Original **paper**

THE POLISH NATIONAL REGISTRY FOR FETAL CARDIAC PATHOLOGY (WWW.ORPKP.PL) – SELECTED DATA ANALYSIS FOR 2013 AND 2014 AND COMPARISON WITH DATA FROM 2004 TO 2012

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PRENAT CARDIO. 2015 MAR;5(1):6-12
DOI 10.12847/03151

Abstract

As in every year since 2004, we analyzed data from the Polish National Registry for Fetal Cardiac Pathology to follow actual trends in types of congenital heart disease (CHD) and to assess the development of prenatal cardiology in Poland. Overall, the most frequent cardiac malformation detected prenatally in 2013 -2014, similar to the previous years, was hypoplastic left heart syndrome (HLHS). The average age of the examined fetuses was unchanged and remained above 20 weeks of gestation. An increased trend of detecting other cardiac malformations, such as transposition of the great arteries (d-TGA) and aortic stenosis (AS), and the predominance of vaginal deliveries over cesarean deliveries suggested significant improvements in prenatal and perinatal care in Poland.

Key words: *Data base, Registry, Congenital malformation, Fetal echocardiography*

INTRODUCTION

The Polish National Registry for Fetal Cardiac Pathology (hereafter referred to as the Registry) is an Internet-based, electronic database created to prospectively record the diagnosis (with still images and videos clips), prenatal care, delivery and neonatal follow-up of fetuses with congenital heart disease (CHD) in Poland. Launched in 2004 to monitor occurance of fetal cardiac malformations. The Registry is open to health care providers in Poland who perform prenatal ultrasound and obtained an access code and login to the database. Although it is voluntary registry about 80% of prenatal diagnoses are provided. The Registry has also made possible the implementation of a certification program in fetal cardiac ultrasound and serves as a simple and reproducible assessment tool to train ultrasonographers in fetal echocardiography.

We hypothesized that prenatal recognition of CHD would increase over time and that identification of "critical" cardiac defects, those defects requiring speed postnatal cardiac service would improve postnatal survival. The purpose of our study was to compare the rate of prenatal diagnosis and outcome of fetal CHD from Registry data collected prior to 2013 and from 2013-2014.

How to Cite this Article:
Kordjalik P, Radzymińska-Chruściel B, Słodki M, Włoch A, Szymkiewicz-Dangel J, Respondek-Liberska M, Tobota Z.: The Polish National Registry for Fetal Cardiac Pathology (www.orpkp.pl) - selected data analysis for 2013 and 2014 and comparison with data from 2004 to 2012. Prenat Cardio. 2015 Mar;5(1):6-12

MATERIALS AND METHODS

We retrospectively analyzed data entered in to the registry from 2004 to 2012 (Period 1) and from 2013- 2014 (Period 2). The data, generated on the basis of standardized reports from the Registry (www.orkp.pl), are presented as mean ± SD or the number of cases (%).

Each center has its 3 digit code (for instance Warsaw code is LSF, Lodz code is PBU, Silesia code is YHG), and center providing > 100 CHD per year is labeled type C prenatal cardiac center, center providing > 50 CHD is labeled type B center, and center providing > 10 per year is labeled type A center.

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Submitted: 2015-02-17; accepted: 2015-03-19

CHD in Registry had diagnoses according to the structural anomalies (for istance d-TGA) and in addition also "alerting" diagnoses classified into four categories:

- "Not-urgent" (formerly "benign") meaning cardiac surgery not planned during the first month after delivery
- Severe CHD – ductal dependent for prostin infusion and classical neonatal cardiac procedures
- Critical CHD – ductal dependent for prostin infusion but early therapeutic catheterisation and early surgery in 1-2 week of postnatal life
- Very severe CHD – (usually with lung hypoplasia) – neonatal demise expected…heart /lung transplant is not available currently in Poland

The Section of Prenatal Echocardiography and Prenatal Cardiology Polish Ultrasound Society approved the conduct of this study.

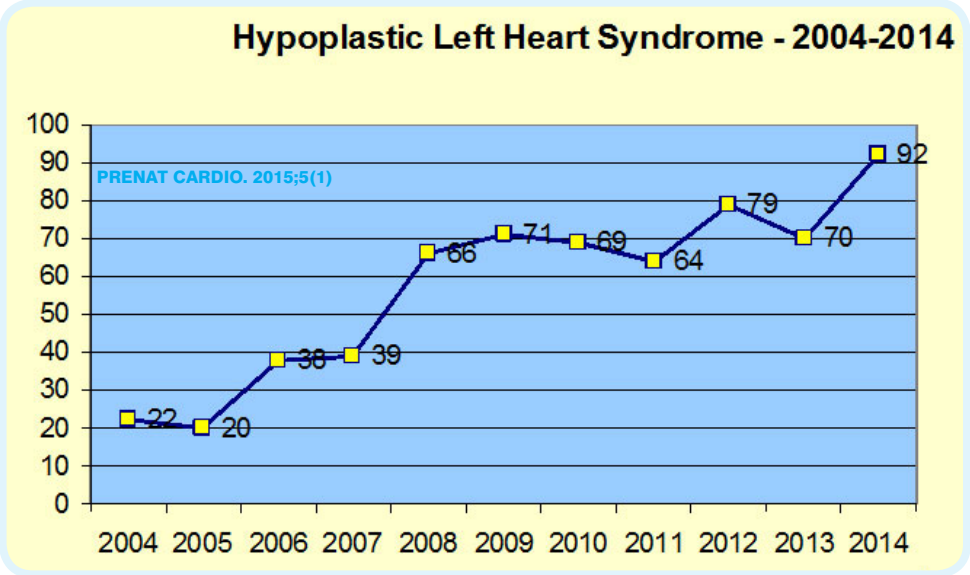


Figure 1. Number of fetuses with HLHS during 2004-2014 in the ORPKP Registry in Poland (www.orpkp.pl.)

RESULTS

Input from the leading centers

In Period 1 and 2 the two leading centers in Warsaw and Lodz each recorded more than 100 cases of cardiac malformations per year. In Period 1 the number of physicians reporting more than five cases of fetal cardiac malformations annually was 10% and this remained unchanged in Period 2: 2013 (10.5%) and 2014 (10%). Thus, the majority of physicians infrequently encountered prenatal cardiac malformations, and this trend has remained relatively stable since 2012 (2012, 89.0%; 2013, 89.5%; 2014, 89.9%).

In 2013 and 2014, 856 and 690 records, respectively, were entered into the Registry. This represented a significant increase from the 342 records in 2012. Collectively, between 2004 and 2014, 6,030 records were entered. In 2013, 603 (70.4%) of all data were entered by the type C centers from Warsaw (code LSF=314), Lodz (code PBU=155) and Silesia (code YHG=134). This remained largely unchanged in Period 2 : 2014, with the highest number of records entered by type C centers, which collectively comprised 80.0%. It is noteworthy, however, that the ranking of the "leading" centers in 2014 was Warsaw (321), Lodz (128) and Krakow (103), instead of Warsaw, Lodz and Silesia in 2013. So both in Period 1 and 2 we had basically the same leading centers.

Rank	2013 CHD	Number of cases and %		2014 CHD	Number of cases and %	
1	Hypoplastic left heart syndrome	71	8.0%	Hypoplastic left heart syndrome	92	12.3%
2	Ventricular Septal Defect	67	7.5%	AVSD: atrial & ventricular components (complete)	48	6,5%
3	AVSD: atrial & ventricular components (complete)	61	6.8%	Aortic valvular stenosis	33	4.4%
4	Aortic valvular stenosis	50	5.6%	Ventricular Septal Defect	33	4.4%
5	Tetralogy of Fallot	47	5.3%	Aortic coarctation	32	4.3%
6	Complete transposition of great arteries – TGA	46	5.2%	Complete transposition of great arteries – TGA	32	4.3%
7	Discordant VA connections (TGA	26	2.9%	Tetralogy of Fallot	26	3.5%
8	Double outlet RV - Fallot type	24	2.7%	Left SVC persisting to coronary sinus	26	3.5%
9	Pulmonary valvular stenosis	23	2.6%	Aberrant origin R subclavian artery	23	3.1%
10	Left SVC persisting to coronary sinus	21	2.4%	Muscular Ventricular Septal Defect	23	3.1%

Table 1. The most common CHD diagnoses in 2013 and 2014 in the ORPKP Registry in Poland.

Number and types of fetal cardiac malformations

In Periods 2 , the most frequently detected congenital cardiac malformation was hypoplastic left heart syndrome (HLHS) (n= 163: 71 cases in 2013 and 92 in 2014). This represents a significant increase from 22 cases in 2004 (Figure 1). Subsequent most frequently detected malformations in Period 2, in 2013 were ventricular septal defect (VSD), 67 cases and atrioventricular septal defect (AVSD), 61 cases; while in 2014, AVSD comprised 48 cases, while VSD 33 cases (Table 1).

In comparison to data from 2012, HLHS still remained the most frequently diagnosed cardiac malformation; the second place was occupied by Tetralogy of Fallot (TOF) which was replaced by VSD in 2013 and by AVSD in 2014;

Year 2013					
Center	**Number of exams**		**Type of CHD**	**Number %**	
LSF	342	35.8%	CHD severe		29.6%
			CHD non-urgent		28.1%
			CHD critical		28.1%
			CHD most severe		1.8%
YGH	162	17%	CHD severe		30.2%
			CHD non-urgent		27.5%
			CHD critical		20.3%
			CHD most severe		
PBU	99	10.4%	CHD severe		63.5%
			CHD non-urgent		15.5%
			CHD critical		6.5%
			CHD most severe		0.4%
Year 2014					
Center	**Number of exams**		**Type of CHD**	**Number %**	
LSF	311	39.2%	CHD severe	106	30.6%
			CHD non-urgent	92	26.5%
			CHD critical	83	23.9%
			CHD most severe	9	2.6%
YGH	99	12.5%	CHD severe	161	69.4%
			CHD non-urgent	41	17.7%
			CHD critical	13	5.6%
			CHD most severe	2	0.9%
PBU	93	11.7%	CHD severe	46	38.0%
			CHD non-urgent	43	35.5%
			CHD critical	9	7.4%
			CHD most severe	0	

Table 2. Number of examinations of fetuses with congenital heart defects in different tertiary centers in 2013 and 2014.

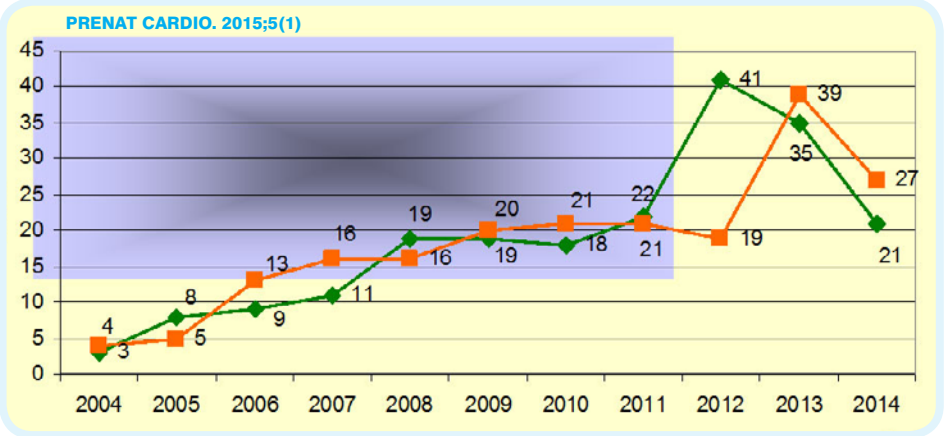


Figure 2. Number of fetuses with d-TGA and Aortic stenosis during 2004-2014 in the ORPKP Registry in Poland (www.orpkp.pl)

Follow-up in 2013	Number of cases	
Continuation of pregnancy	284	84.3%
Termination of pregnancy (fetus) : 14.10.38	26	7.7%
In utero death : 14.10.18	19	5.6%
Spontaneous abortion/miscarriage (< 24 wks) :	8	2.4%
	337	**100%**
Follow-up in 2014	**Number of cases**	
Continuation of pregnancy	187	85.4%
Termination of pregnancy (fetus) : 14.10.38	13	5.9%
In utero death : 14.10.18	13	5.9%
Spontaneous abortion/miscarriage (< 24 wks) :	3	1.4%
Stillbirth (> 24 wks) :	3	1.4%
	219	**100%**

Table 3. Follow-up in 2013 and 2014.

the third place was occupied by AVSD, as in 2013, but was replaced by aortic valvular stenosis in 2014 (Figure 2).

Similar like in Period 1, in Period 2 (2013 and 2014), severe malformations predominated (2013, 47%; 2014, 48%). Subsequent categories were benign and critical malformations. The lowest rank was occupied by very severe malformations (8 cases in 2013 and 11 in 2014).

In 2013, the structure of categories of cardiac malformations was similar in all leading centers; severe malformations were most frequently detected, followed by "benign" (not urgent), critical and lastly, very severe malformations. In 2014, changes were observed: in the Warsaw center, critical malformations predominated (106 cases), while in the Łódz and Krakow centers, severe malformations were the most frequent (161 and 46 cases, respectively) (Table 2 and Figure 3).

Chromosomal abnormalities

In Period 2 total of 150 fetuses with chromosomal abnormalities were recorded: in 2013 (95 cases, 10.6%) and 2014 (55 cases, 7.8%), including in majority (n=51: Down's syndrome (33 cases, 34.7% in 2013; 18 cases, 32.7% in 2014). Percentages were similar as in Period 1.

We did not registered non-cardiac defects or syndromes without heart defects.

Main reason for referrals

Both in Period 1 and Period 2 , abnormalities in the four-chamber view of the fetal heart were the most common reason to detect fetal heart problems. In both 2013 and 2014, 60.4% and 61.8% of cases, respectively, were referred for fetal echocardiography.

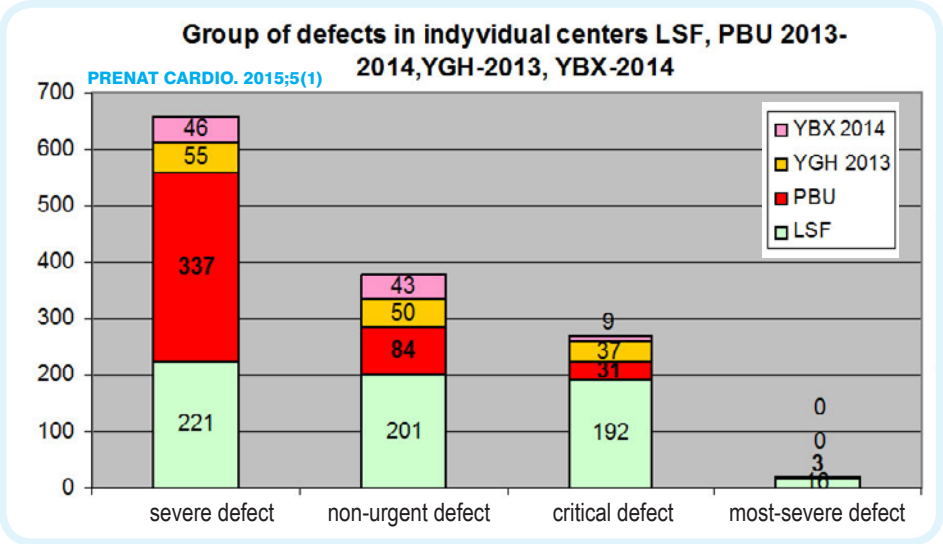


Figure 3. Types of congenital heart defects diagnosed in fetuses at tertiary centers: LSF and PBU in 2013-2014, YBX in 2014, and YGH in 2013.

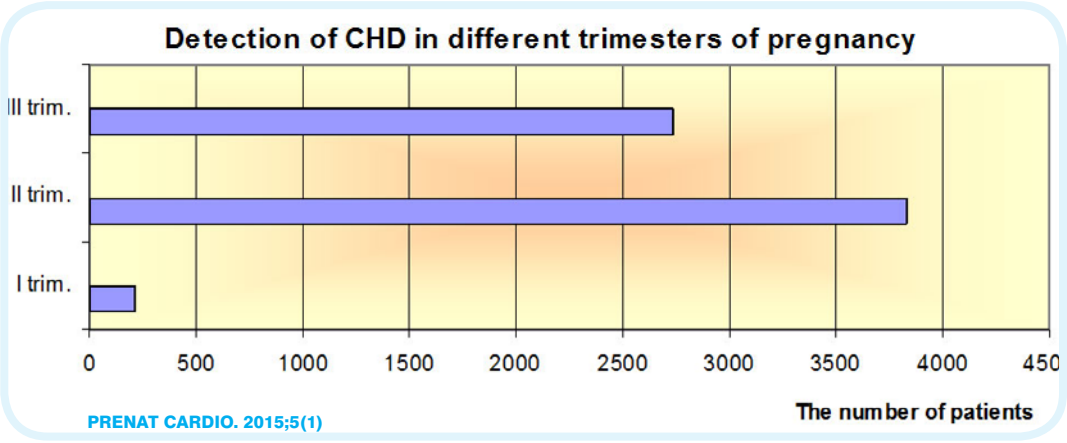


Figure 4. Detection of CHD in three trimesters of pregnancy

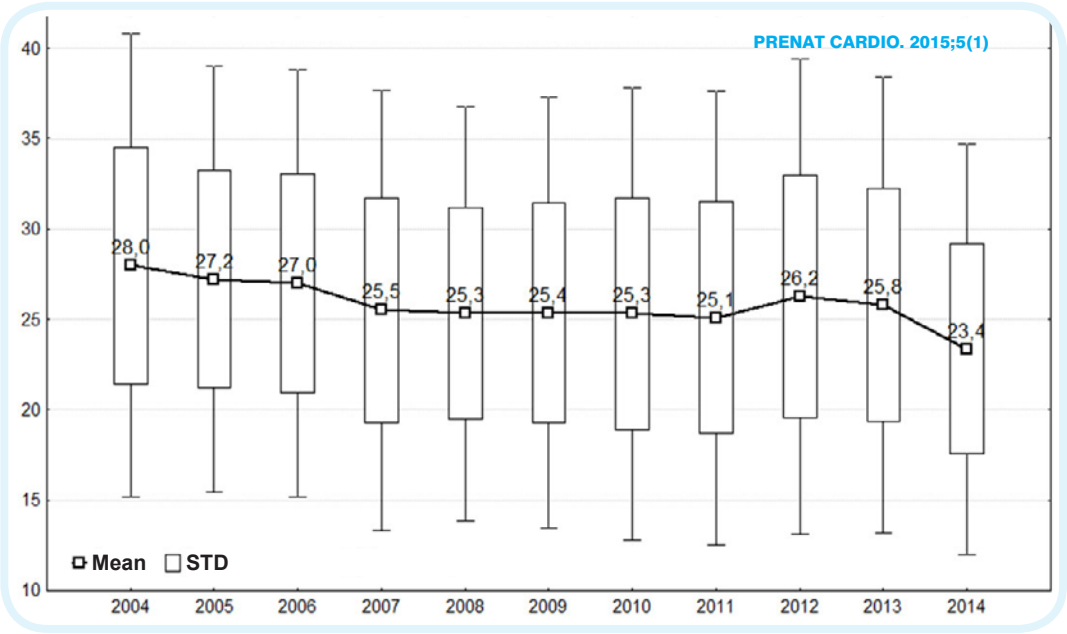


Figure 5. Mean and standard deviation of gestational age of fetuses with CHD in years 2004-2014

Gestational age

In Period 2 (2013 and 2014), the majority of cases were examined in the second half of pregnancy, which points out to the dominant role of prenatal examinations (Figure 4).

The average age of examined fetuses decreased significantly from 28 ± 6.5 weeks in 2004 to 23.4 ± 5.8 weeks in 2014 (p=0,05) (Figure 5).

Progression of hemodynamic alterations

In Period 1 we registered only 15,5% of fetuses who had progression of haemodynamic changes in the fetal heart in the second half of pregnancy. In Period 2 progression of hemodynamic alterations was observed much more frequently: in 54 cases (18.6%) in 2013, while in 2014, it comprised 62 cases (34.8%).

Fetal CHD and fetal weight based on biometry

In Period 1, majority of fetuses despite the presence of congenital heart defect presented normal biometry in comparison to the gestational age based on maternal last menstrual period or biometry in 1st trimester. In Period 2: it was similar: In 2013 and 2014, 88.3% and 88.7% of cases, respectively, were fetuses with normal body weight. Small for gestational age (10.5% in 2013, and 11.0% in 2014) or large for gestational age (1.1% in 2013, and 0.3% in 2014), were small groups.

Polish Registry of Congenital Malformations (all kinds for children up to 2 years of age)
Polish National Registry of Cardiac Surgery Procedures
Polish National Registry of Neonatal Surgeries
Registry for Arythmogenic Kardiomyopathy of RV
EUROCAT
European Surveillance of Congenital Anomalies
EUROWILSON
Orphanet Medicine Database
California Birth Defects Monitoring Program
New York State Department: Congenital Malformations Registry
Texas Birth Defects Registry
Iowa Registry for Congenital and Inherited Disorders
Metropolitan Atlanta Congenital Defects Program
Center for Birth Defects Research and Prevention
National Birth Defects Prevention Network
Canadian Congenital Anomalies Surveillance System
Victoria Birth Defects Registry
Latin-Amercan Collaborative Study of Congenital Malformations
Chinese Birth Defects Monitoring Network
Israel Birth Defects Monitoring System
South African Birth Defects Surveillance System
International Clearinghouse for Birth Defects Surveillance and Research
Down Syndrome National Patient Registry

Table 4. Representative registries of congenital anomalies in Poland, across Europe and elsewhere in the world.

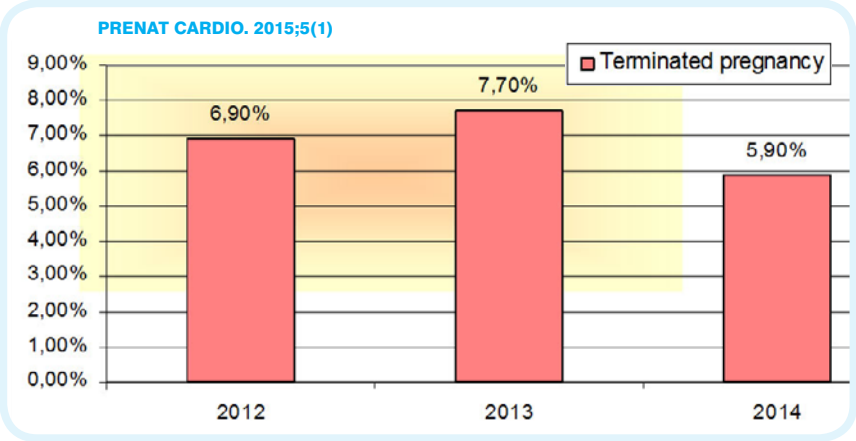


Figure 6. Rates of termination of pregnancies in year 2012, 2013 and 2014

Follow-up and outcome

Both in Period 1 and 2 the analysis of the outcome was limited to those cases who had completed postnatal data. In period 1 it was only 255 follow-up and in period 2 we had 594 follow-ups. Based on these limited information in Period 1: 85.5% of women decided to continue their pregnancy and 6.9% decided to terminate; and there were 5% in utero deaths and 2.7% miscarriages) (Table 3).

In Period 2 (2013 and 2014, 84% and 85% of women, respectively , decided to continue the pregnancy despite the detection of cardiac malformation and 7.7% and 5.9% of women decided to terminate their pregnancy in 2013 and 2014 (Fig. 6). In utero deaths were recorded in 19% and 13% of fetuses in 2013 and 2014, respectively, while spontaneous miscarriage was observed in 2.4% in 2013 and in 2.8% in 2014.

The way of delivery

In Period 1 approximately half of pregnancies ended with cesarean sections (47.2% in 2012), and in Period 2 there was change: an increased tendency of vaginal deliveries in 2013 (55.1%) and 2014 (61.1%) were observed.

DISCUSSION

Analysis of data from the Polish National Registry for Fetal Cardiac Pathology (www.orpkp.pl) for 2013 and 2014 demonstrated many similarities but also distinct differences in comparison to previous analyses and publications[1-4]. The dominant rank in Poland was taken by two "leading" centers of prenatal cardiology, in Warsaw and Lodz which have the highest level of type C reference centers that deal with the detection of cardiac malformations and the preparation of fetuses and pregnant mothers for delivery. The Warsaw center, however, was unique as the only one in Poland to use invasive therapies in selected cases of fetal cardiac problems (valvular stenosis and closed foramen ovale in HLHS)[5]. By contrast, the Lodz centre was unique as the only one in Poland to offer cardiac catheterization and/or surgery at the same institution to newborns with cardiac malformation, without the need of external transportation to other centers.[6] It is noteworthy, that the Krakow center took third place in our ranking in recent years, thus joining three other leading centers in Warsaw, Lodz and Silesia.

The most frequently detected cardiac malformation in Poland is still HLHS. The next most common type of CHD was septal defects (VSD and AVSD), and in 2014, the third place was aortic valvular stenosis (AS). it is worth to underline this type of prenatal diagnosis in Poland, specially in contrast to the recent data from USA: in multicenter study only 10 out of 117 critical aortic stenosis had prenatal diagnoses[7].

Pregnant women are typically referred to a centre of prenatal cardiology because of an abnormal four-chamber view of the fetal heart. In 2012, half of the pregnancies were delivered by cesarean section[2-4], while in 2013 and 2014, there was a trend to vaginal delivery. Perhaps this trend resulted from the employment of echocardiography just before delivery, resulting in the better monitoring of the hemodynamic status of the fetus.

An interesting finding was the differences in classification of heart malformations into four categories between the type C references centers (not-urgent or "benign", to

be treated in infancy; severe, to be treated during the neonatal period; critical, to be treated prenatally or in the first 24/48 hours of postnatal life; and most severe, for which there is no current therapy and fetal or neonatal death is unavoidable)[8-9]. Such a situation underscores the necessity to establish better criteria for fetal heart malformations from a prenatal cardiology viewpoint.

The definition of critical cardiac malformations is changing. Approximately 20 years ago, critical malformations were defined as those requiring therapy during the first year of life. And 15 years ago, critical malformations were defined as those accompanied by anoxemic attacks, while 10 years ago, cardiologists regarded as critical malformations those ductal-dependent malformations requiring prostin administration.

Currently, due to advances in prenatal cardiology, cardiac malformations can be not only detected during the first or second trimester of pregnancy (e.g., HLHS) and CHD can be further (in the third trimester) subclassified into severe malformations (such as ductal-dependent, destined to the classical cardiac surgery within the 7 to 10 days of life) and critical malformations (for which cardiac intervention must be performed in the first or second day of life to allow newborns to reach the cardiac surgeon). Rychik from Children's Hospital of Philadelphia[10] suggested a term "IMPACT" for those neonates in whom hemodynamic instability is anticipated after cesarean section. The Polish National Registry for Fetal Cardiac Pathology (www.orpkp.pl) provides and interesting data for the analysis of new congenital classification in prenatal cardiology.

ORPKP Registry data were also sorted into separate lists composed of community physicians who detected fetal cardiac malformations and physicians who worked in reference centers. However, it should be noted that a physician in the first list might correctly diagnose a cardiac malformation, and a physician from a reference center might also be the first to detect a malformation. The number of cardiac malformations diagnosed by any physician is the basis of awarding and prolonging the Certificate of Basic Examination of Fetal Heart and Certificate of Echocardiographic Examination of Fetal Heart of Echocardiography and Prenatal Cardiology section of the Polish Ultrasound Society. These certificates (total number by the end of 2014 in Poland was 52) form the basis of contracts signed with National Health Service[11-13].

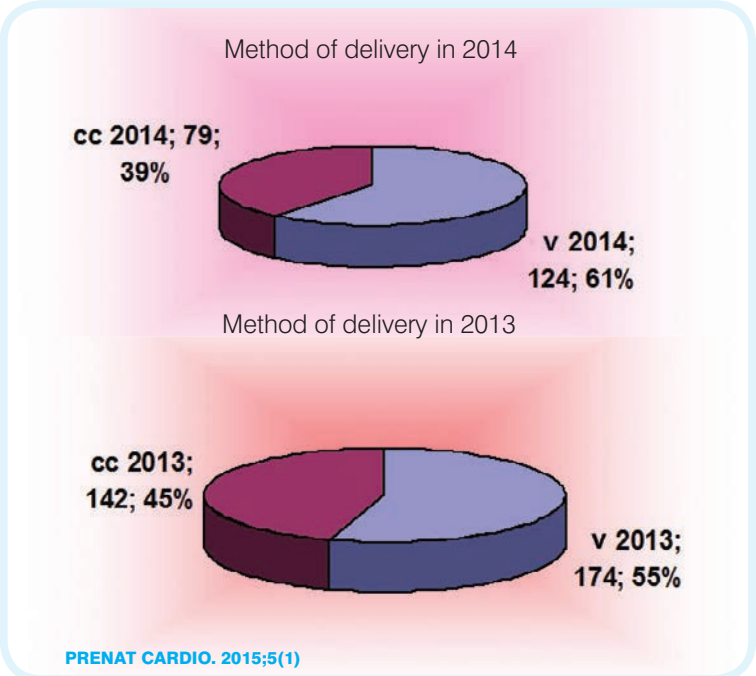
ORPKP registry has also some limitations. Our Registry is not obligation so it does not reflect 100% detection of fetal cardiac anomalies in Poland, but over 5000 records provided by > 4285 physicians in years 2004-2014 reflects our daily work. The data about neonatal follow-up were filled up in 31% up to 2012 and in 35% in 2013-2014 and an improvement in this regard should be our next goal. We did not analyzed cases who had examinations in 2 or 3 centers (they had separated records with the same code number), we did not analyzed so called "negative" verification (in case of different opinions of cardiac center type C about the type of severity of the heart defect).

Despite of these limitations our Registry is unique in Poland and Europe, but it should be stressed that since the beginning of global computerization, practically every research project is associated with databases[14-17]. One of the first registries based on data of prenatal diagnoses was the Eurofetus[17] started by Professor Levi of Brussels. Because the correct practice of ultrasound is strongly operator-dependent, education and training are of paramount importance. The best results in detecting malformations are invariably obtained by the most skilled operators performing targeted examinations. Prof. Levi was interested in a mass screening program, but he failed to achieve a satisfactory cost-benefit analysis.

In collecting data for the Registry, the principal focus was not on the process of screening but on the results of screening and process of diagnosing CHD. The heads of type C centers verified each entry to the database, using computer programs and by sending alerts.

Eurofetus has shown that the global sensitivity of CHD detection (34%) was significantly lower when compared to CNS (88%) and urogenital malformations (89%). Therefore our database is unique not only from Polish perspectives.

There are multiple other registries in Poland, Europe and elsewhere in the world[17-19] (Table 4), which provide vast amounts of epidemiological information. However, none of the other registries can be simply compared with our data.



Figures 7 and 8. Deliveries in pregnancies with congenital heart defects diagnosed prenatally in 2013 and 2014 (CC – cesarean section, V – vaginal delivery)

And as 1 in 100 neonates is born with CHD (and 1:1,000 with Down Syndrome), prenatal cardiology nowadays is one of the most important fields of medicine, and we look forward to see the next registry for "adults with congenital heart defects" including our prenatally detected problems, solved by current and future medical technologies. And in connection with the in vitro program supported by the Polish Ministry of Health, fetuses conceived by in vitro fertilization should be monitored for the presence of cardiac malformations and data should be compared to those resulting from natural fertilization. The other emerging problem is the necessity to analyze data from multiple pregnancies, the number of which is now increasing.

The following conclusions can be drawn from the updated analysis of the Registry data.

On the basis of a four-chamber view, the most frequently detected and diagnosed fetal cardiac malformation in Poland continues to be HLHS.

A tendency of increased detection of d-TGA and AS underscores that Polish ultrasonographers are assessing not only the four-chamber view but also the outflow tracts.

In the past two years, a tendency of hemodynamic progression was found in almost every fifth examined fetus, suggesting the necessity of enhanced echocardiographic and cardiac surveillance during the third trimester of pregnancy.

Since the time of Registry initiation in 2004 to the present time of, 2013 to 2014, the predominance of natural delivery over cesarean delivery has been noticed. This finding is suggestive that Polish obstetricians are increasingly accepting the guidelines on how to deliver fetuses with CHD.

The criteria for defining critical heart malformations need to be refined.

Importantly, the Registry is the central component of an overall national system to better integrate and coordinate the diagnosis, care and management of fetuses with structural and functional CHD. The Registry has already spurred CHD research as well as improvements in prenatal and perinatal health care in Poland.

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Conflict of interest: The authors declare no conflict of interest

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Individual part in creating the manuscript:

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