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Definition of the complications of cardiac catheterization in children in Slovenia

Opredelitev zapletov srčnih kateterizacij pri otrocih v Sloveniji

Laura Kekec,[1] Rina R Rus,[2,3] Gorazd Mlakar,[2,3] Miroslav Elek[2,3]

Abstract

Background: Although cardiac catheterizations are less invasive compared to cardiac surgical procedures, they have fewer complications, and patients recover faster after them, they are not without complications. With our research, we wanted to identify the population's characteristics, the most common pathologies, types of catheterizations, and complications during catheterizations in our centre, and identify possible risk factors.

Methods: We collected data on all pediatric cardiac catheterizations performed between June 2018 and August 2021. We defined them according to the type of catheterization (diagnostic and therapeutic), weight, age, and sex of the patients, and complexity of pathology. Complications were divided into major and minor, and using the Pearson chi-square test and the Mann-Whitney U test, we determined their correlation with the possible risk factors.

Results: During the mentioned period, 191 cardiac catheterizations (54 diagnostic and 137 therapeutic) were performed in 175 children, of which 95 were boys, and 80 were girls. The children were between a few hours and 18 years old and weighed between 2.6 kg and 85.5 kg. We recorded 9 complications; 5 were major and 4 were minor. With our research, we did not demonstrate a statistically significant relationship between risk factors (body weight, sex, type of catheterization, age of patients, complexity of pathology) and the occurrence of complications.

Conclusion: Most catheterizations were performed in children aged between 1 and 10 years and those weighing between 10 and 40 kg. Slightly more catheterizations were performed in boys; the most frequent were therapeutic catheterizations. The incidence of complications in our centre is comparable to other centres. In our centre, we did not determine the correlation between body weight, sex, type of catheterization, age, the complexity of the pathology, and the incidence of complications.

[1] University Medical Centre Ljubljana, Ljubljana, Slovenia
[2] Department of Cardiology, Division of Pediatrics, University Medical Centre Ljubljana, Ljubljana, Slovenia
[3] Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia

Correspondence / Korespondenca: Laura Kekec, e: laura.kekec@gmail.com

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Izvleček

Izhodišča: Čeprav so srčne kateterizacije v primerjavi s kardiokirurškimi posegi manj invazivne, imajo manj zapletov, bolniki pa po njih hitreje okrevajo, te niso brez zapletov. Z raziskavo smo želeli ugotoviti značilnosti populacije, najpogostejše patologije, vrste kateterizacij, zaplete pri kateterizacijah v našem centru ter opredeliti morebitne dejavnike tveganja.

Metode: Zbrali smo podatke o vseh pediatričnih srčnih kateterizacijah, opravljenih med junijem 2018 in avgustom 2021. Opredelili smo jih glede na vrsto kateterizacije (diagnostične in terapevtske), težo, starost, spol bolnikov in kompleksnost patologije. Zaplete smo ločili na lažje in težje ter z uporabo Pearsonovega testa hi-kvadrat in testa Mann-Whitney U ugotavljali njihovo povezanost z morebitnimi dejavniki tveganja.

Rezultati: V tem obdobju je bilo opravljenih 191 srčnih kateterizacij (54 diagnostičnih in 137 terapevtskih) pri 175 otrocih, od tega pri 95 dečkih in 80 deklicah. Otroci so bili stari od nekaj ur do 18 let, tehtali so od 2,6 kg do 85,5 kg. Zabeležili smo 9 zapletov, od tega 5 težjih in 4 lažje. Z našo raziskavo nismo dokazali statistično pomembne povezave med dejavniki tveganja (telesna teža, spol, vrsta kateterizacije, starost, kompleksnost patologije) in pojavom zapletov.

Zaključek: Največ kateterizacij je bilo opravljenih pri otrocih, starih med 1 letom in 10 let in tistih, ki so tehtali med 10 in 40 kg. Nekoliko več kateterizacij je bilo opravljenih pri dečkih. Najpogostejše so bile terapevtske kateterizacije. Pojavnost zapletov v našem centru je primerljiva z drugimi centri. Telesna teža, spol, starost otroka, vrsta kateterizacije in kompleksnost patologije v našem centru niso bili statistično značilno povezani s pojavom zapletov ob katerizaciji.

1 Introduction

Cardiac catheterization is a procedure in which an operator inserts a thin, flexible tube (catheter) through a vessel (artery or vein) into the heart. When catheterizing the right heart, the catheter is inserted antegrade through the vein (mostly femoral vein in children) and in catheterization of the left heart retrogradely through the artery (mostly femoral artery in children). Cardiac catheterizations can be diagnostic, in which structures are visualized with the help of X-ray and contrast dye, and pressures and blood oxygen saturation are measured. Moreover, they can be therapeutic when a procedure is performed to resolve a pathological condition, which in pediatric cardiology means the creation of inter-atrial communication, closure of the PDA (patent ductus arteriosus), ASD (atrial septal defect), PFO (patent foramen ovale), or VSD (ventricular septal defect), balloon dilation of narrowed vessels and valves, insertion of stents into vascular and cardiac structures, and insertion of biological valves.

Because cardiac catheterizations are less invasive compared to cardiac surgery, have fewer complications and patients recover faster, they are being performed more and more frequently. Sometimes, they can also allow for a temporary improvement of the heart defect, which can postpone an otherwise necessary surgical intervention to a later time.

Despite the less invasive nature of cardiac catheterizations, they are not without complications. Research (1-7) has shown that complications occur in 5.5-19% of pediatric cardiac catheterizations, with 1.4-6.2% being major, potentially life-threatening, and 4.1-16.3% minor, resolved with or without treatment. Mortality of paediatric cardiac catheterizations is 0.14-0.4% (1-7). The most frequently recorded are arrhythmias, bleeding, vein thrombosis, device embolization, and perforation of the heart walls or vessels (1-7).

With the research, we wanted to determine the characteristics of the population, the most common pathologies, types of catheterizations, and complications during catheterizations in our centre, and identify potential risk factors.

2 Methods

Our research took place at the Cardiology Department of the Paediatric Clinic in Ljubljana. We retrospectively collected data on cardiac catheterizations from the files of children with heart disease aged 0 to 18 years. In the research we included those children who underwent cardiac catheterization between June 2018 and August 2021. We separated catheterisations into diagnostic or therapeutic and classified each into 4 main groups: isolated cyanotic and acyanotic congenital heart defects (CHD), which are clearly defined CHD or defect associations in the literature, and combined cyanotic and acyanotic defects with the presence of at least two different CHD that are individually described in the literature. We also calculated the share that an individual

pathology or a group of pathologies represents within the type of catheterization. Next, we analyzed interventions that were performed during therapeutic catheterizations. We divided them into three main groups: closure devices use, balloon dilatations, and other therapeutic catheterizations. For each group, we listed which procedures and how often they were performed and calculated the proportion of all procedures performed as part of therapeutic catheterizations (with one therapeutic catheterization, several procedures could be performed). For ASD and/or PFO closure, we used Amplatzer septal occluders (Abbot, United States of America); for PDA closure MReye Flipper Coil (COOK Medical, United States of America) and Amplatzer PDA closure devices (ADO I, ADO II, Piccolo) (Abbot, United States of America). Z5 atriseptostomy balloon catheters with a balloon size of 13.5 mm (NuMed, Lebanon) were used for atrioseptostomies.

Following, we focused on the number of complications. We divided them into major and minor complications and calculated their share. Following the example of foreign literature (1,2,7), we defined more severe complications as those that are potentially life-threatening and require immediate treatment (for example, complications that require intervention or surgery, blood transfusion, more severe infections, more severe arrhythmias that cause decompensation), and minor complications are those that are not life-threatening and resolve on their own or with specific treatment (for example bleeding that stops after a few minutes, arrhythmias that stop on their own or after specific treatment and do not cause decompensation). We focused on complications arising from the catheterization procedure and excluded those arising from anesthesia. We also took into account the type of catheterization (diagnostic, therapeutic), sex, age, body weight of the children and the complexity of pathology, determining whether any of these factors are correlated with the occurrence of complications.

To calculate the statistical significance of the correlation of the occurrence of complications with the type of catheterization and sex, we used the Pearson chi-square test. The Mann-Whitney U test was used to calculate the statistically significant correlation of age, weight, and complexity of pathology. The p-value was calculated based on the total number of complications (major and minor combined) in each category. A value of $p < 0.05$ was used as the limit of statistical significance.

3 Results

3.1 Population

Between June 2018 and August 2021, 191 cardiac catheterizations were performed in our centre in 175 children, 95 boys (M) and 80 girls (F). The children ranged in age from a few hours to 18 years, with a median age of 5 years (interquartile range (IQR) = 9.1 years). They weighed between 2.6 kilograms (kg) and 85.5 kg; the median body weight was 17.9 kg (IQR = 31.7 kg) (Table 1).

Table 1: Characteristics of the population undergoing cardiac catheterization.

Property	Value	Diagnostic n (%)	Therapeutic n (%)	Combined n (%)
Age	< 1 month	3 (5.6)	20 (14.6)	23 (12.0)
	1-11 months	9 (16.7)	21 (15.3)	30 (15.7)
	1-9,9 years	24 (44.4)	66 (48.2)	90 (47.1)
	≥ 10 years	18 (33.3)	30 (21.9)	48 (25.1)
Sex	Men	37 (68.5)	71 (51.8)	108 (56.5)
	Female	17 (31.5)	66 (48.2)	83 (43.5)
Weight	< 4 kg	1 (1.9)	21 (15.3)	22 (11.5)
	4-9,9 kg	12 (22.2)	26 (19.0)	38 (19.9)
	10-39,9 kg	23 (42.6)	62 (45.3)	85 (44.5)
	≥ 40 kg	18 (33.3)	28 (20.4)	46 (24.0)

3.1.1 Diagnostic catheterizations

A total of 54 diagnostic catheterizations were performed (M:37, F:17) in 49 children (M:33, F:16). Re-catheterization was required five times, once in a girl and four times in boys (of which twice in the same boy). Children were aged 5 days to 18 years, with a median age of 6.75 years (IQR = 11.4 years). They weighed between 3.9 kg and 80.4 kg, with a median weight of 20.7 kg (IQR = 32.9 kg) (Table 1).

3.1.2 Therapeutic catheterizations

There were 137 therapeutic catheterizations (M:71, F:66) performed in 127 children (M:63, F:64). There were ten therapeutic re-catheterizations, twice in girls and 8 times in boys (of which twice in the same boy). One of the boys had previously undergone a diagnostic catheterization. The children were aged from a few hours to 17 years, with a median age of 4 years (IQR = 8.5 years). They weighed from 2.6 kg to 85.5 kg, with a median weight of 17.2 kg (IQR = 30.0 kg) (Table 1).

3.2 Initial pathologies

3.2.1 Diagnostic catheterizations

Table 2 shows the types of heart defects in children who underwent diagnostic catheterization; 32 catheterizations were performed in children with isolated heart defects, and 22 catheterizations in children with combined heart defects.

Table 2: Initial pathologies of patients who underwent diagnostic catheterization.

PATHOLOGY	MALE n (%)	FEMALE n (%)	TOTAL n (%)
Isolated cyanotic defects	**8 (24.2)**	**6 (37.5)**	**14 (28.6)**
HLH	*7 (21.2)*	*1 (6.3)*	*8 (16.3)*
Truncus arteriosus	*0*	*3 (18.8)*	*3 (6.1)*
TOF	*0*	*2 (12.5)*	*2 (4.1)*
TGA	*1 (3.0)*	*0*	*1 (2.0)*
Isolated acyanotic defects	**11 (33.3)**	**5 (31.3)**	**16 (32.7)**
Coarctation of the aorta	*4 (12.1)*	*0*	*4 (8.1)*
VSD	*3 (9.1)*	*0*	*3 (6.1)*
Coronary artery diseases	*1 (3.0)*	*2 (12.5)*	*3 (6.1)*
PDA	*1 (3.0)*	*1 (6.3)*	*2 (4.1)*
ASD/PFO	*0*	*1 (6.3)*	*1 (2.0)*
AVSD	*1 (3.0)*	*0*	*1 (2.0)*
AV stenosis	*1 (3.0)*	*0*	*1 (2.0)*
PAPVC	*0*	*1 (6.3)*	*1 (2.0)*
Combined cyanotic defects	**7 (21.2)**	**3 (18.8)**	**10 (20.4)**
Combined acyanotic defects	**7 (21.2)**	**2 (12.5)**	**9 (18.4)**
TOGETHER	**33 (100.0)**	**16 (100.0)**	**49 (100.0)**

Legend: HLH –hypoplastic left heart; TOF – tetralogy of Fallot; TGA – transposition of great arteries; VSD – ventricular septal defect; PDA – patent ductus arteriosus; ASD – atrial septal defect; PFO – patent foramen ovale; AVSD – atrioventricular septal defect; AV – aortic valve; PAPVC – *angl.* partial anomalous pulmonary venous connection.

Table 3: Initial pathologies of patients who underwent therapeutic catheterization.

PATHOLOGY	MALE n (%)	FEMALE n (%)	TOTAL n (%)
Isolated cyanotic defects	**7 (11.1)**	**5 (7.8)**	**12 (9.4)**
TGA	*3 (4.8)*	*2 (3.1)*	*5 (3.9)*
DORV	*2 (3.2)*	*1 (1.6)*	*3 (2.4)*
TOF	*0*	*1 (1.6)*	*1 (0.8)*
HLH	*1 (1.6)*	*0*	*1 (0.8)*
Truncus arteriosus	*1 (1.6)*	*0*	*1 (0.8)*
Pulmonary atresia	*0*	*1 (1.6)*	*1 (0.8)*
Isolated acyanotic defects	**43 (68.3)**	**47 (73.4)**	**90 (70.9)**
ASD/PFO	*12 (19.0)*	*20 (31.2)*	*32 (25.2)*
PDA	*7 (11.1)*	*13 (20.3)*	*20 (15.7)*
AV stenosis	*9 (14.3)*	*5 (7.8)*	*14 (11.0)*
PV stenosis	*10 (15.9)*	*4 (6.3)*	*14 (11.0)*
Coarctation of the aorta	*3 (4.8)*	*4 (6.3)*	*7 (5.5)*
Aortic arch stenosis	*2 (3.2)*	*0*	*2 (1.6)*
Interruption of the aortic arch	*0*	*1 (1.6)*	*1 (0.8)*
Combined cyanotic defects	**10 (15.9)**	**6 (9.4)**	**16 (12.6)**
Combined acyanotic defects	**3 (4.8)**	**6 (9.4)**	**9 (7.1)**
TOGETHER	**63 (100.0)**	**64 (100.0)**	**127 (100.0)**

Legend: TGA – transposition of great arteries; DORV – double outlet right ventricle; TOF – tetralogy of Fallot; HLH – hypoplastic left heart; ASD – atrial septal defect; PFO – patent foramen ovale; PDA – patent ductus arteriosus; AV – aortic valve; PV – pulmonary valve.

3.2.2 Therapeutic catheterizations

Table 3 shows the types of heart defects in children who underwent therapeutic catheterization; 110 catheterizations were performed in children with isolated heart defects and 27 catheterizations in children with combined heart defects.

3.3 Procedures during therapeutic catheterizations

As part of 137 therapeutic catheterizations, 143 procedures were performed. Interventions as part of therapeutic catheterizations are shown in more detail in Table 4.

3.4 Complications

Table 5 shows the number of complications according to the type of catheterization, age, gender, body weight and the complexity of the pathology. We found that the occurrence of complications is not correlated with the listed risk factors ($p > 0.05$).

3.4.1 Major complications

We recorded embolisation of the occluder during ASD closure twice, when in one case it was necessary to remove the occluder from the femoral artery surgically, and in the other case with a catheter, which means 5.9% frequency (95% confidence interval (CI): 0.7%-19.7 %)

Table 4: Procedures during therapeutic catheterizations.

INTERVENTION	MALE n (%)	FEMALE n (%)	TOTAL n (%)
Closing with closure devices	**24 (32.9)**	**37 (52.9)**	**61 (42.7)**
ASD/PFO closure	*13 (17.8)*	*21 (30.0)*	*34 (23.8)*
Closing the PDA	*8 (11.0)*	*15 (21.4)*	*23 (16.1)*
Closing the fenestration	*1 (1.4)*	*1 (1.4)*	*2 (1.4)*
Closing the left VCS	*1 (1.4)*	*0*	*1 (0.7)*
Closing MAPCA	*1 (1.4)*	*0*	*1 (0.7)*
Balloon dilations	**35 (48.0)**	**25 (35.7)**	**60 (42.0)**
Balloon dilatation of the PV	*11 (15.1)*	*11 (15.7)*	*22 (15.4)*
Balloon dilatation of AV	*12 (16.4)*	*5 (7.1)*	*17 (11.9)*
Balloon dilatation of coarctation of the aorta	*4 (5.5)*	*4 (5.7)*	*8 (5.6)*
Balloon dilatation of the pulmonary arteries	*2 (2.7)*	*4 (5.7)*	*6 (4.2)*
Balloon dilatation of the aortic arch	*3 (4.1)*	*1 (1.4)*	*4 (2.8)*
Balloon dilatation of the homograft	*2 (2.7)*	*0*	*2 (1.4)*
Neoaortic balloon dilatation	*1 (1.4)*	*0*	*1 (0.7)*
Other	**14 (19.2)**	**8 (11.4)**	**22 (15.4)**
Balloon atrioseptostomy	*11 (15.1)*	*7 (10.0)*	*18 (12.6)*
Insertion of the Melody (pulmonary) valve	*1 (1.4)*	*1 (1.4)*	*2 (1.4)*
Removing the closure device	*1 (1.4)*	*0*	*1 (0.7)*
Stent insertion into the homograft	*1 (1.4)*	*0*	*1 (0.7)*
TOGETHER	**73 (100.0)**	**70 (100.0)**	**143 (100.0)**

Legend: ASD – atrial septal defect; PFO – patent foramen ovale; PDA – patent ductus arteriosus; VCS – vena cava superior; MAPCA – major aortopulmonary collateral arteries; PV – pulmonary valve; AV – aortic valve.

of occluder embolisation during this procedure. We also recorded more severe bleeding with the need for blood transfusion (0.5% frequency, 95% CI: 0.01%-2.9%) and infection requiring double-line antibiotic therapy (0.5% frequency, 95% CI: 0.01%-2.9%); both complications occurred after diagnostic catheterizations. One perforation with cardiac tamponade during balloon atrioseptostomy required urgent surgery (0.5% frequency, 95% CI: 0.01%-2.9%).

3.4.2 Minor complications

In two cases, we recorded SVT (supraventricular tachycardia) (1.1% frequency, 95% CI: 0.1%-3.7%); these occurred during diagnostic catheterization and during balloon dilatation of coarctation of the aorta. We recorded one minor bleeding from the puncture site (0.5% frequency, 95% CI: 0.01%-2.9%) and one slippage of the wire into the pericardial space, without registered apparent pericardial effusion (0.5% frequency, 95% CI: 0.01%-2.9%), both occurred during pulmonary valve (PV) dilatation.

3.5 Catheterization performers

In our centre, most of the catheterizations were performed by three different pairs of doctors. Pair A

Table 5: Number of complications according to catheterization type, age, sex, body weight and complexity of pathology.

Risk factor	Value	Major complications n (%) OR (95% CI)	Minor complications n (%) OR (95% CI)	Combined n (%) OR (95% CI)	Total catheterizations
Type p = 0.730	Diagnostic	2 (3.7) 1.72 (0.28-10.58)	1 (1.9) 0.84 (0.09-8.28)	3 (5.6) 1.28 (0.31-5.33)	54
	Therapeutic	3 (2.2) 1 (reference)	3 (2.2) 1 (reference)	6 (4.4) 1 (reference)	137
Age p = 0.086	< 1 month	1 (4.3) 1 (reference)	2 (8.7) 1 (reference)	3 (13.0) 1 (reference)	23
	1-11 months	2 (6.7) 1.57 (0.13-18.48)	1 (3.3) 0.36 (0.03-4.26)	3 (10.0) 0.74 (0.14-4.06)	30
	1-9.9 years	1 (1.1) 0.25 (0.01-4.11)	1 (1.1) 0.12 (0.01-1.36)	2 (2.2) 0.15 (0.02-0.97)	90
	≥ 10 years	1 (2.1) 0.47 (0.03-7.83)	0	1 (2.1) 0.14 (0.01-1.45)	48
Sex p = 0.530	Male	3 (2.8) 1.16 (0.19-7.09)	3 (2.8) 2.34 (0.24-22.94)	6 (5.6) 1.57 (0.38-6.47)	108
	Female	2 (2.4) 1 (reference)	1 (1.2) 1 (reference)	3 (3.6) 1 (reference)	83
Weight p = 0.088	< 4 kg	1 (4.5) 1 (reference)	2 (9.1) 1 (reference)	3 (13.6) 1 (reference)	22
	4-9.9 kg	2 (5.3) 1.17 (0.1-13.66)	1 (2.6) 0.27 (0.02-3.17)	3 (7.9) 0.54 (0.1-2.96)	38
	10-39.9 kg	1 (1.2) 0.25 (0.02-4.16)	1 (1.2) 0.12 (0.01-1.38)	2 (2.4) 0.15 (0.02-0.98)	85
	≥ 40 kg	1 (2.2) 0.47 (0.03-7.83)	0	1 (2.2) 0.14 (0.01-1.44)	46
Patologija p = 0.186	Isolated defect	2 (1.4) 0.22 (0.04-1.35)	3 (2.1) 1.04 (0.11-10.2)	5 (3.5) 0.41 (0.11-1.6)	142
	Combined defect	3 (6.1) 1 (reference)	1 (2.0) 1 (reference)	4 (8.1) 1 (reference)	49

Legend: OR – odds ratio; CI – confidence interval. The p-value was calculated based on the total number of complications (major and minor combined) in each category. A value of $p < 0.05$ was used as the limit of statistical significance.

performed 88 catheterizations with 5 complications (3 minor and 2 major). Pair B performed 86 catheterizations with 4 complications (2 minor and 2 major). Pair C performed 4 catheterizations with no complications. Five catheterizations were performed by other doctors, and there were no complications.

4 Discussion

Between July 2018 and August 2021, 191 cardiac catheterizations were performed on children up to 18 years of age at the Paediatric Clinic of the University Hospital Ljubljana. As in many other centres (3,5,7,8), therapeutic interventions were also in majority in our case. Vitiello *et al.* (2) found that the share represented by therapeutic procedures in their centre increased from 14% to 43% from 1987 to 1993, which could indicate a shift in the direction of therapeutic catheterizations over the years. However, some recent studies did not confirm the increase in therapeutic catheterizations (1,4).

Diagnostic catheterizations were performed more often in boys, while in therapeutic catheterizations the

sex ratio was equal. We did not find data on the sex ratio specifically for diagnostic or therapeutic catheterizations, but most centres reported the sex ratio as equal for all catheterizations performed (2,3).

The most therapeutic catheterizations were performed in children aged between 1 and 10 years. Our experience was similar to that of some other centres. Bergersen *et al.* (5) reported that 33% of diagnostic catheterizations were performed in children over 10 years and 30% in children between 1 and 10 years of age. 42% of therapeutic catheterizations were performed in children aged between 1 and 10 years. Ravndal *et al.* (3) stated that most were performed in children aged between 1 and 10 years (50.7% of all catheterizations). Furthermore, in our centre, catheterizations were most often performed in children who weighed between 10 and 40 kg, which coincides with the age at which most catheterizations were performed. Similarly, Ravndal *et al.* (3) described that 61.8% of all catheterizations were performed in children who weighed more than 10 kg. The reason for the highest number of catheterizations performed in the period from 1 to 10 years is most likely that in children with congenital heart defects during this period it is most often time for additional invasive diagnostic procedures to monitor the condition or before planned surgery. It is also necessary to correct the pathology in time with therapeutic intervention, which can otherwise leave significant consequences for the heart. If possible, certain invasive procedures such as ASD closure, vascular stenting, or pulmonary valve implantation are avoided in younger children because complications are more common (1-3,6-9), and the child may outgrow the implanted material, which might cause problems.

The most common pathologies in diagnostic catheterization were isolated acyanotic and isolated cyanotic heart defects. Isolated defects are easier to identify with other non-invasive methods, while complex congenital heart defects or combinations of defects usually require additional invasive diagnostics. This higher frequency may be attributed to isolated defects being more common than combined defects, both in general and in our population. In our population, diagnostic catheterization was most often performed in children diagnosed with hypoplastic left heart (HLH). In the literature, few centres reported which were the most common pathologies in diagnostic catheterizations. Yilmazer *et al.* (1) observed VSD and tetralogy of Fallot (TOF) as the most common pathologies, while Bergersen *et al.* (5,6) reported a higher proportion of complex heart defects. The latter, therefore, most likely depends on the incidence of certain congenital heart defects and the experience of the individual centre.

In almost three-quarters of cases, children with an isolated acyanotic heart defect had therapeutic catheterization. The most common pathologies for which therapeutic catheterization was performed were found in only one research, where they were performed in 61% of complex and 34% of isolated defects (5). However, Mori *et al.* reported that 83.2% of all catheterizations were performed in complex pathologies (4). Differences also somewhat depend on the definition of groups of pathologies; while we divided them into isolated and combined, some divided them further into isolated, complex and heart defects without a structural defect (4) or into even more groups (5). Almost half of the therapeutic catheterizations performed in our centre (42.7%) involved closing defects with closure devices (closure of ASD/PFO and PDA). Balloon dilatation of PV and aortic valve (AV), and balloon atrioseptostomy were performed in most other cases (42%). At some centres, ASD and PDA closure procedures prevailed (3,5), while at others, balloon dilatation of valves, especially PV, prevailed (1).

Among all catheterizations performed, 9 (4.7%) complications were noted. Based on the number of catheterizations performed, this gives a 95% confidence interval between 2.1% and 8.8%, which is at the lower end of the complication rates of some other centres performing pediatric cardiac catheterizations (1-7), which state that the rate is between 5.5% and 19%. In the case of minor complications, we note a frequency of 2.1% (95% CI 0.6%-5.3%), which is slightly less compared to foreign centres (between 4.1% and 16.3%) (1-7). For major complications, which we recorded in 2.6% (95% CI 0.9%-6.0%), we note a similar frequency as in foreign centres (between 1.4% and 6.2%) (1-7). According to foreign data, death due to catheterizations occurred in 0.14% to 0.4% (1-7), while we did not record any deaths.

In our centre, the most common complications recorded were arrhythmias, bleeding, and embolization of the closure during ASD closure. The most common major and minor complications in foreign literature include arrhythmias and vascular thrombosis (1-5,7). Minor bleeding and damage to blood vessels or myocardium are also common complications (3,4).

According to foreign data, the probability of embolisation of the closure device during ASD closure ranges from 0.05 % to 9.4% (average 4.46%) (1,10-13); in our case, we determined it as 5.9%. The lower probability of closure device displacement was in studies in which adults were also included or in studies with higher average age. In our case, the embolisation occurred in 2

patients aged 8 and 16 years. A higher percentage of embolisations was observed in studies where the sample of all ASD closures was smaller, and different closing devices than those in our centre were used (1,10). With a better selection of patients suitable for transcatheter closure of ASD, as well as with a better selection of the occluder size, the number of complications can be reduced, and as the number of performed catheterizations increases, so does operator experience.

Severe bleeding as a complication was recorded in 0.5%, compared to other centres where it occurred, in 0.01% to 0.1% (average 0.04%) (5-7). A confidence interval between 0.01% and 2.9% indicates the frequency of the mentioned complication within the frequency limits of other centres. Moreover, bleeding occurred in a 2-month-old baby weighing 6.3 kg, where even a small amount of blood loss means a greater percentage of the total volume, hastening the need for transfusion. The frequency of minor bleeding in our centre was 0.5%, similar to other centres where it ranged between 0.2% and 0.6% (mean 0.46%) (2,4-7).

Perforation of the heart wall and tamponade during balloon atrioseptostomy, a procedure with a high risk of the above complication, occurred in one case, representing 0.5% of all cases. According to foreign research data, serious perforations of the heart walls occurred between 0.04% and 0.35% of cases (2,4-7). The complication happened in a few-hour-old baby weighing 3.4 kg, whose heart structures are smaller and catheterizations are technically more difficult. Balloon atrioseptostomy is a rather invasive, imperfectly controlled and high-risk catheter procedure. In one case, there was a perforation of the heart wall with minimal effusion and no further complications, which means a frequency of 0.5% in our centre. In other centres, minor cardiac perforations were described in 0.05% to 0.16% of cases (average 0.1%) (2,5-7). According to the confidence interval (in both cases between 0.01% and 2.9%), the proportions are consistent with the frequency in other centres.

Infection of catheterization site occurred in one patient, representing 0.5% of all catheterizations, while other centres again reported infection rates between 0.02% and 0.1% (mean 0.06%) (5,6). With a confidence interval of between 0.01% and 2.9%, our experience is similar to that of other centres. Since all children received a preventive dose of antibiotics, the number of infection cases is low.

The frequency of SVT occurrence during catheterizations in other centres was between 0.2% and 0.6% (average 0.43%) (1,2,7), and the frequency of rhythm disturbances (in both cases of SVT) in our centre was 1.0%, with a confidence interval between 0.1% and 3.7%, corresponding to the experience of other centres.

The incidence of complications in diagnostic catheterizations was 5.6%, and in therapeutic 4.4%, so the probability between both types is similar ($p = 0.730$). Our findings are consistent with the studies of some foreign centres (7), while others indicate an increased probability of complications during therapeutic procedures (1-3,5,6). Mehta *et al.* reported a higher incidence of major complications in therapeutic procedures, while the incidence of minor complications did not correlate with the type of catheterization (7). The incidence of complications in our centre also was not correlated with the type of therapeutic procedure. In foreign literature, the most complications were observed in balloon dilatation of the aorta or AV (1,2). The difference may be explained by the fact that in our balloon dilatation centre we only use low-pressure balloons (Tyshak balloon catheter, NuMed, Libanon), while the materials of other centres were not stated. We also note that the incidence of complications was not correlated with sex, since complications were found in 5.6% of all boys and 3.6% of all girls ($p=0.530$). Again, the findings differ depending on the centre; some noted a higher incidence in men (7), while others did not observe any differences between the sexes (1). We did not find statistically significant differences according to age ($p = 0.086$) or weight ($p = 0.088$), but it can be noted that complications occurred somewhat more often in younger and lighter children. They occurred in 13.0% of children under 1 month of age, 10.0% of those aged 1 to 11 months and in only 2.1% of children 1 year of age or older. The reason is likely that children of this age are lighter and smaller, their vascular and heart structures also being smaller, so procedures are technically more difficult to perform. Moreover, with more complex defects, catheterizations are required at a younger age, which might increase the likelihood of complications. We also observed that complications occurred in 13.6% of all children weighing less than 4 kg and 8.3% of children weighing between 4 kg and 9.9 kg (a total of 10.3% of children weighing < 10 kg), but only 2.4% for those weighing 10 kg or more. Despite this, we could not demonstrate any statistically significant differences regarding the more frequent occurrence of complications in lighter children. Some other centres stated an increased probability of complications in children younger than 1 month or younger than 2 years and in children weighing less than 4 kg or less than 10 kg (1-3,6-9). Complications were found in 3.5% of all children with an isolated and in 8.1% of children with a combined birth defect; we did not find any statistically significant

difference in the frequency of complications according to the complexity of the pathology. Similarly, Mori *et al.* (4) determined the frequency of complications in 5.6% of patients with complex and 7.4% of children with an isolated congenital heart defect; no statistically significant differences were found between them, while Bergersen *et al.* (6) found the presence of complications in 18% of children with an isolated defect, 25% of children with a complex defect with one ventricle, and 26% of children with a complex defect with two ventricles. The cause of the differences between the centres might be different definitions of pathologies, as we separated them into isolated and combined, and the centres above into isolated and complex. Also, the reason for the differences may be the way complications were recorded, as both Mori *et al.* and Bergersen *et al.* (4,6) recorded data prospectively, while we recorded them retrospectively. The frequency of complications in our centre was also not correlated with the catheterization providers.

4.1 Limitations and possible improvements of the research

The main limitation of our study is the small size of our patient sample. The comparison with some other centres may be less applicable due to possible different techniques or materials and different definitions of groups of initial pathologies and complications. There may also be differences in the inclusion and exclusion criteria for complications. Some centres also included transient arrhythmias as complications, which we did not, nor did we record the number of minor haematomas, which may have contributed to a lower incidence of minor complications. Differences in the proportion of some complications can also be attributed to retrospective data collection.

For a better comparison with foreign centres, it would be necessary to have a larger number of catheterisations. Following the example of other research (5,6,9), the association of other factors with the occurrence of complications could be studied in the future. Factors that could be considered include risk assessment of the procedure, risk assessment according to the pathology, whether catheterization is urgent or elective, the duration of catheterization and fluoroscopy, the amount of contrast used, and hemodynamic indicators of patient vulnerability. For a complete assessment of the occurrence of complications, complications due to anesthesia should also be included. For easier comparison with foreign centres, the complications could be divided into several groups according to the severity level of the complication (none, minor, moderate, major, catastrophic) (5), which did not make sense in our case with a small number of catheterizations and complications. With prospectively designed research, more data could be collected in a targeted manner, which would also be recorded more precisely.

5 Conclusion

In our research, we presented all catheterizations performed at the Paediatric Clinic in Ljubljana between June 2018 and August 2021. We divided them into diagnostic and therapeutic and identified all procedures performed during therapeutic catheterizations. The results show that therapeutic catheterizations are predominant in our centre and that most catheterizations were performed in children aged between 1 and 10 years and those weighing between 1 and 40 kg. More catheterizations were performed in boys.

We found that the incidence of complications in our centre is comparable to other centres. We classified the complications into minor and major. Body weight, sex, age of the child, complexity of pathology or type of catheterisation were not statistically significantly correlated with the occurrence of complications during catheterization in our centre.

Conflict of interest

None declared.

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