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Validation of the Simbionix PROcedure Rehearsal Studio sizing module: A comparison of software for endovascular aneurysm repair sizing and planning

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Abstract

An important determinant of successful endovascular aortic aneurysm repair is proper sizing of the dimensions of the aortic-iliac vessels. The goal of the present study was to determine the concurrent validity, a method for comparison of test scores, for EVAR sizing and planning of the recently introduced Simbionix PROcedure Rehearsal Studio (PRORS). Seven vascular specialists analyzed anonymized computed tomography angiography scans of 70 patients with an infrarenal aneurysm of the abdominal aorta, using three different sizing software packages Simbionix PRORS (Simbionix USA Corp., Cleveland, OH, USA), 3mensio (Pie Medical Imaging BV, Maastricht, The Netherlands), and TeraRecon (Aquarius, Foster City, CA, USA). The following measurements were included in the protocol: diameter 1 mm below the most distal main renal artery, diameter 15 mm below the lowest renal artery, maximum aneurysm diameter, and length from the most distal renal artery to the left iliac artery bifurcation. Averaged over the locations, the intraclass correlation coefficient is 0.83 for Simbionix versus 3mensio, 0.81 for Simbionix versus TeraRecon, and 0.86 for 3mensio versus TeraRecon. It can be concluded that the Simbionix sizing software is as precise as two other validated and commercially available software packages.

Keywords

Aneurysm, endovascular aneurysm repair, diameter, stent-graft, sizing, software

Introduction

One of the most common complications of endovascular aneurysm repair (EVAR) is endoleak. The incidence of all types of endoleaks reported in the literature varies between 12% and 44%.[1–4] Incorrect diameter measurements and graft selection can lead to a type I endoleak as well as migration. Besides diameter measurements it is important to determine lengths accurately to prevent unnecessary extensions, which entails higher costs and the risk of type III endoleaks[4,5] and unintentional occlusion of side branches. Appropriate sizing of the aortic-iliac dimensions represents an essential step in cost-effective and safe endovascular treatment of the aneurysm of the abdominal aorta (AAA).[6]

The preferred imaging modality for sizing is computed tomography angiography (CTA). The CTA offers post-processing measurement techniques, and provides all necessary detailed anatomical information for pre EVAR planning.[7,8] In the conventional axial CTA slices, an error can be introduced when the measurements are not perpendicular to the vessel wall. Center-lumen-line (CLL) reconstruction is a measurement method for sizing, which automatically generates a measuring plane perpendicular to the vessel wall. Previous research concluded that the 3D CTA semi-automated CLL analysis is the most reliable method with minimum intraobserver and interobserver

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variability in diameter and length measurements.[9–11] Rengier et al.[10] reported an absolute measurement deviation for axial, multi-planar reconstruction (MPR) and CLL techniques of respectively $7.3 \pm 7.7\%$, $6.7 \pm 4.5\%$, and $4.7 \pm 4.8\%$. Whether 3D-CTA semiautomatic CLL analysis results in less complications and reinterventions has not been studied yet.[9–12]

3mensio (Pie Medical Imaging BV, Maastricht, The Netherlands)[13–15] and TeraRecon (Aquarius, Foster City, CA, USA)[10,16,17] are the most often used commercially available software packages for semiautomatic CLL measurements. Both 3mensio[15] and TeraRecon[17] sizing software are FDA cleared, validated, and successfully incorporated in daily practices. The Simbionix PROcedure Rehearsal Studio (PRORS) (Simbionix USA Corp., Cleveland, OH, USA) is FDA cleared.

The Simbionix PRORS is a new software package for semiautomatic CLL analysis. Moreover, Simbionix PRORS combines sizing methods with the possibility to perform CTA-based patient-specific simulations. However, the Simbionix PRORS has not been validated for AAA sizing yet. In this study, the concurrent validity of the sizing package of Simbionix PRORS will be determined. Concurrent validity is defined as ''an evaluation in which the relationship between the test scores and the scores on another instrument purporting to measure the same construct are related''. It can be used when introducing a new assessment tool to replace a preexisting ''gold standard'' assessment tool.[18]

The goal of the present study was to determine the concurrent validity of the Simbionix PRORS with the commercially available software packages of 3mensio[15] and TeraRecon.[17] In addition, the influence on the concurrent validity of measuring the outer-to-outer wall diameter (adventitia-to-adventia) or the inner-to-inner wall diameter (intima-to-intima) is investigated.

Methods

This study was conducted with approval of the local ethics committee (Id: K13-48), all patients gave consent. Preoperative anonymized CTAs of 70 patients with an infrarenal AAA who sequentially underwent an EVAR procedure in one center (St. Antonius Hospital) were included. CTA images were acquired on a 256 slice CT scanner. Scan parameters were: tube voltage 120 kV, tube current time product 180 mAs, distance between slices 0.75 mm, pitch 0.9 mm, collimation 128 mm $\times$ 0.625 mm, and 100 mL iodine contrast with 100 mg iodixanol/mL was administered intravenous in the arterial phase with 4 mL/s.

Three commercially available packages were included in this study: Simbionix, 3mensio, and TeraRecon. CLL reconstructions were created by one of the authors (JFV) using the three sizing software packages. The software did not receive any updates during the study in order to avoid update-based differences. A CLL reconstruction using 3mensio or TeraRecon consists of a one click vessel segmentation and automated center lumen line detection. A CLL reconstruction using Simbionix consists, in addition to these steps, of indicating which voxels represents the lumen of the aorta and the boundaries of the aortic wall. The time to create the CLL was noted. The observers were allowed to manually adjust the CLL proposal. Whether and why a CLL reconstruction was adjusted was also noted.

The scans were randomly divided into cohorts of ten patients. The CTAs were presented to the observers in a random order. Observers were blinded to each others' measurements and to earlier measurements when using different software packages. The order of both, patients and software systems, was different for each observer. The seven observers were vascular specialists derived from three hospitals in the Netherlands with an EVAR sizing experience of at least 2 years and at least 50 cases. Each observer received a training session to familiarize with the protocol and the three software packages. The training session consisted of the measurement of two CTA scans. The sample size of 70 scans was based on a power calculation ($\alpha = 0.01667$, expected intraclass correlation coefficients (ICC) $= 0.90$, minimum ICC $= 0.80$) and resulted in a required sample size of 65 different patients.

Definitions and measurements

The observers performed predefined measurements on the CLL reconstructed CT scans using the three sizing packages according to a pre-established protocol (Figure 1). The protocol is an abridged version of the infrarenal AAA worksheet according to the EUROSTAR guidelines.[19]

The following measurements were included in the protocol: D2a: aortic diameter 1 mm below the most distal main renal artery, D2c: aortic diameter 15 mm below D2a, D3: maximum aortic aneurysm diameter, and H4b: length from most distal renal artery to the upper edge of the left iliac artery bifurcation.

The infrarenal aortic neck diameters were measured perpendicular to the CLL anterior-posterior and left-right. Both the inner to inner wall diameter (intima to intima) and the outer-to-outer wall diameter (adventitia to adventitia) were measured. The maximum aneurysm diameter was the largest diameter from adventitia to adventitia in any direction.

Statistical analysis

Agreement between diameter and length measurements obtained from different sizing packages was evaluated

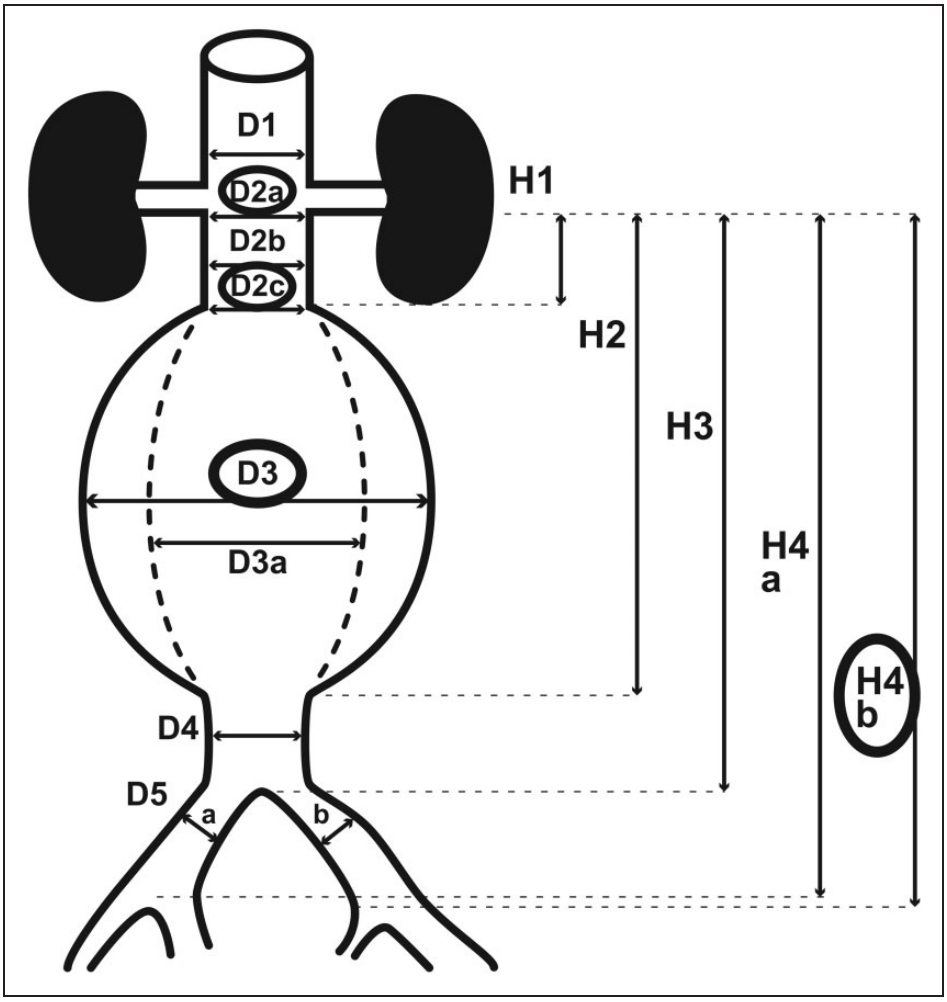

Figure 1. The locations of the measured diameters and length. The protocol is an abridged version of the infrarenal AAA worksheet according to the EUROSTAR guidelines.[19] The circled measurements are included in the abridged version: D2a: diameter 1 mm below the most distal main renal artery, D2c: diameter 15 mm below D2a, D3: maximum aneurysm diameter, and H4b: length from the most distal renal artery to left common iliac artery bifurcation.

and each location and direction was evaluated pairwise. The agreement was evaluated using ICCs. An ICC of 1.0 is equal to a perfect agreement, an ICC of 1.0–0.81 to an almost perfect agreement and 0.8–0.61 to a substantial agreement.[20] Statistical analyses were performed using SPSS for Windows version 22 (SPSS, Chicago, IL, USA). The two-way mixed single measures (absolute agreement) were used for the statistical analyses.

Results

All 70 observed CTA scans were included in the analysis. The average time to create the CLL was 42 min (20–100 min) with the Simbionix software, 9 min (6–15 min) with software of 3mensio and 13 min (10–20 min) with the TeraRecon software. The CLL was not adjusted by the physicians in any case. None of the surgeons required any help from a researcher during the measurements. We determined the time which was needed for the physicians to complete the measurements, but there was no difference between the physicians or between the software packages. The ICC and 95% confidence interval (CI) for D2a, D2c, D3, and H4b are shown in Table 1. Comparisons were made between the three included software packages: Simbionix versus 3mensio, Simbionix versus TeraRecon, and 3mensio versus TeraRecon. The ICCs of the separate locations vary between 0.72 and 0.97. The average values of the locations per software package comparison results in 0.83 for Simbionix versus 3mensio, 0.81 for Simbionix versus TeraRecon, and 0.86 for 3mensio versus TeraRecon. The mean values of the three software packages shows that there was an almost perfect agreement between the three software packages.

Table 1. The intraclass correlation coefficient (ICC) and 95% confidence interval (CI).

	Simbionix vs 3mensio	Simbionix vs TeraRecon	3mensio vs TeraRecon	Mean ICC (per location)
D2a inner-to-inner wall A-P	0.85 (0.77; 0.91)	0.78 (0.67; 0.86)	0.87 (0.80; 0.92)	0.83
D2a inner-to-inner wall L-R	0.83 (0.75; 0.89)	0.81 (0.70; 0.88)	0.81 (0.72; 0.88)	0.82
D2a outer-to-outer wall A-P	0.82 (0.73; 0.88)	0.80 (0.69; 0.87)	0.89 (0.83; 0.93)	0.84
D2a outer-to-outer wall L-R	0.79 (0.62; 0.88)	0.72 (0.57; 0.82)	0.82 (0.73; 0.89)	0.78
D2c inner-to-inner wall A-P	0.81 (0.65; 0.88)	0.77 (0.65; 0.85)	0.86 (0.79; 0.91)	0.81
D2c inner-to-inner wall L-R	0.80 (0.68; 0.87)	0.84 (0.75; 0.90)	0.78 (0.67; 0.86)	0.81
D2c outer-to-outer wall A-P	0.87 (0.79; 0.92)	0.87 (0.80; 0.92)	0.91 (0.85; 0.94)	0.88
D2c outer-to-outer wall L-R	0.81 (0.71; 0.88)	0.84 (0.75; 0.90)	0.78 (0.66; 0.86)	0.81
D3	0.87 (0.80; 0.92)	0.88 (0.82; 0.93)	0.97 (0.94; 0.98)	0.91
H4b	0.88 (0.81; 0.92)	0.83 (0.74; 0.89)	0.88 (0.82; 0.92)	0.86
Mean ICC (per software comparison)	0.83	0.81	0.86	

A-P: anterior-posterior, D2a: diameter 1 mm below the most distal main renal artery, D2c: diameter 15 mm below D2a, D3: maximum aneurysm diameter, H4b: length from the most distal renal artery to left common iliac artery bifurcation, inner-to-inner wall: diameter intima-to-intima, L-R: Left-Right, outer-to-outer wall: diameter adventitia-to-adventitia.

The mean ICC for the inner-to-inner wall is comparable to the mean ICC for the outer-to-outer wall (0.82 respectively 0.83, averaged over the neck diameters).

Discussion

The concurrent validity of the Simbionix PRORS is good and in line with the current literature. Recently, Corriere et al.[17] concluded that similar results can be obtained from different image processing programs TeraRecon, Osirix and Preview. The ICCs between the programs for diameter measurements were high ($ICC > 0.82$ for all pairwise comparisons). The ICCs for the length measurements were also high ($ICC > 0.88$ for all pairwise comparisons).

The results of the study of Iezzi et al.[6] are also in line with the results of this study. They concluded that the variation within the inner-to-inner wall diameter measurements ($9.75\% \pm 4.01\%$) is comparable to the variation within the outer-to-outer wall measurements ($8.66\% \pm 3.71\%$). In addition, they concluded that stent-graft selection using outer-to-outer wall or inner-to-inner wall sizing changed significantly on the basis of the respective measurement methods. Therefore, they concluded that stent-graft sizing should follow the manufacturer's recommendations for using inner or outer diameters.

Because of the comparable ICC for the inner-to-inner wall diameter measurements and the outer-to-outer wall measurements, we conclude that the physician has the freedom to choose his measurement method. The physician should have in mind how the stent-graft size is determined by the manufacturer. The quantity of oversizing should be aligned with the measuring method.

Our study shows that the sizing capabilities of the Simbionix software are appropriate. However, further work is required to establish the technical fidelity of the patient specific simulation part of the Simbionix PRORS system before assessing its usefulness in clinical practice.

Our study found an average time of 42 min to create a segmentation. Creating the reconstruction in Simbionix will take between 60 and 180 min according to the literature.[21] Creating a segmentation using the Simbionix software is more complex than the CLL-creation based on 3mensio and TeraRecon software, because it can also be used for patient-specific simulation. The Simbionix software is more complex since it also includes segmentation steps in addition to the creation of the CLL. Therefore, this extra time investment will only be worthwhile if future studies can prove that incorporation of the Simbionix (simulation) software will lead to less complications and shorter operating time. Currently, the sizing function of Simbionix does not per se have a unique value when compared to other commercially available software packages.

Limitations of this study

A total of seven observers were selected, four observers already had experience with the 3mensio software, only one observer already had experience with the TeraRecon software and none of the observer had experience with the Simbionix software. The substantial prior familiarity might lead to better results with the 3mensio software package. However, this difference in experience per software system was not reflected in the data. Moreover, the observers were always able to enlist the help of a researcher who was experienced

with all three stations. In this study we chose to create the CLL in advance by one of the authors (JFV). This predefined CLL might have led to a decreased variability of the measurements. Our measurement protocol was an abridged version of the infrarenal AAA worksheet according to the EUROSTAR guidelines. Based on our previous pilot study, we expect that by expanding the study with more parameters, the probability to come to a different conclusion is very small.

Conclusion

The results demonstrate an almost perfect agreement between 3mensio, TeraRecon, and Simbionix software package for 3D-CTA semiautomatic CLL analysis. The 95% CI of the ICCs of the separate locations overlapped strongly. It can be concluded that, in terms of sizing, the Simbionix software is comparable to two other validated and commercially available software packages. However, due to the significant increase in preparation time of the CLL, Simbionix will only be of benefit if the procedure rehearsal stage is beneficial. Future research should focus on the patient-specific simulation of the Simbionix PRORS.

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Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Simbionix and 3mensio provided unrestricted research software licenses. Permission to publish the results of this study was not needed.

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