, have shown increased lactate values.[20] Utilizing our simplified GHA, fractional tissue oxygen extraction measured by cerebral NIRS tended to increase at the end of the procedure, which indicates a well-tolerated minor increase of oxygen consumption during the surgical procedure. Complications after drops in blood pressure levels and a return to the PICU on ECMO therapy after hybrid procedures, as described,[8] or return to the PICU with open thorax, did not occur. However, securing stable hemodynamics under concurrent sedation and analgesia in a procedure with distinct impact on systemic and pulmonary perfusion remains highly challenging with HLHC/HLHS patients featuring a high incidence of intraoperative hypotension.[8] Our standard monitoring devices include invasive blood pressure and central venous pressure measurement and arterial and central venous blood gas analysis, supported by cerebral near-infrared spectroscopy (NIRS); while some centers still avoid routine central venous catheterization.[9] Summarizing our experience of hemodynamics during GHA and considering the missing consent of the definition of hypotension in neonates at all,[21] we used the mean blood pressure values, knowing that they are insufficient to estimate the retrograde blood flow in the aortic arch and thus to monitor coronary and cerebral perfusion pressure in newborns with HLHS if they are not measured in the right radial artery. Usually the arterial line for bPAB at the GPHC is placed in a femoral artery, since it can then be used as access for subsequent duct stenting. We usually spare the right radial artery for the monitoring of selective cerebral perfusion during the subsequent comprehensive stage II procedure. However, an oxygen saturation probe placed at the right hand and 5 lead ECG are mandatory in all cases. In high-risk patients, an arterial access in the right radial artery is appropriate, if an aberrant right subclavian artery is excluded. Risks for intraoperative cardiac arrest are insufficient coronary perfusion during hypotension may be associated with pulmonary overcirculation or retrograde aortic obstruction. In fact, we found myocardial infarction as leading cause of death in 2 of the 4 patients who died during hospitalization. In the two other patients, an occlusion of the aortic end of the ductal stent was involved in cardiac decompensation. Continuous exclusion of any morphological reasons during surgery (ie, direct or indirect manipulation of the tiny ascending aorta during surgical preparation and placement of the pulmonary artery bands), retaining of adequate perfusion pressures together with strict avoidance of unlimited oxygen supply and hyperventilation while ventilating a HLHS baby are therefore crucial measures preserving adequate blood flow within the systemic circulation (ie, brain and coronary arteries) during anesthesia. Reduced blood pressure was immediately treated with a volume bolus (10 mL/kg): Ringer's solution and human albumin 10%, packed red cells (if indicated) followed by vasopressors and/or inotropes if necessary, but as mentioned above, catecholamines may have been used too often in cases of doubt. Regarding the entire cohort, 28% of the patients (n = 52) received vasopressors and/or inotropes during the procedure with preference of Group B. In 15 patients, a bolus application during the surgical preparation was sufficient to secure hemodynamics. However, a decrease in blood pressure may indicate systemic flow impairment. To treat such conditions by catecholamines with further increase of heart rate and systemic vascular resistance is from the theoretical point of view problematic. Therefore, in 2008, we changed our therapy from dopamine, dobutamine and adrenaline to milrinone and noradrenaline for pronounced perioperative hemodynamic instability. MAP alone is not sufficient to choose always the immediate and right decision especially considering patients with a need for a balanced parallel circulation. In this context, we appreciate NIRS[22] and $EtCO_2$ monitoring,[23] but low values let not immediately differentiate between low pulmonary (and systemic) blood flow and hyperventilation in particular when bPAB is already placed.

5 | CONCLUSION

In conclusion, the described management for the stage I Giessen hybrid approach enables stable anesthesia and analgesia without compromising hemodynamics, ventilation, and perfusion even for patients with

already impaired cardiac function (Group B). Rather than the preoperative status of the patient, the avoidance of extended surgery (routine placement of a reverse BT shunt, intraoperative stenting of the PDA) together with an individualized pressure and flow-oriented hemodynamic management may be accountable for the presented results.

DISCLOSURES

The authors report no conflict of interest.

ETHICS APPROVAL

The IRB of the Justus-Liebig-University Giessen gave approval for the presented study (ref.-no. 127/15) on 13.08.2015.

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