The Value of Multiple 2D Ultrasound Scanning Views in the Detection of Congenital Heart Disease in the Second Trimester (18 to 24 weeks)

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Abstract

Antenatal detection for Congenital Heart Disease (CHD) is poor, but may be improved by adding views to routine ultrasound scanning.

From June 2014-July 2015, 600 randomly selected women between 18 to 24 weeks of pregnancy, had a routine 4-chamber ultrasound scan at Mater Dei Hospital view (Basic 4CV). In addition, they completed an Extended Cardiac Ultrasound Examination (ExCUSE) including the left outflow tract, right outflow tract, 5-chamber view and 3-vessel view. All views were timed. The results obtained from the 600 women who received Basic and the ExCUSE scanning were followed-up clinically after delivery of the infants. Validity testing of both 4CV and ExCUSE views was carried out, and the detection rate of CHD compared.

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During the 12-month period, 61 cases from a total of 4,200 children up to 1 year of age were diagnosed with CHD by Paediatric Echocardiography. 19 were included in the 600-study cohort, of which 12 were detected antenatally, 1 via the 4CV alone, 4 by both the 4CV plus at least 1 of the ExCUSE views and 7 by 1 or more of the ExCUSE views alone. On average, ExCUSE views took approximately 6 minutes longer, yet there was a significant difference between the detection rate of CHD by the 4CV compared with the ExCUSE views (χ^2=0.031, p=0.05). Sensitivity and specificity of the 4CV were 31.6% and 100%, respectively, and 63.1% and 100%, respectively for ExCUSE views.

Antenatal diagnosis of CHD is improved with additional ultrasound views, but this will necessitate staff training and adjustments in clinic schedules to accommodate increased scan time.

Keywords

congenital heart disease, detection, antenatal scanning

Introduction

Congenital heart disease (CHD) represents the most common type of congenital malformations,[1] with an estimated incidence of about 4-13 per 1,000 live births.[2-3] In Malta, there were 48 neonates with CHD out of 4,435 live births in 2015, resulting in a prevalence of CHD in Malta of 11.2 /1,000 live births in 2015.[4] Despite the high incidence of CHD in newborns, the rate of antenatal detection CHD is very low, ranging from 15 to 20% of all cases diagnosed shortly after or within a few weeks of birth.[1] This would translate into an average of 6 or 7 cases in Malta. An improvement in antenatal detection of this condition could lead to better prenatal and postnatal care that may significantly

reduce neonatal morbidity and mortality.[3] Routine surveillance using 2-dimensional (2D) antenatal ultrasound scanning for CHD had been introduced in 1958 by Ian Donald and rapidly became established as the standard of care in the United States (US) and most European countries.[5] Initially, these scans employed a four-chamber view (4CV) alone, showing the two atria and ventricles, atrial and ventricular septum and atrioventricular (AV) valves, with real-time images of valve function.[7] The 4CV was appropriate for the detection of anomalies of the atria, ventricles, AV junctions and atrial and ventricular septa, but less effective for lesions involving the outflow tracts, great arteries and visceral and atrial situs. Hence, lesions such as transposition of the great arteries (TGA), Tetralogy of Fallot (TOF), severe pulmonary stenosis, pulmonary atresia, double outlet right ventricle (DORV) and common arterial trunk (CAT) were missed by the 4CV alone.[6]

The implementation of additional, multiple scanning planes to the routine anomaly 2D ultrasound scan have improved antenatal detection of CHD.[7] These usually include the evaluation of the left and right outflow tracts (LOT and ROT views), the aorta, pulmonary artery and superior vena cava (the three-vessel view, 3VV) and the aortic root (the five-chamber view, 5CV).[6,8] For the purpose of this study, these views, when performed in conjunction with the 4CV of the heart, are referred to as the 'Extended Cardiac Ultrasound Examination', whilst the 4CV, when taken as a stand-alone evaluation of the foetal heart, is being referred to as the 'Basic Cardiac Examination'.
In many countries, the extended examination comprising multiple views has been the standard approach for several years. Therefore Malta, where the solitary 4CV was still in use in 2014, was arguably falling short of the accepted standard practice. Indeed, at this time, out of approximately 40 CHD cases per annum, only 6 or 7 cases of CHD were being diagnosed antenatally.

This study assessed whether there was any significant increase in antenatal detection of CHD in Malta by implementing ExCUSE scanning routinely. Furthermore, the feasibility and increase in scanning time by ExCUSE was also determined.

Methodology
Data Collection
Data collection spanned July 2014 to June 2015

with permission from all relevant parties. Furthermore, ethical approval was granted by the University Research Ethics Committee and access to health records allowed by the Directorate of Health Information and Research. Women between 18-24 weeks of gestation were recruited sequentially on attendance for their routine antenatal scan. They were given an information sheet explaining the research and, if willing to participate, were asked to sign the informed consent form. The following data was collected: gestational age, mother's age, mother's Body Mass Index (BMI) and foetal gender. The entire study sample of 600 women was scanned by the same researcher using the conventional 4CV and four additional views, namely the left outflow tract (LOT), the right outflow tract (ROT), the five-chamber view (5CV) and the three-vessel view (3VV), as shown in Figures 1 to 5. The composite scan including all views was denoted as the Extended Cardiac Ultrasound Examination (ExCUSE). All ultrasound scans were timed. Firstly, the routine 4CV standard anomaly scan was performed and timed, this representing the actual scan time for a routine anomaly ultrasound scan in Malta. Thereafter, all the above-mentioned extra views comprising ExCUSE were performed and timed separately.

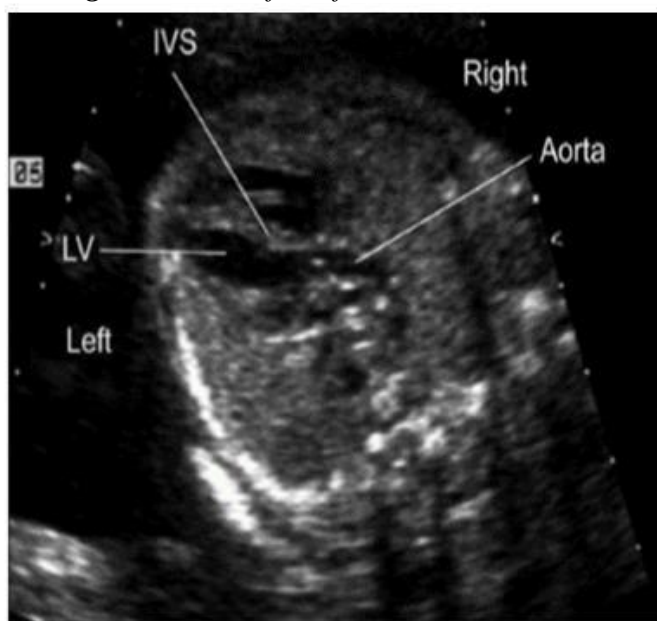*Figure 1: The four chamber view*

Legend: Ao – Aorta; LA – Left Atrium; LV- Left Ventricle; MB – Moderator Band; RA – Right Atrium; RV – Right Ventricle; PV – Pulmonary Veins; S – Foetal Spine

Figure 2: *The right outflow tract view*

Legend: RA – Right Atrium; RV – Right Ventricle

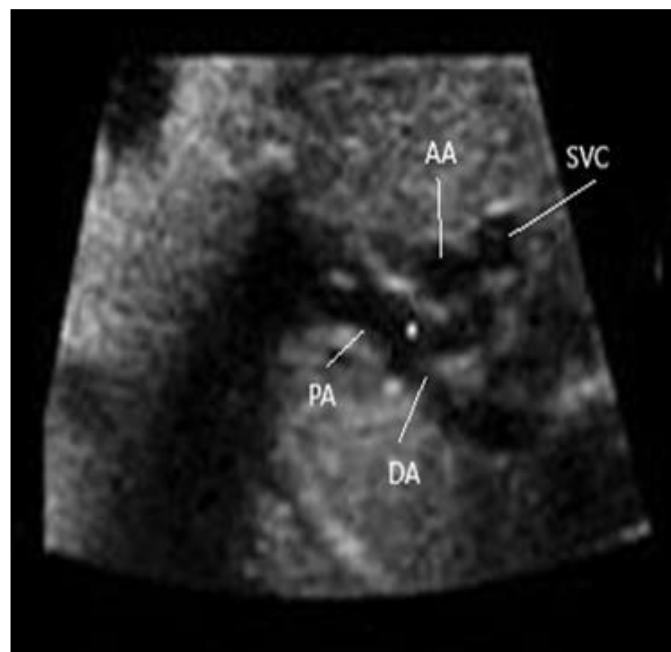**Figure 3:** *The left outflow tract view*

Legend: LV- Left Ventricle; IVS – Inter-Ventricular Septum

Figure 4: *The five-chamber view*

Legend: AA – Ascending Aorta; Ao – Aorta; DA – Ductus Arteriosus; LA – Left Atrium; LV- Left Ventricle; MPA – Main Pulmonary Artery; RA – Right Atrium; RV – Right Ventricle; SVC – Superior Vena Cava

Figure 5: *The three-vessel view*

Legend: AA – Ascending Aorta; DA - Ductus Arteriosus ; MPA – Main Pulmonary Artery; PA - Pulmonary Artery; SVC – Superior Vena Cava

Inclusion and Exclusion Criteria

All mothers 18 to 24 weeks pregnant of all ages residing in Malta with a doctor's referral for an elective or urgent antenatal ultrasound appointment were included, whereas those with an Intra-Uterine Death (IUD), refusal to sign the Consent form and non-resident pregnant females were excluded.

Outcomes

The outcome of the study sample group of mothers that gave birth to neonates with or without CHD was followed prospectively. The results obtained by the Basic 4CV and ExCUSE scanning were then confirmed clinically after the delivery of the infants. All infants were then followed up for a further twelve months, in case of any late diagnoses of CHD, thereby significantly reducing the incidence of false negatives.[9] Any infant with a suspicion of CHD underwent postnatal echocardiography, as per current, routine practice. The actual clinical and echocardiographical findings of newborns found to have CHD were compared to the results of the antenatal ultrasound scan, thus confirming or refuting whether the cardiac malformation had been detected accurately or not, and if so, by which view had it been detected.

Statistical Analysis

Demographic data was compared with data from the National Statistics Office (NSO, Demographic Review, 2015). Validity testing was performed to obtain the sensitivity and specificity of ExCUSE scanning. The definitive confirmation of CHD was taken on the basis of the result of a postnatal echocardiogram. Chi-Square Test (χ^2 test) using SPSS® was used to check for any significant difference between the 4CV as a stand-alone view and the ExCUSE scan. McNemar χ^2 test was used for 'Agreement Analysis' in the event of marginal homogeneity. A p-value of ≤ 0.05 was taken to represent a significant difference.[10]

Results

600 mothers were recruited with no mother refusing to sign the consent form. Since they were all residing in Malta at that time all were eligible for the study.

Statistics concerning the demographics of the population sample were carried out to determine how representative the study sample was of the general population. The mean age of the population sample was 29 years compared with 30-34 years of age for the national cohort,[11] whereas the mean BMI for the population sample was 24.9 which compares well with that of the whole national pregnant population since 53.2% of the female population in Malta had BMIs equal to or more than 25.[12] Out of 600 subjects, there were 291 mothers with male foetuses (48.5%), 291 mothers with female foetuses (48.5%) whilst in 18 cases, i.e. 3% of the cases, the foetal gender could not be determined. The latter was mainly due to high mothers' BMI which reduced image quality due to decreased resolution therefore making it difficult to determine foetal sex by ultrasound scanning.

During the 12-month study period there were 61 cases of children of up to 1 year of age who were diagnosed with CHD by definitive postnatal Paediatric Echocardiography. There were 25 (41%) male children versus 36 females (59%) with CHD. The types of CHDs varied from simple ASDs and VSDs to TGAs, TOFs and coarctation of the aorta.

Of these, 19 were born to mothers who formed part of the study cohort of 600. A diagnosis of some type of CHD was made by antenatal scanning in 12 of these 19 cases, 1 via the 4CV alone, 4 by both the 4CV plus at least 1 of the ExCUSE views and 7 by 1 or more of the ExCUSE views alone (that is, where the 4CV was normal), as shown in table 1. This meant that there was a significant difference between the detection rate of CHD by the 4CV compared with the ExCUSE views ($\chi^2=0.031^a$; $p=0.05$). The sensitivity of the 4CV was found to be 31.6% and its specificity was calculated to be 100%, whilst the sensitivity and specificity of the ExCUSE views (that is, the 4CV plus all the other views) were found to be 63.1% and 100%, respectively. These denominators included all CHD babies since all forms of CHD that were present in these 19 subjects could have been potentially detected and in which an early diagnosis would have been helpful in the management of the CHD. Furthermore, all CHD babies detected antenatally were subsequently born, that is, there were no intra-uterine deaths.

Furthermore, as shown in Table 2, on average anomaly scanning that included the ExCUSE views took approximately 6 minutes longer to perform.

Table 1*: Number of cases with CHD detected by 4CV and ExCUSE views*

CHD only picked up	Number
4CV	1
4CV + at least 1 ExCUSE view	4
1 or more ExCUSE view whilst 4CV appeared normal	7

Table 2*: Timing for 4CV and ExCUSE views*

View	Time (mean, in minutes)
4CV	1.16
LOT	1.14
ROT	1.16
5CV	1.12
3W	1.15

Discussion

This study set out to objectively show the necessity of implementing change using local data so as to be wholly relevant to Malta. Despite multiple studies abroad, whereby antenatal foetal ultrasound scanning routinely employ the application of several scan views, Malta was still lagging in this regard in 2014. Hence, it was important to make a case for change in the health service in Malta, so as to include the extra views when assessing the foetal heart. Moreover, this study had not been previously undertaken in Malta, and no local data was available to support or refute the use of multiple images in order to augment the pick-up of foetal CHD in Malta. In this regard, this study was original, unique and comprehensive, and also included the variable of time.

The demographic results obtained showed that the population sample compared well to the general pregnant population in terms of age, BMI and foetal gender since the results obtained were very similar to those of the general population according to the National Statistics Office (NSO) for the Demographic Review published in 2015.

The study did show that, even within the health service framework in Malta, additional antenatal ultrasound scan views do increase the detection of congenital heart disease during this critical period, thereby facilitating the planning of care and intervention for these children. The study highlighted the need for an enhanced protocol that is required to standardise the approach to the diagnosis of CHD antenatally using the Extended Cardiac Examination views as well as the routine 4CV. It would also recommend that training in foetal cardiac scanning is needed to ensure a standard approach and improve the diagnostic acumen for CHD of 'obstetric' ultrasonographers. In order to achieve this, sonographers should have achieved a certain level of expertise (a minimum of 3 years as full-time sonographers), and be performing this on a full-time basis. Diagnostic yield would also be enhanced with the routine use of other and/or new techniques such as the use of Doppler, transvaginal (TV) scanning and 3-Dimensional (3D) Echocardiography that all increase diagnostic reliability of ultrasound scanning in the case of the foetal heart.

In this study, the aortic arch view was not included in the recommended extra views since it frequently proves difficult and time-consuming. However, it must be pointed out that it is essential in the diagnosis of aortic arch malformations that, albeit rare, tend to be life-threatening and require urgent intervention. Therefore, early pick-up is very important. In fact, whenever it proved possible, whilst scanning the 600 subjects, the aortic arch view was included in the sequence of extra views. However, due to time constraints, this was only done when it did not prove too problematic to obtain.

This study had limitations. Ultrasound is operator-dependent, and this may have influenced the effectiveness of using the Extended Cardiac Examination as a screening tool since, apart from training, operator-dependency is highly reliant on the experience of the sonographer(s) in question.[13] Since there was only one principal researcher performing all 600 cases, there was the risk of operator-bias. However, this ensured that all views were performed in a standardised manner.

Time-constraints and cohort size limitations (one researcher scanning a cohort of 600 patients in one year) made it impossible to include a strict control group in the population sample. The study cohort was compared to historical data rather than an age and demographically matched control group. Furthermore, the ultrasound machine used (Siemens Sonoline G50) was older than 10 years. As a result, since over time, image resolution decreases due to normal wear and tear, image quality (and diagnostic potential) may have been adversely affected. The

importance of the suitability of the equipment being used and its maintenance cannot be stressed enough since it can be a major limiting factor in scanning the foetal heart.

It was decided that the babies scanned antenatally would be followed up until they would be one year of age. However, there may have been some cases where no clinical symptoms presented in this period, albeit uncommonly. Hence, limiting follow up to just 12 months may have resulted in some cases of CHD being missed (although very few, if any).

Finally, implementation of the study recommendations would increase the workload in the antenatal ultrasound clinic, and increase the scanning time for each patient. Hence, a new, extended protocol for antenatal scanning using ExCUSE views would need to be taken into consideration and accommodated.

Since completion of this study, dedicated list of anomaly scans are being performed by personnel using the afore-mentioned views.

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