Echocardiographic Assessment of Right Ventricular Volumes after Surgical Repair of Tetralogy of Fallot: Clinical Validation of a New Echocardiographic Method

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Background: Assessment of right ventricular (RV) volumes and function is important in patients after tetralogy of Fallot (TOF) repair. Currently, cardiac magnetic resonance imaging (MRI) is considered the clinical reference method for RV volume and function measurements. Three-dimensional (3D) knowledge-based reconstruction derived from two-dimensional echocardiographic imaging with magnetic tracking is a novel approach to RV volumetrics. The aim of this study was to assess the feasibility and reliability of this novel echocardiographic technique in patients after TOF repair. The accuracy of the method was assessed by comparison with measurements obtained by cardiac MRI.

Methods: Thirty patients (mean age, 13.7 ± 2.8 years) after TOF repair, referred for cardiac MRI, were included. Immediately after MRI, echocardiographic image acquisition was performed using a standard ultrasound scanner linked to a Ventripoint Medical Systems unit. Echocardiographic and MRI measurements were performed offline. Parameters analyzed were end-diastolic volume (EDV), end-systolic volume (ESV), and ejection fraction. Intraobserver, interobserver, and intertechnique variability was assessed using Pearson’s correlation analysis, coefficients of variation, and Bland-Altman analysis.

Results: Echocardiographic two-dimensionally based 3D reconstruction was highly feasible, with low intraobserver and interobserver variability for EDV and slightly higher variability for ESV and ejection fraction. The 3D reconstruction values for EDV, ESV, and ejection fraction were correlated highly with MRI values, with low coefficients of variation. The agreement between both methods was high. Three-dimensional reconstruction slightly underestimated RV volumes, by 2.5% for EDV and 4.6% for ESV compared with MRI volumes.

Conclusions: In patients after TOF repair, echocardiographic 3D reconstruction is highly feasible, with good reproducibility for measurements of RV EDV. There is good agreement with MRI measurements, with a small underestimation of RV volumes. The use of this method in clinical practice warrants further investigation. (J Am Soc Echocardiogr 2011;:

Keywords: Echocardiography, Cardiac volume, Tetralogy of Fallot, Magnetic resonance imaging

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This study was funded through The Labatt Family Heart Centre Innovation Fund. Ms Waiss is vice president of clinical affairs at Ventripoint. Ms Riffle is a clinical application specialist and former employee at Ventripoint. There was no financial support from Ventripoint for this study.

Michael H. Picard, MD, FASE served as Guest Editor for this article.
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0894-7317/$36.00
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doi:10.1016/j.echo.2011.08.006

Assessment of right ventricular (RV) volumes and function is important in the follow-up of cardiac lesions when the right ventricle is affected.1-3 This is particularly relevant in patients after surgical repair of tetralogy of Fallot (TOF), who often develop progressive RV dilatation and dysfunction, related to postoperative pulmonary regurgitation.4,5 Currently, cardiac magnetic resonance imaging (MRI) is considered the method of choice for the assessment of RV volumes and ejection fraction (EF).6 Quantitative three-dimensional (3D) echocardiography using real-time volumetric acquisition and dedicated RV volume analysis software has emerged as a promising clinical alternative to MRI.7,8 However, the feasibility of this method is problematic, especially in postoperative patients with significantly dilated RV volumes. Poor echocardiographic windows can limit RV endocardial border detection in about 20% to 50% of all patients, limiting the feasibility of the method.8,9 Additionally, 3D echocardiography was shown to underestimate RV volumes by up to 15% to 25%, with the underestimation being more important.
Abbreviations

EDV = End-diastolic volume  
EF = Ejection fraction  
ESV = End-systolic volume  
MRI = Magnetic resonance imaging  
RV = Right ventricle  
3D = Three-dimensional  
3DR = Three-dimensional reconstruction  
TOF = Tetralogy of Fallot  
2D = Two-dimensional

METHODS

This was a single-center, prospective, observational study. The study was approved by the institutional research ethics board. Informed consent was obtained from all participants and/or their legal guardians before enrollment.

Patients after TOF repair, aged 8 to 17 years, who were scheduled to undergo cardiac MRI for clinical indications were included. Exclusion criteria were an inability to cooperate, known or detected arrhythmia interfering with image acquisition, and pacemakers or any contraindication to MRI. We also excluded patients after surgical repair with a wide spectrum of different RV volumes and shapes. The current TOF database used for RV volume reconstruction does not include patients with conduits. A different catalog for patients with conduits has been developed but was not used in the present study. Just before or immediately after cardiac MRI, a limited echocardiographic study was performed, including image acquisition for 3DR. All echocardiographic studies were performed using a GE Vivid 7 machine (GE Healthcare, Milwaukee, WI). Data were digitally stored and analyzed offline. RV end-diastolic volume (EDV), end-systolic volume (ESV), and EF were calculated. Intraobserver variability was performed using repeated analysis for the 3DR method, with ≥2 weeks between the analyses. For interobserver variability, two independent observers analyzed the 20 first echocardiographic data sets. Both observers were experienced with the technique.

3DR Method

The 3DR method enables 2D-based full volumetric reconstructions of cardiac chambers from 2D echocardiographic images localized in 3D space, using proprietary software and a catalog of heart shapes. This knowledge-based 3DR of ventricular volumes has been previously described and validated in vitro from 3D echocardiographic data sets using the piecewise smooth subdivision surface reconstruction method. It was also clinically validated for the left ventricle, and more recently, a catalog of fully traced MRI acquisitions of a wide range of RV shapes and sizes was shown to allow accurate knowledge-based reconstructions of RV volumes using MRI data sets. On the basis of the same principles, an echocardiographic method was developed. The method involves the acquisition of 2D echocardiographic images with a magnetic localizer attached to the ultrasound probe, allowing localization of the different 2D images in 3D space. The image acquisition protocol should provide good coverage of the different parts of the right ventricle. After acquisition, offline analysis is performed, including the identification of different anatomic landmarks on the 2D images. The data points (anatomic landmarks with their spatial localization) are matched to a catalog of 3D shapes obtained from cardiac MRI studies in patients after TOF repair, and the RV volumes and EFs are calculated. The different steps are explained in more detail.

Image Acquisition. The acquisition involves freehand 2D trans-thoracic scanning using a standard 2D probe with a magnetic field localizing system (Ascension Technology Corporation, Andover, MA) to track the position and orientation of the ultrasound probe in 3D space. The system consists of a magnetic field transmitter located under the exam bed. This generates different orthogonal magnetic fields that are sensed by the receiver, which is attached to the ultrasound probe. The position and orientation of the receiver and thus the plane of the 2D image can be computed and placed within the volume created by the magnetic transmitter. Different 2D images of the right ventricle are obtained. To obtain maximal coverage of the right ventricle, 10 to 15 different echocardiographic views should be acquired in each patient. These are summarized in Table 1 and illustrated in Figure 1. For each view, short clips of 2 to 4 sec are recorded to include at least three full cardiac cycles. Subjects are not allowed to change position on the exam bed during the acquisition process, and when possible, we obtained each clip using breath holding at end-expiration. The ultrasound scanner is linked to a computer (Ventrilpoint Medical Systems; Ventrilpoint, Inc., Seattle, WA) through the video output, and every clip is digitized at 30 frames/sec. The magnetic field data are entered at the same time, and 3D localizing data are linked in the computer online. The entire acquisition protocol generally takes about 5 min.

Image Analysis. The images and spatial information are stored on the Ventrilpoint Medical Systems computer, which has an Internet connection to the centralized database. First, timing of the cardiac cycle needs to be performed, with identification of end-diastole and end-systole. End-diastole is automatically set to correspond to the electrocardiographic R wave but can be adjusted manually. End-systole is identified manually on one clip, and the time interval is automatically applied to all clips on the basis of the electrocardiogram. This requires the heart rate to be relatively stable during the acquisition process. After the user approves the timing, identification of the different anatomic landmarks is performed on the different images. A small number of key anatomic points need to be identified for both end-diastole and end-systole. This includes the tricuspid and pulmonary valve annuli, the RV apex, the RV side of the interventricular septum, the RV free wall, the subpulmonary area (just below the pulmonary valve), and the subtricuspid area (on the RV inferior wall). For full 3DR, 17 to 23 points need to be identified on the 2D images. No additional anatomic tracing or border detection is required.

Surface Generation Using Catalog-Based Method. Once the anatomic points have been identified and localized in the magnetic 3D space, the RV volumetric reconstruction is performed by sending the data to the online database. The “knowledge” MRI database consists of fully traced RV volumes of postoperative patients after TOF repair with a wide spectrum of different RV volumes and shapes. The identified landmarks on the 2D images with their location in
3D space are matched with the database, and the best fit is computed using a proprietary algorithm. Once a minimum number of points have been placed on the anatomic structures, ideally 15 to 20, the first reconstruction can be run. The reconstructed RV volume is projected on the 2D data set (Figure 1), and on the basis of this quality check, the placement of points can be adjusted and more points can be added to refine the RV volumetric modeling and end up with the best fit for EDV (Figure 2). For calculating ESV, the same process is repeated. RV volumes and EF are calculated by the system.

Cardiac MRI
MRI scans were performed on a 1.5-T scanner (Avanto; Siemens Medical Systems, Erlangen, Germany). For ventricular volumetry, a short-axis cine stack was acquired during breath hold, using a balanced steady-state free precession gradient-echo sequence with minimum echo and repetition times, a flip angle of 45°, bandwidth of 31.25 kHz, one excitation, views (lines) per segment to allow for 31.25 kHz, one excitation, views (lines) per segment to allow for 20 true reconstructed phases per cardiac cycle, 5 to 6 mm of slice thickness, 10 to 12 slices, gap adjusted to cover both ventricles, and in-plane spatial resolution of 1.5 to 2.5 mm. The MRI data were analyzed with commercially available software packages (Mass Analysis and CV Flow, Medis Medical Imaging Systems, Leiden, The Netherlands). Left ventricular and RV end-diastolic (maximal) and end-systolic (minimal) volumes, stroke volumes, and EFs were measured. The interobserver variability of the RV volumes was assessed by independent analysis of the first 20 studies by two experienced observers.

Statistical Analysis
Different statistical methods were used to analyze intraobserver, interobserver, and intertechnique variability. The agreement between the measurements is described using Bland-Altman statistics, including the calculation of mean bias (average difference between measurements), with standard deviation. The statistical significance of the mean bias was tested using a paired, two-tailed t test (the null hypothesis was zero bias). The lower and upper limits of agreement (95% limits of agreement of mean bias) were calculated. The percentage differences (the difference between paired measurements divided by the average of the two measurements times 100) and percentage bias were calculated for the different Bland-Altman analysis. The correlation between observers and techniques was calculated using Pearson’s correlations. Variability of the measurements was also assessed by calculating the coefficient of variation as the standard deviation of the difference of paired samples divided by the average of the paired samples.

RESULTS

Feasibility
Thirty children (mean age, 13.7 ± 2.8 years) were included in the study. The 3DR analysis was successfully completed in all studies. Small respiratory artifacts were noted in a few patients, but they did not preclude the reconstructions. Generally, three to four reconstructions with point adjustments were required to obtain optimal reconstructions, with easier adjustments when fewer initial points were entered. Overall image acquisition took about 5 min, and the analysis took about 15 min.

Reproducibility
The results of the intraobserver and interobserver variability analysis are shown in Table 2, and the Bland-Altman plots are depicted in Figure 3. The intraobserver and interobserver variability of 3DR for calculating EDV was low, with excellent correlation coefficients, low coefficients of variation, no significant bias, and narrow limits of agreement. Intraobserver and interobserver variability was slightly higher for ESV and less good for EF. The differences between intraobserver and interobserver measurements were not significant for any of the parameters analyzed. The reproducibility of MRI measurements between observers is presented in Table 2, with overall good agreement between the two observers, especially for EDV and less so for ESV and EF. A small but significant bias was detected between the two observers: a 2.4% (5.3 mL) difference for EDV (P = .01) and a 4.4% (5.7 mL) difference for ESV (P = .002).

Accuracy
The accuracy of the 3DR method was evaluated for the entire group of patients by comparing the echocardiographic and MRI measurements. The results are presented in Table 3 and Figure 4. The correlation coefficients between both methods were high for all three measurements. The coefficient of variation was low for EDV and slightly higher for ESV and EF. The 3DR method resulted in a small but statistically significant underestimation of RV volumes (negative

Table 1 Image acquisition protocol

<table>
<thead>
<tr>
<th>View</th>
<th>Region of interest</th>
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<tbody>
<tr>
<td>1. Apical four-chamber view</td>
<td>Tricuspid annulus, basal bulge, RV endocardium, RV apex, RV septum</td>
</tr>
<tr>
<td>2. Apical two-chamber view of the right ventricle</td>
<td>Tricuspid annulus, subtricuspid inferior wall, RV endocardium, pulmonary annulus</td>
</tr>
<tr>
<td>3. Foreshortened apical three-chamber view</td>
<td>Tricuspid annulus, RV endocardium, RV septum, RV outflow</td>
</tr>
<tr>
<td>4. Modified oblique view of the true RV apex</td>
<td>RV apex</td>
</tr>
<tr>
<td>5. Parasternal long-axis view, mitral valve</td>
<td>Interventricular septum, RV endocardium</td>
</tr>
<tr>
<td>6. Parasternal long-axis view, tricuspid valve</td>
<td>Tricuspid annulus, RV endocardium</td>
</tr>
<tr>
<td>7. Parasternal long-axis view, pulmonary valve</td>
<td>Pulmonary annulus, RV endocardium, RV outflow</td>
</tr>
<tr>
<td>8. Parasternal short-axis view, pulmonary valve</td>
<td>Pulmonary annulus, subpulmonary area, RV endocardium</td>
</tr>
<tr>
<td>9. Short-axis view, base</td>
<td>Interventricular septum, RV endocardium</td>
</tr>
<tr>
<td>10. Short-axis view, mid/apex</td>
<td>Interventricular septum, RV endocardium</td>
</tr>
<tr>
<td>11. Rotated apical views</td>
<td>Tricuspid annulus, basal bulge, RV endocardium, RV apex, RV septum</td>
</tr>
<tr>
<td>12. Foreshortened apical view, RV outflow</td>
<td>RV endocardium, pulmonary annulus, RV outflow</td>
</tr>
<tr>
<td>13. Subcostal four-chamber view</td>
<td>RV endocardium, RV apex, RV septum</td>
</tr>
<tr>
<td>14. Subcostal sagittal view</td>
<td>RV endocardium, RV outflow</td>
</tr>
</tbody>
</table>


bias): EDV by 2.5% (7 mL; \( P = .002 \)) and ESV by 4.6% (6.9 mL; \( P = .0004 \)). The 95% limits of agreement were relatively narrow for EDV and EF but wider for ESV.

The most biased RV volume reconstructions were obtained in patients with RV hypertrophy, estimated by the thickness of the RV anterior wall in the parasternal long-axis view. Overall, there was a significant correlation between RV thickness and the observed bias (\( R = 0.54 \) for EDV and \( R = 0.51 \) for ESV, \( P < .001 \)).

**DISCUSSION**

RV dilatation and failure is the main cause of morbidity and mortality in patients after TOF repair with significant pulmonary regurgitation. RV EDV and EF were shown to predict outcomes, defined as death, the occurrence of sustained ventricular tachycardia, and functional status (New York Heart Association class III or IV).\(^{13}\) RV EDV has also been shown to be an important predictor of RV remodeling after pulmonary valve replacement.\(^{14,15}\) Thus, the availability of a reliable and accurate echocardiographic method to assess RV volumes and function is clinically important for this patient population. In the present study, we evaluated a new echocardiographic method for assessing RV volumes using a 3DR technique based on 2D images localized in 3D space. We demonstrate that this method has low intraobserver and interobserver variability and that the intertechnique agreement between the echocardiographic and MRI methods was high. In a previous study, the principle of the method was validated on MRI data used to build the TOF catalog.\(^{12}\) It was

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**Figure 1** Two-dimensional views used for 3DR. Anatomic landmarks are identified on 2D images (**colored points**). Once the volume is calculated, projections of the reconstructed RV on the acquired 2D images can be visualized (**yellow tracings**).
shown that there was very high agreement between the reconstructed and traced RV volumes. Our study is the first independent validation study using echocardiographic data from patients who were not included in the reference database used for 3DR.

We show in our pediatric study group that the method is highly feasible, as we could calculate RV volumes in every patient. This is because the method is based on 2D recognition of anatomic landmarks, which are generally easy to identify on 2D images, even when the image quality is suboptimal. It is important that during the image acquisition, these key anatomic landmarks are visualized as well as possible (the tricuspid annulus in at least two planes, the pulmonary valve, the RV apex, and the different RV walls [lateral, anterior, inferior, and septum]). Because the model “fills in” the volumes on the basis of the knowledge database, identification of the entire endocardial borders is not as necessary, contrary to the endocardial border detection methods. This is possibly an advantage when comparing 3DR to real-time 3D echocardiographic methods, which are dependent on border detection. Especially the RV anterior wall and the apical part of the RV lateral wall can be difficult to visualize in postoperative

<table>
<thead>
<tr>
<th>Inframethod variability</th>
<th>Intramethod variability</th>
<th>Coefficient of variation</th>
<th>Mean bias (mL)</th>
<th>P</th>
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<tbody>
<tr>
<td>3DR intraobserver (n = 20)</td>
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<td></td>
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<tr>
<td>EDV</td>
<td>.997</td>
<td>3.4</td>
<td>1.1 ± 7.6</td>
<td>.68</td>
</tr>
<tr>
<td>ESV</td>
<td>.984</td>
<td>7.4</td>
<td>1.6 ± 9.5</td>
<td>.75</td>
</tr>
<tr>
<td>EF</td>
<td>.733</td>
<td>7.9</td>
<td>−0.7 ± 3.7</td>
<td>.51</td>
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<tr>
<td>3DR interobserver (n = 20)</td>
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<td></td>
</tr>
<tr>
<td>EDV</td>
<td>.995</td>
<td>3.8</td>
<td>−2.2 ± 8.8</td>
<td>.28</td>
</tr>
<tr>
<td>ESV</td>
<td>.989</td>
<td>5.7</td>
<td>−0.5 ± 7.2</td>
<td>.78</td>
</tr>
<tr>
<td>EF</td>
<td>.611</td>
<td>8.4</td>
<td>−0.5 ± 3.8</td>
<td>.56</td>
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<tr>
<td>MRI interobserver (n = 20)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>EDV</td>
<td>.993</td>
<td>3.5</td>
<td>−5.3 ± 8.5</td>
<td>.01</td>
</tr>
<tr>
<td>ESV</td>
<td>.986</td>
<td>5.3</td>
<td>−5.7 ± 7.2</td>
<td>.002</td>
</tr>
<tr>
<td>EF</td>
<td>.911</td>
<td>6.6</td>
<td>1 ± 2.9</td>
<td>.11</td>
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*All correlations were significant at the .001 level.
patients with dilated ventricles. This possibly explains why the feasibility of 3D echocardiography has been reported to vary between 50% and 80% of all patients after TOF repair. Compared with previous studies, our patients were younger, with potentially better imaging windows. The feasibility of the 3DR method needs to be further explored in an adult group of postoperative patients with TOF.

The reproducibility of the RV volumetric calculations as represented by the intraobserver and interobserver variability was relatively good. Compared with the interobserver variability of cardiac MRI measurements, the 3DR method had slightly wider limits of agreement, although the MRI measurements also varied between the two experienced observers. This suggests that the measurement of RV volumes in postoperative patients with TOF is complicated by different intrinsic factors, independent of the volumetric imaging method used. The right ventricle is heavily trabeculated, and RV volumes will be influenced dependent on whether trabeculations are included or excluded in the measurements. Our MRI analysis of RV volumes included RV trabeculations, because this has been shown to improve the reproducibility of measurements in the systemic right ventricle. We used the same approach for the echocardiographic 3DR method, also based on the fact that the “knowledge” used for 3DR consisted of MRI volumetric data sets including RV trabeculations. It can be difficult, in any method, to identify the base of the trabeculations, because the RV “compacted zone” is relatively thin. The higher spatial resolution of cardiac MRI is an advantage compared to echocardiographic imaging. This problem is even more important during systole, because the trabeculations are compressed and it can be extremely difficult to delineate the RV compacted layer. This probably contributes to the higher intrinsic variability of any imaging method used to measure RV ESV. We observed higher variability in ESV compared with EDV in both 3DR and MRI. Despite the generally acceptable 2D resolution, the identification of anatomic landmarks can sometimes be difficult, and this may also affect RV volume analysis. For severely dilated right ventricles, it can be challenging or impossible to define the RV apex from

Table 3  Intermethod variability comparing measurements of RV volumes and EF using 3DR and MRI

<table>
<thead>
<tr>
<th>Intermethod variability</th>
<th>Correlation coefficient*</th>
<th>Coefficient of variation</th>
<th>Mean bias (mL)</th>
<th>P</th>
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<tr>
<td>3DR versus MRI (n = 30)</td>
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<tr>
<td>EDV</td>
<td>.995</td>
<td>4.3</td>
<td>-7 ± 11.4</td>
<td>.002</td>
</tr>
<tr>
<td>ESV</td>
<td>.994</td>
<td>6.7</td>
<td>-6.9 ± 9.4</td>
<td>.0004</td>
</tr>
<tr>
<td>EF</td>
<td>.871</td>
<td>7.6</td>
<td>1.2 ± 2.9</td>
<td>.03</td>
</tr>
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*All correlations were significant at the .001 level.
apical four-chamber views, because of ventricular foreshortening. As a possible solution to this, we used modified RV views to better identify the RV apex (Figure 1, scan 4). Identification of the pulmonary valve can be difficult in patients with large transannular patches and only remnants of the pulmonary valve. This influences the correct depiction of the RV outflow tract distal limits on both echocardiography and cardiac MRI, which can cause variability in the measurements independent of the technique used. We found that in the 3DR method, the pulmonary valve can be extremely difficult to identify, especially in systole when the valve is open. This can further contribute to the higher variability of ESV measurements compared with EDV measurements.

The results of intraobserver and interobserver variability of 3DR were comparable with previously published data on 3D echocardiography and MRI. In our study, 3DR variability was slightly higher compared with MRI, but no significant differences could be observed. Despite intrinsic limitations influencing reliability, cardiac MRI is considered to be the reference technique for RV volume calculation, and current clinical recommendations rely on MRI volumetric measurements. Previous studies have looked at using 2D echocardiographic estimations of RV volumes using different mathematical assumptions of RV shape, but these methods resulted in RV volumetric measurements that were not in good agreement with the MRI calculations. A recent study used a simplified linear regression formula (RV EDV index = 11.5 + 17 \times \text{indexed end-diastolic area}), on the basis of the good agreement between RV diastolic area measured from the apical four-chamber view and RV EDV on MRI. The interobserver variability of this method, however, was high, and in a prospective validation, the limits of agreement between this method and MRI-based RV EDV were relatively wide. The use of 3D echocardiography and offline volumetric analysis resulted in better agreement of RV volumes with the MRI measurements, but some studies have reported underestimations of RV EDV of up to 25%, especially in patients with dilated right ventricles. No good explanation has been given for this underestimation, but the lower 2D resolution of 3D echocardiography can make it difficult to identify the RV walls and structures. In our study, we found very good agreement between the 3DR method and MRI. We noted a small underestimation of RV volumes by 3DR compared with MRI. The underestimation we found with the 3DR method is much smaller compared with the previously published data on 3D echocardiography, and we did not find an effect of RV dilatation on the observed bias. Interestingly, we found an effect of RV hypertrophy with significant but relatively weak correlations between the RV wall thickness and the detected bias between the two methods. This indicated that in the thicker RV walls, it is more difficult to delineate the base of the trabeculations, especially by echocardiography, resulting in a minor underestimation of the echocardiographic measurements.

Limitations and Future Perspectives
We acknowledge that our study group was relatively small, because we could only include children and adolescents undergoing MRI without sedation. Still, a wide spectrum of different RV sizes, ranging between 114.6 and 281 mL/m², was included in the study. The patients underwent MRI studies that were clinically indicated and ordered by treating physicians. This likely introduced bias toward higher ventricular volumes, which may have influenced the results. Apart from our study limitations, the 3DR method currently has important limitations: it requires an additional computer linked to the ultrasound machine and a magnetic tracker attached to the probe. A very weak magnetic field is generated to localize the probe in 3D space, and this requires the study to be performed on a special non-ferromagnetic bed. This influences the integration of the method within a busy clinical echocardiography laboratory. During image acquisition, which takes about 5 min, the patient is not allowed to move. This can be a challenge, especially in smaller children. Motion between the different acquired 2D images changes the relative position of the cardiac structures and creates artifacts precluding an accurate 3D surface reconstruction. Special equipment is required that
CONCLUSIONS

Three-dimensional reconstruction seems to be a highly feasible method to measure RV volumes. Compared with cardiac MRI, it has similar reproducibility of the measurements, and when clinical MRI is used as reference, its accuracy seems high. Further improvements and wider applicability of this method are needed before establishing its place in clinical practice.

REFERENCES


