Prenatal diagnosis of congenital heart defects: quality analysis of telemedicine using four-dimensional ultrasound with spatiotemporal image correlation

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ABSTRACT

Objective: To determine whether four-dimensional (4D) tele-ultrasound imaging is a reliable diagnostic tool for assessing congenital heart defects.

Methodology: Clinical investigators from 10 Spanish prenatal diagnosis centers participated in this study. Each participant was requested to upload between four and six retrospective cases onto a centralized file protocol server (4D tele-ultrasound volume data sets) to be analyzed "off line" by the other investigators. The rate of normal and heart defect cases was variable and unknown to the rest of the participants.

Results: A total of 56 cases were uploaded (37 normal and 19 with congenital heart defects), and 504 diagnostic assessments were provided. The quality of the volume data sets acquired was analyzed. In 14 of the diagnostic assessments, the result was inconclusive (2.8%). The procedure obtained a sensitivity of 88.7% (83.5 – 93.9), a specificity of 94.2% (91.6 – 96.9), as well as a false negative rate of 10.5% (18/171) and false positive rate of 5.7% (19/333). There was good inter-center agreement (k=0.74). Quality control of the diagnosis in pathological cases was performed using the American College Radiology score.

Conclusions: Appropriate acquisition of volume data sets is important for subsequent "off-line" diagnosis. The sensitivity and specificity values obtained in this study confirm that tele-echocardiography is a useful procedure for the identification of congenital heart diseases. In addition, implementation of a quality control score provides 4D ultrasound imaging with the characteristics of an optimal training tool.

KEYWORDS

Congenital heart defects, fetal echocardiography, four-dimensional ultrasonography, prenatal diagnosis.

Introduction

Heart defects are the most frequent congenital abnormalities, with an incidence of 4–12 in 1000 newborns, and they carry a considerable burden of perinatal morbidity and mortality [1,2]. However, it is difficult to establish from the literature the precise incidence of congenital heart defects, owing to differences in diagnostic capacity, tools used, populations studied, and types of heart defects included. Differences in the heart defect rate can be attributed, to a certain extent, to the different diagnostic criteria used, as well as the periods in which studies were conducted. The capability of routine echocardiography to detect congenital heart defects ranges from 35 to 86% in low-risk populations [3]. Thus, when it is performed in a population at high risk of congenital heart defects, its diagnostic sensitivity can reach very high percentages. However, since 90% of heart defects occur in low-risk gestational cases, [4] prenatal diagnosis of congenital heart defects continues to be a major challenge.

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Spatiotemporal image correlation (STIC) technology was developed in 2003 [5]. Since then, different authors have explored its potential to facilitate the diagnosis of congenital heart defects [6,7]. This technology is based on the three-dimensional (3D) storage of images of cardiac structures with a time correlation based on the movements of a cardiac cycle. One of the main potential advantages is that this technology lends itself to application in telemedicine, allowing "off-line" assessment of the fetal heart. The authors of several studies have considered a prospective role for four-dimensional (4D) echocardiography with STIC technology in the prenatal diagnosis of congenital heart defects, particularly in view of its potential to reduce the "operator dependency" of conventional two-dimensional (2D) ultrasound imaging [8-11]. Various recent works explore the reproducibility of the procedure and its intra- and inter-observer correlation [12-16].

In 2010, Espinoza *et al*. [17] published the results of the Collaborative Study on 4-Dimensional Echocardiography for the Diagnosis of Fetal Heart Defects, which showed a heart defect detection rate of 93.0% and a false-negative rate of 6.8%. Against this background, our research sets out to determine the usefulness of this tool in the "off-line" diagnosis of congenital heart defects, and to assess the quality of the procedure itself.

Material and methods

This study was carried out by ten clinical investigators from ten Spanish centers for prenatal diagnosis: Hospital Universitario (Granada), Instituto Dexeus (Barcelona), Hospital Clínico (Zaragoza), Hospital Universitario Valle de Hebrón (Barcelona), Clínica Gutenberg (Málaga), Hospital Virgen de la Arrixaca (Murcia), Hospital Universitario Materno Infantil (Canarias), Hospital La Fe (Valencia), Centro Sanitario Virgen del Pilar (San Sebastián) and Hospital 12 de Octubre (Madrid).

An external coordinator asked each participant to transfer 6 retrospective cases with a known outcome, i.e., normality or heart defect (confirmed through autopsy or neonatal echocardiography), to an "on-line" database. This coordinator, who was responsible for selecting the cases to be transferred, was not involved in the subsequent diagnosis. The proportion of normal and pathological cases selected from each center was variable and unknown to the participants from the other centers. The study was approved by the Ethics Committee of the Aragon Institute of Health Sciences and abides by the Law on Privacy and Data Protection (Royal Decree 2009).

To facilitate the transfer of files onto the server, a Winzip 15.0 compression program was used. The transfer, whenever possible, of at least two STIC volume data sets was recommended. The characteristics of the images captured, in terms of time and angle of acquisition (7.5-10 seconds and 30°-45°), were dependent on the gestational age, fetal motion, maternal conditions or personal preference of the clinical investigator who uploaded the case.

Subsequently, the ten participants analyzed all the volume data sets uploaded, except for their own, using General Electric 4DView software, Zipf, Austria, in order to provide both a general diagnosis (normal, pathological or inconclusive) and a specific diagnosis of any suspected heart defect. No time limit was set for the off-line analysis. Some cases had limited clinical value due to some of the following circumstances: storage problems such as absence of color Doppler, STIC scanning not including the whole cardiac structures, low-quality images caused by fetal motion at the moment of acquisition.

The categories for the diagnosis of heart defects were the 16 major congenital heart defects described in the Eurocat 2000-2005 study plus an open field. These congenital heart defects are classified into 3 groups according to their severity:

- **Very severe**: single ventricle, hypoplastic left heart, hypoplastic right heart, Ebstein's anomaly, and tricuspid atresia.
- **Severe**: pulmonary valve atresia, common arterial trunk, atrioventricular canal defect, aortic valve atresia/stenosis, great artery transposition, tetralogy of Fallot, total anomalous pulmonary venous connection, and aortic coarctation.
- **Non-severe**: interventricular communication, interatrial communication, and pulmonary valve stenosis.

To demonstrate whether 4D ultrasonographic imaging is an efficient procedure for identifying a fetal heart as "normal" or "abnormal", a statistical analysis of the diagnostic process was used. The tool's sensitivity and specificity were determined, as well as its false-positive and false-negative rates. Inter-center agreement was analyzed using a generalized kappa statistic for multiple raters. The SPSS 15.0 (IBM Corp., Armonk, New York, United States) and Epidat 4.0 (Xunta de Galicia, Santiago de Compostela, A Coruña, Spain) software packages were used for statistical analysis. $P<0.05$ was considered significant. Finally, the American College of Radiology rating system [17] was used to perform quality analysis of the investigators' "off-line" diagnoses of the 19 cases with congenital heart defects, assessing, as follows, the levels of disagreement and their clinical significance:

1. Agreement.
2. Minor disagreement (high difficulty diagnosis); 2a: of low clinical relevance and 2b: of clinical relevance.
3. Moderate disagreement (average difficulty diagnosis); 3a: of low clinical relevance and 3b: of clinical relevance.
4. Serious disagreement (easy diagnosis, there should be no error); 4a: of low clinical relevance and 4b: of clinical relevance.

Results

A total of 56 cases were uploaded (37 normal and 19 abnormal) and 504 diagnostic assessments were provided: 333 (66.1%) in normal cases, and 171 (33.9%) in cases with heart defects. The gestational age of the cases under study ranged from 17 to 30 weeks, with an average of 20w+6d. The confirmed diagnoses in the 56 cases uploaded for "off-line" diagnosis are shown in table 1.

The result of the general study using 4D tele-echocardiography was 453 diagnoses in agreement (89.9 %) and 37 in disagreement (6.7%). On 14 occasions (2.7%) the volume data sets under study were deemed to contain insufficient information to allow a diagnosis to be made.

The statistical analysis to determine the usefulness of tele-echocardiography as a simple diagnostic test to detect congenital heart defects showed the following results: sensitivity: 88.7% (83.5-93.9), false-negative rate: 10.5%, specificity: 94.2% (91.6-96.9), false positive rate: 5.7%. The inter-center agreement was $k=0.74$ (0.63-0.86). Data on diagnostic efficiency per center and per heart defect considered in the study are shown in tables 2 and 3, respectively.

Table 1 Confirmed diagnoses of the 56 cases uploaded for 4D tele-echocardiography assessment.

Diagnosis	Number	Percentage	Diagnosis	Number	Percentage
Normal heart	37	66.1%	Single ventricle	1	1.8%
Tetralogy of Fallot	3	5.3%	Tricuspid atresia	1	1.8%
Atrio-ventricular canal defect	3	5.3%	Common arterial trunk	1	1.8%
Pulmonary valve atresia	2	3.5%	Aortic coarctation	1	1.8%
Great artery transposition	2	3.5%	Rhabdomyoma	1	1.8%
Interventricular communication	2	3.5%	Pulmonary valve stenosis	1	1.8%
			Hypoplastic left heart	1	1.8%

Table 2 Sensitivity, specificity, predictive positive value and predictive negative value of 4D tele-echocardiography with a confidence interval of 95% for each center.

Diagnosis	Sensitivity	Specificity	Predictive positive value	Predictive negative value
Center 1	88.2% (69.9 – 100)	91.2% (80.2 – 100)	83.3% (63.4 – 100)	93.9% (84.3 – 100)
Center 2	88.3% (61.3 – 100)	93.7% (83.8 – 100)	87.5% (68.2 – 100)	90.9% (79.6 – 100)
Center 3	88.2% (69.9 – 100)	100% (98.5 – 100)	100% (96.7 – 100)	94.3% (85.2 – 100)
Center 4	94.1% (79.9 – 100)	97.1% (90.2 – 100)	94.1% (79.9 – 100)	97.1% (90.2 – 100)
Center 5	88.9% (71.6 – 100)	100% (98.4 – 100)	100% (96.9 – 100)	94.1% (84.7 – 100)
Center 6	92.9% (75.8 – 100)	97.1% (89.9 – 100)	92.9% (75.8 – 100)	97.1% (89.9 – 100)
Center 7	100% (96.7 – 100)	96.9% (89.6 – 100)	93.7% (78.8 – 100)	100% (98.4 – 100)
Center 8	100% (96.9 – 100)	93.5% (83.3 – 100)	88.9% (71.6 – 100)	100% (98.3 – 100)
Center 9	50% (17.5 – 82.5)	90.9% (79.6 – 100)	66.7% (30.3 – 100)	83.3% (69.8 – 96.9)
Center 10	94.1% (79.9 – 100)	81.8% (67.1 – 96.5)	72.7% (51.8 – 93.6)	96.4% (87.8 – 100)
Total	88.7% (83.5 – 93.9)	94.2% (91.6 – 96.9)	88.2% (82.9 – 93.5)	94.5% (91.9 – 100)

Table 3 Sensitivity, specificity, predictive positive value and predictive negative value of 4D tele-echocardiography with a confidence interval of 95% for each heart defect.

Clinical conditions	Sensitivity	Specificity	Predictive positive value	Predictive negative value
Tetralogy of Fallot	92.6% (80.9 – 100)	98.7% (97.6 - 99.8)	80.6% (65.1 – 96.2)	99.6% (98.9 – 100)
Great artery transposition	94.4% (81.1 – 100)	99.6% (98.9 – 100)	89.5% (73.0 – 100)	99.8% (99.3 – 100)
Common arterial trunk	100% (94.4 – 100)	99.8% (99.3 – 100)	90% (66.4 – 100)	100% (99.9 – 100)
Atrio-ventricular canal defect	77.8% (60.2 – 95.3)	99.6% (98.9 – 100)	91.3% (77.6 – 100)	98.7% (97.7 – 99.8)
Tricuspid atresia	100% (94.4 – 100)	99.0% (98.0 – 99.9)	64.3% (35.6 – 93.0)	100% (99.9 – 100)
Pulmonary valve atresia	61.1% (35.8 – 86.4)	99.8% (9.3.0 – 100)	91.7% (71.9 – 100)	98.6% (97.4 – 99.7)
Interventricular communication	55.6% (29.8 – 81.3)	96.5% (94.8 – 98.2)	37.0% (17.0 – 57.1)	98.3% (97.1 – 99.6)
Single ventricle	100% (94.4 – 100)	99.8% (99.3 – 100)	90.0% (66.4 – 100)	100% (99.9 – 100)
Aortic coarctation	100% (94.4 – 100)	100% (99.9 – 100)	100% (94.4 – 100)	100% (99.9 – 100)
Rhabdomyomas	44.4% (6.4 – 82.5)	100% (99.9 – 100)	100% (87.5 – 100)	99.0% (98.0 – 100)
Pulmonary valve stenosis	100% (94.4 – 100)	99.4% (98.6 – 100)	75.0% (46.3 – 100)	100% (99.9 – 100)
Hypoplastic left heart syndrome	100% (94.4 – 100)	97.8% (96.4 – 99.2)	45.0% (20.7 – 69.3)	100% (99.9 – 100)
Total heart defects	88.7% (83.5 – 93.9)	94.2% (91.6 – 96.9)	88.2% (82.9 – 93.5)	94.5% (91.9 – 100)

Table 4 Quality analysis of diagnostics based on the rating system from the American College of Radiology, showing the agreement or disagreement rate found on the given diagnoses and their clinical significance.

	Agreement	Minor disagreement		Moderate disagreement		Serious disagreement		Inconclusive
	1	2a	2b	3a	3b	4a	4b	
Center 1	11	4	2	0	0	0	0	1
Center 2	10	4	2	0	1	0	0	0
Center 3	8	7	2	0	0	0	0	0
Center 4	4	11	1	1	0	0	0	0
Center 5	12	4	0	0	2	0	0	0
Center 6	7	5	2	0	0	0	0	2
Center 7	8	7	0	0	0	0	0	2
Center 8	11	5	0	0	0	0	0	2
Center 9	6	0	2	0	4	0	0	4
Center 10	8	7	2	0	0	0	0	0
TOTAL	85	54	13	1	7	0	0	11

Quality analysis of the 171 diagnoses given in cases with heart defects showed some minor disagreements: 2a for 54 diagnoses and 2b for 13 diagnoses; moderate disagreement, of clinical relevance (3b), was found on only 7 occasions. Table 4 shows the quality scores broken down by center.

Discussion

Our exploration of 4D tele-echocardiography showed this tool to have a sensitivity of 88.7% and a specificity of 94.2%; these results confirm that STIC ultrasound imaging is a useful procedure for the prenatal diagnoses of congenital heart defects. The study showed that it improves on the detection rate of routine 2D echocardiography performed in low-risk populations. It gave sensitivity, specificity, false-positive and false-negatives rates in line with those reported by Espinoza *et al.* [18] (93%, 96%, 4.8% and 6.8% respectively); instead, the differences found between the two studies may be ascribed to the use of a survey with two controls per case in our work as opposed to the 1:1 ratio used in the Espinoza study.

In our study, 96.9% of volume data sets acquired using STIC technology contained sufficient functional and anatomical information to perform a wide basic screening of congenital heart defects. Instead, 14 cases were labeled as inconclusive due to errors in the acquisition procedure, thus limiting the clinical value of the volume data sets. Other authors [19-21], too, have reported the limitations of this new technology, including low resolution and artifacts due to fetal or maternal motion during acquisition. There is also a lower resolution with color Doppler and some regions of interest may remain out of the acquired volume data set in the event of an inadequate scrolling angle. Guasina *et al.*, in a recent study performed using an electronic 4D probe in the acquisition of sonographic cardiac volumes, reached optimal diagnostic quality in more than 90% of cases [22].

Multiplane navigation was the tool most commonly used in our study, although numerous algorithms have been proposed in the literature on 4D ultrasound imaging [23,24], such as the "spin technique" [25], "three-steps technique" [26], "en-face view of atrioventricular valves" [27], as well as other software tools included in the General Electric 4DView software package which facilitates diagnosis [28-30].

Our study showed good inter-center agreement, recording a kappa statistic for multiple raters of 0.74, with wide inter-observer variability (sensitivity range from 50% to 100%), a step under the excellent agreement observed in Spinoza's collaborative study (K=0.94) [18].

Some authors [20,21,31,32] maintain that STIC ultrasound imaging might not only be regarded as a screening tool, but also used for diagnosing the type of congenital heart defect present. In our study, the quality American College of Radiology score was adopted to account for our results. On most occasions, the "off-line" diagnoses of congenital heart defects were in agreement with the "on-line" (85/171) ones, or were in disagreement but presented low clinical relevance (54/171). Disagreement with clinical relevance occurred in only 21 cases. The implementation of a quality control score based on the clinical repercussions of misdiagnoses provides 4D ultrasound imaging with the characteristics of an optimal training tool.

Some limitations of our study include those coming from the capture and analysis of STIC volume data sets. Expertise in 4D ultrasound is required both to acquire volumes of optimal quality and to issue an accurate diagnosis by tele-echocardiography, limiting the reproducibility of the technique in other centers. Low rates of some of the pathologies could have biased the results.

Conclusions

This study underscores the importance of appropriate acquisition of STIC volume data sets with a view to a subsequent "off-line" diagnosis. The sensitivity and specificity obtained confirm that tele-echocardiography is an appropriate procedure for the identification of congenital heart defects in centers with adequate technical expertise. In addition, implementation of a quality control score provides 4D ultrasound imaging with the characteristics of an optimal training tool.

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