

Conotruncal anomalies in the fetus: Referral patterns and pregnancy outcomes in a dedicated fetal cardiology unit in South India

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ABSTRACT

- Objective** : To describe the referral patterns and pregnancy outcomes of fetuses with conotruncal anomalies (CTA) from a fetal cardiology unit in South India.
- Methods** : Records of 68 women identified to have diagnosis of CTA on fetal echocardiography (mean gestational age 26.8 ± 5.9 weeks; range 17-38 weeks) during the period 2008-2011 were reviewed.
- Results** : The most common indication for referral was suspected congenital heart disease during routine antenatal scan (89.7%). The various CTA diagnosed included Tetralogy of Fallot (TOF, 44.1%), Double outlet right ventricle (DORV, 27.9%), Transposition of great vessels (TGA, 8.8%), TOF with pulmonary atresia (TOF-PA, 8.8%), TOF absent pulmonary valve (TOF-APV, 7.4%) and truncus arteriosus (TA, 2.9%). Extra cardiac anomalies were reported in 4 fetuses (7.1%). Pregnancy outcomes included pregnancies not culminating in live-birth (54.4%), delivery at term (41.2%) with 3 patients (4.4%) being lost to follow-up. Proportion of pregnancies not culminating in live-birth lesion wise include: TOF (53.3%), DORV (52.6%), TGA (50%), TOF -APV (80%), TOF-PA (50%), and TA (50%). Twenty-four babies (35.3%) received post-natal cardiac care with 5 (7.4%) undergoing neonatal surgical procedures. Seven babies (10.3%) died in neonatal period, including 2 who underwent surgery. The accuracy of fetal echo was 96.4% for primary lesion and 67.9% for complete segmental diagnosis.
- Conclusions** : Pre-natal diagnosis of CTA, despite a high diagnostic accuracy, prompted utilization of post-natal tertiary cardiac care in a limited proportion of patients, including those with reparable lesions. Focus in developing countries should shift towards earlier referral, improving awareness about treatment options and a comprehensive evaluation for associated anomalies.
- Key words** : Conotruncal anomalies, fetal echocardiography, outcomes

INTRODUCTION

Conotruncal anomalies (CTA) are a broad category of congenital heart disease (CHD) that includes a variety of conditions like Tetralogy of Fallot (TOF) and its variants

absent pulmonary valve (TOF-APV) and pulmonary atresia (TOF-PA), double outlet right ventricle and its variants (DORV), Transposition of great arteries (TGA) and persistent truncus arteriosus (TA). These are relatively common anomalies in the post-natal series comprising about 10-12% of all congenital heart defects (CHD) diagnosed after birth.^[1,2] However, pre-natal diagnosis of these anomalies is more challenging since most of these anomalies have a normal four-chamber view during routine fetal heart screening.^[3,4] The prevalence in reported fetal series varies from 2.5-21% with a diagnostic accuracy of 75-90% for achieving a complete diagnosis.^[5-10]

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Several studies have documented the impact of prenatal diagnosis and the effect of associated anomalies on pregnancy outcomes of fetuses with various CTA.^[5-16] The overall outcomes after fetal diagnosis of these anomalies has been poor, especially when associated with extra cardiac and genetic anomalies.^[5-9,12] Survival rates after excluding terminations and intra-uterine deaths have ranged from 40-71%.^[5,6,9,12] Termination of pregnancy ranged from 30-50% and was decided by factors like complexity of the cardiac diagnosis and associated anomalies.^[5-16] Recent studies report that in the absence of associated co-morbidities, the prognosis of isolated CTA primarily depends on the lesion anatomy and is favorable for reparable lesions like TOF and TGA.^[6,11-13] The reported prevalence of genetic anomalies in these fetuses ranges from 11-18% in with a higher prevalence in TOF-PA, TOF-APV and TA.^[17-19] Bonnet, *et al.*, report the significant benefit of prenatal diagnosis in reducing peri-operative mortality as well as optimizing pre-operative condition in neonates with transposition of great arteries.^[13] In fetuses with TOF-PA, prenatal diagnosis may reduce the severity of post-natal hypoxia though not affecting the morbidity or mortality.^[15]

There is, however, limited data regarding the current practice and the potential impact of prenatal diagnosis on outcomes of CHD from the limited resource environments. The majority of patients have limited access to high quality prenatal care or prenatal ultrasound screening for fetal anomalies.^[20] Routine screening for genetic anomalies using novel markers like nuchal translucency is not uniformly performed. Cultural factors and socio-economic considerations may also significantly influence decision-making. Recently, selected centers have started performing neonatal heart surgery with outcomes that bear comparison to those from the developed countries.^[21] In this context, pre-natal diagnosis of critical but reparable anomalies like CTA may possibly facilitate a more optimal peri-natal care and better utilization of health care resources.

This study reports the referral patterns for fetal echocardiography and immediate pregnancy outcomes for fetuses diagnosed to have CTA from a dedicated fetal cardiology unit in South India.

MATERIALS AND METHODS

Study setting

The study was conducted in a tertiary care pediatric cardiology center in Kochi catering to a population of about 30 million in the state of Kerala in Southern India. The center is a private sector tertiary care teaching hospital established with the purpose of catering to the average citizen in the region. The hospital has a system for providing subsidized care for patients based on socio-economic considerations. Neonatal heart surgeries

are routinely performed in the center. A dedicated fetal cardiology division was founded in January 2008, providing comprehensive diagnostic services and antenatal management of CHD. The center also has an obstetric and perinatal care facility providing tertiary level peripartum care.

Study period and inclusion criteria

The present study was a retrospective review of all patients diagnosed to have a CTA on fetal echocardiography during the study period 2008-11. The lesions included under this category of anomalies included TOF along with its variants TOF-PA and TOF-APV, DORV and its variants, TGA and its variants and TA. Variants of these anomalies associated with hypoplasia of either of the ventricles were excluded from the analysis. The data was collected in a formal database and outcomes were tracked by direct follow-up, questionnaire or telephone enquiry. The Institutional Ethics Committee approved the study protocol.

Study protocol

The variables recorded in the database included maternal age, gestational age and indication for referral, maternal systemic illnesses, fetal risk factors (extra-cardiac anomalies, genetic defects, hydrops), family history of CHD (in first degree relatives) and details of previous ante-natal scans (nuchal fold thickness, amniotic fluid volume). Fetal echocardiography was performed using the IE33 ultrasound equipment (Philips Healthcare systems, Netherlands) using a standard protocol consisting of evaluation of abdominal situs, 4 chamber view, outflow tracts, 3 vessel view, tracheal view and the arches supplemented by color flow mapping and Doppler.^[22] The study was rated as either optimal or sub-optimal based on whether all the standard views were recorded or not. A pediatric cardiologist trained in fetal echocardiography performed all scans. Post-natal echocardiography was also done using the same ultrasound equipment as soon as feasible after birth using a standard protocol for pediatric echocardiography.

Counseling protocols

Following diagnosis, parents received detailed counseling regarding the nature of the anomaly, management options and the expected outcomes based on current literature and local institutional experience.^[21] A fetal cardiologist and a trained medical social worker provided counseling; a perinatology consultation was obtained whenever non-cardiac lesions were associated. Patients were classified into simple or complex CTA on the basis of whether a right ventricle to pulmonary artery conduit was deemed necessary (complex) or not (simple) for post-natal corrective surgery. For all patients, a detailed search for extra-cardiac anomalies and a genetic evaluation for 22q deletion syndrome as well as karyotyping were advised. The option of planned delivery in a cardiac center to

facilitate post-natal care was discussed with the family whenever the diagnosis of a critical, potentially life threatening lesion was made. The final decision regarding the management of the pregnancy (including the decision to go for additional tests like amniocentesis) was made by the respective families. In India, the legal limit for termination of pregnancy is 20 weeks gestational age.^[23]

Outcome variables and follow-up

Outcomes of the pregnancy were tracked by direct evaluation of the baby in the study center whenever possible or from hospital records and by telephone/questionnaire-based enquiry with the parents. A postnatal evaluation of the baby at the study center was advised in all cases. The accuracy of the pre-natal diagnosis was compared with the findings of the post-natal echocardiography with respect to the primary diagnosis of the anomaly as well as individual components like relationship of great vessels and outflow obstructions. The post-natal management was decided by the clinical status of the patient and the institutional policies. In patients undergoing corrective intervention for the CHD after birth, the immediate hospital outcomes were recorded. Pregnancy outcomes were categorized as: pregnancies not culminating in a live-birth, live-birth at term or lost to follow-up. In babies delivered alive at term, the immediate neonatal outcomes were categorized as post-natal cardiac care, no cardiac care and neonatal deaths (NND).

Statistical analysis

Data was expressed as percentage for nominal variables and mean with standard deviation or median with range for continuous variables. Fisher's exact test was used for comparison of continuous variables. *P* value of <0.05 was considered as significant. Statistical analysis was done using SPSS 11 version.

RESULTS

A total of 1292 women were referred for fetal echocardiography to our center during the study period 2008-11. Of these, 68 fetuses (5.3%) were diagnosed to have CTA, representing 19.9% of the total anomalies diagnosed during the study period. The mean gestational age at referral was 26.8 ± 5.9 weeks (range 17-38 weeks). The mean maternal age was 27.4 ± 4.5 years (range 20-41 years). The predominant indication for referral for fetal echocardiography was CHD suspected during routine antenatal scan in 61 cases (89.7%). The other indications included previous child with CHD in 3 (4.4%), maternal illnesses and extra cardiac anomalies in 2 cases (2.9%) each. Sixty-six fetuses (97.1%) were conceived naturally, while 2 (2.9%) were conceived by intra-uterine insemination. History of consanguinity (second degree) was noted in one patient (1.45%). History of maternal diabetes and maternal drug intake

was noted in 2 patients (2.9%) each.

Figure 1 summarizes the various types of CTA diagnosed during the study period. The most common anomaly diagnosed was TOF (30 fetuses, 44.1%). Fifty-one (75%) fetuses were categorized as simple and 17 (25%) as complex. Fetuses with complex CTA were referred at a later gestational age for fetal echocardiography (29.2 ± 5.4 vs. 25.9 ± 5.9 weeks; $P = 0.05$). A survey for extra-cardiac anomalies was reported in 56 fetuses (82.3%) with 4 (7.1%) having these anomalies. These included hydrocephalus in 2 fetuses and single umbilical artery and gastro-intestinal anomaly in one each. Nuchal translucency was reported only in 15 fetuses (22%) with 6 having an abnormal result. Genetic evaluation by non-invasive methods was attempted in 27 (39.7%) with one fetus (1.5%) having an abnormal result. Amniocentesis and tissue genetic studies were not done in any patient.

Data on pregnancy outcomes was available for 65 fetuses (95.6%) with 3 fetuses (4.4%) being lost to follow-up. The most common outcomes included pregnancies not culminating in a live-birth in 37 fetuses (54.4%) and successful completion of pregnancy with a live birth in 28 (41.2%). Proportion of pregnancies not culminating in a live-birth lesion wise include: 52.6% (10/19) for DORV, 50% (3/6) for TGA, 53.3% (16/30) for TOF, 80% (4/5) for TOF APV, 50% (3/6) for TOF PA, and 50% (1/2) for TA. Table 1 summarizes the outcomes of individual anomalies. There was no significant difference between simple and complex CTA with respect to the outcomes, though neonatal deaths were more common in the complex group [Table 2].

A total of 28 (41.2%) pregnancies culminated in a live birth, with 18 (26.5%) patients being delivered in

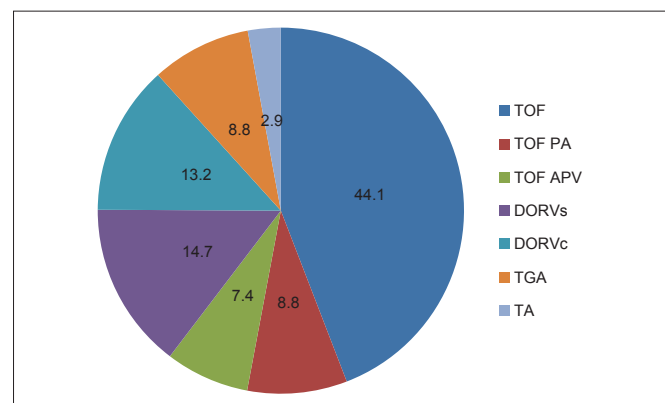


Figure 1: Types of conotruncal anomalies diagnosed (N = 68); All numbers in percentages. TOF = Tetralogy of Fallot, TOF PA = Tetralogy of Fallot with pulmonary atresia, TOF APV = Tetralogy of Fallot with absent pulmonary valve, DORV = Double outlet right ventricle, TGA = Transposition of great arteries, TA = Truncus Arteriosus

Table 1: Outcomes of individual anomalies

Lesion	No live birth N (%)	Neonatal death N (%)	Delivered treated N (%)	Delivered not treated N (%)	Lost to follow-up N (%)
TOF (30)	16 (53.3)	1 (3.3)	10 (33)	1 (3.3)	2 (6.7)
TOF PA (6)	3 (50)	2 (33.3)	1 (16.7)	0	0
TOF-APV (5)	4 (80)	-	-	-	1 (20)
DORV NRGV (10)	5 (50)	-	4 (40)	1 (10)	-
DORV malposed vessels (9)	5 (55.5)	1 (11.1)	3 (33.3)	-	-
TGA (6)	3 (50)	1 (16.7)	2 (33.3)	-	-
TA (2)	1 (50)	-	1 (50)	-	-

TOF: Tetralogy of Fallot, TOF-PA: Tetralogy of Fallot with pulmonary atresia, TOF APV: TOF with absent pulmonary valve, DORV NRGV: Double outlet right ventricle with normally related great vessels, TGA: Transposition of great arteries, TA: Truncus arteriosus

Table 2: Comparison of fetuses with simple CTA versus complex CTA

Variable	Simple (N=51)	Complex (N=17)	P value
Gestational age at diagnosis (weeks)	25.9±5.9	29.2±5.4	0.05
No live-birth	54.9% (N=28)	52.9% (N=9)	0.3
Neonatal death	3.9% (2)	23.5% (4)	0.03
Total mortality	58.8% (N=30)	70.6% (N=12)	0.4
Delivered and treated	31.4% (N=16)	29.4% (N=5)	0.9

Simple CTA includes Tetralogy of Fallot (TOF), TOF of fallot with absent pulmonary valve, Transposition of great vessels and Double outlet right ventricle (DORV) with normally related great vessels. Complex CTA includes TOF with pulmonary atresia, DORV with malposed great vessels and Truncus arteriosus

the study institution and 10 (14.7%) in the referring hospital. All babies born alive underwent a post-natal echocardiography in the study center. Prenatal diagnosis was completely accurate in 19 of 28 patients (67.9%). One patient (3.6%) had a major error in diagnosis with a prenatal diagnosis of TOF turning out to be TA on post-natal echocardiography. The other errors included errors *in situs* and cardiac position in 2 (7.4%) patients (missed diagnosis of dextrocardia in a patient with DORV and situs inversus in a TOF), incorrect diagnosis of VSD in one patient (3.6%) with TGA intact septum, errors in great artery relationship in 3 (10.7%) patients (all with DORV) and errors in assessment of outflow obstruction in 2 (7.4%) patients (one patient with TOF PA diagnosed as TOF and left ventricular outflow obstruction diagnosed as pulmonic stenosis in a fetus with DORV). There was no significant difference in gestational age at diagnosis for those with completely accurate diagnosis versus those with variations (30.5 ± 5.6 vs. 31.5 ± 4.3 weeks, $P = 0.8$). Table 3 summarizes the accuracy of fetal diagnosis in comparison with post-natal diagnosis in fetuses delivered alive.

Five babies (7.4%) died in neonatal period. Of these 4 babies were delivered in the study institution, while one infant with TOF-PA was delivered in the referring hospital. Four neonatal deaths occurred in situations where the parents refused specific cardiac care (TOF-PA delivered in referring hospital, TGA with a post-natal diagnosis of Crouzon's syndrome, TOF with dysmorphic features and a DORV with PS). One infant

with TOF-PA died despite attempted post-natal cardiac specific management. One baby with TOF died after the neonatal period while waiting for definitive repair. Five patients (7.4%) underwent surgery in neonatal period, including 3 aorto-pulmonary shunts (one TOF-PA and two TOF), one arterial switch operation for TGA and one TA repair with conduit. Of these, 2 (2.9%) babies died in the post-operative period (one shunt for TOF and TA repair). The remaining 20 patients (29.4%) are alive and on follow-up. The immediate post-natal survival of patients with intention to treat was 83.3% (20/24 patients). Figure 2 summarizes the immediate post-natal outcomes of all patients delivered alive.

DISCUSSION

The findings of our study reflect the current practice of fetal cardiology in the developing world. Typically, women are referred for a fetal echocardiography in late gestation, prompted by suspicion of CHD in a routine antenatal anomaly scan. Late performance of targeted anomaly scans or inability to diagnose lesions like CTA in earlier scans could be the reasons for the late referral. The overall accuracy of fetal echocardiography for diagnosis of CTA was comparable to the data from the developed world.^[5-7] The most common errors were associated with determination of great artery relationship in DORV as previously reported.^[5] A detailed survey for extra-cardiac and genetic anomalies was reported in a small proportion of patients in this study. Data on nuchal translucency was available only in 22% of patients. Genetic testing by tissue methods (amniocentesis) was not attempted in any patient, despite a formal counseling. The very low prevalence of extra-cardiac anomalies (7.1%) in the study population is likely to be due to under-reporting. This is significantly different from studies reported from developed countries.^[5-8,11,12,17-19]

A striking feature of our data is the relatively low utilization of post-natal tertiary cardiac care despite a high diagnostic accuracy of pre-natal diagnosis, even for lesions deemed repairable. A high proportion (54.4%) of affected pregnancies did not culminate in a live-birth, including fetuses with lesions like TOF and TGA [Table 1]. Pregnancy outcomes were not significantly influenced by

Table 3: Comparison of fetal echocardiography with post-natal echocardiography in fetuses delivered alive (N=28)

Pre-natal diagnosis	Primary diagnosis N (%)	Accuracy compared to post-natal diagnosis			
		Situs N (%)	VSD N (%)	Great vessels N (%)	Outflow stenosis N (%)
TOF (15)	14 (93.3)	13 (86.7)	15 (100)	14 (93.3)	13 (86.7)
DORV (9)	9 (100)	8 (88.9)	9 (100)	6 (66.7)	8 (88.9)
TGA(3)	3 (100)	3 (100)	2 (66.7)	3 (100)	3 (100)
TA (1)	1 (100)	1 (100)	1 (100)	1 (100)	1 (100)
Total (28)	27 (96.4)	26 (92.6)	27 (96.4)	24 (85.7)	25 (89.3)

TOF: Tetralogy of fallot, DORV: Double outlet right ventricle, TGA: Transposition of great arteries, TA: Truncus arteriosus

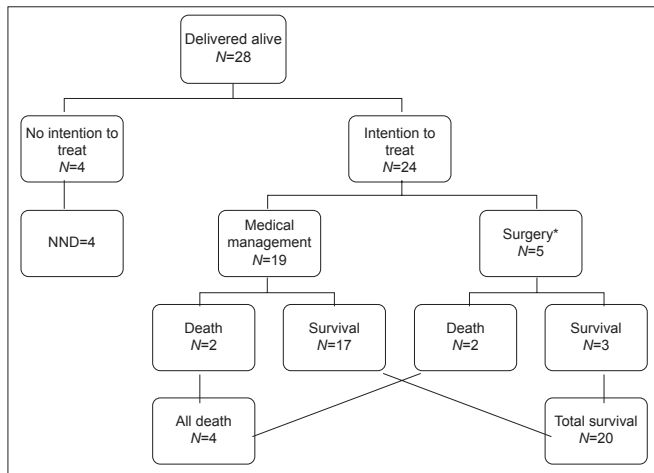


Figure 2: Immediate post-natal outcomes of fetuses delivered alive (N=28) Footnote: NND = neonatal death, *Surgery = included 3 aorto-pulmonary shunts (one TOF and 2 TOF PA), one arterial switch operation (TGA) and one truncus arteriosus repair with conduit

the complexity of the CTA [Table 2]. This is in striking contradistinction to the data from the developed world where the outcomes of fetal CTA was primarily decided by the presence of extra-cardiac and genetic anomalies or complexity of the individual lesion.^[5-15]

The socio-economic environment unique to a limited resource environment may have contributed to the relatively low utilization of post-natal tertiary cardiac services despite an accurate pre-natal diagnosis. Racial, cultural and ethnic factors may also have contributed to these decisions, though it was not systematically analyzed in this study. The lack of availability of prompt post-natal tertiary cardiac care was perhaps not a significant factor, since all families were counseled about the option of planned delivery in a cardiac centre after the pre-natal diagnosis.

The neonatal survival of patients with intention to treat was 83.3%. A total of 7 infants of the 28 delivered alive at term died in the neonatal period, 4 of which primarily occurring in cases where the families refused active post-natal cardiac care due to significant associated co-morbidities. These results concur with the findings of the studies from the developed world, which suggest that outcomes of fetal CTA are favorable in the absence of

significant co-morbid issues, especially in lesions amenable for anatomic correction.^[5-8,11-16] With better awareness about outcomes of anatomic repair, it is possible that more families may opt to undertake planned post-natal care in the future. As reported from previous studies, a strategy of directed deliveries and planned post-natal care could potentially improve the pre-operative condition of these critical CHDs resulting in significant reduction of peri-operative mortality and morbidity.^[13-16] A more thorough evaluation for extra-cardiac and genetic anomalies will facilitate a better utilization of health care resources by triaging patients with isolated CHDs with good prognosis for targeted post-natal care.

Limitations

The study is limited by the retrospective design and the significant lacunae of the data regarding associated extra-cardiac and genetic anomalies in the study population. Fetal autopsy was not attempted in fetuses undergoing termination of pregnancy or those who died in-utero. The impact of socio-economic, racial and cultural factors on pregnancy outcomes were not analyzed in this study. A longer-term follow-up will throw more light on the impact of pre-natal diagnosis on the eventual outcomes for these patients.

CONCLUSIONS

Pre-natal diagnosis of CTA, despite a high diagnostic accuracy, prompted utilization of post-natal tertiary cardiac care in a limited proportion of patients, including those with repairable lesions. Focus in developing countries should shift towards earlier referral, improving awareness about treatment options and a comprehensive evaluation for associated anomalies.

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