PRENATAL QUALIFICATION FOR POSTNATAL BALLOON VALVULOPLASTY IN ISOLATED CRITICAL PULMONARY VALVE STENOSIS BASED ON 10 CASES FROM A TERTIARY CENTRE OF FETAL CARDIOLOGY

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Abstract

Pulmonary valve stenosis is a congenital heart defect that is possible to detect and diagnose during prenatal life. We present a retrospective analysis of ten cases with isolated critical pulmonary valve stenosis (IPVS) to establish echocardiographic criteria which could predict the possibility for postnatal balloon valvuloplasty performed shortly after delivery.

Key words: *Prenatal critical pulmonary valve stenosis, postnatal balloon valvuloplasty*

INTRODUCTION

There is limited data on prenatal isolated pulmonary valve stenosis, which has often been misinterpreted as pulmonary atresia with an intact ventricular septum[1-6]. Currently, we should discriminate between these two entities, because both prenatal and postnatal opportunities for intervention may be different.

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The aim of our study was a retrospective analysis of cases with isolated pulmonary valve stenosis (IPVS) to establish echocardiographic criteria which could predict the possibility for postnatal balloon valvuloplasty performed shortly after delivery. To date, it is one of the first such publications in Poland and one of the very few in the world.

MATERIAL AND METHODS

From our database (File maker pro), we collected for the first stage of analysis 28 fetuses from 1993-2014 with isolated pulmonary valve stenosis (IPVS), including 27 singleton pregnancies and one from a twin pregnancy. No other cardiac or extracardiac anomalies were present in this series. In the second phase of the analysis, those cases which were prenatally qualified for cardiac surgery (valvulotomy and Blalock-Taussig shunt) were excluded. Benign pulmonary valve stenosis (pulmonary valve maximal blood velocity < 2 m/sec) was also excluded as well as cases in which, in addition to pulmonary valve stenosis, there were coexisting features of the Ebstein anomaly, a dysplastic tricuspid valve, functional or structural pulmonary atresia.

In the second phase of this analysis, we collected 10 fetuses from the years 2000-2014 with prenatal qualification for postnatal balloon valvuloplasty in our tertiary center.

All fetal echocardiography and ultrasonography examinations were retrospectively analysed (frozen frames and cine loops). The following parameters were analysed: maternal age, gestational age according to biometrics, fetal estimated weight, reasons for referral for fetal echocardiography, fetal heart size such as heart area/chest area ratio (HA/CA), pulmonary valve diameter, right ventricular outflow tract (RVOT) diameter, tricuspid valve diameter, maximum blood flow velocity of the tricuspid valve regurgitation, maximum pulmonary blood flow velocity, intraventricular septal thickness, aortic valve diameter, and from M-mode tracings: shortening fraction of the right and left atrium, shortening fraction of the right and left ventricles, type of septal movement, time between last fetal echo and delivery either by cesarean section or vaginal delivery, neonatal birth weight, Apgar score, day of life in which the neonate was discharged from the

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Table 1. Fetal echocardiography results in 10 fetuses with critical pulmonary valve stenosis with bidirectional blood flow in mediastinum

Case	Year	Gest age	HA/CA	4ch	Med	TR (m/s)	PS (m/s)	PV (mm)	AV (mm)	PV/AV	Post stenotic dilatation
1	2001	30	0,46	Dis(RA)	Norma	4	3	5,2	8,6	0,6	5.2/10.3
2	2004	28	0,45	Dis(RA)	Norma	5,2	2	5,5	6,5	0,8	7.1/8.6
3	2007	25,3	0,46	Dis	Dis	3	2,2	2,3	6	0,8	2.3/5
4	2009	28	0,4	Dis(RA)RV hypertrophy	Norma	4,5	3	2	7	0,28	2.5/6.8
5	2009	22	0,38	Normal	Norma	2,3	3,1	2,7	6,4	0,38	2.7/5.4
6	2011	29,3	0,44	Normal	Dis	4,7	3,6	5,9	5,4	1,46	5.9/8.8
7	2012	31,4	0,45	Normal	Dis	3,5	3,8	5,2	8	0,65	
8	2012	35,6	0,53	Normal	Dis	4	3,3	7,8	7,4	1	7.8/9.2
9	2013	37	0,3	Dis	Dis	3	4	8,5	8,6	1	8.5/1.29
10	2013, 14	30	0,43	RVH	Dis	3,2	3,8	6	7		6.0/12
Mean		**29,66**	**0,43**			**3,74**	**3,18**	**5,11**	**7,09**	**0,77**	
STD		**ratio 4,41**	**0,06**			**0,89**	**0,67**	**2,2**	**1,07**	**0,35**	

HA/CA heart area/chest area, TR – tricuspid valve regurgitation, PS – pulmonary valve max velocity, PV – pulmonary valve diameter, Av – aortic valve diameter, PV/AV : ratio; Dis- disproportion; Med- mediastinum

hospital, and finally follow-up. The reference values for RVOT and tricuspid valve were taken from monograms [3].

The main goal of our retrospective analysis was to look for prenatal echocardiographic criteria which would allow for the prenatal assessment of postnatal management in pulmonary valve stenosis: being considered as either a "critical heart defect" with prostin infusion and urgent neonatal valvuloplasty max up to 3rd day of postnatal life or "planned heart defect" with later cardiac surgery (with previous prostin administration).

Case	Year	Gest age	RA SF(%)	LA SF (%)	RV SF (%)	LV SF (%)	SEP (mm)	SEP motion
1	2001	30						paradox
2	2004	28						paradox
3	2007	25,3	45	40	3	55	4,5	paradox
4	2009	28			52	43	6	paradox
5	2009	22			30	32	4,5	
6	2011	29,3	12	21	0???	61	3,9	paradox
7	2012	31,4	10	20	34	40	3	
8	2012	35,6	28	42	50	29	6,6	
9	2013	37	27	50	9	41	3,4	paradox
10	2013. / 14	30	???	???	???	58	3,5	paradox
Mean		**30,2**	**24,4**	**34,6**	**25,42**	**44,87**	**4,37**	
STD		**4,41**	**14,18**	**13,4**	**21,69**	**11,92**	**1,2**	

Table 2: Fetal echocardiography data from M-mode tracings in 10 fetuses with critical pulmonary valve stenosis (measurements were not possible in all of the cases)

RESULTS

The mean maternal age was 25.4 +/- 3.2 years; the mean gestational age at the time of first diagnostic echocardiography according to the biometry was 30 +/- 2 days

For 7 fetuses, there was information about nuchal translucency (NT) in the first trimester; the mean value was 1.66 +/0.7 mm (minimum 0.7, maximum 2.7 mm). All fetuses were referred to our tertiary center following positive screening performed by obstetricians. The earliest time of detection of the anomaly was at 22 weeks of gestation and the latest was in the 37th week of gestation . The mean estimated fetal weight was 1876+/956g; in 8/10 fetuses the weights were appropriate for gestational age and in two fetuses the weights were reduced in relation to gestational age. In all 10 fetuses, the mean pulsatility index (PI) for the umbilical artery was (1.2 +/- 0.1).

By echocardiography, the heart size HA/CA was 0.43 +/-0.06 (minimum 0.3, maximum 0.53) in one case it was normal (0,3). All fetuses had tricuspid valve regurgitation, with a mean value of 3,74 +/- 0,89 m/s and all had increased pulmonary blood flow: mean value 3.18 +/- 0.67 m/s (Table 1).

In 6 fetuses, the 4 chamber view was abnormal with right atrial enlargement (disproportion at the atrial level or atrial and chamber level). In 4 fetuses, the 4 chamber view was normal and in two cases there was right ventricular hypertrophy (RVH).

The mean diameter of the pulmonary valve was 5,11 mm ranging from 2mm (at 25 weeks of gestation) up to 8.5 mm (at 37 weeks of gestation)(Fig. 1 and 3). All fetuses presented an abnormal mediastinal Doppler blood flow with poststenotic pulmonary outflow dilatation (lack of data for one fetus). All fetuses, had significant tricuspid valve regurgitation (mean value 3,74 +/- 0,89 m/s, with a maximum pressure gradient 60mm Hg).

In all fetuses, there was turbulent pulmonary blood flow (mean 3.18 +/- 0.67 m/s, with a maximum pressure gradient of 45.7mmHg. The diameter of the aortic valve ranged from 5.4 mm up to 8.6 mm (Fig.4). The pulmonary valve/ aortic valve ratio was 0.77. In 8 fetuses there was

significant post-stenotic right ventricular outflow tract dilatation (Table 1).

In four fetuses, the shortening fraction of the left atrium (LA SF) was higher than shortening fraction for the right atrium (RA SF). In 3 fetuses, the shortening fraction of the right ventricle was diminished and paradoxical interventricular septal movement was present. In three fetuses, hyperkinesis of the left ventricle was present (Table 2).

The time gap between the last echocardiography and delivery was mean 8 days (minimum 2 days, maximum 20 days). Deliveries occurred at mean gestational age of 37,3 +/- 1,7 weeks. 8 cases were delivered by Cesarean section (Table 3) and there were two vaginal deliveries. The mean birth weight was 2860 +/- 576 g and the mean Apgar score was 7.5 +/-1.1. There were 7 girls and 3 boys.

Balloon valvuloplasty was performed on the 2nd or 3rd day after delivery in 8 out of 10 newborns. One neonate with prenatal measurement of the pulmonary valve being 2,3mm (birth weight 2300g, year 2007) had sinusoids detected during prenatal and postnatal echocardiography and cardiac catheterization, and qualified for cardiac surgery and a pulmonary-systemic shunt. He never left the hospital and died at 6 weeks after delivery. The other neonate had RV hypertrophy and tricuspid valve regurgitation, and qualified for cardiac surgery instead of balloon valvuloplasty in 2014. After delivery, there was no forward flow across the pulmonary valve. Based on fetal echocardiography, 3 weeks prior to delivery, forward flow was seen.

The mean time of hospital stay after delivery for the 8 neonates who underwent valvuloplasty was 14 days.

DISCUSSION

Pulmonary valve stenosis is a congenital heart defect that is possible to detect and diagnose during prenatal life using an "electronic stethoscope" in the form of targeted echocardiography at a referral center for fetal cardiology. The prevalence of this malformation according to Hernandez at al. is 1:22,000, and it is present in 8-10% of children with congenital heart defects[7]. In the National Polish Registry for Fetal Cardiac Anomalies (www.orpkp.pl) in the years 2010-2013, this anomaly was 18th in place among the most common fetal cardiac heart defects[9].

Pulmonary valve stenosis may be present in both singleton or multiple (in our series case 4) pregnancies. It may be an isolated anomaly (present in our series), or it may coincide with Williams syndrome, Noonan syndrome, or microdeletion of chromosome 22q11.

Prenatal detection and diagnosis of pulmonary valve stenosis has been possible for 25 years.

Pulmonary valve stenosis is a heterogenous malformation. During embryogenesis, the 3 leaflets of the pulmonary valve may initially develop normally, but later on grow thicker, less "loose" and may become secondarily obliterated, resulting in a small hole or even turning completely atretic before delivery. Pulmonary blood flow is ductal-dependent under these circumstances; both before and after delivery, normal blood circulation is

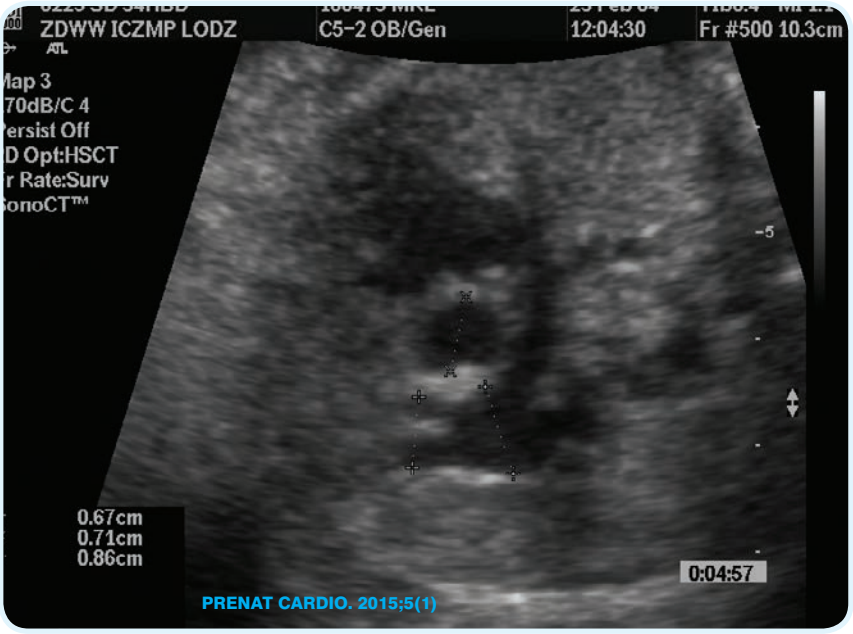

Figure 1. Poststenotic dilatation of right ventricular outlow tract in the fetus with critical pulmonary valve stenosis (successful postnatal valvuloplasty)

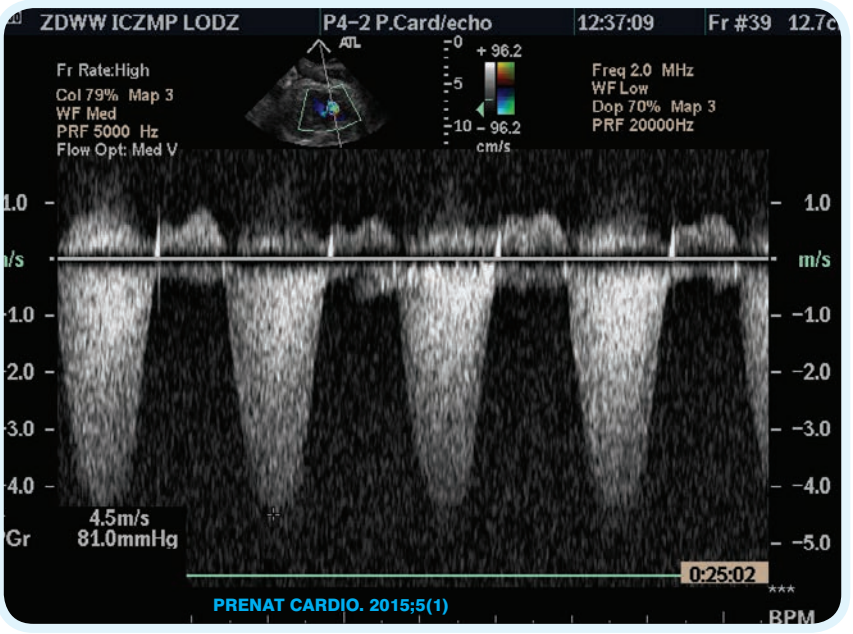

Figure 2 Tricuspid valve regurgitation in fetus with critical pulmonary valve stenosis

		Gest age	Delivery	Birth weight (g)	Apgar	Day after delivery of BVP	Follow-up
1.	2001	38	V	3105	6	2	Death on day 9 (bronchopneumonia purulenta)
2.	2004	38	CS	2480	6	3 + BTS 5th day	Death at 16 days
3.	2007	40	CS	2300	8	BTS	Sinusoids in catheterisation Death at 6 weeks of hospitalisation
4.	2009	Twin pregnancy 32	CS	1560	7	1	Discharge from hospital at 40 days with 25mmHg gradient. At 5 years of age no cardiac clinical symptoms
5.	2009	37	CS	3270	6	3	Initial good result after BVP:gradient 12mmHg, 2 wks later:50mmHg and significant TR Surgery at the age of 3,5 years- transannular patch with homograft and TV repair
6.	2011	37	V	3270	8	2	At the age of 5 months gradient 10 mmHg
7.	2012	36	CS	3000	8	3	At the age of 3 months gradient 30 mmHg
8.	2012	37	CS	3000	8	3	At the age of 2 months gradient 51 mmHg
9.	2013	37	CS	3170	9	1	4 wks gradient 20 mmHg, no clinical symptoms
10.	2013/14	39	CS	3400	9	BTS	After delivery no flow across PV, TR gradient 120mmHg. Cardiac surgery.
Mean		**37,3**		**2860**	**7,5**		
STD		**1,7**		**576,88**	**1,17**		

CS – cesarean section, V-vaginal delivery, BTS – Blalock-Taussig shunt

Table 3: Follow-up of 10 fetuses and neonates with prenatal diagnosis of critical pulmonary valve stenosis.

dependent on a patent ductus arteriosus. Haemodynamic consequences of diminished pulmonary blood flow may be secondary hypoplasia of the right ventricle, or hypertrophy, crossing over the narrow pathway of the right ventricular outflow tract.

This anomaly may be associated with abnormal connections of coronary vessels. In our series, one fetus was prenatally suspected of having such an anomaly which was later confirmed postnatally during cardiac catheterisation. Despite cardiac surgery, the baby died at 6 weeks of age (Table 3, case nr 3).

In the case of prenatal right ventricular hypoplasia, after delivery there is usually a single ventricle circulation (Table 3, case nr 10).

In 1988, Todros et al.[4] published a case report describing normal heart anatomy at 20 weeks of gestation and detection of this heart defect at 34 weeks, suggestive of prenatal progression of this anomaly. A similar conclusion came from Mexico[8]: at 22 weeks of gestation, the pulmonary pressure gradient was 15 mm Hg and at 35 weeks, 47 mm Hg. Our observation confirms these suggestions that prenatal pulmonary stenosis may result in pulmonary atresia at delivery (Table 3, case nr 10).

Taking into consideration the possible progression of this anomaly in the second half of pregnancy and a future single ventricle circulation, the idea of fetal valvuloplasty was suggested by a team of coworkers: a fetal cardiologist and a fetal surgeon-obstetrician; it was initially performed experimentally in sheep and later in human fetuses[10, 11,12,13].

Thus, prenatal detection, accurate diagnosis and proper intervention at the appropriate time might change the natural course of congenital pulmonary valve stenosis.

Intrauterine surgery is not a common practice and no more than 5 perinatal centers in the world are offering this type of procedure. Prenatal valvuloplasty is not 100% effective, as it may lead to complications and result in premature delivery. Thus, an alternative to this prenatal procedure has been proposed, with in utero transport to a tertiary

Types of heart defects based on prenatal diagnosis and prognosis for postnatal management:
Non urgent fetal congenital heart defect (surgery not required in the first month of postnatal life)
Urgent fetal congenital heart defect (ductal dependent, prostin administration is required and planned cardiac surgery in the 1st month after delivery)
Critical fetal congenital heart defect (ductal dependent, prostin administration is required as well as urgent catheterisation with valvuloplasty or Rashkind procedure)
The most severe congenital heart defect: resuscitation is not recommended, conservative approach

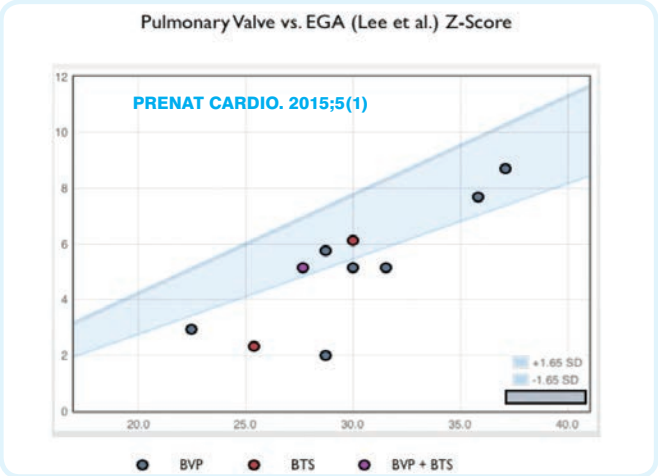

Figure 3. Pulmonary valve in 8 fetuses who underwent postnatal pulmonary valvuloplasty and 2 fetuses who had cardiac surgery, superimposed on Z-score Lee at al.2010[25]

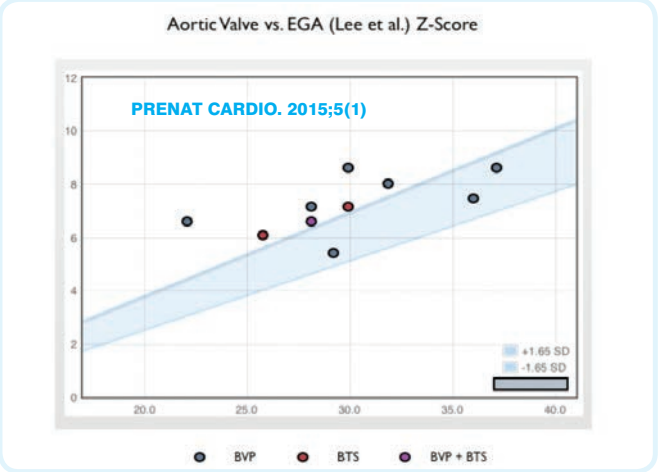

Figure 4. Aortic Valve measurement in 8 fetuses who underwent postnatal pulmonary valvuloplasty and 2 fetuses who had cardiac surgery, superimposed on Z-score Lee at al.2010 [25]

center, such as our hospital, where balloon valvuloplasty might be offered just after delivery.

In cases of a well-developed right ventricle the patient is qualified for catheterisation and an attempt to perform balloon valvuloplasty on the stenotic pulmonary valve is made. After effective treatment, administration of prostaglandin E1 can be discontinued. In the case of coexisting hypoplastic pulmonary arteries, despite effective balloon valvuloplasty and expansion of valve, sometimes to ensure optimal pulmonary flow, it may be necessary to maintain ductal patency or to surgically perform a systemic to pulmonary shunt.

We believe, based on our experience and analysis presented here, that this is a good way of clinical management.

The first publications on prenatal detection of pulmonary valve stenosis and neonatal valvuloplasty after elective cesarean sections came from India, Taiwan and Mexico[14,15,16]. Chinese authors[17] in 2013 suggested the advantages of early pulmonary valvuloplasty in contrast to late pulmonary valvuloplasty (> 6th day). They compared 7 newborns after prenatal diagnosis and 14 newborns without prenatal diagnosis. Pulmonary valvuloplasty was performed by 6th day of life, up until 28 days, and in the second month of life. It was suggested that improvement of the right ventricle Tei index occurred earlier in the prenatal group (after 1 month), in contrast to the postnatal group (after 1 year). This suggests not only a shorter time of hypoxemia, but also better regeneration of heart muscle in newborns who underwent early valvuloplasty ($p<0,05$).

Thus, with a prenatal diagnosis of pulmonary valve stenosis, there are several options for management: to do nothing, to perform pulmonary valvuloplasty before delivery, or just after delivery [17].

The best option cannot be decided upon the basis of a single echocardiographic parameter. Using, in addition to the 4 chamber view in obstetric screening with the use of Doppler, a mediastinal window is the best way to detect this malformation [18]. Our observation confirms this opinion, as all ten cases were accurately diagnosed by obstetricians. Although even in a tertiary center for fetal cardiology, a Doppler gradient assessment alone may produce false negative results, especially in a case of RV dysfunction.

Different groups [19-23] analysed different parameters such as tricuspid valve diameter, mitral valve diameter, the length of the RV and LV, diameter of the RVOT and LVOT (right and left ventricular outflow tracts) and their relations to qualitative indexes, as a basis for the best decision. The weak point of these publications was the large diversity of the analyzed material, a high percentage of termination of pregnancies, a very long time of observation, and the very variable clinical status of the newborns: from cases without any clinical symptoms to demise of newborns. Apart from all of that data, the authors had compiled a mixture of cases of prenatal critical pulmonary stenosis and pulmonary atresia, both with an intact septum or with VSD.

Therefore we decided to perform a retrospective analysis of our own data. According to our experience, we made an accurate assessment for prenatal qualification for postnatal balloon valvuloplasty in 8 out of 10 cases. According to the guidelines used by us to define heart defects prenatally, there are certain critical congenital heart defects, such as cases with a ductal dependent circulation, that require urgent valvuloplasty (before the 3rd day of postnatal life).

Two of 10 cases had an alternative diagnosis, namely coronary sinusoids and right ventricular hypertrophy.

One of the legal options in the case of early detection of a congenital heart defect in Poland and other countries, is termination of pregnancy. However, according to the data from the National Polish Registry, this option was chosen in less than 10% of cases. This in contrast to other countries: in Italy[7], termination rate for pregnancies was 43%, in Great Britain[22] 60%, and in Canada 40%[5].

In prenatal cardiology, the classification used regards to type of delivery and postnatal management according

to predicted time of intervention (Table 4), this being, our data confirms that based on prenatal echocardiography not only diagnosis, but also prognosis and planned postnatal management can be made. Isolated critical pulmonary stenosis in the majority of cases fits into the critical group of congenital heart defect, not only due to a ductal dependent circulation but also due to planned urgent valvuloplasty.

CONCLUSIONS

In our fetal tertiary cardiology center, in 8/10 cases, prenatal assessment for postnatal early balloon valvuloplasty was correct in 80%.

There is no single echocardiographic parameter that we may use for such a decision; however, progression of right ventricular hypertrophy, progression of the pulmonary valve pressure gradient over a couple of weeks and the presence of sinusoids were established as predictors of suboptimal outcome.

Prenatal critical pulmonary valve stenosis with a maximum blood flow velocity > 3 m/s in the majority of cases was considered as being a "critical congenital heart defect", rather than an "severe congenital heart defect" according to our prenatal classification of heart defects.

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Contribution of the authors in this research:

Joanna Płużańska: charts, English corrections, search for references, submitting manuscript for publication

Hanna Moczulska: discussion

Maciej Słodki: discussion

Michał Krekora: discussion

Ewa Gulczyńska: discussion

Paweł Dryżek: collecting data for the research, discussion:

Tomasz Moszura: discussion

Jadwiga Moll: discussion

Maria Respondek-Liberska: concept of the research, concept of the tables, discussion, final version of the manuscript

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