




German Registry for Cardiac Operations and Interventions in Patients with Congenital Heart Disease: Report 2021 and 9 Years' Longitudinal Observations on Fallot and Coarctation Patients

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Thorac Cardiovasc Surg 2022;70:e21–e33.

Abstract

Keywords

- congenital heart disease
- outcomes
- multicenter registry
- risk categorization
- pediatric cardiology
- congenital heart surgery
- transcatheter intervention
- Fallot
- coarctation

Background The annual report of the German Quality Assurance of Congenital Heart Disease displays a broad overview on outcome of interventional and surgical treatment with respect to patient's age and risk categorization. Particular features of the German all-comers registry are the inclusion of all interventional and surgical procedures, the possibility to record repeated treatments with distinct individual patient assignment, and to record various procedures within one case.

Methods International Pediatric and Congenital Cardiac Code terminology for diagnoses and procedures as well as classified adverse events, also recording of demographic data, key procedural performance indicators, and key quality indicators (mortality, adverse event rates). Surgical and interventional adverse events were classified according to the Society of Thoracic Surgeons and to the Congenital Heart Disease Adjustment for Risk Method of the congenital cardiac catheterization project on outcomes. Annual analysis of all cases and additional long-term evaluation of patients after repair of Fallot and primary treatment of native coarctation of the aorta were performed.

received
May 12, 2022
accepted after revision
July 30, 2022

DOI <https://doi.org/10.1055/s-0042-1757175>.
ISSN 0171-6425.

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Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Results In 2020, 5,532 patients with 6,051 cases (hospital stays) with 6,986 procedures were treated in 23 German institutions. Cases dispense on 618 newborns (10.2%), 1,532 infants (25.3%), 3,077 children (50.9%), and 824 adults (13.6%). Freedom from adverse events was 94.5% in 2,795 interventional cases, 67.9% in 2,887 surgical cases, and 42.9% in 336 cases with multiple procedures (without considering the 33 hybrid interventions). In-hospital mortality was 0.5% in interventional, 1.6% in surgical, and 5.7% in cases with multiple treatments. Long-term observation of 1,632 patient after repair of Fallot depicts the impact of previous palliation in 18% of the patients on the rate of 20.8% redo cases. Differentiated analysis of 1,864 patients with native coarctation picture clear differences of patient, age, and procedure selection and outcome. The overall redo procedure rate in this patient population is high with 30.8%.

Conclusion Improvement in quality of care requires detailed analysis of risks, performance indicators, and outcomes. The high necessity of redo procedures in patients with complex congenital heart disease underlines the imperative need of long-term observations.

Introduction

Until now obligatory quality assurance measure, according to § 136ff Social Code Book V, was suspended for treatment of patients with congenital heart disease (CHD) for various reasons. Quality of care has a major impact on patients' long-term outcome including quality of life, especially in CHD. Therefore, since 2012 the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and German Society for Pediatric Cardiology and Congenital Heart Defects (DGPK) as the scientific societies execute a multicenter registry study concerning interventional and surgical therapies in patients with CHD. The structure of the database has been described in detail previously.¹ The voluntary German Registry for Quality Assurance in CHD (Nationale Qualitätssicherung Angeborene Herzfehler) has been approved by the Charité's Ethics Committee (code number: EA2/011/11). The structure of the registry, data acquisition, and evaluation is in accordance with the guidelines of "Good Epidemiological Practice,"² "Good Hospital Practice,"³ and the Declaration of Helsinki for medical research involving human subjects.⁴ The registry contains detailed information on diagnoses and procedures, which enable detailed risk categorization^{5,6} in nearly 90% of cases. Severity of adverse events is assessed in a standardized manner according to patient's outcome.^{5,7} As each patient is distinctly identifiable by his own life-long lasting pseudonymization number, analyses of the data can refer to patients, cases (hospital stays), or procedures. Each year, the responsible scientific societies write an annual report based on two types of analyses: the national report summarizes aggregated and anonymized results of all participating institutions, compared with the previous year. In addition, separate institution-related reports contain the analyses of each participating heart center in comparison with the national results. Due to contractual arrangements, the

institutional report is confidential and not intended for public access. Upon request, each institution can receive an electronic copy of its evaluated data for further use (e.g., transfer to the European Congenital Heart Surgeons Association database: <https://echsacongenitaldb.org>). The purpose of this report is to provide a public comprehensive annual update of the activities and outcomes from the German National Report on CHD 2021.

Methods

Voluntary online data submission into the database with the goal of 100% coverage as previously described.¹ All patients/parents gave written consent. All data sets were monitored with respect to data integrity before case closure. Source data were not monitored. The annual report includes only completed cases. Coding of diagnoses and procedures is based on the International Pediatric and Congenital Cardiac Code (IPCCC).⁸ Completeness of recorded procedures was estimated by comparison with the German Heart Surgery Report 2020⁹ and the online available Deutscher Herzbericht 2021 (www.herzstiftung.de).

Risk Stratification

All cases intended as single interventional treatment were assigned to risk categories 1 to 4 according to the catheterization for Congenital Heart Disease Adjustment for Risk Method.⁵ All cases intended as surgical treatment were assigned to risk categories 1 to 5 according to the Society of Thoracic Surgeons (STS)-European Association for Cardio-Thoracic Surgery (EACTS) mortality categories.⁶ Details are provided in the Supplementary Material. Risk stratification of cases with multiple procedures and those starting with a hybrid procedure was not possible due to the lack of established risk categories for these procedures.

Key Performance Indicators

Length of hospital stay, the need and length of intensive care treatment, the need and length of mechanical ventilation, procedure time, and the requirement of blood transfusion are general key performance indicators presented in this report. In addition, specific key performance indicators were analyzed: use of fluoroscopy, fluoroscopy times, data from cardiopulmonary bypass (CPB), and the use of near-infrared spectroscopy.

Key Quality Indicators

In the German National Report mortality in-hospital, 30, and 90 days after first procedure is analyzed. Adverse events are recorded based on the IPCCC nomenclature. In addition, the number of cases without adverse events is analyzed. Severity of adverse events was categorized according to patient's outcome by the supplying physician and according to the definitions of adverse event severity for congenital cardiac catheterization⁵ or the definition of major complications of the STS Congenital Heart Surgery Database (STSCHSD) database.⁷ Unplanned redo procedures and patient's death trigger automatically notification of an adverse event with severity grades 4 or 5 ("major" or "catastrophic"). Observed mortality and morbidity rates are compared with published data if available.^{5,6}

Definitions for Adverse Event Severity in Cases with Interventions⁵

None: no harm, no change in condition, and may have required monitoring to assess for potential change in condition with no intervention indicated.

Minor: transient change in condition, not life-threatening, condition returns to baseline, required monitoring, required minor intervention such as holding a medication, or obtaining laboratory test.

Moderate: transient change in condition may be life-threatening if not treated, condition returns to baseline, required monitoring, required intervention such as reversal agent, additional medication, transfer to the intensive care unit (ICU) for monitoring, or moderate transcatheter intervention to correct condition.

Major: change in condition, life-threatening if not treated, change in condition may be permanent, may have required an ICU admission or emergent readmit to hospital, may have required invasive monitoring, and required interventions such as electrical cardioversion or unanticipated intubation, or required major invasive procedures or transcatheter interventions to correct condition.

Catastrophic: any death, and emergent surgery, or heart-lung bypass support (extracorporeal membrane oxygenation [ECMO]) to prevent death with failure to wean from bypass support.

Definition of Major Complications in Cases with Operations

Major complications are defined according to complication codes in the STS Congenital Heart Surgery Database (STSCHSD) Data collection form, Version 2.50 as cited in Jacobs et al⁷:

Postoperative acute renal failure requiring temporary or permanent dialysis.

Postoperative neurologic deficit persisting at discharge.

Postoperative atrioventricular block requiring permanent pacemaker.

Postoperative mechanical circulatory support.

Phrenic nerve injury/paralyzed diaphragm.

Unplanned reoperation.

Any death.

All other recorded adverse events according to the IPCCC were rated as minor (most frequent in 2020: postprocedural pulmonary infection 15.80.21, pleural effusion requiring drainage 15.80.61, arrhythmia requiring drug treatment 11.00.30, postprocedural chylothorax 15.80.55, sternum left open: elective [planned] 15.03.57).

Evaluation and Data Presentation

All cases are analyzed with respect to the initial treatment and after allocation to one of four groups: surgery, intervention, multiple procedures, and hybrid procedures. In addition to this analysis of the entire cohort, we performed detailed analyses of 15 index procedures containing 6 defined interventional and 9 defined surgical procedures in specific subgroups of CHD.

Longitudinal Evaluation of Patient's Medical Careers

All patients who since 2012 received surgical correction for Fallot malformation and all patients who received surgical or interventional treatment of native coarctation of the aorta (CoA) were analyzed for requirement of further invasive treatment.

Results

Registry Data Report 2020

The number of patients, cases (number of hospital stays), and procedures, which constitute the 2020 data basis of the registry, are shown in ►Fig. 1. Taking together all surgical and interventional cases, 23 German centers treated 6,051 cases under the terms of quality assurance. Eighteen participating centers provided detailed surgical data from 2,795 single surgery cases and 336 cases with planned multiple procedures, altogether 3,713 surgeries on CHD. In-hospital lethality was 1.6% in all single surgery cases and 5.7% in all cases with planned multiple procedures (►Fig. 2). In comparison, the German Heart Surgery Report based on anonymous self-disclosure of 78 institutions in 2020 counts 5,637 operations on CHD. Reported lethality was 2.7% in cases with extracorporeal bypass use and 2.1% in cases without.⁹ In this quality registry data report, 23 participating centers provided detailed data from 3,226 interventions compared with the reported number of 5,239 interventions by anonymous self-disclosure of 32 institutions published in the Deutscher Herzbericht 2021 (www.herzstiftung.de). Thus, overall completeness of quality recorded procedures nationwide was 66% for surgical and 62% for interventional procedures and larger at the participating centers.

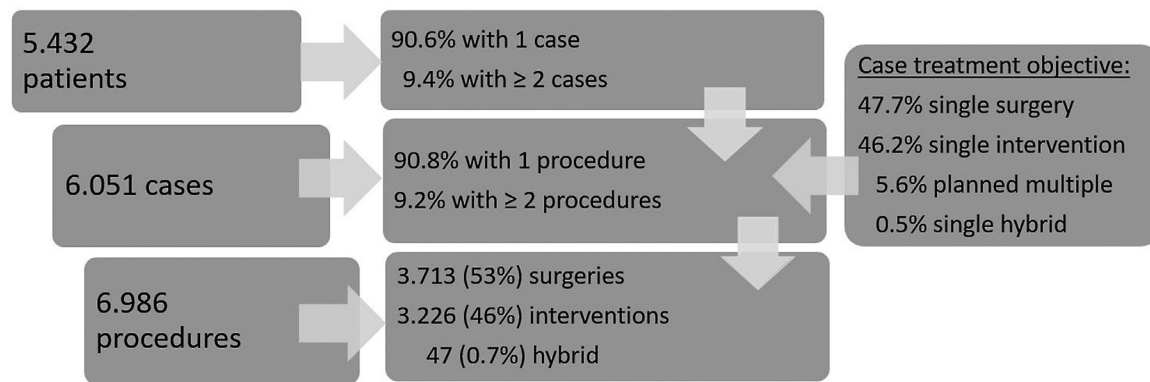


Fig. 1 Numbers of patients, cases, and procedures. Note that 9.4% of 5,432 patients were treated two or more times in hospital. In 9.2% of the 6,051 cases, patients received two or more procedures, which was initially planned only in 5.6% of the cases. The rate of surgical procedures exceeded the rate of planned single surgical cases indicating a major role of surgery in redo procedures.

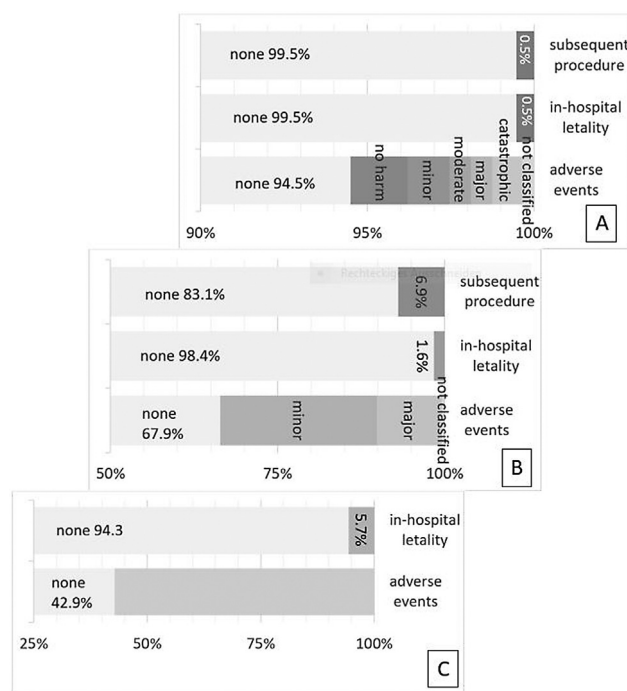


Fig. 2 Key quality indicators in different case subgroups. (A) Key quality indicators of 2,795 cases with single interventional procedures. Adverse events were recorded in 5.5% of the cases. The rate of major or catastrophic adverse events was 1.5% in all cases. Severity of 6.5% of adverse events recordings (0.4% of all cases) was not classified. (B) Key quality indicators of 2,887 cases with single surgical procedures. Adverse events were recorded in 32.1% of the cases. The rate of major adverse events was 9.9% in all cases. Severity of 1.3% of adverse events recordings (0.4% of all cases) was not classified. (C) Key quality indicators of 336 cases with multiple procedures. Adverse events were recorded in 57.1% of the cases. In this case group subsequent procedures were present in 100% by definition and were not conditioned by complications. Note: Different x-axis scales. The definitions of major and minor adverse events for surgical and interventional cases differ fundamentally and are not suitable for direct comparison.

Age and Gender Distribution

The majority of treatments were performed in children and adolescents (►Table 1). Note that 10.2% of the cases were treated in newborns and 13.6% in adults. Males were more affected by treatment for CHD than females.

Case Complexity

This report for the sake of space disclaims the listing of cardiac and noncardiac codiagnoses as well concomitant procedures. The numbers of elective redo cases with previous single or multiple cardiac procedures are shown in ►Fig. 3. In 2020, first treatment for CHD in Germany was performed in 48% of interventional, 57% of surgical, and 62.5% of cases with multiple procedures.

Key Performance Indicators

Details are listed in ►Table 2A for all cases and for those with defined interventional (►Table 2B) or surgical (►Table 2C) index procedures. Interventional cases required the least resources. Hospital stay was 2 days in median while the 75 percentile lay at 3 days. Intensive care treatment was applied in 13.5% of the cases and most cases (83%) were performed under analgesedation without mechanical ventilation. Note that 6.8% of the cases were performed without fluoroscopy (mainly Rashkind procedures in dextro-transposition of the great arteries and atrial septal defect [ASD] closures, see index procedures). Analysis of interventional index procedures revealed significant differences among the different subgroups of these patients. Most frequent intervention were ASD closure with 493 cases. For this procedure, the rate of general anesthesia was 29%, thereby above average. Rare and complex interventions like ventricular septal defect (VSD) closure and native CoA treatment required longer in-hospital stay and in cases with native CoA the largest numbers of ICU stays (29%) and intubations (20%). Beside the large spectrum of age in this subgroup 25% of the patients were newborns or small infants younger than 4 months of age. Only half of the interventional units reported these complex procedures. Percutaneous pulmonary valve implantation is the most laborious interventional index procedure, which is expressed by longest procedure and fluoroscopy times. The median procedure time of 76 minutes and the median fluoroscopy time of 10.1 minutes in the analysis of all interventional cases was slightly higher compared with those other interventional index procedures (compare ►Table 2A and B).

Surgical cases required more resources. Intensive care treatment in 94.4% of the cases with a median length of

Table 1 Age and gender distribution of all cases

	Numbers	Percentage
Newborn	618	10.2
Infants (30 d-year)	1,532	25.3
Children and adolescents	3,077	50.9
Adults	824	13.6
Males	3,237	53.5
Females	2,814	46.5

Note: Assignment of patient's age was done at the date of the first procedure of every case.

stay of 4 days and blood transfusions in 57.2% were required. Again, analysis of index procedures revealed significant differences. Patients with ASD, VSD, or native CoA were far younger than patients in the interventional subgroups. VSD closure was the most frequent surgical procedure with 261 cases. Case performance in VSD closure appears highly standardized with narrow interquartile ranges for perfusion and aortic clamp times as well as for the duration of hospital stay. The complex nature of univentricular heart treatment is visible in the information of Norwood and total cavopulmonary connection (TCPC) cases. Main diagnosis in Norwood cases was hypoplastic left heart syndrome (HLHS) in 81.3%. Eighteen patients (24%) received bilateral pulmonary arterial banding before the Norwood procedure. Norwood patients had longest perfusion times (median 182 minutes), longest mechanical ventilation (median 130 hours), longest ICU stay (median 21 days), and longest in-hospital stay (median 47 days). Three out of 18 pediatric congenital cardiac surgery units did not perform Norwood operations in 2020. HLHS was also the most frequent main diagnosis in TCPC cases (32.5%). TCPC cases showed short ventilation times with small interquartile range (median 8 hours), but an elongated and case variable lengths of hospital stay (median 17 days, 12–24 days, 25 and 75 percentile, respectively).

Key Quality Indicators

In-hospital mortality is specified in detail in ►Table 3. It was 1.6% in isolated surgical and 0.5% in interventional treatments. Cases with multiple procedures carried the highest mortality of 5.7%. The 336 cases of this group compounded 48.5% newborns, 25.9% infants, and 25.6% children, adolescents, and adults. In 27.7% of the cases, patients received not only one but two or more subsequent procedures, in total 528 procedures including 308 operations and 220 interventions. In the subgroup analysis of surgical index procedures, the Norwood procedure sticks out with 18.7% mortality. Overall in-hospital mortality rate in all 2,795 interventional cases (0.5%) is higher compared to defined interventional index procedures (two cases of death [0.2%] out of 966 cases).

Observed mortality in all five STS-EACTS mortality categories was lower compared with the published mortality rates from the performance data set of the STS-EACTS group for 2002 to 2007 (►Table 4).⁶

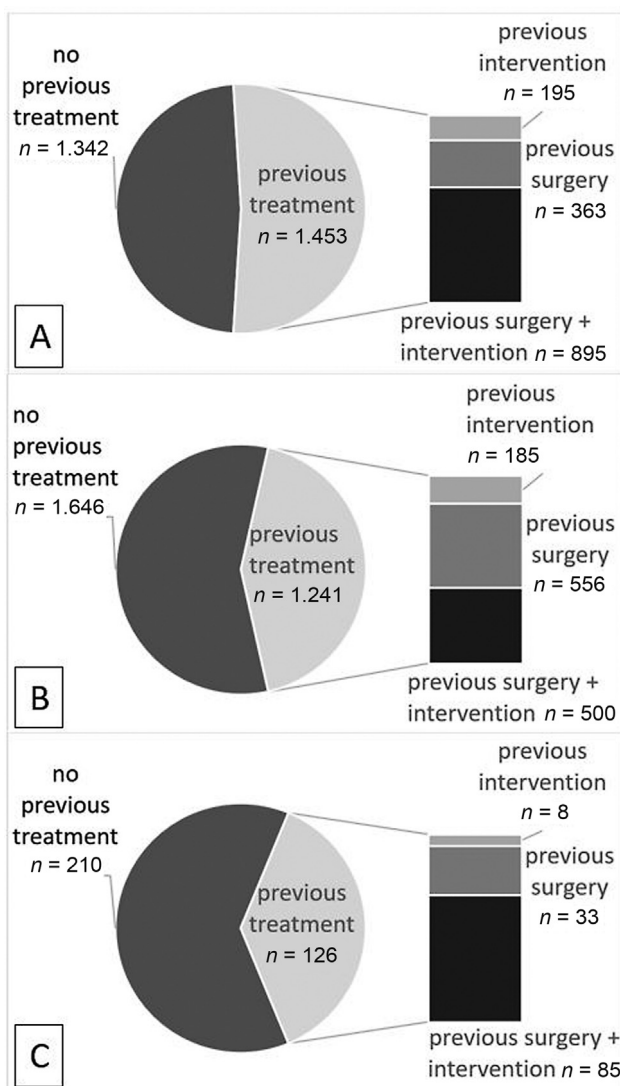


Fig. 3 Pretreatment of patients in different case subgroups. (A) Cases intended for single interventional treatment. (B) Cases intended for single surgical treatment. (C) Cases with multiple procedures. The rate and the distribution of different pretreatments is expressed in the bar charts.

Analysis of cases without adverse events is demonstrated in the bar charts of ►Fig. 2, focusing on the severity categorization of recorded adverse events and in the sunburst diagram of ►Fig. 4, focusing on the adverse event rates related to the risk categorizations and the type of intended procedure.

The German National Quality Assurance Report on CHD contains detailed age and risk-related outcome reports on key quality indicators for all combined case groups and all 15 index procedures, in detail not considered in this overview. These detailed tables allow each participating center detailed comparison with their own separate and confidential institution-related report.

For interventional cases, observed rates of all adverse events are in similar range as compared with published data (►Table 5).¹⁰ Adverse event rates for surgical cases could not be compared with published data in this report because defined major events⁷ have not been analyzed with

Tables 2 General and specific key performance indicators

(A) All cases													
	Number of procedures	Number of centers	Length of hospital stay (d)	ICU	Length of ICU stay (d)	Intubation	Mechanical ventilation (h)	Blood transfusion	Procedure time (min)	Fluoroscopy	Fluoroscopy time (min)	CPB	Perfusion time (min)
Interventional cases	2,795	22	2.0 (2.0/3.0)	13.5%	1.0 (1.0/5.0)	17%	3.0 (2.0/4.0)	0.7%	76 (49–115)	93.2%	10.1 (5.5/18.4)		
Surgical cases	2,887	19	11.0 (8.0–18)	94.4%	4.0 (2.0–8.0)	98.1%	9.0 (6.0–42)	57.2%	202 (133–286)			76.7%	115 (76–168)
Multiple procedures	336	17	28 (17.5–54)	96.1%	15 (8–27)	73.8%	59 (10–190)	67.7%	61.5 (39.5–99.5)	86.7%	11.0 (6.2–18)	65%	147.5 (91–220)
(B) Cases with interventional index procedures													
	Age (y)	Number of procedures	Number of centers	Length of hospital stay (d)	ICU	Length of ICU stay (d)	Intubation	Mechanical ventilation (h)	Blood transfusion	Procedure time (min)	Fluoroscopy	Fluoroscopy time (min)	
ASD	9.2 (5.5/37.9)	493	22	2.0 (2.0–3.0)	5.1%	1.0 (1.0–1.0)	29%	2.0 (2.0–2.0)	0.2%	47 (32–69)		5.0 (2.3–8.0)	
VSD	5.6 (3.8/7.9)	29	9	3.0 (2.0–3.0)	3.4%		13.8%	2.0 (2.0–2.0)	3.4%	85 (69–97)	100%	12.4 (9.5–17.6)	
Native CoA	5.2 (0.3/16.7)	45	12	3.0 (2.0–5.0)	28.9%	5.0 (5.0–8.0)	20%	3.0 (3.0–20)	0%	64 (48–117)	100%	8.6 (5.0–12.4%)	
Recurrent CoA	7.5 (0.8/14.8)	30	13	2.0 (2.0–3.0)	6.7%		0	0	0	60.5 (40.0–95.0)	100%	6.5 (4.0–11.5)	
PDA	2.9 (0.9/5.1)	281	22	2.0 (2.0–3.0)	9.3%	3.0 (1.0–9.0)	9.3%	3.0 (2.0–18)	0.7%	53 (40–75)	100%	6.7 (4.6–10)	
PPVI	18.3 (12.2/29.2)	88	16	5.0 (4.0–6.0)	14.8%	1.0 (1.0–1.0)	54.5%	4.0 (3.0–4.0)	1.1%	155 (115–209)	100%	22.4 (14.9–36.6)	
(C) Cases with surgical index procedures													
	Age (y)	Number of procedures	Number of centers	Length of hospital stay (d)	ICU	Length of ICU stay (d)	Intubation	Mechanical ventilation (h)	Blood transfusion	Procedure time (min)	CPB	Perfusion time (min)	Cross-clamp
ASD	4.0 (2.0/6.7)	180	18	8.0 (6.0–9.0)	100%	2.0 (2.0–3.5)	100%	6.0 (4.0–8.0)	36.7%	153 (119–180)	100%	53 (41.5–65)	77.8%
VSD	0.4 (0.3/0.7)	261	18	10 (8–13)	100%	4.0 (3.0–6.0)	100%	12.0 (6.0–54)	82%	175 (150–221)	100%	93 (71–113)	99.6%
AVSD	0.5 (0.4/1.3)	205	17	12 (9.0–18)	100%	5.0 (3.0–9.0)	100%	24 (7.0–83)	76.1%	236 (187–288)	100%	140 (105–186)	97.1%
Native CoA	0.1 (0.0/0.3)	119	17	10.0 (7.0–15)	100%	4.0 (3.0–7.0)	100%	11.0 (5.0–48)	38.7%	121 (87–162)	26.9%	114 (50–136)	19.3%
SimpleTGA	0.0 (0.0/0.0)	71	17	21 (17–28)	100%	13.0 (6.0–17)	100%	73 (24–120)	93	287 (244–339)	100%	173 (150–222)	100%
Fallot	0.5 (0.4/0.8)	143	18	13 (9.0–18)	100%	5.0 (3.0–8.0)	100%	22 (7.0–52)	90.2	254 (204–305)	100%	155 (114–192)	100%
TCP	3.8 (3.2/4.6)	157	16	17 (12–24)	100%	5.0 (3.0–9.0)	100%	8.0 (6.0–10.0)	60.5%	253 (185–332)	99.4%	93.5 (68.5–136)	12.7%
Norwood I (< 90 d)	0.0 (0.0/0.0)	75	15	47 (29–70)	100%	21 (11–33)	100%	130 (72–199)	96%	315 (263–414)	100%	182 (147–228)	100%
Pulmonary valve replacement	16.3 (9.6/24.2)	112	17	9.0 (7.0–14)	99.1%	3.0 (2.0–5.0)	100%	8.0 (6.0–12)	57.1%	271 (221–372)	100%	111.5 (87.5–166)	38.4%

Abbreviations: ASD, atrial septal defect; AVSD, atrioventricular septal defect; CoA, coarctation aortae; CPB, cardiopulmonary bypass; ICU, intensive care unit; NIRS, near-infrared spectroscopy; PDA, patent ductus arteriosus; PPVI, percutaneous pulmonary valve implantation; TCP, total cavopulmonary connection; TGA, transposition of great arteries; VSD, ventricular septal defect. Data are given as numbers, percentages or median (25. – 75. percentiles).

Table 3 In-hospital mortality—all cases and index procedure cases

	Numbers	Percentage
All cases	85/6,051	1.4
Interventional cases	15/2,795	0.5
Surgical cases	47/2,887	1.6
Multiple procedures	19/336	5.7
Hybrid procedures	No data	
Cases with interventional index procedures		
ASD	0/493	0
VSD	0/29	0
Native CoA	0/45	0
Recurrent CoA	0/30	0
PDA	2/281	0.7
PPVI	0/88	0
Cases with surgical index procedures		
ASD	0/180	0
VSD	0/261	0
AVSD	2/205	1.0
Native CoA	0/119	0
Simple TGA	0/71	0
Fallot	1/143	0.7
TCPC	0/157	0
Norwood I (< 90 d)	14/75	18.7
Pulmonary valve replacement	1/112	0.9

Abbreviations: ASD, atrial septal defect; AVSD, atrioventricular septal defect; CoA, coarctation aortae; PDA, patent ductus arteriosus; PPVI, percutaneous pulmonary valve implantation; TCPC, total cavopulmonary connection; TGA, transposition of great arteries; VSD, ventricular septal defect.

Note: Interventional index procedures represent 966 out of 2,795 interventions (35%) and account for 2 out of 15 in-hospital deaths (13%). Surgical index procedures represent 1,323 out of 2,887 surgical cases (46%) and account for 18 out of 47 in-hospital deaths (38%).

Table 4 Comparison of observed and expected in-hospital mortality according to STS-EACTS mortality categories

STS-EACTS mortality category	Numbers (deaths/patients)	Observed mortality (%)	STS-EACTS mortality 2002–2007 ^a (%)
Category 1	7/1,204	0.6	0.8
Category 2	6/712	0.8	2.6
Category 3	5/396	1.3	5.0
Category 4	11/303	3.6	9.9
Category 5	12/60	20.0	23.1

Abbreviation: STS-EACTS, Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery.

^aObserved mortality rates for performance data set in: O'Brien et al.⁶

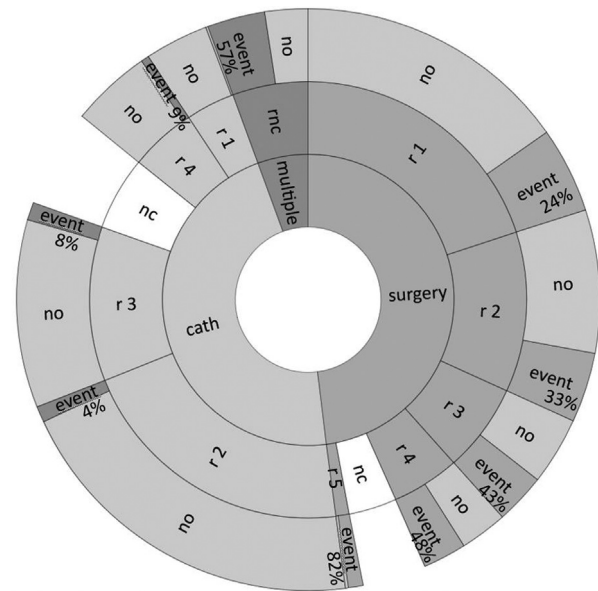


Fig. 4 Case distribution and risk-related outcome for adverse events. This sunburst diagram analyzes data from a total of 6,018 cases. It visualizes the distribution of 4,745 cases without complications (79%) and 1,273 cases with adverse events related to the type of procedure and risk classification. Risk classes 1–5 for surgery refer to STAT mortality categories and are not comparable to the interventional procedure-type risk categories 1–4. A case-related risk classification is not applicable in cases with multiple procedures. Displayed event rates in the outer circle refer to the particular dedicated risk category. Surgical risk categories are shown in the right half of the diagram and assorted according to their frequencies clockwise from top to down. Most surgeries were performed in lower risk categories 1 and 2 with highest freedom of recorded complications in risk category 1 (76%). Lowest rates of freedom from recorded complications were 52% in risk category 4 and 18% in risk category 5 (smallest group representing only 60 cases [2%] in the surgical group). Interventional risk categories are shown in the left half of the diagram and assorted clockwise from down to top. Most interventions were performed at medium procedural risk categories 2 and 3. Freedom from recorded complications ranged from 97% in category 1 to 91% in category 4. Cases with multiple procedures showed with a 43% freedom rate of recorded complications a lower score compared with cases with surgical or interventional treatment. Labeling: Inner circle: cath – interventional cases; multiple – cases with ≥ 2 procedures at different times; surgery – surgical cases. Middle circle: r – risk category (1 lowest; 4⁵ highest); nc – not classified. Outer circle: no – cases without recorded complications; event – cases with recorded complications.

respect to STS-EACTS risk categories (reporting was only on all adverse events) (► Table 6).

Longitudinal Data Analysis

Tetralogy of Fallot

The database included 1,632 patients following repair of Fallot over 9 years from 2012 to 2020. Eighteen percent of the patients received palliative procedures prior to surgical repair. Until the end of 2020 20.8% of the patient's redo procedures were recorded. The flowchart of ► Fig. 5 describes patient's medical career and the bar chart of ► Fig. 6 visualizes the frequency of redo cases in relation to the time interval after Fallot repair. The largest number of redo cases and redo

Table 5 Rate of any adverse event according to procedural risk classification in interventional cases

Procedural risk category	Numbers (any AE/patients)	Observed rate of any AE ^a (%)	Expected rate of any AE (%) ^b
Category 1	7/219	3.2	5.2
Category 2	52/1,265	4.1	13
Category 3	58/686	8.5	19
Category 4	26/295	8.8	25

Abbreviations: AE, adverse event; IPCCC, International Pediatric and Congenital Cardiac Code.

^aAny adverse event (AE) as defined for pediatric and congenital interventions—not to compare with the IPCC code list and the STSCHSD Data collection form for surgical procedures.

^bObserved adverse event rates for performance data set in: Bergersen et al.¹⁰

procedures took place in the first year after initial repair. The list of the five most frequent types of operations comprises delayed closure of sternum and weaning from ECMO indicating complex postoperative courses (►Fig. 5). Patients with palliative treatment prior to repair were more often subjects of redo procedures (40.3% vs. 16.5%, respectively).

Coarctation

Over 9 years, from 2012 to 2020, the registry recorded 1,864 patients with primary treatment of native coarctation. Data from 1,821 patients could be analyzed. Primary treatment has been transcatheter intervention in 30% and surgery in 70% of the patients. Native CoA was treated in 786 newborns

Table 6 Rate of any adverse event according to STS-EACTS mortality categories in surgical cases

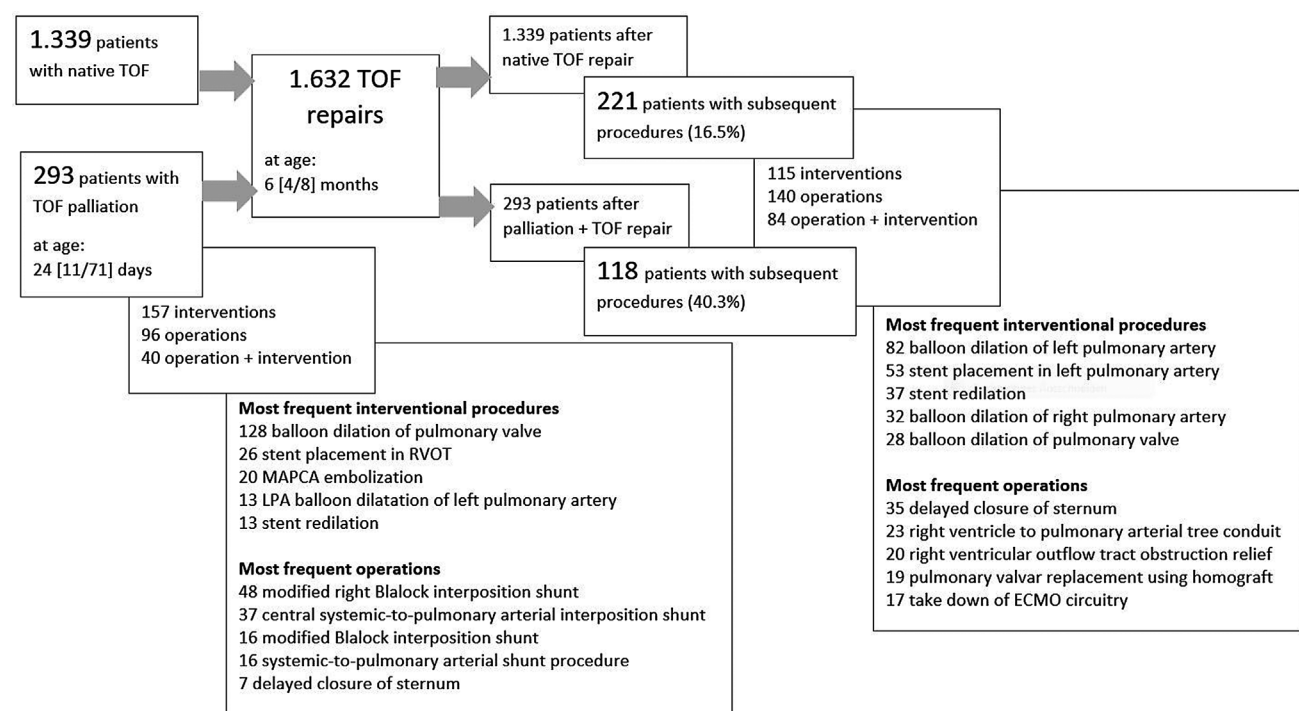
STS-EACTS mortality category	Numbers (any AE/patients)	Observed rate of any AE ^a (%)
Category 1	288/1,204	23.9
Category 2	235/712	33
Category 3	170/396	42.9
Category 4	145/303	47.9
Category 5	49/60	81.7

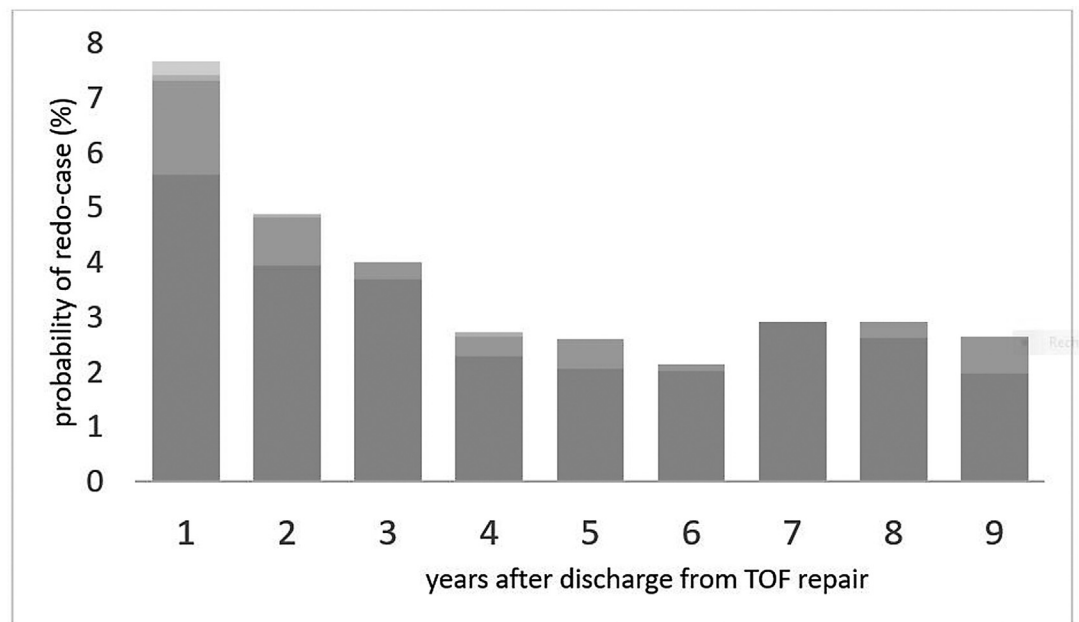
Abbreviations: AE, adverse event; IPCCC, International Pediatric and Congenital Cardiac Code; STS-EACTS, Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery.

^aAny adverse event (AE) as documented from the IPCC code list. 67.7% of all adverse events were rated “minor,” 31% were rated “major” according to complication codes in the STSCHSD Data collection form, Version 2.50, as cited in Jacobs et al.⁷ 1.3% of all AE were not classified.

(43.2%), 455 infants (25.0%), 454 children and adolescents (24.9%), and 126 adults (6.9%). Types of procedures dispersed in 202 balloon dilations (10.8%), 353 stent implantations (18.9%), 960 operations without CPB (51.5%), and 306 operations using CPB (16.4%). The distribution of procedures according to age is demonstrated in ►Fig. 7.

Until the end of 2020, redo procedures in 574 patients (30.8%) were recorded. A total of 385 (67.1%) of the patients received 1 and 189 (32.9%) ≥ 2 subsequent procedures; exclusively interventional treatment in 48.8%, exclusively surgery in 31.7%, and both treatment strategies in 19.5%. The flowchart of ►Fig. 8 describes patient's medical career

**Fig. 5** Comparison of redo procedures after repair of tetralogy of Fallot with or without preceding palliation. In this 9-year follow-up observation in patients after repair of Fallot, the rate of redo procedures was 40.3% compared with 16.5% after previous palliation.



number of patients with ≥ 1 redo-case	124	72	52	31	24	16	16	10	4
number of patients after discharge	1.618	1.476	1.301	1.137	922	750	550	344	152

Fig. 6 Recorded proportion of patients with repeat treatments in relation to the total number of patients with Fallot correction recorded in this period. This figure demonstrates the relative probability to require a redo case in relation to the time after tetralogy of Fallot (TOF) repair. Lower part in each column: patients with one redo case; above: patients with 2, 3, ... up to 5 redo procedures. After corrective surgery dated from 2012 to 2020, patients have not reached adolescent age. Note: This is no systematically collected information. Since no data are available on the completeness of follow-up, these figures must be interpreted as "minimum proportion." Redo cases are counted when entered into the registry database (upper line of the table). The scale basis (lower line of the table) gives the maximal possible number of patients in the specific time period (patients discharged after TOF repair). Thus, the probability may be underestimated due to missing cases or due to overestimation of the basis population.

and the bar chart of ▶**Fig. 9** visualizes the frequency of redo procedures in relation to the time after primary procedure in native CoA.

Discussion

This multicenter registry was initiated by the scientific associations DGTHG and DGPK¹ based on the scientific awareness, that surgical and interventional treatment of CHD represent complementary parts of common treatment concepts.^{11,12} The data of our registry support this thesis. In 2020, one-third to one-half of the cases received interventional or surgical treatment or even both prior to the actual procedures (▶**Fig. 2**). In 5.6% of all cases, patients received scheduled multiple procedures (mostly combinations of surgery and intervention). Several CHD diagnoses can be treated either by interventional or surgical methods.^{13–15} Detailed analysis of the index procedures (ASD, VSD, CoA) in the German Report exposes the heart team access in patients with CHD. Surgical and interventional ASD, VSD, and CoA patients obviously even by age represent a different spectrum of the diseases (▶**Table 2**). The necessity of evidence-based heart team decisions especially becomes obvious in the long-term observations (▶**Figs. 5–9**). Prerepair palliation

in Fallot patients was performed by various interventional and surgical treatment options.^{16,17} Palliated patients obviously represent the more complex spectrum of CHD with further impact on redo cases and redo procedures after repair of Fallot—requiring a large variety of interventional and surgical methods.¹⁸ Coarctation patients present themselves at different age with other symptoms and unlike anatomy of the aortic disease. Though the vast majority of patients underwent primary treatment of native coarctation in newborn and infant age, 6.9% of the patients in our report received primary treatment in adulthood.¹⁹ While stent procedures dominated in older patients, surgery was the domain in newborn and infants. However, our data show that balloon dilations and stent implantations may represent therapeutic options in rare individual patients to start treatment of coarctation even in newborn and infants. In the future, long-term assessment will become increasingly more important in CHD since the quality of treatment frequently does not become apparent within the first months after the procedure.^{20,21}

Combined case group analysis provides a real, live description of the time and effort and the performance of surgical and interventional treatment in Germany.²² Cases planned with single interventions required the least

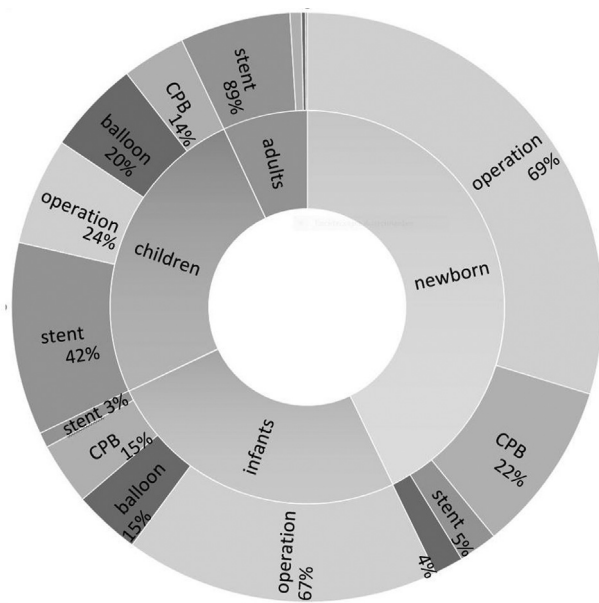


Fig. 7 Distribution of different coarctation of the aorta (CoA) treatment strategies to age groups. This sunburst diagram shows the distribution of primary native CoA treatment in 1,864 patients with respect to age and type of treatment. Frequencies were shown with descend numbers in clockwise direction. Most patients (43.2%) were treated at newborn age but 126 patients (6.9%) not until adulthood. Operations without cardiopulmonary bypass (CPB) are most frequent in newborns and infants while stent procedures dominated treatment in children and adults. Relative procedure frequencies in the outer circle refer to the particular dedicated age group.

resources. Surgical therapy needed far more intensive care resources and transfusion medicine. Analysis of subgroups underlines the integrity of our data sets. As expected, the rates of intensive care treatments, mechanical ventilation, and CPB usage were 100% in some of the procedures in contrast to the information on native CoA treatment, which was performed according to different surgical strategies.^{20,21} Various planned treatment strategies become visible by analyzing defined surgical and interventional procedures. Overall, the key performance indicators (–Table 2) mirror

the how-to-do standard in Germany. As an example, the rate of general anesthesia was higher in ASD interventions, which can be explained by the need for transesophageal echocardiography guidance.²³ Fluoroscopy times are still an issue in interventional procedures.^{24–26} Mean fluoroscopy in most of the index procedures were below average as well as the in-hospital mortality rates. This may be evidence for an increasing number of complex interventions underrepresented in the interventional index procedures.

Key quality indicators were the freedom of adverse events and in-hospital mortality rates (–Table 3, –Figs. 3 and 4). The overall in-hospital mortality of all cases was low with 1.6%.²² When compared with published data, observed mortality and morbidity in this report (–Tables 3–6) suggest overall good quality of medical treatment. However, this has to be carefully interpreted with the given limitations of data acquisition and with respect to the fact that we only report observed mortality and morbidity and did not compare with calculated expected mortality and morbidity rates.^{27–29} As expected, mortality was highest after Norwood I procedures.³⁰ These patients carried the largest morbidity burden as well, which was expressed by all key performance indicators (–Table 2). Adverse event rates can be related to increasing risk classification (–Fig. 4). As obvious in Norwood patients, adverse event rates were related to patient's age too. However, demonstrating this data would have blown up the sunburst diagram in –Fig. 4. It is the nature of complex heart disease that there is remaining risk for major or catastrophic adverse events (–Fig. 3). This was more frequent in surgical cases but again it has to be emphasized that interventions and operations must not be understood as competing, but as complementary therapeutic options. Procedural results, process numbers, and event rates are frequently unsuitable for direct comparison between these treatment modalities.

Completeness, validity, and further developments of this registry will depend on continued efforts of the DGTHG and the DGPK in close collaboration with all pediatric cardiac and heart surgical departments in Germany. It will be of outstanding importance to increase patient safety even further

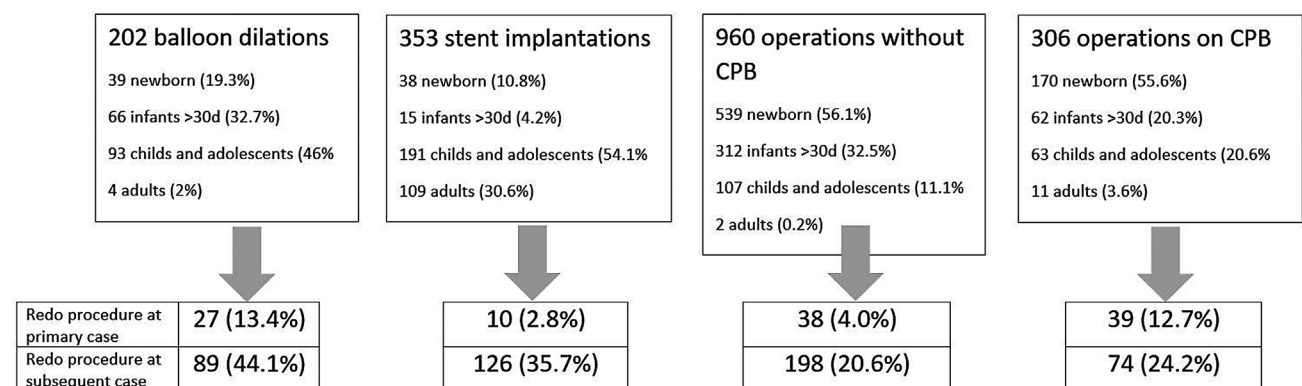
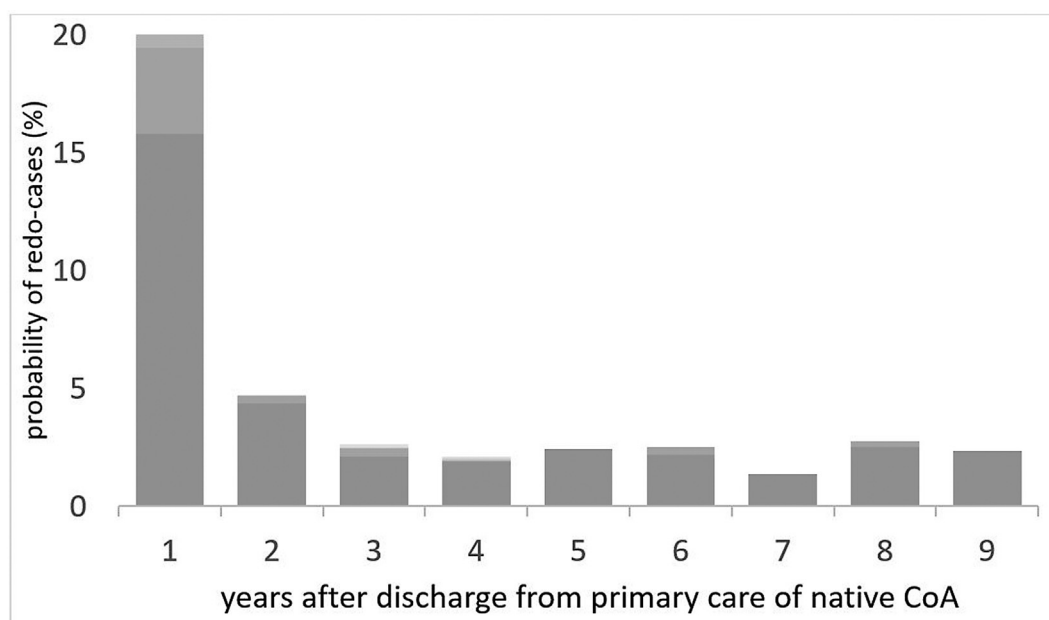


Fig. 8 Nine years' follow-up observation in patients with native coarctation of the aorta. Subsequent procedures during the primary case occurred in 13.4% after balloon dilations and in 12.7% after cardiopulmonary bypass (CPB) operations. After discharge from primary care, redo cases with follow-up procedures were frequent in all treatment arms but more frequent after primary interventional treatment (44.1% and 35.7% in this 9-year observation period so far).



number of patients with ≥ 1 redo-case	380	80	40	28	27	22	9	12	5
number of patients after discharge	1.855	1.692	1.527	1.331	1.110	878	653	438	213

Fig. 9 Recorded proportion of patients with repeat treatments in relation to the total number of patients with primary treatment of native coarctation of the aorta (CoA) recorded in this period. This figure demonstrates the relative probability of redo cases in relation to the time after primary care of native CoA. Lower part in each column: patients with one redo case; above: patients with 2 or 3 redo procedures. The majority of redo cases occurred in the first year after primary treatment and should be interpreted in the context of 43.2% newborn and 25% infant cases. Probability of redo cases after the first year levels off between 2 and 3%/year. Note: This is no systematically collected information. Since no data are available on the completeness of follow-up, these figures must be interpreted as “minimum proportion.” Redo cases were counted when entered into the registry database (upper line of the table). The scale basis (lower line of the table) gives the maximal possible number of patients in the specific time period (patients discharged after primary treatment of native CoA). Thus, the

and to ascertain the continued high quality of invasive procedures for the treatment of CHD.

Limitations

This registry is limited by its all-comers registry design and the voluntary participation of patients and institutions. Currently, in this report we analyze at least 66% of the surgical and 62% of the interventional procedures nationwide with larger completeness from the participating centers. The range of reported lethality in cases with single surgery or planned multiple procedures compares to anonymous self-disclosure data in the current German Heart Surgery Report.⁹ However, the number of not reported cases might significantly affect the real postinterventional and postoperative mortality and morbidity. Though data integrity is monitored before case closure, no source data monitoring could be performed in this registry so far. This registry does not execute active follow-up tracking of patients.

Conclusion

Improvement of quality of care requires detailed analysis of risks, performance indicators, and outcomes. The need of

redo cases and redo procedures in patients with complex CHD underlines the necessity of long-term observations. Reported mortality and morbidity in this report are comparable to published outcomes.^{5,6}

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Participating Centers in 2020

Aachen; Bad Oeynhausen; Bonn; Berlin (DHZB & Charité), Duisburg; Erlangen; Freiburg/Bad Krozingen; Gießen; Göttingen; Hamburg; Hannover; Heidelberg; Homburg; Kaiserslautern; Kiel; Leipzig; München (LMU); Münster; Oldenburg; Stuttgart; Tübingen.

Funding

The responsible bodies for the registry are the German Society for Thoracic and Cardiovascular Surgery and the German Society for Pediatric Cardiology and Congenital Heart Defects. The registry receives financial support by all participating institutions and for the years 2012–2016 from the German Heart Foundation (Deutsche Herzstiftung).

Conflict of Interest

None declared.

Acknowledgments

On behalf of the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and the German Society for Pediatric Cardiology and Congenital Heart Defects (DGPK), the authors would like to thank the heads of the departments and their teams of all participating heart centers in Germany for their continued cooperation and support to realize this registry.

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