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# German Registry for Cardiac Operations and Interventions in CHD: Annual Report 2022

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**Conflict of Interest:** The authors declare that they have no conflict of interest.

**Abstract:**
In 2021 a total of 5439 patients were included by 22 participating centers. In total 3721 surgical, 3413 interventional and 34 hybrid procedures were performed during 6122 hospital stays. 2220 cases (36.3%) could be allocated to the 15 index procedures. The mean unadjusted in-hospital mortality ranged from 0.4% among interventional and 2% among surgical cases up to 6.2 % in cases with multiple procedures. In-hospital mortality among index procedures accounted for 2.3% in TCPC, 20.3% in Norwood procedures and 0.4% following interventional closure of patent ductus arteriosus. For the remaining 7 surgical and 5 interventional index procedures no in-hospital deaths were recorded. The 10 years longitudinal evaluation of 1795 patients after tetralogy of Fallot repair revealed repeat interventional or surgical procedures in 21% of the patients. Over the same period 31.1% of 2037 patients, following initial treatment of native coarctation, required at least one additional hospital admission, 39.4% after initial interventional and 21.3% after initial surgical therapy.
Conclusion The annual report 2021 of the German Registry for Cardiac Operations and Interventions in CHD shows continuously good results in accordance with previous data of the registry. Compared to international registries on CHD it can be ascertained that in Germany invasive treatment of CHD is offered on a high medical level with excellent quality. The proven fact that patients with various malformations like tetralogy of Fallot and coarctation of the aorta require repeat procedures during follow-up confirms the urgent requirement of longitudinal assessment of all patients presenting with complex lesions.

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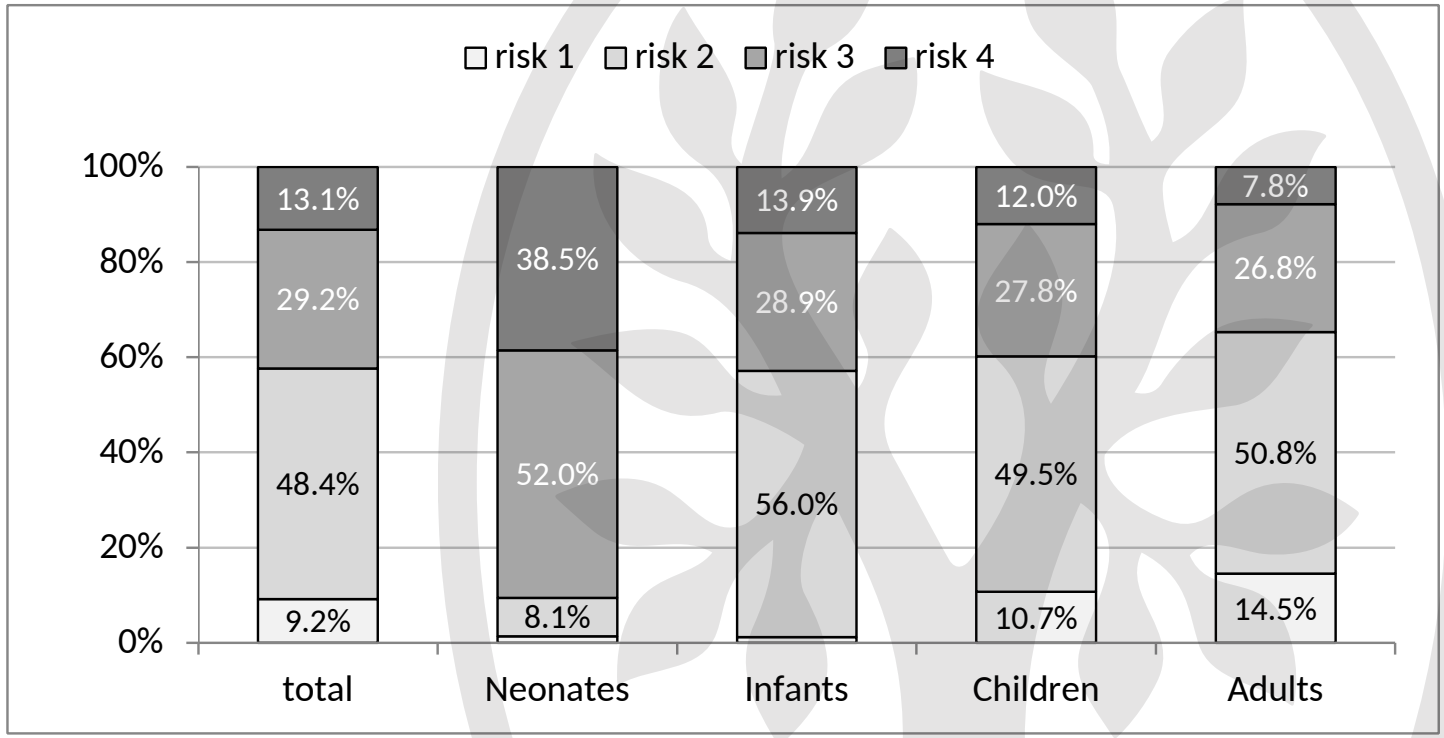


Fig. 1: Interventional cases: Risk diversification in different age groups according to the Bergersen risk score[2].

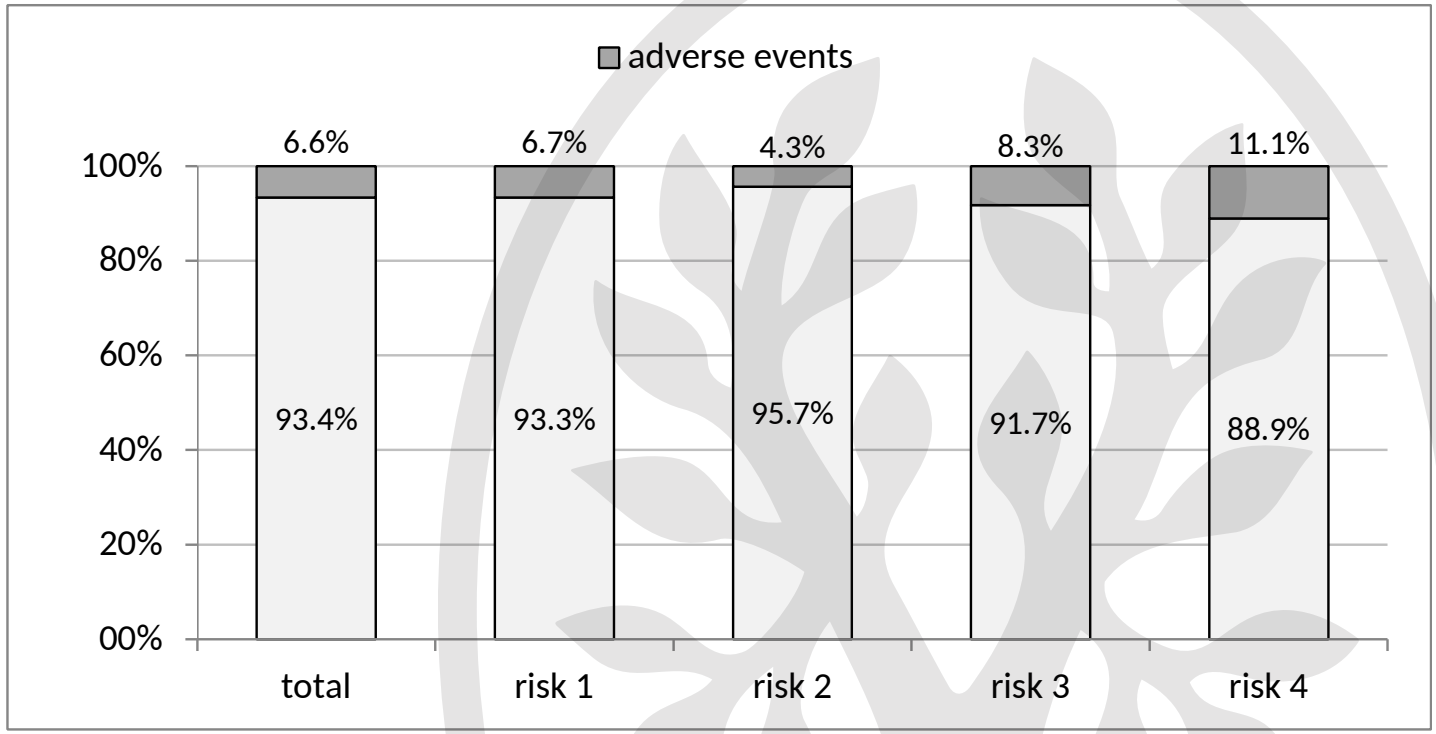


Fig. 2: Interventional cases: Association of Bergersen risk score categories[2] and adverse events

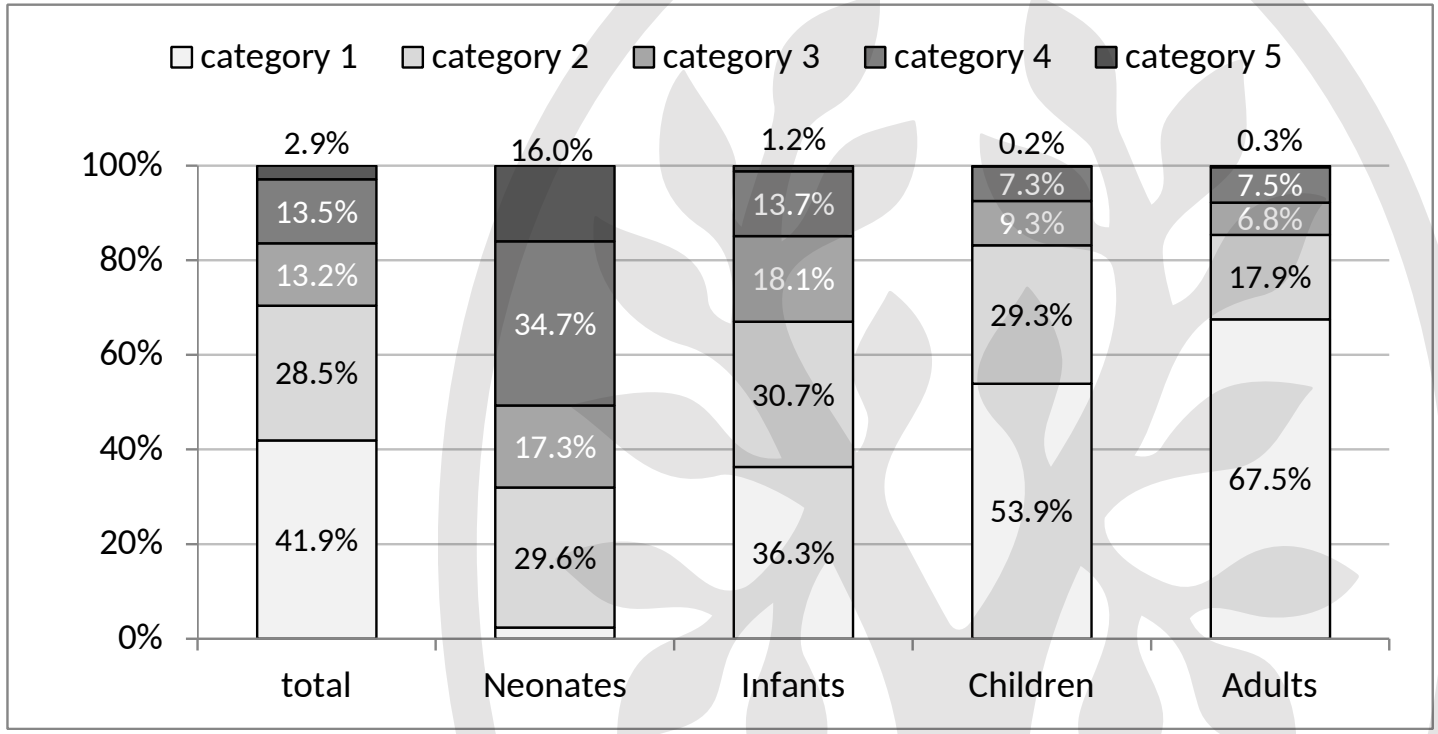


Fig. 3: Surgical cases: Risk diversification according to STAT mortality categories[1] in different age groups

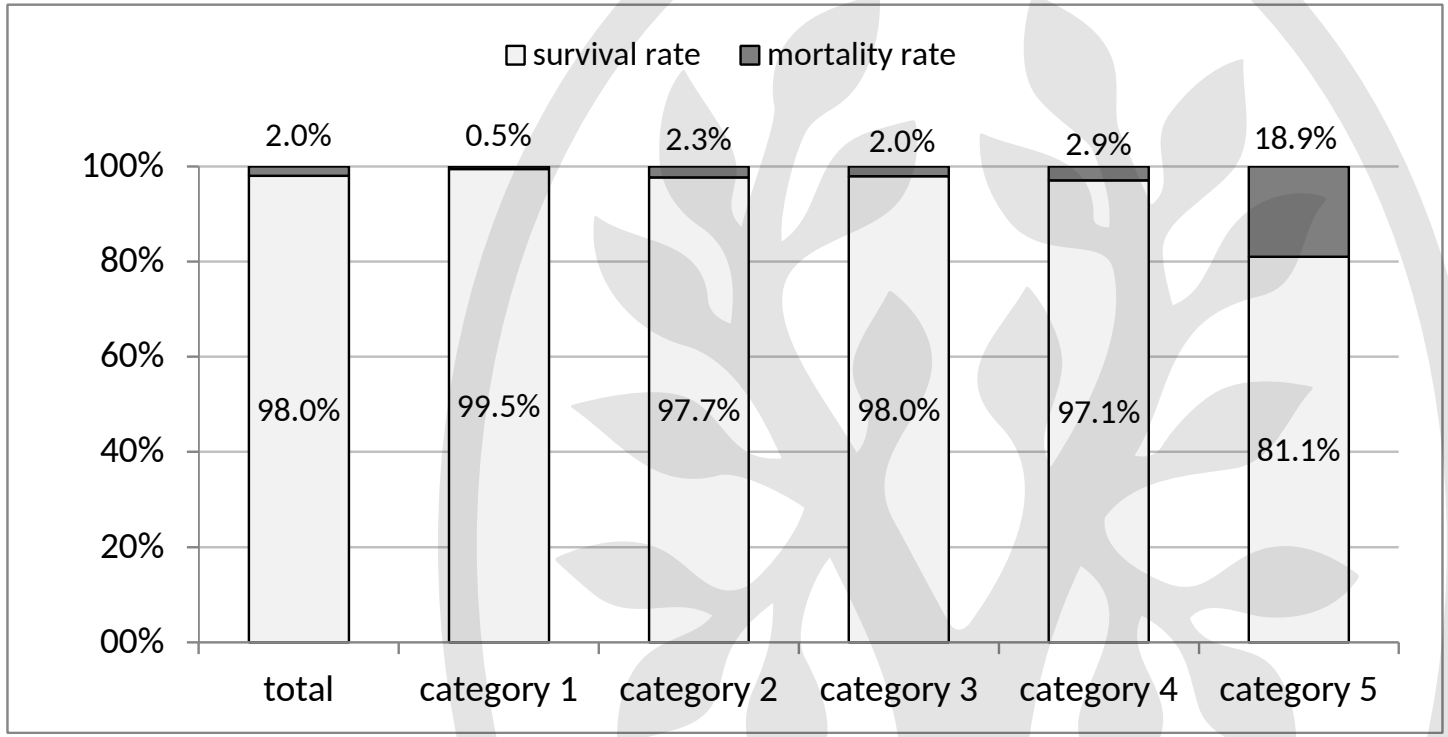


Fig. 4: Surgical cases: Association of STAT mortality categories[1] and in-hospital mortality

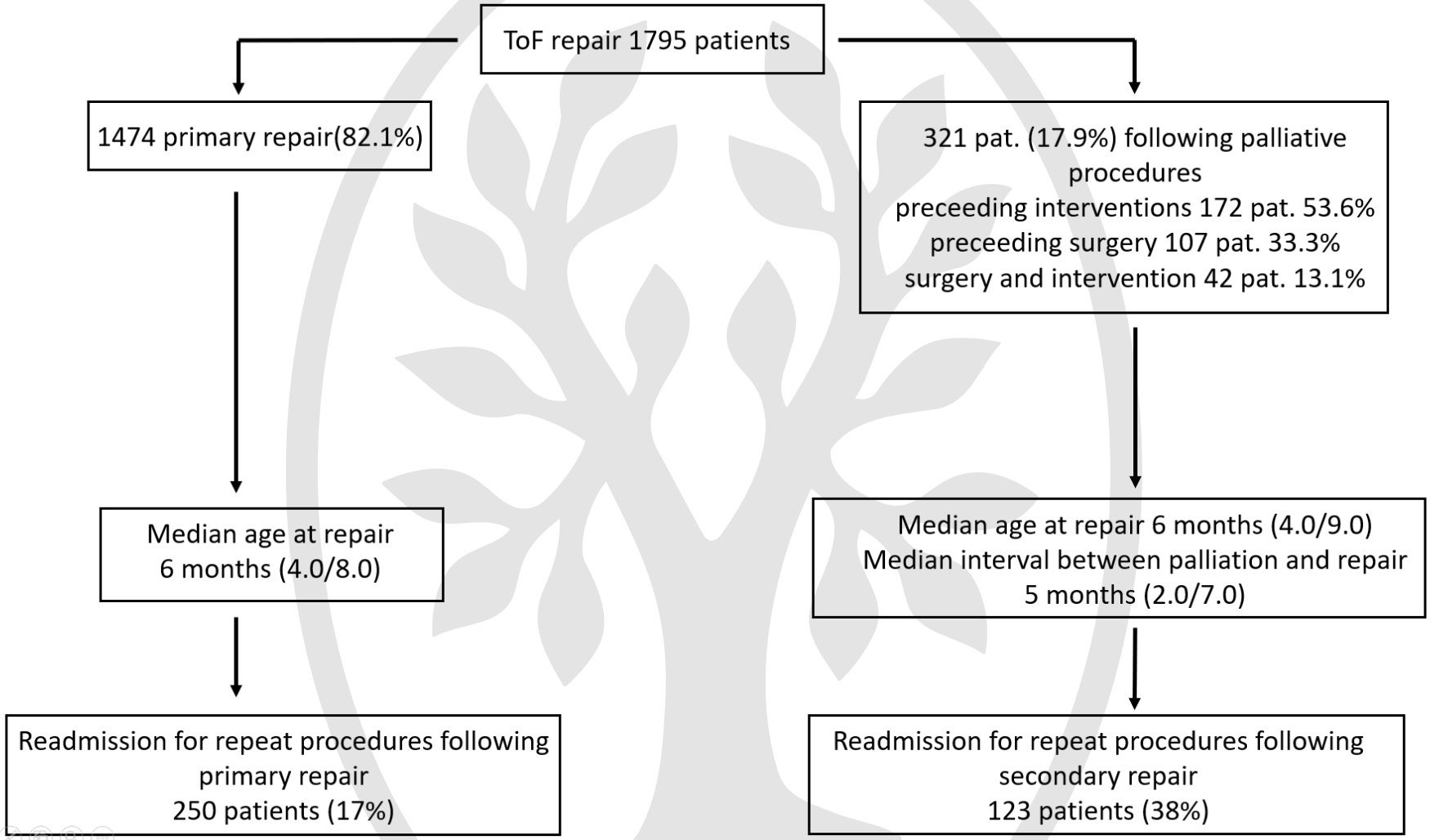


Fig. 5: Surgical repair in TOF from 2012 – 2021. Comparison of readmissions for repeat procedures in patients following primary and secondary repair.

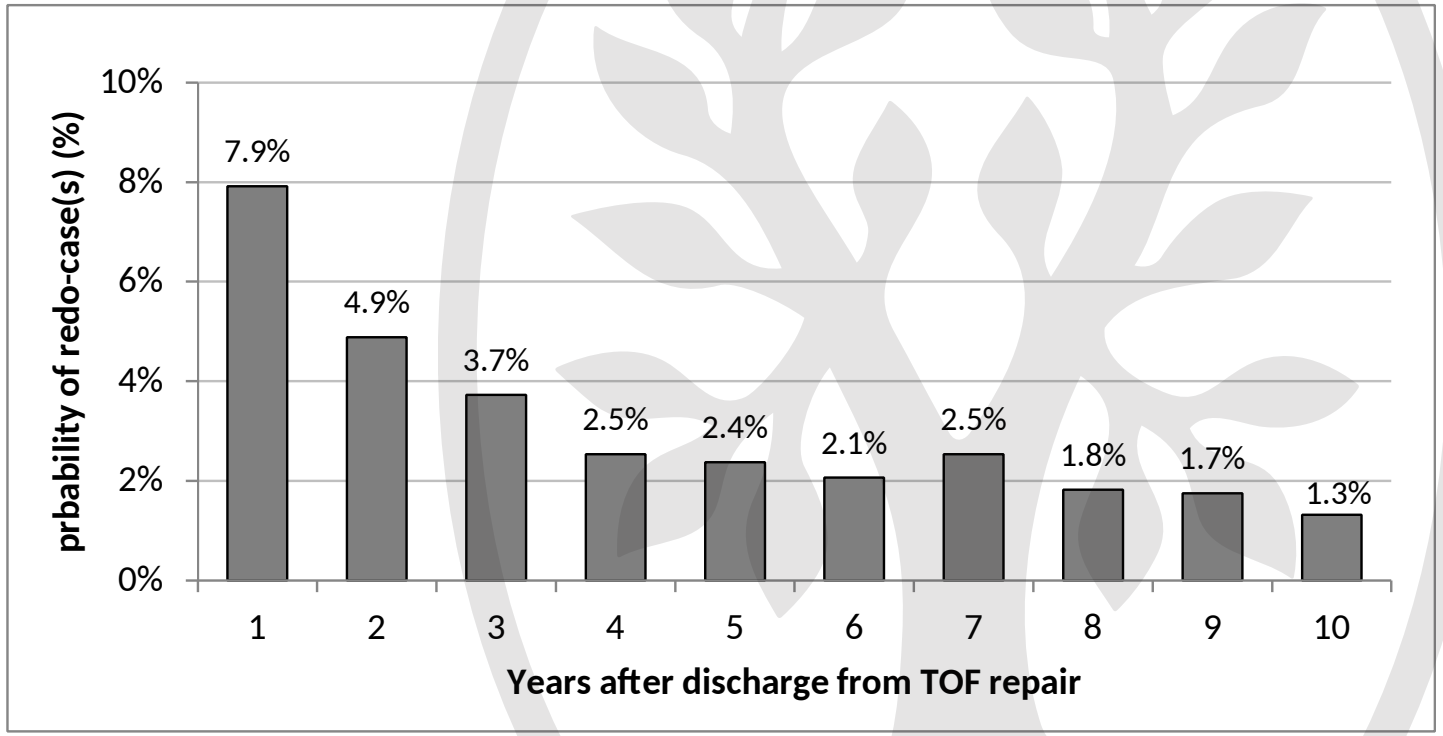

Fig. 6: Proportion of patients following TOF repair requiring repeat hospital admission for surgical or interventional treatment. The probability refers to the total number of patients during the respective time interval. Since no data are available on the completeness of follow-up, the probability may be underestimated and requires interpretation as minimum proportion.

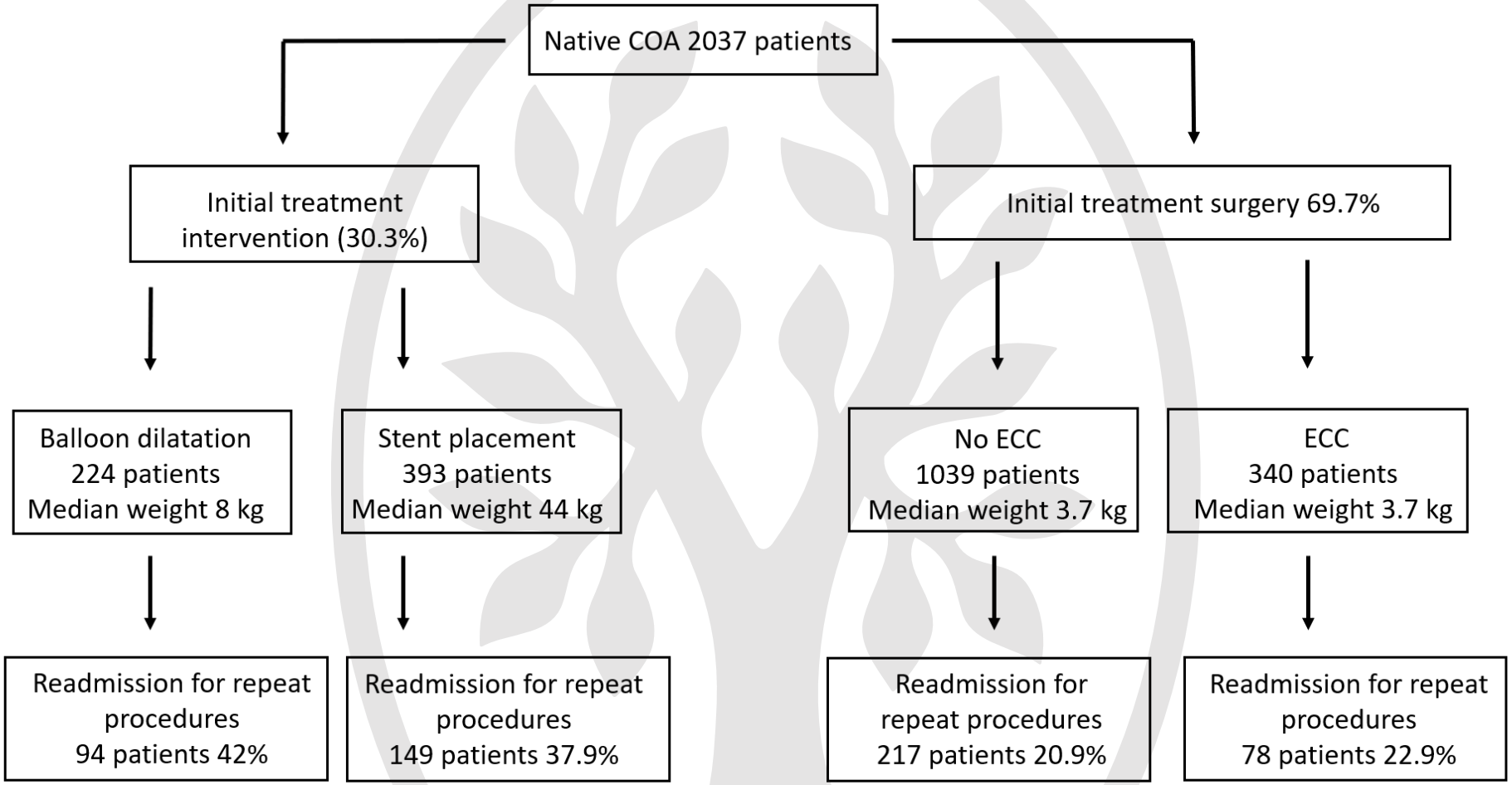


Fig. 7: Treatment of patients with native COA from 2012 – 2021. Comparison of readmissions for repeat procedures following initial interventional or surgical treatment.

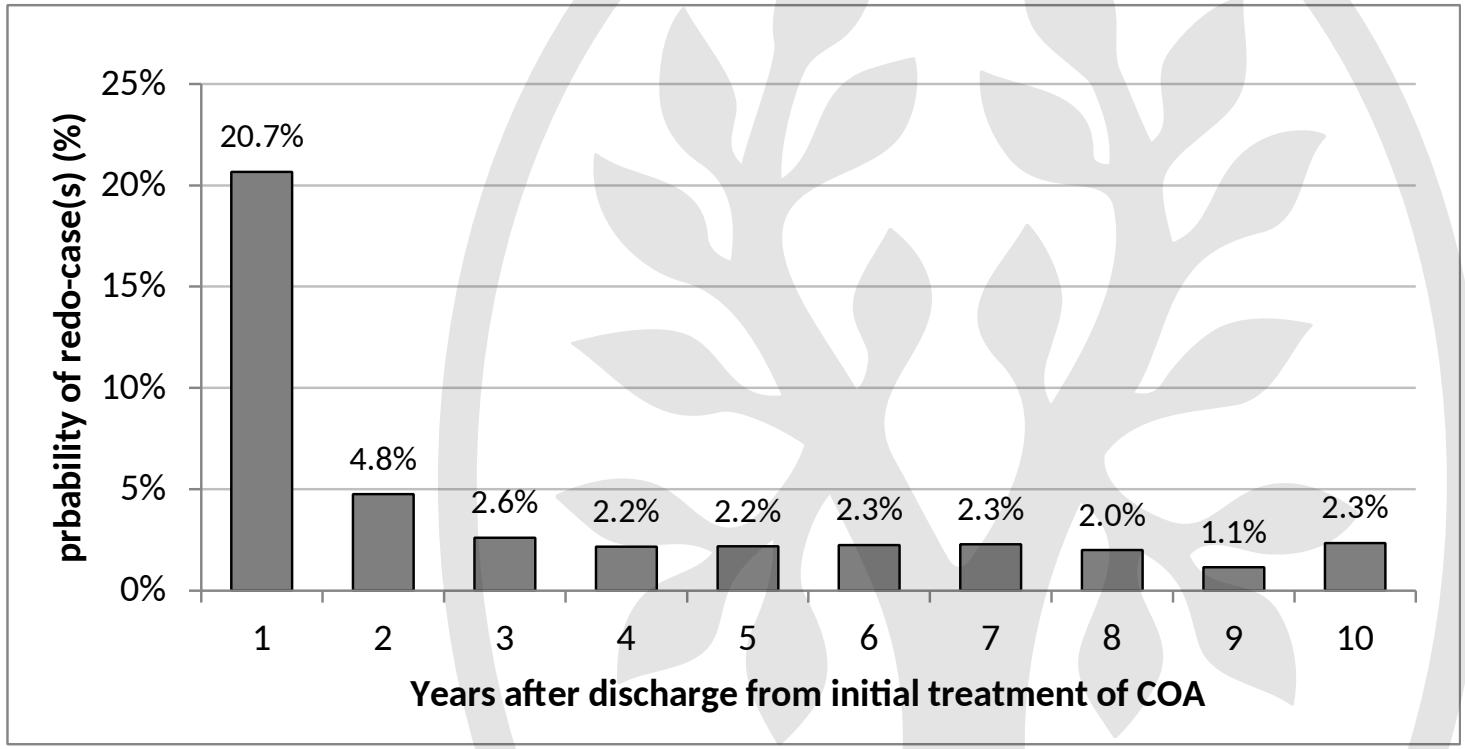


Fig. 8: Proportion of patients following primary treatment of native COA requiring repeat hospital admission for surgical or interventional treatment. The probability refers to the total number of patients during the respective time interval. Since no data are available on the completeness of follow-up, the probability may be underestimated and requires interpretation as minimum proportion.

**Abstract**

**Background** The German Registry for Cardiac Operations and Interventions in Patients with Congenital Heart Disease is a voluntary registry initiated by the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and the German Society for Pediatric Cardiology and Congenital Heart Defects (DGPK). Since 2012 the registry collects data for the assessment of treatment and outcomes of surgical and interventional procedures in patients with congenital heart disease of all age groups.

**Methods** This real-world, prospective all-comers registry collects clinical and procedural characteristics, adverse events, mortality and medium-term outcomes (up to 90 days) of patients undergoing surgical and interventional. A unique pseudonymous patient identifier (PID) allows longitudinal data acquisition in case of further invasive treatment in any participating German heart center. Prior to evaluation all data sets are monitored for data completeness and integrity. Evaluation includes risk stratification of interventional and surgical procedures and classification of adverse events. Each year's data are summarized in annual reports containing detailed information for the entire cohort, all subgroups and for 15 index procedures. In addition each participating center receives an institutional benchmark report for comparison with the national results. This paper presents a comprehensive summary of the Annual report 2021.

**Results** In 2021 a total of 5439 patients were included by 22 participating centers. In total 3721 surgical, 3413 interventional and 34 hybrid procedures were performed during 6122 hospital stays. 2220 cases (36.3%) could be allocated to the 15 index procedures. The mean unadjusted in-hospital mortality ranged from 0.4% among interventional and 2% among surgical cases up to 6.2 % in cases with multiple procedures. In-hospital mortality among index procedures accounted for 2.3% in TCPC, 20.3% in Norwood procedures and 0.4% following interventional closure of patent ductus arteriosus. For the remaining 7 surgical and 5 interventional index procedures no in-hospital deaths were recorded. The 10 years longitudinal evaluation of 1795 patients after tetralogy of Fallot repair revealed repeat interventional or surgical procedures in 21% of the patients. Over the same period 31.1% of 2037 patients, following initial treatment of native coarctation, required at least one

additional hospital admission, 39.4% after initial interventional and 21.3% after initial surgical therapy.

**Conclusion** The annual report 2021 of the German Registry for Cardiac Operations and Interventions in CHD shows continuously good results in accordance with previous data of the registry. Compared to international registries on CHD it can be ascertained that in Germany invasive treatment of CHD is offered on a high medical level with excellent quality. The proven fact that patients with various malformations like tetralogy of Fallot and coarctation of the aorta require repeat procedures during follow-up confirms the urgent requirement of longitudinal assessment of all patients presenting with complex lesions.





## Introduction

Treatment of congenital heart (CHD) disease is complex and carries a significant risk of morbidity. Therapeutic concepts frequently require several consecutive interventional and/or surgical procedures. Since quality of care has major impact on patients' long-term outcome and quality of life, several scientific registries have been established worldwide during the recent decades to assess the outcome and to improve the quality of treatment.[1-9] At the beginning of this century cardiac surgical procedures in CHD were subject to a nationwide obligatory external quality assurance in Germany. In 2004, this obligatory quality assurance measure, according to § 136ff Social Code Book V, was suspended by the political representatives (Bundeskuratorium) for various reasons. Based on the scientific awareness, that surgical and interventional treatment of CHD patients represent complementary parts of common treatment concepts the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and the German Society for Pediatric Cardiology and Congenital Heart Defects (DGPK), took the initiative and the responsibility to establish a prospective multicenter registry collecting data from German heart centers on interventional and surgical therapies in patients with CHD.[10,11] The nationwide registry started in 2012. The purpose of this report is to provide a public comprehensive update based on the Annual report of the German Quality assurance for congenital heart disease 2022.

## Materials and Methods

The voluntary German Registry for Quality Assurance in CHD (Nationale Qualitätssicherung Angeborene Herzfehler) is designed to collect data on the treatment and outcome of patients suffering from CHD in Germany. The structure of the Registry and the data submission have been described in detail previously.[10,11] The structures of the registry, data acquisition and evaluation are in accordance with the guidelines of "Good Epidemiological Practice" [12], "Good Clinical Practice" [13] and the Declaration of Helsiniki for medical research involving human subjects.[14] The Registry has been approved by the Charité's Ethics Committee (code number: EA2/011/11).

Inclusion criteria are the presence of a congenital heart defect and performance of any cardiac surgical or transcatheter procedure. Inclusion of patients is based on intention to treat rather on success. Since treatment of CHD extends into adulthood patients are included irrespective of their age. Coding of diagnoses and procedures is performed by the International Pediatric and Congenital Cardiac Code (IPCCC).[15,16]

Each included patient receives a unique Personal Identifier (PID) for generation of a pseudonym. Based on this PID any cardiac surgical or interventional procedure whenever performed in one of the participating German cardiac centers can be assigned to an individual patient. This enables longitudinal data acquisition as well as short- mid- and long-term evaluations.

Prior to evaluation the collected data are monitored with respect to data integrity and plausibility before case closure. Participation in this voluntary registry requires informed consent either of the patient or guardian, absence of consent being the only exclusion criterium.

Based on the initial treatment all cases are allocated to one of four groups assorted by interventional, surgical, multiple or hybrid procedures. Interventional and surgical cases include all hospital admissions with an intention to treat the patient with a single procedure as well as those requiring subsequent additional treatment by a second or more procedures during the same admission due to an unpredicted complication. The group "multiple procedures" summarizes all patients with a predefined treatment concept, which consists of at least two procedures during one admission (e.g., arterial switch operation following balloon atrioseptostomy). Hybrid procedures are defined as combined surgical and interventional one-stage procedures. For risk stratification the interventional cases are

assigned to risk categories 1 to 4 according to the Catheterization for Congenital Heart Disease Adjustment for Risk Method[2] while surgical cases are assigned to risk categories 1 to 5 according to the Society of Thoracic Surgeons (STS) - European Association for Cardio-Thoracic Surgery (EACTS) mortality categories.[1] Risk stratification of the two remaining groups (multiple and hybrid procedures) is not possible yet due to the lack of established risk categories for these treatment options.

Evaluation of the four groups includes analysis of procedure-related data as well as analysis of various indicators, including adverse events, in-hospital mortality, 30- and 90-day mortality. Major adverse events following surgical procedures are classified according to the society of thoracic surgeons (STS) morbidity classification codes in the STS Congenital Heart Surgery Database (STSCHSD) Data collection form, Version 2.50 as cited in Jacobs et al.[17]. Adverse events following interventional procedures are categorized in five categories according to Bergersen et al.[2]. To allow a detailed and differentiated view on specific procedures in homogeneous subgroups of CHD, 15 index procedures (nine surgical and six interventional) were defined. The surgical procedures include atrial septal defect (ASD) and ventricular septal defect (VSD) closure, repair of atrioventricular septal defect (AVSD), repair of aortic coarctation (COA), arterial switch operation for transposition of the great arteries with intact ventricular septum (TGA), repair of tetralogy of Fallot (TOF), total cavopulmonary connection (TCPC), Norwood procedure, and pulmonary valve replacement (PVR). Interventional procedures include ASD and VSD closure, treatment of aortic coarctation (COA) and recoarctation (ReCOA), closure of patent ductus arteriosus (PDA) and percutaneous pulmonary valve replacement (PPVI).

Longitudinal evaluation was performed for all patients following surgical TOF repair and for all patients who received surgical or interventional treatment of native COA from 2012 until 2021. These patients were analyzed for subsequent invasive treatment during the follow-up.

**Results**

In 2021 a total number of 22 German centers contributed 6122 cases (hospital stays) under the terms of quality assurance. Numbers of patients, cases and procedures, documented in the registry in 2021 are shown in Tab. 1. Detailed data from 2810 surgical cases and 356 cases with multiple procedures were provided by 18 centers, accounting for a total of 3721

surgical procedures. 23 departments submitted data from 2931 interventional cases resulting in a total of 3413 interventional procedures, while hybrid procedures accounted for only 25 (0.4%) of the reported cases including 34 procedures. In 10.1% of the patients included in 2021 more than one hospital stay for interventional or surgical treatment was recorded.

According to the data of the German Heart Foundation, published in the German Cardiac Report (Deutscher Herzbericht 2022, www.herzstiftung.de)[18], the German Registry represents 72% of institutions performing surgical and 92% of institutions performing interventional treatment of congenital heart disease. The 3721 surgical procedures included in the German Registry represent 67.2% of operations for CHD reported in the German Heart Surgery Report 2021, which is based on a voluntary public report of 78 German heart surgery departments.[19] The 3413 interventional procedures of the German registry represent 73% of the procedures from 24 institutions listed in the German Cardiac Report (Deutscher Herzbericht 2022).[18]

**Age and gender distribution**

Almost 36% of cases were performed in newborns and infants, 50% of the cases in children and adolescents. Treatment in adults with CHD accounted for 14.5% of cases (Tab. 2). The age distributions as well as the predominance of male gender remained nearly unchanged compared to previous years.

**Key performance indicators**

Details for interventional and surgical cases as well as for the index procedures are summarized in Table 2, 3 and 4. 56.4% of the interventional cases were performed in patients who had previously undergone either surgical (12.1%) or interventional treatment (7.4%) or a combination of both (36.9%). Median hospital stay of interventional cases was 2 days, intensive care unit stay was required in 14.2% only (Tab. 3). In the majority of cases (82.5%) the procedure was performed under analgosedation without requirement of general anesthesia and mechanical ventilation. It was noticeable that 4.7% of the cases were performed without fluoroscopy (mainly ASD closures and balloon-atrioseptostomies in TGA). The analysis of interventional index procedures revealed significant differences among the different procedures partially related to the complexity of the procedure and partially associated with the age group requiring the specific treatment. ASD closure was the most frequent intervention (442 cases) among the index procedures, 24.7% of these procedures

were performed for closure of PFO. General anesthesia was required in 29.9%, fluoroscopy was avoided in 17.2% of these cases (Tab. 3). The most laborious interventional index procedure was PPVI, which was performed under general anesthesia in 51.5% of the cases. Almost half of the procedures were performed in adults (47.5%). Median procedure time (160 minutes) and median fluoroscopy time (24.4 minutes) exceeded all other procedures (Tab. 3).

Due to the different nature of the treatment surgical cases required more resources. Intensive care treatment was required in 93.5% of the cases with a median length of stay in the ICU of 4 days and in the hospital of 11 days (Tab. 4). Preceding interventional (5.7%), surgical (20.2%) or combined invasive treatment (18.4%) was common accounting for 44.3% of surgical cases. 74.8% of the procedures were performed under cardiopulmonary bypass conditions, in 54.4% of the cases blood transfusions were required (Tab. 4). VSD closure (233 cases) was the most frequent surgical index procedure followed by TCPC (174 cases), ASD and AVSD closure (172 cases each) and TOF repair (163 cases). Surgical treatment appeared highly standardized with narrow interquartile ranges for perfusion and aortic cross clamp times as well as for the duration of hospital stay. There were only minor differences of these parameters as compared to previous years.

The complex nature of univentricular heart treatment was apparent in the evaluation of Norwood operation and TCPC cases. The predominant diagnosis in Norwood cases was hypoplastic left heart syndrome (HLHS) with 78.5%. Fourteen patients (18%) received bilateral pulmonary arterial banding prior to the Norwood procedure. Norwood patients had the longest perfusion times (median 210 min.), longest mechanical ventilation (median 127 h), longest ICU stay (median 28.5 d), and longest in-hospital stay (median 45 d) (Tab. 4). 20% of the patients required one, and 44% required two or more subsequent interventional or surgical procedures during the same hospital stay. In 2021 14/18 units participating in this registry entered data on Norwood procedures. Concerning the index procedure TCPC HLHS was also the most frequent main diagnosis (36.8%), followed by tricuspid atresia (16.1%). Bidirectional superior cavopulmonary anastomosis was the most frequent preceding palliative procedure (79,3%). Extracardiac conduit from inferior caval vein to pulmonary artery without (58%) or with fenestration (28.2%) was the predominant surgical technique. TCPC cases showed short ventilation periods with a small interquartile range (median 7 h), but relatively long and variable lengths of hospital stay (median 16.5 d) (Tab. 4).

**Key quality indicators**

The in-hospital mortality during 2021 (2.0 % in surgical and 0.4% in interventional cases) is specified in Tab. 5. Cases with multiple procedures carried a higher mortality rate of 6.2%.

75% in-hospital deaths in interventional cases occurred in neonates and infants. Risk stratification according to the Catheterization for Congenital Heart Disease Adjustment for Risk Method[2] was possible in 89.1% of interventional cases. Analysis of the different age groups revealed that in neonates a higher percentage of procedures belonged to risk categories 3 or 4 (90.5%) as compared to infants (42.8%), children/adolescents (39.8%) or adults (34.7%) (Fig. 1). Adverse events (AE) were noted in 6.9% of interventional cases (Tab. 5). Irrespective of the age group the highest rate of AE was recorded among patients of the highest risk categories (Fig. 2). Due to the predominance of procedures in the higher risk categories the largest percentage of AE (13,9%) was recorded in the neonatal age group. 73% of AE resulted in minor or transient harm to the patients, while 23% were categorized as major or catastrophic occurring in 1,6% of all interventional cases (Tab. 6). No categorization was available yet in 4% of adverse events. Tab. 7 presents a comparison of observed adverse events with data of the Congenital Cardiac Catheterization Project on Outcomes (C3PO) registry[2] while a comparison of major adverse events[2] including the categories “major” and “catastrophic” is given in Tab. 6.

No in-hospital mortality was noted among patients with interventional index procedures except for 1/274 patients (0.4%) following interventional closure of patent ductus arteriosus (Tab. 5). Freedom of adverse events > 95% was reported in cases of interventional closure of ASD and ductus arteriosus as well as treatment of ReCOA (Tab. 5). Freedom of adverse events was lower for interventional treatment of native COA (88.5%), PPVI (87.1%) and during interventional VSD closure (82.9%).

Classification of complexity according to the risk categories of the STS-EACTS mortality score[1] was possible in 91.9% of the cases. In-hospital mortality correlated with the level of complexity ranging from 0.5% in category 1 up to 18.9% in category 5 (Tab. 8). Procedures of the risk categories 4 and 5 were prevalent in the neonatal age group (50.7.6%) as compared to their proportion among infants (14.9%), children/adolescents (7.5%) or adults (7.8%) (Fig. 3). Due to the predominance of higher risk operations the in-hospital mortality was higher in neonates (7.8%) as compared to infants (1%), children and adolescents (1%) or adults (1.4%).

In the subgroup analysis of surgical index procedures, the in-hospital mortality following the Norwood (20.3%) procedure was remarkable but similar to previous years (2020: 18.7%, 2019 19.8%). The in-hospital mortality rate following TCPC was 2.3%, while no mortality was noticed among patients undergoing one of the remaining 7 surgical index procedures (Tab. 5). A comparison of in-hospital mortality rates among 5 index procedures matching to index procedures from the ECHSA database[20] is provided in Tab. 9.

Adverse events were recorded in 32.5% of surgical cases (Tab. 5). Their frequency correlated with the complexity according to the risk categories of the STS-EACTS mortality score ranging from 19.2% in category 1 to 87.8% in category 5. Procedures of higher risk categories were prevalent in the neonatal age group (Fig. 3). Comparison of adverse events in the German registry with data in the literature has to take into consideration that many registries are reporting major adverse events only.[17,23] The reporting of the German registry also includes minor adverse events (67.4%), while 31.2% were classified as major complications according to Jacobs et al. [17]

Adverse events among the surgical Index procedures were < 30% after ASD and VSD closure, PVR and treatment of native COA (Tab. 5). Values between 30 – 60% were recorded in patients following AVSD repair, TOF repair, TCPC and arterial switch operation for TGA. As expected patients after Norwood procedures showed the highest adverse event rate (83.5%) (Tab. 5).

The case volume in the category multiple procedures was significantly smaller (356) than isolated surgical or interventional cases (Tab. 5). Although there is presently no risk categorization for these combinations of treatment, the fact that the majority of cases in this group was treated in the first year of life (44.9% newborns, 23.9% infants) suggests that these treatment concepts are performed preferentially in high risk patients with complex congenital heart disease. 71.9% underwent one subsequent and 28.1% required two or more subsequent procedures accounting for a total of 563 procedures (347 operations, 216 interventions). The complexity of this group is also evident in the in-hospital mortality rate of 6.2% and a rate of cases without adverse events of 39.9% (Tab. 5).

**Longitudinal observations tetralogy of Fallot**

The database included 1,795 patients following TOF repair during the 10 years period from 2012 to 2021. Palliative procedures prior to surgical repair were performed in 17.9% of the

patients (Fig. 5). These palliative procedures included interventional (53.6%) and surgical procedures (33.3%) or a combination of both (13.1%). Following surgical repair repeat procedures were recorded in 373 patients (21%). They were less common among patients undergoing primary repair (17%) as compared to patients with preceding palliative procedures (38%). The largest number of repeat procedures was recorded during the first year after repair: 141/1781 patients (7.9%) required at least one additional hospital admission (Fig. 6). This number decreased continuously during the subsequent years resulting in 1.3% of the patients requiring repeat interventional or surgical treatment in the tenth postprocedural year.

**Longitudinal observations coarctation of the aorta**

From 2012 to 2021, the registry recorded 2037 patients following primary treatment of native COA. 883 patients (43.3%) were newborns, 522 infants (25.6%), 500 children and adolescents (24.5%) and 132 were adults (6.5%). Initial treatment was performed by transcatheter intervention in 30.3 % and by surgery in 69.7 % of the patients (Fig. 7). With respect to patients' age there was a clear dominance of surgical strategies in the primary treatment of neonates (89.8%) and infants (82.2%), while interventional procedures dominated the treatment in children and adolescents (63.2%) as well as in adulthood (89.4%). Among patients who underwent interventions balloon dilatation was the preferred method in infants (81.7%) while stent implantation was the dominant procedure in children/adolescents (68.4%) and especially in adults (96.6%). Notably there was also a significant percentage of stent implantations (51.1%) among interventions in the neonatal period. The majority of surgical treatments (86%) was performed in the 1$^{st}$ year of life. Extracorporeal circulation (ECC) was required in 24.7 % of the surgical procedures.

Repeat procedures requiring further hospital admissions were noted in in 39.4% of patients with initial interventional and in 21.3% of patients who underwent primary surgical treatment. The requirement of hospital readmissions was highest in the 1$^{st}$ year of treatment (20.7%) and decreased significantly in the 3$^{rd}$ year to a level < 3%. However, this rate of 2 – 3 % remained quite constant during the following years (Fig. 8).

## Discussion

Since 2012 the German Registry for Cardiac Operations and Interventions in patients with congenital heart disease collects data on interventional and surgical treatment from the neonatal age until adulthood.[10,11] So far, these data cover an entire decade describing the results of current invasive treatment in these complex patients in Germany. The data of each year were summarized in annual reports containing detailed age and risk-related outcome data on key quality indicators for all different case groups and for 15 index procedures (www.dgpk.org, www.dgthg.org). In addition, all participating institutions received a specific center-related report allowing a benchmark of the institutional performance to the national cohort. The underlying paper presents a comprehensive summary of the Annual report 2022 of the German Quality assurance for congenital heart disease. It has to be mentioned that some selected data from the German Registry have already been included in the German Heart report 2022 (Deutscher Herzbericht).[18]

Like in previous years the data of this registry reflect the complexity of congenital heart disease and the complementary nature of interventional and surgical procedures: 56.4% of interventional cases were performed in patients following prior hospital admissions for surgical and/or interventional treatment while preceding procedures were also recorded in 44.3% of the surgical cases. 10.1% of the patients required more than one hospital treatment in 2021.

The overall in-hospital mortality of surgical cases (2.0%) was slightly higher than in 2020 (1.6%) but remained within the average mortality of previous years (1.4 – 2.6%) in the German registry.[10,11] The observed mortality rates correlated with the level of complexity according to the risk categories of the STS-EACTS mortality score.[1] Comparison of the surgical mortality in the German registry 2021 and the expected in-hospital mortality according to the STS-EACTS data base[1] revealed excellent results over the entire range of mortality categories (Tab. 8). This applies as well for data concerning the surgical index procedures VSD-closure, TOF repair, arterial switch operation in TGA, TCPC and Norwood procedure. Both the mortality in the German registry in 2021 and the average mortality over the last 5 years compare favorably to data of the ECHSA database (Tab. 9) published in 2022.[20]

Cases with multiple procedures carried a significantly higher in-hospital mortality of 6.2% reflecting the complex nature of these patients, who were predominantly treated either in

the neonatal age or in infancy (68.8%). The mortality rate was similar compared to 2020[11] and lower than the average mortality of multiple cases (6.2% - 10.4%) observed from 2015 – 2019.[10]

In-hospital mortality among interventional cases (0.4%) was similar compared to data of the German registry from previous years (0.2 – 0.8%).[10,11] It didn't play a significant role among interventional cases, although 42.4% of the cases in 2021 belonged to the risk categories 3 and 4. The frequency of observed adverse events was in the expected range (Tab. 6,7) or below as compared to data published by the CCCPO registry.[2]

The structure of the German registry provides the possibility of longitudinal assessment since readmissions for repeat interventional or surgical treatment can be assigned by the PID, even if the treatment is provided by different centers. Therefore, this report also includes data on 10 years' longitudinal evaluation of TOF patients following corrective surgery and patients following treatment of native COA. Evaluation of children with TOF revealed two groups of patients: While the majority of patients underwent primary surgical repair (82.1%), a smaller group of patients required prior palliative procedures (17.9%). Among these palliative procedures interventions have gained a significant share either as exclusive interventional palliations (53.6%) or as combinations of interventional and surgical palliative procedures (13.1%) confirming trends reported in the international literature.[21] After surgical repair repeat procedures were required less frequently among patients following primary repair (17%) as compared to patients who underwent preceding palliation (38%). In our opinion this can be explained by the fact, that the latter group represents patients with a less favorable anatomic spectrum regarding the morphology of the right ventricular outflow tract and the central pulmonary arteries. This is supported by the fact that 70% of repeat interventional procedures addressed problems of the central pulmonary arteries (61%) or the right ventricular outflow tract (9%). Similar data have been reported in the literature.[22] The annual report 2021 recorded no mortality following TOF repair. This is in accordance with the results of previous years and compares very favorably with data reported from the ECHSA database in 2022 (Tab. 9).[20]

Longitudinal analysis of patients who underwent treatment of native COA revealed significant differences depending on the patients' age, which are certainly also influenced by the underlying morphology of the obstruction. While surgical strategies dominated the

primary treatment in neonates and infants, interventional methods were the preferred treatment in children and adolescents as well as in adults (Fig. 7). The significant number of repeat procedures especially in the first year after initial treatment (20.7%) confirms the complex nature of this cardiovascular malformation (Fig. 8).

**Future perspectives**

The data sets covering surgical and interventional procedures are compatible with the ECHSA database to provide the possibility of future data transfer/migration and international compatibility. STAT mortality categories and Bergersen risk categories as well as adverse events scores will be adjusted according to recent updates to allow continuous comparison with other databases.[7, 20, 23-26] Demands on biocompatibility and longevity are particularly important for medical devices implanted in neonates, children and adolescents for treatment of congenital heart disease.[27,28] To meet the future requirements of an obligatory implant registry the German database started in 2023 to include specific details for ASD- and PDA-occluders as well as PPVI. Implementation of defined surgical devices is provided for 2024.

**Limitations**

The registry is limited by its all-comers registry design and the voluntary participation of patients and institutions. Financial restrictions are due to the fact, that presently the registry does not receive public funding. Financial support of the registry is provided exclusively by the participating centers, the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and the German Society for Pediatric Cardiology and Congenital Heart Defects (DGPK). Comparisons of in-hospital mortality and adverse events of the German registry with results of the STS-EACTS database and the CCCPO registry have to take into consideration, that these data were obtained in different time periods.

**Collaborators**

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**Participating Centers in 2021**

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The responsible bodies for the registry are the German Society for Thoracic and Cardiovascular Surgery (DGTHG) and the German Society for Pediatric Cardiology and Congenital Heart Defects (DGPK). The registry receives financial support by all participating institutions. From 2012 – 2016 the registry was funded by the German Heart Foundation (DHS).

**Conflict of interest**

None declared

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**Abbreviations**

| | |
|---|---|
| AE | Adverse events |
| ASD | Atrial septal defect |
| AVSD | Atrioventricular septal defect |

| | |
|---|---|
| CHD | Congenital heart disease |
| ECC | Extracorporeal circulation |
| GA | General anaesthesia |
| ICU | Intensive care unit |
| PDA | Patent ductus arteriosus |
| COA | Native coarctation |
| ReCOA | Re-Coarctation |
| PVR | Pulmonary valve replacement |
| PPVI | Percutaneous pulmonary valve replacement |
| TCPC | Total cavopulmonary connection |
| TGA | Transposition of the great arteries with intact ventricular septum |
| TOF | Tetralogy of Fallot |
| VSD | Ventricular septal defect |

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| | | | |
|---|---|---|---|
| Patients | 5,439 | 89.85%<br>10.15% | 1 hospital stay<br>≥ 2 hospital stay |
| Cases | 6,122 | 90.38%<br>9.62% | single procedure<br>≥ 2 procedures |
| Procedures | 7,168 | 3,721<br>3,413<br>34 | surgical<br>interventional<br>hybrid |

Tab. 1: Patients, cases and procedures in 2021.

| | Cases | % |
|---|---|---|
| Newborns | 694 | 11.3 |
| Infants | 1,481 | 24.2 |
| Children & adolescents | 3,060 | 50 |
| Adults | 887 | 14.5 |
| Males | 3,307 | 54 |
| Females | 2,815 | 46 |

Tab. 2: Age and gender distribution in 2021

| | Centers | Cases | Age (years)* | Hospital stay (d)* | ICU-stay | GA | Fluoroscopy | Fluoroscopy time (min)* |
|---|---|---|---|---|---|---|---|---|
| Interventions | 23 | 2,931 | | 2.0 (2.0/3.0) | 14.2% | 17.4 % | 95.3% | 11.0 (5.9/19.5) |
| ASD | 22 | 442 | 9.1 (5.4/38.3) | 2.0 (2.0/3.0) | 6.1% | 29.9 % | 82.8% | 4.2 (2.4/7.5) |
| VSD | 13 | 35 | 6.3 (2.3/11.3) | 3.0 (2.0/3.0) | 8.6% | 20.0 % | 97.1% | 16.9 (10.0/26.5) |
| COA | 15 | 61 | 4.1 (0.2/11.1) | 3.0 (2.0/7.0) | 37.7% | 27.9 % | 100% | 6.2 (4.0/9.2) |
| ReCOA | 12 | 23 | 16.8 (10.1/24.0) | 2.0 (2.0/3.0) | 26.1% | 0% | 100% | 9.6 (3.2/12.0) |
| PDA | 22 | 274 | 1.9 (0.6/4.3) | 2.0 (2.0/3.0) | 16.4% | 8.8 % | 100% | 7.0 (4.4/11.4) |
| PPVI | 15 | 101 | 17.8 (14/30.3) | 5.0 (4.0/6.0) | 16.8% | 51.5 % | 100% | 24.4 (16.4/38.3) |

Tab. 3: Interventional cases: Key performance indicators. *Numbers represent median and standard deviation.

| | Centers | Cases | Age (years)* | Hospital stay (d)* | ICU-stay (d)* | Ventilation-period (h)* | CPB (%) | Perfusion time (min)* | Cross-Clamp (%) |
|---|---|---|---|---|---|---|---|---|---|
| Surgical procedures | | 2,810 | | 11 (8/17) | 4 (2/8) | 8 (5/30) | 74.8 | 113 (76/167) | 59.1 |
| ASD | 18 | 172 | 4.0 (2.4/6.0) | 8 (6/9) | 2 (2/3) | 5 (3/7) | 100 | 51 (33/66) | 70.9 |
| VSD | 17 | 233 | 0.4 (0.3/0.8) | 9 (8/12) | 4 (2/6) | 8 (5/50) | 100 | 93 (77/121) | 100 |
| AVSD | 17 | 172 | 0.5 (0.4/2.0) | 12 (8/16) | 6 (3/9) | 12 (6/97.5) | 100 | 137 (102/182) | 98.3 |
| Coa | 14 | 119 | 0.0 (0.0/0.1) | 11(7/17) | 4 (3/7) | 13 (6/50) | 28.6 | 80 (55/109) | 26.1 |
| TGA | 18 | 73 | 0.0 (0.0/0.0) | 21 (18/28) | 10 (8/14) | 51.5 (8/138) | 100 | 155 (134/209) | 100 |
| TOF repair | 18 | 163 | 0.5 (0.4/0.7) | 12 (9/18) | 5 (3/8) | 11 (7/78) | 100 | 136 (106/169) | 100 |
| TCPC | 16 | 174 | 3.8 (3.1/4.4) | 16.5 (13/24) | 5 (3/10) | 7 (5/11) | 100 | 96 (65/124) | 19 |
| Norwood | 14 | 79 | 7 (5/9)** | 45 (34/92) | 28.5 (14/50) | 127 (48/221) | 100 | 210 (162/267) | 100 |
| PVR | 15 | 99 | 17.9 (8.5/30.5) | 9 (8/13) | 3 (2/5) | 8 (6/11) | 99 | 143 (99/182) | 38.4 |

Tab. 4: Surgical cases: Key performance indicators. *Numbers represent median and standard deviation. **In patients with Norwood procedure the median and standard deviation of age are given in days.

| | Mortality/Cases | % | Freedom from AE/Cases | % |
|---|---|---|---|---|
| Cases: Total | 90/6,122 | 1.5 | 4,786/6,122 | 78.2 |
| Interventional cases | 12/2,931 | 0.4 | 2,730/2,931 | 93.1 |
| Surgical cases | 55/2,810 | 2 | 1,897/2,810 | 67.5 |
| Multiple procedure cases | 22/356 | 6.2 | 142/356 | 39.9 |
| Interventional index procedures | | | | |
| ASD | 0/442 | 0 | 423/442 | 95.7 |
| VSD | 0/35 | 0 | 29/35 | 82.9 |
| COA | 0/61 | 0 | 54/61 | 88.5 |
| ReCOA | 0/23 | 0 | 23/23 | 100 |
| PDA | 1/274 | 0.4 | 261/274 | 95.3 |
| PPVI | 0/101 | 0 | 88/101 | 87.1 |
| Surgical index procedures | | | | |
| ASD | 0/172 | 0 | 159/172 | 92.4 |
| VSD | 0/233 | 0 | 191/233 | 82 |
| AVSD | 0/172 | 0 | 110/172 | 64 |
| COA | 0/119 | 0 | 87/119 | 73.1 |
| TGA | 0/73 | 0 | 31/73 | 42.5 |
| TOF repair | 0/163 | 0 | 90/163 | 55.2 |
| TCPC | 4/174 | 2.3 | 85/174 | 48.9 |
| Norwood (< 90 days) | 16/79 | 20.3 | 13/79 | 16.5 |
| PVR | 0/99 | 0 | 78/99 | 78.8 |

Tab. 5: Cases and index procedures: In-hospital mortality and freedom from adverse events.

| Risk Categories | AE/cases | German Registry Rate of AE (%) | 3CPO Registry Rate of AE (%) |
|---|---|---|---|
| Category 1 | 16/240 | 6.7 | 5.2 |
| Category 2 | 55/1,265 | 4.3 | 13 |
| Category 3 | 63/763 | 8.3 | 19 |
| Category 4 | 38/343 | 11.1 | 25 |

Tab. 6: Interventional cases: Comparison of adverse events (AE) in the German registry according to procedure-type risk categories[2] with AE rates (performance data set 05/2008-12/2009) of the 3CPO project [2].

| Adverse events | German Registry AE/patients | German Registry AE rate (%) | CCCPO data set (5/2008-12/2009) AE/patients | CCCPO data set (5/2008-12/2009) AE rate (%) |
|---|---|---|---|---|
| Any AE | 201/2,931 | 6.9 | 858/7,043 | 12.2 |
| AE level 4 and 5 | 47/2,931 | 1.6 | 99/7,043 | 1.4 |

Tab. 7: Interventional cases: Comparison of major AE (severity level 4 and 5 according to Bergersen et al.[2]) in the German registry with AE rates (performance data set 05/2008-12/2009) of the 3CPO project.[2]

| STS-EACTS mortality risk category[1] | German Registry Mortality/patients | German Registry Mortality rate (%) | STS-EACTS[1] mortality rate 2002-2007 (%) |
|---|---|---|---|
| Category 1 | 5/1,083 | 0.5 | 0.8 |
| Category 2 | 17/735 | 2.3 | 2.6 |
| Category 3 | 7/342 | 2.0 | 5.0 |
| Category 4 | 10/349 | 2.9 | 9.9 |
| Category 5 | 14/74 | 18.9 | 23.1 |

Tab. 8: Surgical cases: Comparison of in-hospital mortality in the German registry according to STS-EACTS mortality risk categories[1] with mortality rates (2002-2007) according to O'Brien et al.[1]

| Index procedures | German Registry cases 2021 | Mortality 2021 (%) | German Registry cases 2017-2021 | Mortality 2017 – 2021 (%) | ECHSA Database cases 2016- | ECHSA Database mortality 2016-2021 (%) |
|---|---|---|---|---|---|---|

| | | | | | 2019 | |
|---|---|---|---|---|---|---|
| VSD | 233 | 0 | 1,326 | 0 | 2,503 | 0.4 |
| TOF repair | 163 | 0 | 865 | 0.6 | 249 | 1.2 |
| TGA | 73 | 0 | 430 | 1.4 | 757 | 5.4 |
| TCPC | 174 | 2.3 % | 797 | 1.0 | 420 | 2.9 |
| Norwood | 79 | 20.3 % | 332 | 19.6 | 564 | 28.4 |

Tab. 9: Surgical index cases: Comparison of in-hospital mortality in the German registry with ECHSA Database data according to Bertsimas et al.[20]