



Evaluation of contraceptive methods in women with congenital heart disease in Germany, Hungary and Japan



M.-A. Koerten^{a,b,j}, A. Szatmári^c, K. Niwa^d, Z. Ruzsa^e, N. Nagdyman^{a,f,j}, E. Niggemeyer^b, B. Peters^g, K.T.M. Schneider^h, B. Kuschel^h, Y. Mizunoⁱ, F. Berger^{fj}, U.M.M. Bauer^{b,*}, H. Kaemmerer^{aj}

^a German Heart Centre Munich, Department of Paediatric Cardiology and Congenital Heart Defects, Technical University of Munich, Germany

^b Competence Network for Congenital Heart Defects, Berlin, Germany

^c Gottsegen Hungarian Institute of Cardiology, Pediatric Cardiac Centre, Budapest, Hungary

^d St. Luke's International Hospital, Tokyo, Japan

^e University of Szeged, Medical Faculty, 2nd Department of Medicine and Cardiology Center, Division of Invasive Cardiology, Szeged, Hungary

^f German Heart Institute Berlin, Department of Congenital Heart Disease and Pediatric Cardiology, Berlin, Germany

^g Otto-von-Guericke University of Magdeburg, Germany

^h Frauenklinik, Klinikum rechts der Isar, Technische Universität München, Munich, Germany

ⁱ Chiba Cardiovascular Center, Department of Adult Congenital Heart Disease and Pediatrics, Ichihara, Japan

^j DZHK (German Centre for Cardiovascular Research), Partner Site Munich, Germany

ARTICLE INFO

Article history:

Received 14 July 2015

Received in revised form 10 November 2015

Accepted 28 December 2015

Available online 30 December 2015

Keywords:

Congenital heart disease

Women

Contraception

Multicentre study

Pregnancy associated cardiovascular risk

ABSTRACT

Aims: For women with congenital heart defects (CHD), pregnancy may pose a health risk. Sexually active women with CHD without the desire for own children or for whom pregnancy would imply considerable health risks require adequate counselling regarding appropriate contraception. This study gathers data on the contraceptive behaviour of women with CHD from three different cultural regions.

Methods and results: 634 women with CHD from Germany, Hungary and Japan were surveyed regarding contraception and contraceptive methods (CM) used. The patients were divided into groups according to different criteria such as pregnancy associated cardiovascular risk or “safety” of the contraceptive methods used. 59% of the study participants had already gained experience with CM. The average age at the first time of use was 18.4 years; the German patients were significantly younger at the first time of using a CM than those from Hungary and Japan. Overall the condom was the method used the most (38%), followed by oral contraceptives (30%) and coitus interruptus (11%). The range of CM used in Japan was much smaller than that in Germany or Hungary. Unsafe contraceptives were currently, or had previously been used, by 29% of the surveyed patients (Germany: 25%, Hungary: 37%, Japan: 32%).

Conclusion: Most women with CHD use CM. There are differences between the participating countries. Adequate contraceptive counselling of women with CHD requires considering the individual characteristics of each patient, including potential contraindications. For choosing an appropriate CM, both the methods’ “safety”, as well as the maternal cardiovascular risk, are important.

© 2015 Elsevier Ireland Ltd. All rights reserved.

1. Background

Almost all patients with a congenital heart defect (CHD) nowadays reach adulthood [1]. With the increase in both life expectancy and quality of life, adults with CHD (ACHD) often develop the wish for starting a family and having children. However, particularly in patients with CHD, the haemodynamic changes associated with pregnancy can cause cardiac complications [2,3]. The risk of complications such as heart failure and rhythm disorders increases with an

increasing complexity of the underlying heart anomaly. In some cases, a pregnancy is contraindicated due to the high maternal risk it poses and should thus be prevented by means of effective contraception; otherwise, termination of pregnancy might become necessary [2,4,5,6]. The guidelines of the European Society of Cardiology (ESC) on the management of cardiovascular diseases during pregnancy of 2011 recommend a risk stratification of pregnant women with CHD according to the guidelines of the World Health Organization (WHO) [7]. An overview of the risk classes and management recommendations can be found in Table 1. The modified WHO classification for the maternal cardiovascular pregnancy associated risk in women with CHD is shown in Table 2.

Sexually active women who have no desire for a child or for whom becoming pregnant would represent an unwarranted health threat

* Corresponding author at: Competence Network for Congenital Heart Defects, Augustenburger Platz 1, 13353, Berlin, Germany.

E-mail addresses: niggemeyer@kompetenznetz-ahf.de (M.-A. Koerten), ubauer@kompetenznetz-ahf.de (U.M.M. Bauer).

Table 1
Modified WHO classification of maternal cardiovascular risk (according to [7]).

Risk class	Risk of pregnancy by medical condition	Recommendation
I	No detectable increased risk of maternal mortality and no/mild increase in morbidity.	Cardiology follow-up during pregnancy may be limited to one or two visits.
II	Small increased risk of maternal mortality or moderate increase in morbidity.	Cardiology follow-up every trimester
III	Significantly increased risk of maternal mortality or severe morbidity. Expert counselling required.	If pregnancy is decided upon, intensive specialist cardiac and obstetric monitoring are needed throughout pregnancy, childbirth and the puerperium. Frequent (monthly or bimonthly) cardiology and obstetric review during pregnancy is recommended.
IV	Extremely high risk of maternal mortality or severe morbidity; Pregnancy contraindicated.	If pregnancy occurs termination should be discussed. If pregnancy continues, care as for class III.

require adequate counselling concerning appropriate and efficient contraception to prevent pregnancy.

In the present study, data on the contraceptive behaviour of women with CHD from three different cultural regions of the world were assembled for the first time. The aim of the study was to evaluate the choice of the contraceptive method chosen on the background of the underlying cardiac condition and compared to the efficiency required to prevent pregnancy given the perceived underlying risks of pregnancy for the potential mother.

2. Material and methods

In a multicentre cross-sectional approach, 634 women with CHD were surveyed in five participating centres in Germany (German Heart Centre Munich, German Heart Institute Berlin), Hungary (Gottsegen Hungarian Institute of Cardiology, Pediatric Cardiac Centre, Budapest; University of Szeged, Faculty of Medicine, Szeged) and Japan (Chiba Cardiovascular Centre, Ichihara) over a period of twelve months. The survey took place via a questionnaire administered in clinic

Table 2
Modified WHO classification of maternal cardiovascular risk in relation to diagnosis (according to [7]).

WHO risk class	Condition
I	Uncomplicated, small or mild: PS, PDA, MiVP Successfully repaired simple lesions ASD, VSD, PDA, PAPVC, TAPVC Isolated SVES or VES
II (if otherwise well and uncomplicated)	Unoperated ASD or VSD Repaired TOF Most arrhythmias
II–III (depending on individual)	Mild left ventricular impairment HOCM Native or tissue valvular heart disease not considered WHO I or IV Marfan syndrome without aortic dilatation Aorta < 45 mm in aortic disease associated with bicuspid aortic valve Repaired CoA
III	Mechanical valve Systemic right ventricle Fontan circulation Cyanotic heart disease (unrepaired) Other complex CHD Aortic dilatation 40–45 mm in Marfan syndrome Aortic dilatation 45–50 mm in aortic disease associated with bicuspid aortic valve
IV (pregnancy contraindicated)	PAH of any cause Severe systemic ventricular dysfunction (LVEF < 39%, NYHA III or IV) Previous peripartum cardiomyopathy with any residual impairment of left ventricular function Severe mitral stenosis, severe symptomatic aortic stenosis Marfan syndrome with aorta dilated > 45 mm Aortic dilatation > 50 mm in aortic disease associated with bicuspid aortic valve Native severe CoA

to all attending women and containing items on contraception, menstruation, pregnancy and sexuality, as well as on the participants' life situation and received medical care. In addition, the treating physicians were asked to complete a questionnaire recording the cardiac main diagnosis, operations and catheter based interventions, clinical status and current cardiac medication. Only women aged ≥ 18 years with a diagnosis of congenital heart disease and providing written consent to participate in the study were included. Women with cognitive disorders or developmental delay were excluded. The study was approved by the ethics committees of the participating centres.

The patients were clinically classified according to cardiac main diagnosis (native CHD), severity of the CHD, functional class and pregnancy associated cardiovascular risk [7,8,9] as illustrated in Table 4. The classes II and III regarding the maternal cardiovascular risk during pregnancy were grouped together, resulting in the three risk groups "low" (WHO class I), "medium" (WHO class II or III), and "high" (i.e. contraindicated, WHO class IV).

The contraceptive methods used by the participants were divided into two categories "safe" and "unsafe", the threshold value being a pearl index of two in the case of ideal use [10]. This classification refers to the efficiency/safety of contraceptive methods in preventing pregnancy. Named classification is based on the assumption that the pearl index of a condom equals two in the case of ideal use. In fact, the failure rate is high in the case of typical use (especially in adolescents); however, in the case of ideal use (and in stable, sexually more experienced partnerships), condoms come close to the reliability of oral contraceptives [11]. The pearl indices of all hormonal contraceptive methods, intrauterine devices (IUD) and sterilisation of either the woman or the man are below that of the condom. Among the methods with higher pearl indices are calendar-based methods, other barrier methods (e.g. diaphragm, cervical cap) and coitus interruptus.

To assess the contraceptive habits, both the currently used methods, as well as those used formerly, were considered. For classification, the method with the highest pearl index, regardless of the time of use,

Table 3
Pearl indices of different contraceptive methods (modified according to [10]).

Method	Adjusted pearl index (ideal use)	Pearl index (typical use)
Gestagene implant	0.05	0.05
Male sterilisation	0.1	0.15
Levonorgestrel IUD	0.2	0.2
Depot progestagen (medroxyprogesterone acetate)	0.3	3
Progestagen only pill (desogestrel)	0.3	8
Contraceptive patch, contraceptive vaginal ring	0.3	8
Combined oral contraceptive pill (oestrogen/gestagen)	0.3	8
Female sterilisation (tubal ligation)	0.5	0.5
Copper IUD	0.6	0.8
Condom	2	15
Rhythm method	3–5	25
Coitus interruptus	4	27
Diaphragm, cervical cap	6	16

was considered. An overview of the pearl indices of different contraceptive methods is given in Table 3.

For statistical data analysis the programme SPSS, version 19 (SPSS Inc., IBM) was used. In the descriptive statistics, metrically scaled data are given as median or mean value, while nominally and ordinally scaled data are given as frequency and percent. The Kolmogorov–Smirnov test was used for testing normal distribution. In the case of normal distribution, differences between the two groups were tested for significance by using the Student's t-test or, if there were more than two groups, by means of variance analysis. In case of a non-normal distribution, the Mann–Whitney U test and the Kruskal–Wallis test were used. The level of significance was set at 0.05, according to convention [12].

3. Results

3.1. Medical patient characteristics

Six hundred and thirty-four patients were included, of whom 61.5% (n = 390) were from Germany, 24.1% (n = 153) from Hungary and 14.4% (n = 91) from Japan.

The median age was 30 years (mean: 32.4 years, SD: 10.8 years, range: 18–84 years). Regarding age, no significant differences were found between Germany, Hungary and Japan.

Approximately half of the patients from all participating countries were between 18 and 29 years old (Germany: 44.1%, Hungary: 50.3%, Japan: 47.3%); at the time of the survey, 80% of the total study population were younger than 40 years (see Table 4).

The median age at first sexual activity was 18.0 years (minimum 12 years, maximum 35 years). There were significant differences between the countries included (Germany's median 17 years, Hungary 18 years, Japan 19 years; $p < 0.001$). Overall, 3.5% of women had their first sexual activity before the age of 15 years.

3.2. Contraceptive methods

The question concerning the first time of using a contraceptive method was answered by 87.1% of the study participants (n = 552) (Germany: 94.9%, Hungary: 77.1%, Japan: 70.3%). 4.9% (n = 27) had not used a contraceptive method yet; of these, 59.3% (n = 16) stated to not have had sexual intercourse yet.

Table 4
Baseline characteristics of study participants.

Variable	Germany n = 390 (61%)	Hungary n = 153 (24%)	Japan n = 91 (15%)	Total n = 634
Age (years)				
Median	30	29	31	30
Mean value (SD)	32.1 (\pm 10.0)	33.0 (\pm 12.9)	32.7 (\pm 9.9)	32.4 (\pm 10.8)
Minimum	18	18	19	18
Maximum	84	76	72	84
Severity of CHD*				
Simple	108 (27.7%)	96 (62.7%)	38 (41.8%)	242 (38.2%)
Moderate	179 (45.9%)	42 (27.5%)	38 (41.8%)	259 (40.9%)
Severe	103 (26.4%)	15 (9.8%)	15 (16.5%)	133 (21.0%)
Functional class**				
I + II	361 (92.6%)	151 (98.7%)	88 (96.7%)	600 (94.6%)
III + IV	29 (7.4%)	2 (1.3%)	3 (3.3%)	34 (5.4%)
Diagnosis				
Post-tricuspid shunts	49 (12.6%)	19 (12.4%)	27 (29.7%)	95 (15.0%)
Pre-tricuspid shunts	59 (15.1%)	59 (38.6%)	11 (12.1%)	129 (20.3%)
Left heart obstructions	67 (17.2%)	35 (22.9%)	10 (11.0%)	112 (17.7%)
Right heart obstructions	85 (21.8%)	20 (13.1%)	20 (22.0%)	125 (19.7%)
Complex anomalies	70 (17.9%)	12 (7.8%)	12 (13.2%)	94 (14.8%)
Marfan's syndrome	22 (5.6%)	3 (2.0%)	1 (1.1%)	26 (4.1%)
Cardiomyopathies (familial)	5 (1.3%)	0 (0%)	2 (2.2%)	7 (1.1%)
Other	33 (8.5%)	5 (3.3%)	8 (8.8%)	46 (7.3%)
Cyanosis/Eisenmenger syndrome				
Cyanosis	36 (9.2%)	3 (2.0%)	4 (4.4%)	43 (6.8%)
Eisenmenger syndrome	16 (4.1%)	2 (1.3%)	2 (2.2%)	20 (3.2%)
Received treatment				
Native CHD	90 (23.4%)	30 (19.6%)	22 (24.2%)	142 (22.6%)
Palliative surgery	35 (9.1%)	5 (3.3%)	6 (6.6%)	46 (7.3%)
Reparative surgery	233 (60.7%)	76 (49.7%)	62 (68.1%)	371 (59.1%)
Intervention	26 (6.8%)	42 (27.5%)	1 (1.1%)	69 (11.0%)
Missing values	6	0	0	6
Implants				
Valve replacement or conduit	38 (9.7%)	11 (7.2%)	6 (6.6%)	55 (8.7%)
Pacemaker implantation	29 (7.4%)	0	2 (2.2%)	31 (4.9%)
ICD implantation	8 (2.1%)	3 (2.0%)	0	11 (1.7%)
Arterial hypertension				
No hypertension	343 (88.4%)	129 (84.3%)	87 (95.6%)	559 (88.4%)
Mild hypertension	20 (5.2%)	5 (3.3%)	1 (1.1%)	26 (4.1%)
Moderate hypertension	2 (0.5%)	0	0	2 (0.3%)
Antihypertensive therapy	23 (5.9%)	19 (12.4%)	3 (3.3%)	45 (7.1%)
Missing values	2	0	0	2
History of infective endocarditis	11 (2.8%)	0	7 (7.7%)	18 (2.6%)
History of thromboembolism***	34 (8.8%)	17 (11.2%)	5 (5.5%)	56 (8.8%)
History of heart failure	31 (7.9%)	3 (2.0%)	11 (12.1%)	45 (7.1%)

* According to the American College of Cardiology [9].

** According to Perloff [8].

*** Including patients with a history of at least one of the following diagnoses: phlebothrombosis, pulmonary embolism, TIA/PRIND/cerebral insult, peripheral arterial embolism.

Table 5
Use of contraceptive methods.

Variable	Germany (n = 390)	Hungary (n = 153)	Japan (n = 91)	Total (n = 634)	p
Former/current use of contraceptive methods					
Yes	355 (95.9%)	106 (89.8%)	64 (100%)	525 (95.1%)	
No	15 (4.1%)	12 (10.2%)	0	27 (4.9%)	
Missing values	20	35	27	82	
Age at first use (in years)					
Median	17	19	19	18	
Mean value (SD)	17.5 (±2.8)	20.3 (±3.6)	20.0 (±3.7)	18.4 (±3.4)	<0.001
Minimum	12	15	14	12	
Maximum	35	34	31	35	

The total median age at the first time of using a contraceptive method was 18 years (mean value: 18.4 years, SD: 3.4 years). With a median age of 17 years (mean value: 17.5 years, SD: 2.8 years) at the first time of using a contraceptive method, the patients from Germany were significantly younger ($p < 0.001$) than the patients from Hungary (median: 19 years, mean value: 20.3 years, SD: 3.6 years) and Japan (median: 19 years, mean value: 20.0 years, SD: 3.7 years). No statistically significant difference was found between Hungary and Japan (see Table 5).

Information on the contraceptive method currently used was provided by 58.0% (Germany: 62.3%, Hungary: 52.9%, Japan: 48.4%) of the study participants ($n = 368$); multiple answers were possible, if several methods were used simultaneously. The method used most frequently was the condom (37.8%), followed by oral contraceptives in the form of the combined oral contraceptive pill, which was used by 30.4%, and coitus interruptus, used by 11.4% of the participants.

Compared with the other methods currently used, oral contraceptives were the method used most frequently by the German patients (25.9%). In the Hungarian patients, oral contraceptives were the second most frequent choice (30.9%) after the condom (37.0%). The Japanese patients currently used only three contraceptive methods: the condom (90.9%), coitus interruptus (25.0%) and calendar based methods (2.3%). None of the Japanese participants used a hormonal contraceptive (see Table 6).

Regarding women not providing information on the contraceptive methods currently used, 69 were currently pregnant and 26 tried to get pregnant; 27 had not used a contraceptive method yet. In addition, 38 were older than 50 years at the time of the survey and were not considered as part of this particular analysis.

The question concerning contraceptive methods used at least once before was answered by 68.8% ($n = 436$) of the study participants (Germany: 73.1%, Hungary: 66.0%, Japan: 54.9%); multiple answers were possible. In this context, the condom was referred to most frequently (62.2%), followed by the combined oral contraceptive pill

(50.9%) and coitus interruptus (18.3%) (see Table 6). No information concerning this issue was provided by 198 patients. Of these, 54.0% ($n = 107$) were younger than 30 years and 20 had not used a contraceptive method yet (seven of the patients older than 30 years also stated to never have used contraceptives before). As the groups of patients providing information on currently and formerly used contraceptive methods are overlapping, data from only 52 patients (8.2%) are lacking on this issue.

3.3. Efficiency of the contraceptive methods chosen

Of the study participants answering the question concerning contraceptives, 71.0% ($n = 413$) had used exclusively “safe” contraceptive methods (Pearl Index ≤ 2) at the time of the survey, as well as in the past. The percentage of women having used or currently using a contraceptive method rated as unsafe at least once was the lowest in Germany (25.3%) and highest in Hungary (37.4%), while the Japanese patients were in between.

In all three risk classes (for maternal cardiovascular complications during pregnancy), the proportion of women currently using and having used exclusively contraceptive methods rated as “safe” was approximately equal (low risk: 72.1%, medium risk: 69.5%, high risk: 71.1%) (see Table 7).

3.4. Information deficit

The question on how good they felt informed about the impact of different contraceptive methods on the CHD was answered by 597 of the surveyed women (94.2%).

Of these, 45.7% ($n = 290$) indicated to be poorly informed, 30.6% ($n = 194$) felt moderately informed and only 17.8% ($n = 113$) assessed themselves as being informed very well. While in Germany and

Table 6
Contraceptive methods currently or formerly in use (in order of total percentage in the category “current use”).

Patients	Germany		Hungary		Japan		Total	
	n = 243	n = 285	n = 81	n = 101	n = 44	n = 50	n = 368	n = 436
Contraceptive methods (current/former use)	Current use n (%)	Former use n (%)	Current use n (%)	Former use n (%)	Current use n (%)	Former use n (%)	Current use n (%)	Former use n (%)
Condom	69 (28.4%)	174 (61.1%)	30 (37.0%)	52 (51.5%)	40 (90.9%)	47 (94.0%)	139 (37.8%)	273 (62.6%)
Combined oral contraceptive pill (oestrogen/gestagen)	87 (35.8%)	171 (60.0%)	25 (30.9%)	50 (49.5%)	0	1 (2.0%)	112 (30.4%)	222 (50.9%)
Coitus interruptus	16 (6.6%)	45 (15.8%)	15 (18.5%)	22 (21.8%)	11 (25.0%)	13 (26.0%)	42 (11.4%)	80 (18.3%)
Intrauterine device	29 (11.9%)	25 (8.8%)	7 (8.6%)	10 (9.9%)	0	1 (2.0%)	36 (9.8%)	36 (8.3%)
Female sterilisation (tubal ligation)	20 (8.2%)	8 (2.8%)	8 (9.9%)	1 (1.0%)	0	0	28 (7.6%)	9 (2.1%)
Progestagen only pill (desogestrel)	19 (7.8%)	60 (21.1%)	1 (1.2%)	1 (1.0%)	0	0	20 (5.4%)	61 (14.0%)
Contraceptive patch, contraceptive vaginal ring	13 (5.3%)	11 (3.9%)	2 (2.5%)	1 (1.0%)	0	0	15 (4.1%)	12 (2.8%)
Male sterilisation	8 (3.3%)	2 (0.7%)	1 (1.2%)	0	0	0	9 (2.4%)	2 (0.5%)
Rhythm method	5 (2.1%)	20 (7.0%)	0	3 (3.0%)	1 (2.3%)	2 (4.0%)	6 (1.6%)	25 (5.7%)
Diaphragm, cervical cap	1 (0.4%)	6 (2.1%)	1 (1.2%)	4 (4.0%)	0	0	2 (0.5%)	10 (2.3%)
Gestagene implant	2 (0.8%)	4 (1.4%)	0	0	0	0	2 (0.5%)	4 (0.9%)
Depot progestagen (medroxyprogesterone acetate)	1 (0.4%)	3 (1.1%)	0	0	0	0	1 (0.3%)	3 (0.7%)
Postcoital emergency contraception	0	31 (10.9%)	0	11 (10.9%)	0	0	0	42 (9.6%)

Table 7
Efficiency of contraceptive methods.

	WHO risk classification			Total (n = 390)
	Low (n = 183)	Medium (n = 148)	High (n = 59)	
Germany				
Safe	137 (78.3%)	99 (70.2%)	41 (74.5%)	277 (74.7%)
Unsafe	38 (21.7%)	42 (29.8%)	14 (25.5%)	94 (25.3%)
Missing values	8	7	4	19
Hungary				
Safe	53 (62.4%)	31 (66.0%)	3 (42.9%)	87 (62.6%)
Unsafe	32 (37.6%)	16 (34.0%)	4 (57.1%)	52 (37.4%)
Missing values	12	2	0	14
Japan				
Safe	30 (66.7%)	16 (72.7%)	3 (60.0%)	49 (68.1%)
Unsafe	15 (33.3%)	6 (27.3%)	2 (40.0%)	23 (31.9%)
Missing values	11	4	4	19
Total				
Safe	220 (72.1%)	146 (69.5%)	47 (71.1%)	413 (71.0%)
Unsafe	85 (27.9%)	64 (30.5%)	20 (29.9%)	169 (29.0%)
Missing values	31	13	8	52

Hungary, 42.2% and 41.1%, respectively, felt very poorly informed, this applied to 88.2% of the Japanese participants (see Table 8).

4. Discussion

The study for the first time recorded data on the contraceptive behaviour of women with CHD from three different cultural regions (Germany, Hungary, Japan). In the context of contraceptive counselling of ACHD, the individual characteristics of each single patient, as well as potential contraindications of the different contraceptive methods, have to be taken into consideration. Due to potential side effects, some contraceptive methods, such as sterilisation, can be contraindicated or represent an irreversible intervention. For choosing the appropriate contraceptive method for women with CHD, the method's safety (in preventing pregnancy), as well as the maternal cardiovascular risk, are of pivotal importance.

As the present study shows, the majority of women with CHD use contraception. However, at least in Europe, the preferences regarding the use of contraceptive methods differ from those of the general public.

The total average age at the first use of contraceptives was 18.4 years; there was a significant age difference between Germany, on the one hand, and Hungary and Japan, on the other hand. This corresponds with the recorded age at the first sexual intercourse: also in this connection, the patients from Germany were significantly younger than the women from Hungary and Japan. A later start of sexual activity obviously is associated with a later time of first using a contraceptive method.

These observations are also supported by the data from the report on the health situation of women in Germany (2001) and an investigation by Cibula (2008) in over 11,000 women from 14 European countries. According to these, girls in Germany have their first sexual intercourse between the age of 16 and 16.6 years and, according to Cibula, first use of contraceptives at an average age of 16.7 years [13,14]. Thus, compared to other European nations, German girls are the youngest users of contraceptives. The presented study shows that girls and young women with CHD engage in their first sexual intercourse and accordingly gain experience with contraceptives at a later time than girls from the general public (in both Germany and Europe).

According to the investigation by Cibula, the contraceptive methods used most frequently at the time of the survey were the combined oral

contraceptive pill and the condom (28% and 17%, respectively, of the participating women). Twenty-five percent of the participants stated to not use contraceptives at all, which in most cases was due to the lack of a sexual partner or sexual activity [14]. Of the patients surveyed in the present study, 95% have at least once used a contraceptive method. All patients from Japan had already used contraceptives, while 4% of the German participants and 10% of the Hungarian participants had not used contraceptives ever. Of these women, 60% indicated to not have had sexual intercourse yet. The condom (used by 38%) and oral contraceptives (used by 30%) were the methods used most frequently. Coitus interruptus was currently used by 11% of the patients, and an IUD was used by 10% of the participating women.

There were country-specific differences regarding the methods used. While a variety of contraceptives was used in Germany and Hungary, the contraceptive use was limited to three methods in Japan (see Table 6).

Considering not only those contraceptive methods used currently, but those used ever, almost all available methods had been used in Germany and Hungary. In contrast, the surveyed patients from Japan only used condoms, coitus interruptus, rhythm methods, IUDs and oral contraceptives (see Table 6).

The latter could be explained by the fact that, with the exception of rhythm methods (e.g. calendar based methods), the only contraceptive methods currently available in Japan are condoms, sterilisation, IUDs and oral contraceptives. Methods such as the contraceptive patch, vaginal rings, depot progestagen or hormonal implants are not available. Oral contraceptives have not been approved before 1999 in Japan. Before that, only highly dosed hormonal preparations licenced for the treatment of period pains were used "off-label" for contraceptive purposes [15,16,17]. According to recent investigations [16], only 1.1% of all Japanese women use the "pill" as a contraceptive method. According to Matsumoto et al., the little response the "pill" meets despite its introduction as a legal contraceptive in Japan in 1999 is attributed partly to the incurring costs [15,16,17]. Another reason for the lack of acceptance of the "pill" in Japan might be the approach to sex education in schools: According to Fu it is underdeveloped compared to many other industrialised societies [18]. In contrast, there is a widespread use of the combined oral contraceptive pill in Germany and Hungary. Currently, they are used by approximately a third of the surveyed women in both countries, thus being used to a larger extent than compared to the European average and the general public. In Germany women using the combined oral contraceptive pill have to bear the costs of these preparations themselves while in Hungary the costs are only partially covered by health insurance. The reasons for the differences between Germany and Hungary on the one hand and Japan on the other hand in willingness to use this method, are currently unknown.

Table 8
Level of information regarding contraceptive methods.

Level of information	Germany (n = 390)	Hungary (n = 153)	Japan (n = 91)	Total (n = 634)
Very good	90 (24.2%)	22 (15.7%)	1 (1.2%)	113 (18.9%)
Moderate	125 (33.6%)	60 (42.9%)	9 (9.9%)	194 (32.5%)
Very bad	157 (42.2%)	58 (41.1%)	75 (88.2%)	290 (48.6%)
Missing values	18	13	6	37

The results of the presented study highlight the need of an adequate contraceptive counselling of women with CHD, as 29% of the participants used unsafe methods. Comparing the three participating countries, the proportion of women using unsafe methods was the lowest in Germany (25%) and highest in Hungary (37%), with Japan ranging in-between (32%).

Regarding the maternal risk of cardiovascular complications during pregnancy, there were only marginal differences between the three risk classes “low” (28% unsafe methods), “medium” (31% unsafe methods) and “high” (30% unsafe methods) (Table 7).

Contrary to the assumption that the “safety” of the chosen contraceptive methods (in preventing pregnancy) increases with a higher risk, underlying risk factors seem to have no influence on the choice of the contraceptive method. This fact leads to implications in a high risk collective. Regarding this issue, there seems to be a considerable information deficit. In fact, the majority of the study participants from all three countries indicated to be informed only moderately (Germany: 34%, Hungary: 43%, Japan: 10%) or even poorly (Germany: 42%, Hungary: 41%, Japan: 88%) about the use of contraceptives and the potential impact of different contraceptive methods on their CHD. Accordingly, contraceptive counselling of women with CHD is in need of improvement. Especially early age counselling before the first sexual activity is of paramount importance to prevent pregnancies in high risk patients. The results from Japan are particularly noticeable: here, the proportion of women who consider themselves to be poorly informed is by far the largest as compared to the other participating countries. Increased counselling could not only lead to a broader spectrum of contraceptive methods being used (if available), but also reduce the use of the coitus interruptus as the method used most frequently as compared to the other countries. However, there is also an undeniable need for improvements in contraceptive counselling in both Germany and Hungary.

5. Limitations

The conclusions of the presented study are limited by the fact that it is a quantitative cross-sectional study which took place at specialised centres. The study participants not necessarily reflect the patient population seen by cardiologists in private practise, gynaecologists in private practise or in specialised centres for ACHD care. However, due to the large sample size, the presented results can be assumed to sufficiently reflect the patient population of ACHD, or, in this case, the patient population of women with CHD. We lack information on the indication for the prescription of contraceptives. Therefore we cannot comment on the percentage of women using contraceptives for gynaecological indications (e.g. menstrual disorders). Further studies are required to investigate the choice of contraceptives (if any) at the time of first sexual activity. Due to the design of the current study it does not draw reliable conclusions regarding this important topic.

6. Conclusions

The current study highlights the use of contraceptive and the differences in contraceptive use between the participating countries. We found important informational deficits and lack of adequate contraceptive counselling of women with CHD. This is of particular relevance for

young women and requires considering the individual characteristics of each patient, including potential contraindications.

Disclosures

None.

Acknowledgements

We thank all participating patients in Germany, Hungary and Japan. Furthermore, we thank all supporting physicians who are not mentioned in the authors list for the data collection at the partner sites.

This work was supported by the Competence Network for Congenital Heart Defects funded by the Federal Ministry of Education and Research Germany (BMBF), FKZ 01GI0601.

References

- [1] P. Moons, L. Bovij, W. Budts, A. Belmans, M. Gewillig, Temporal trends in survival to adulthood among patients born with congenital heart disease from 1970 to 1992 in Belgium, *Circulation* 122 (2010) 2264–2272.
- [2] H. Kaemmerer, K.T.M. Schneider, S. Niesert, J. Hess, Schwangerschaft bei Frauen mit angeborenen Herzfehlern, *Gynakologe* 32 (1999) 377–385.
- [3] A. Uebing, M.A. Gatzoulis, C. von Kaisenberg, H.H. Kramer, A. Strauss, Congenital heart disease in pregnancy, *Dtsch Arztebl Int* 105 (2008) 347–354.
- [4] E. Bédard, K. Dimopoulos, M.A. Gatzoulis, Has there been any progress made on pregnancy outcomes among women with pulmonary arterial hypertension? *Eur Heart J* 30 (2009) 256–265.
- [5] W. Drenthen, P.G. Pieper, J.W. Roos-Hesselink, W.A. van Lottum, A.A. Voors, B.J. Mulder, et al., ZAHARA investigators. Outcome of pregnancy in women with congenital heart disease: a literature review, *J Am Coll Cardiol* 49 (2007) 2303–2311.
- [6] S. Thorne, A. MacGregor, C. Nelson-Piercy, Risks of contraception and pregnancy in heart disease, *Heart* 92 (2006) 1520–1525.
- [7] European Society of Gynecology (ESG), Association for European Paediatric Cardiology (AEPIC), German Society for Gender Medicine (DGesGM), V. Regitz-Zagrosek, C. Blomstrom Lundqvist, C. Borghi, et al., ESC Guidelines on the management of cardiovascular diseases during pregnancy: the Task Force on the Management of Cardiovascular Diseases during Pregnancy of the European Society of Cardiology (ESC), *Eur Heart J* 32 (2011) 3147–3197.
- [8] J.K. Perloff, J.S. Child, J. Aboulhson, *Congenital Heart Disease in Adults*, third ed. WB Saunders, Philadelphia, 2008.
- [9] C.A. Warnes, R. Liberthson, G.K. Danielson, A. Dore, L. Harris, J.I. Hoffman, et al., Task force 1: the changing profile of congenital heart disease in adult life, *J Am Coll Cardiol* 37 (2001) 1170–1175.
- [10] I. Wiegatz, C.J. Thaler, Hormonal contraception – what kind, when, and for whom? *Dtsch Arztebl Int* 108 (2011) 495–505.
- [11] V. Seifert-Klauss, H. Kaemmerer, B. Brunner, K.T. Schneider, J. Hess, Contraception in patients with congenital heart defects, *Z Kardiol* 89 (2000) 606–611.
- [12] B. Rasch, E. Naumann, M. Friese, W. Hofmann, second ed., *Quantitative Methoden* Band, 1, 2006 (pp. 57–57).
- [13] Bundesministerium für Familie, Senioren, Frauen und Jugend (BMFSFJ), Bericht zur gesundheitlichen Situation von Frauen in Deutschland, Kohlhammer Verlag, Stuttgart, 2001.
- [14] D. Cibula, Women's contraceptive practices and sexual behaviour in Europe, *Eur J Contracept Reprod Health Care* 13 (2008) 362–375.
- [15] Y. Matsumoto, S. Yamabe, K. Ideta, M. Kawabata, Impact of use of combined oral contraceptive pill on the quality of life of Japanese women, *J Obstet Gynaecol Res* 33 (2007) 529–535.
- [16] Y. Matsumoto, S. Yamabe, After 10 years: has approval of oral contraceptives really decreased the rate of unintended pregnancy in Japan? *Contraception* 81 (2010) 389–390.
- [17] B.J. Oddens, A. Lolkema, A scenario study of oral contraceptive use in Japan. Toward fewer unintended pregnancies, *Contraception* 58 (1998) 13–19.
- [18] H. Fu, The bumpy road to socialise nature: sex education in Japan, *Cult Health Sex* 13 (2011) 903–915.