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A Novel Acquisition Technique to Utilize Swan-Ganz Catheter data as a Surrogate for High-fidelity Micromanometry within the Right Ventricle and Pulmonary Circuit

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Abstract

We explored the possibility of using conventional right-heart catheterization data, gathered both prospectively and retrospectively, as a surrogate for high-fidelity micro-manometery when analyzing systolic and diastolic RV function and calculating various ventricular and pulmonary hemodynamic parameters in the time domain. Right heart catheterizations were performed on 13 patients (7 female), who were suspected of having pulmonary hypertension. The procedure included use of both fluid-filled catheter and high-fidelity micromanometry to measure right ventricular and pulmonary arterial pressures. A digital data acquisition system was used to record micromanometer readings and data from the fluid-filled catheter system during prospective portion of the study. Retrospective data was obtained by direct digitization of screen captures taken by the conventional clinical system (fluid-filled catheter). From the 13 patients, 12–13 RV waveforms and 12 PA waveforms were acquired from each method. Basic measurements of heart rate, systolic pressure, diastolic pressure, dP/dt_{max}, and dP/dt_{min} were compared between micromanometry, direct acquisition from the PA catheter (voltage acquisition), and re-digitization of the hemodynamic waveforms (tracing). Correlation between Swan and tracing was stronger than that of Millar and Swan. SBP, followed by HR, has the strongest correlation of any parameter for all three methods, while DBP appears to be the weakest. Bland–Altman analysis shows all parameters to have minimal biases that are within clinical limits. Interoperator and intraoperator variability was minimal. Digital right-heart catheterization (RHC) data can be used as a surrogate for micromanometric data under ideal conditions for hemodynamic measures in the time domain. Pre-existing RHC data can be re-digitized for more rigorous hemodynamic analysis.

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Keywords

Catheter; Right heart catheterization; Pulmonary arterial pressure; Right ventricular pressure; Hemodynamics

INTRODUCTION

Clinical right-heart catheterization studies, performed with fluid-filled Swan-Ganz Catheters, remain the standard method of assessing pulmonary hypertension in the clinical setting. However, the information typically provided is generally limited to only average systolic, diastolic, and mean pressures.[1,4] Typically, more extensive analysis is limited to research studies which use high-fidelity micromanometer wires—the gold standard for invasive pressure measurement.[5] Unfortunately, the cost of high-fidelity micromanometer wires and equipment required prevents regular use in conventional clinical procedures.

It has been shown that under ideal conditions, using adequate filtering and proper techniques, it is possible to asses Left ventricular dP/dt with a fluid filled catheter.[2,3] We explored the possibility of using conventional right-heart catheterization data, gathered both prospectively and retrospectively, as a surrogate for high-fidelity Micromanometry when calculating various hemodynamic parameters in the time domain for the right ventricle. We also explored the possibility of obtaining those measures from retrospectively acquired studies via digitization.

METHODS

Right Heart Catheterization Procedure

University of Pittsburgh Institutional Review Board approval for this protocol and informed consent of all patients were obtained prior to beginning this study. A standard RHC was performed using a 7F Swan-Ganz catheter (Edwards Lifesciences, Irvine, CA). After standard hemodynamic values were recorded via Witt Biomedical Catheter System (Phillips Healthcare, Andover, MA), the 7F Swan-Ganz catheter was replaced with a single lumen balloon tipped PA catheter (Arrow International/Teleflex, Research Triangle Park, NC). Traditional fluid-filled catheter data acquisition was performed followed by acquisition from a 2F high-fidelity pressure transducer catheter (Millar Instruments, Houston, TX) which was advanced through the distal lumen of the single lumen balloon tipped PA catheter while in the PA and RV. During each measurement with the single lumen fluid-filled catheter, the images were also captured in the Witt system.

Patient Cohort

This protocol was performed with 13 patients (7 female), ranging from 43 to 82 years of age (mean age 61 ± 13.5 years), who were referred for clinical right heart catheterization for assessment of suspected pulmonary hypertension.

Prospective Data Acquisition

Voltages from Swan-Ganz (Swan) pressure transducer and micromanometer-tipped catheters (Millar Instruments, Huston, TX) were recorded during the study using the Digital Signal Processing Workstation (DSPW) system (Indus Instruments, Webster, TX), and exported as a text file by the accompanying software at a sampling rate of 1 kHz. Figure 1 illustrates how the data were acquired throughout the study.

Retrospective Data Acquisition

Following completion of the right heart catheterization procedure, screen captures of the pressure waveforms were acquired offline from the WITT system and were exported as image files in JPEG format, as shown in Fig. 1. Figure 2 illustrates the re-digitization process, where numeric data were extracted from the JPEG images via custom semi-automated MAT-LAB script which utilized MATLAB's ability to calculate piecewise splines for generation of a best-fit curve of the pressure waveform. Pressure and time values were assigned to pixels, based off of scale marks found in the image. Waypoints used to guide the curve were generated by an investigator and placed at local pressure minima, local pressure maxima, and inflection points. Additional waypoints were added as necessary to refine the curve. Data were then exported as a text file for further analysis.

Data Analysis

Analysis of the hemodynamic data was performed using custom MATLAB scripts, which allowed the selection of multiple beats captured in a larger series. At least two beats, similar in morphology, were used to generate a signal averaged pressure waveform for each method for each patient. It was from this representative wave that the heart rate (HR), systolic pressure (SBP), diastolic pressure (DBP), dP/dt_{max}, dP/dt_{min}, and Cardiac Index (CI—defined as the ratio of dP/dt_{max} to SBP) for RV pressure were calculated. HR, SBP, DBP, and mean pressure (MPAP) were calculated using the PA pressure.

Manual Scans

Screen captures which were used for variability testing were then printed onto a standard 8.5 in. × 11 in. sheet of paper and rescanned individually as PDF files by a standard office flat bed scanner (Sharp MX-M503N, Sharp Electronics Corporation, Mahwah, NJ). When placed on scanner, printout was intentionally rotated to skew the image. The PDF was then converted back to a JPEG and the colors were inverted. These now lower-resolution images were then reloaded into MATLAB, where rotational correction was conducted, followed by retracing and analysis of the wave-form.

Data Selection and Statistical Analysis

Results from MATLAB analyses were compiled in Excel. Grubb's Test was performed in order to identify statistical outliers, which were then removed from further analysis. Results from signals that were technically difficult to analyze due to excessive noise, or that were captured when the patient was experiencing a significant change in rhythm or clinical state (difference of 10 beats/min or greater in HR between the other two measurement methods) were also excluded from further analysis. The remaining results were exported to Graph-Pad

Prism (Version 5.0, GraphPad Software, Inc., La Jolla, CA, USA) to determine correlation between acquisition methods and for Bland–Altman analysis.

Intra- and Inter-operator Variability

Two subjects in the study were selected and their data retraced by two individuals separately from one another. The tracings were then reanalyzed by the same individual who initially analyzed the results from the patients in the study. The data from each individual was collected and compared to the results reported in this paper using Excel.

RESULTS

From the 13 subjects who consented to participate in this study, 13 representative RV beats for the Millar signal, 13 from the direct swan signal, and 12 from re-digitization were produced. A total of 12 representative PA waveforms could be produced for each measurement method. Figure 3 illustrates an overlay of representative RV and PA waveforms, acquired via all three methods. The waveforms have similar morphology. The phase shift in this figure is an artifact of the analysis process and not indicative of the actual time delay between measurement methods.

From the RV pressure waveforms that were obtained, several individual values were excluded for various reasons from each measurement technique. From heart rate, three Millar values and one tracing were excluded due to significant change in clinical state (The respective min and max dP/dt and CIs were also excluded). For dP/dt_{max} one patient was excluded for all three measurements due to excessive noise, one tracing was deemed a statistical outlier, and the swan value for the same patient was excluded for excessive noise (the respective CI's were also excluded). For dP/dt_{min} one swan value was deemed a statistical outlier, and another was excluded due to excessive noise, as was one additional tracing. Finally, one Millar CI was deemed a statistical outlier. From the PA waveforms that could be obtained, one patient's set of Millar measurements were excluded due to offset issues.

The remaining representative waveforms from each acquisition method were compared to each other within the same patient study. Table 1 contains the correlation coefficients of each possible comparison, and the number of studies that were used for each. Overall, the strongest correlation between capture methods was seen in the comparison between swan and tracing, while the weakest was between Millar and tracing. The parameter with the greatest average correlation was SBP for both PA and RV together, followed by HR. The parameter with the worst average correlation was the DBP for both PA and RV.

Figures 4 and 5 show the graphical representations of the Bland–Altman comparisons (using absolute difference) from each parameter for the RV and PA respectively. Table 2 contains the bias and standard deviation from each comparison. Overall the smallest difference is found between the swan and tracing results, and the largest between the tracings and Millar. Biases from each index for each measurement method remain within clinically acceptable ranges.

Figures 6 and 7 show the interoperator and intra-operator variability that are encountered with the re-digitization process. The two figures also show the difference between a digital screen capture re-digitization and the re-tracing of a manually scanned image that was rotated. The overlay shows very little difference between all of the re-tracings.

DISCUSSION

These findings show that RV and PA pressures acquired via fluid-filled Swan-Ganz catheterization can be used for obtaining more than basic systolic function, diastolic function, and pressure values. The values obtained in a retrospective assessment of RV hemodynamic waveforms via digitization represents a viable method for assessing changes in RV function with pulmonary vascular disease. We observed little variability between micromanometry and digitization from fluid filled catheters.

This study is not meant to dethrone high-fidelity Micromanometry as the gold-standard for invasive pressure measurement. Rather, its purpose is to show that in the absence of such a limited resource as micromanometry, it is still possible to acquire data from the RV and PA with a sufficient degree of accuracy as to permit the calculation of hemodynamic parameters in the time domain. This comes with the caveat that the signal used must have limited noise from catheter whip, under damping, or impact.

A major limitation to invasive measurements of hemodynamic function rests in the observation that clinical trials are generally performed in a multi-center manner. As such, the capital investment required for micromanometry systems is a major limitation. Moreover, clinical trial locations generally allow the catheterization operators to report their hemodynamic values based on their own judgment. It has been recognized, however, that many physicians do not take respiratory variation into account, thus instilling an error to the uniformity of the dataset.[6] The present report opens up the possibility of using archived clinical catheterization images, gathered retrospectively or captured prospectively from remote facilities to increase the number and size of studies that can be performed. With this in mind, RV tracings can be obtained at each clinical research site and forwarded to a central hemodynamic assessment site where the RV/ PA pressures can be reported in a blinded and uniform manner. Moreover, the digitation of RV hemodynamics would allow for the reporting of systolic and diastolic function parameters using traditional hemodynamic acquisition software or printouts. It should be noted, however, that it would be imperative that some quality controls be put in place. The decision as to whether or not a signal is adequate should be left to those who are most familiar with the technique. In such instances a core lab, whose main focus is the re-digitization and analysis of hemodynamic data, would be best suited for such an undertaking. However, once validated in larger patient cohorts, these tools could be integrated into commercial catheter systems or provided as open source software for offline analysis. This would enable use by other investigators, and possibly by clinicians outside of the research setting.

Study Limitations

We must acknowledge that there are other limitations to this study. Only catheter data that had limited noise could be used in this study—this eliminated several representative beats.

Measurements were recorded at separate times throughout the study, eliminating the possibility of direct beat-to-beat comparisons. Screen captures were not perfectly synchronized with the data captured by the Witt system. Several patients had arrhythmias which affected waveform morphologies. This however goes both ways, and if the data acquisition for all three methods were performed in unison, the variability may decrease.

CONCLUSION

Digital right-heart catheterization data, acquired via fluid-filled Swan-Ganz catheter, can be used as a surrogate for micromanometric data under ideal conditions for hemodynamic measures in the time domain. Additionally, retrospective analysis of pre-existing waveforms can be performed to gather more data via digitization. Care should be taken when using data that has excessive artifact. Use of these methods for hemodynamic analysis should be limited to experts who are familiar with these techniques.

Acknowledgments

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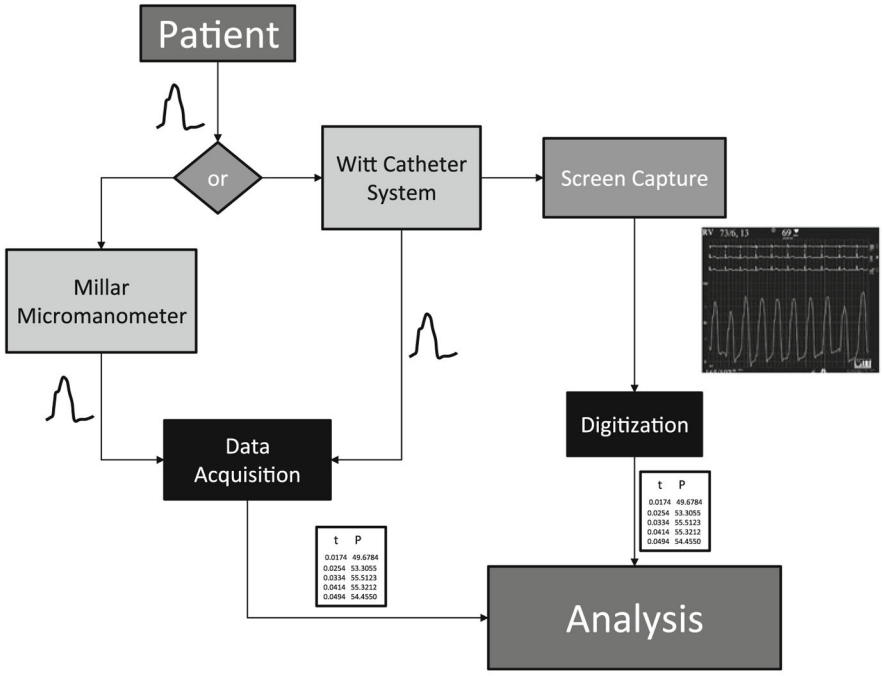

FIGURE 1.

Flow diagram illustrating how the data were obtained during the study. Data was digitally captured either by the Millar system or by the Witt System. It was then exported as text files for analysis in MATLAB. Additionally, when data were being recorded by the Witt System, screen captures of the pressure waveform were also obtained, re-digitized, and exported as text files for analysis in MATLAB.

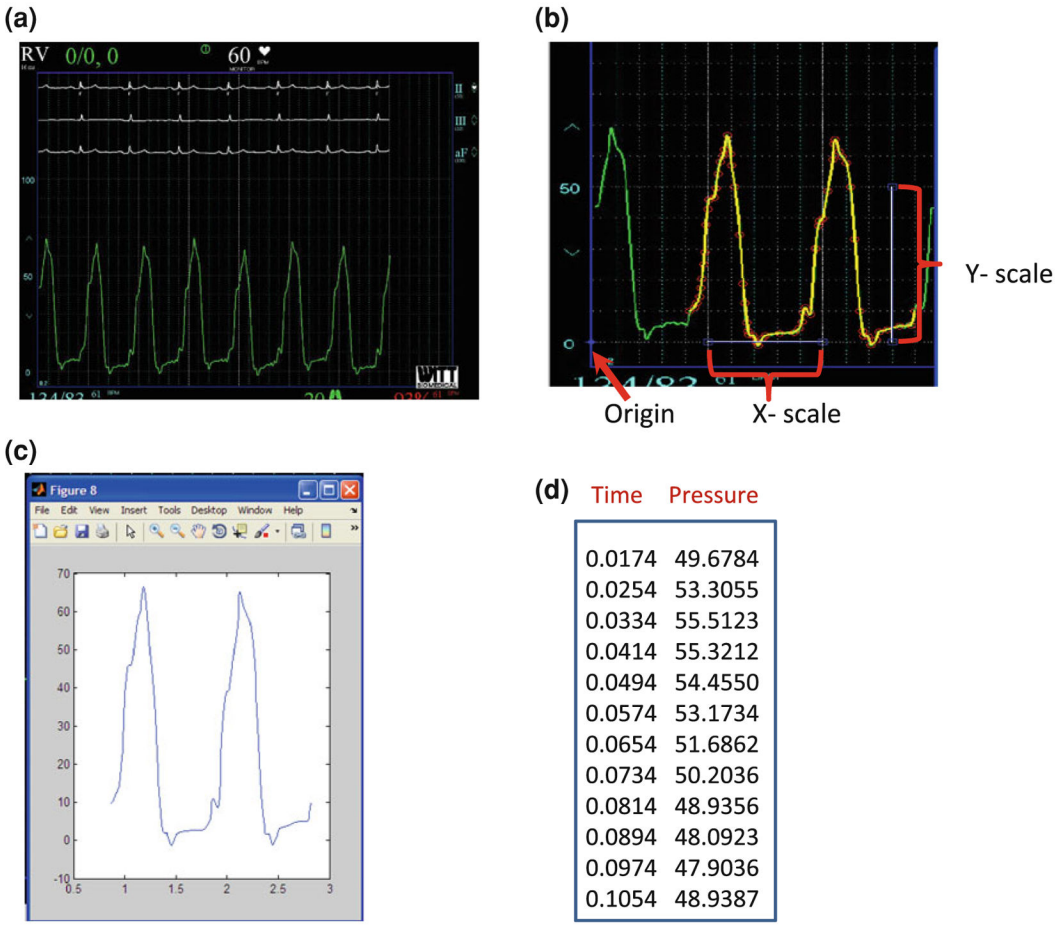

FIGURE 2.

Re-digitization process: (a) screen capture is obtained from Witt System. (b) Image is loaded into MATLAB where operator selects waypoints (red circles) to produce piece-wise spline that accurately represents waveform (yellow). (c) digitally reproduced waveform. (d) Text data is exported for analysis.

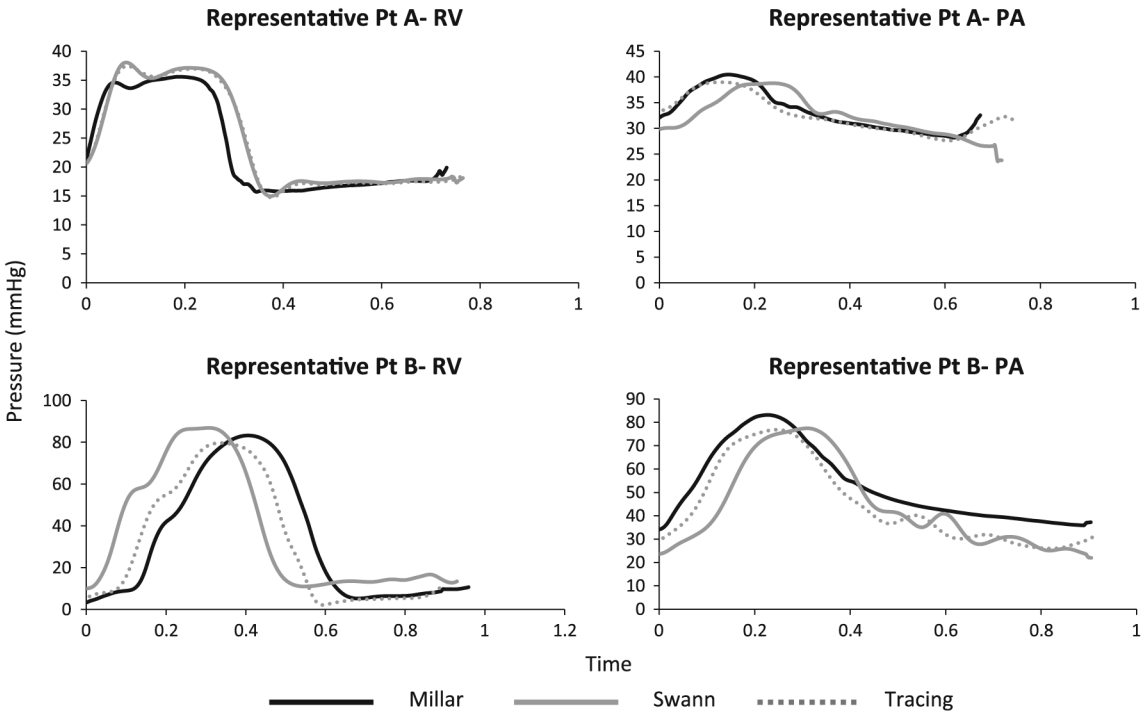

FIGURE 3.
Representative average beats from the three methods of acquisition.

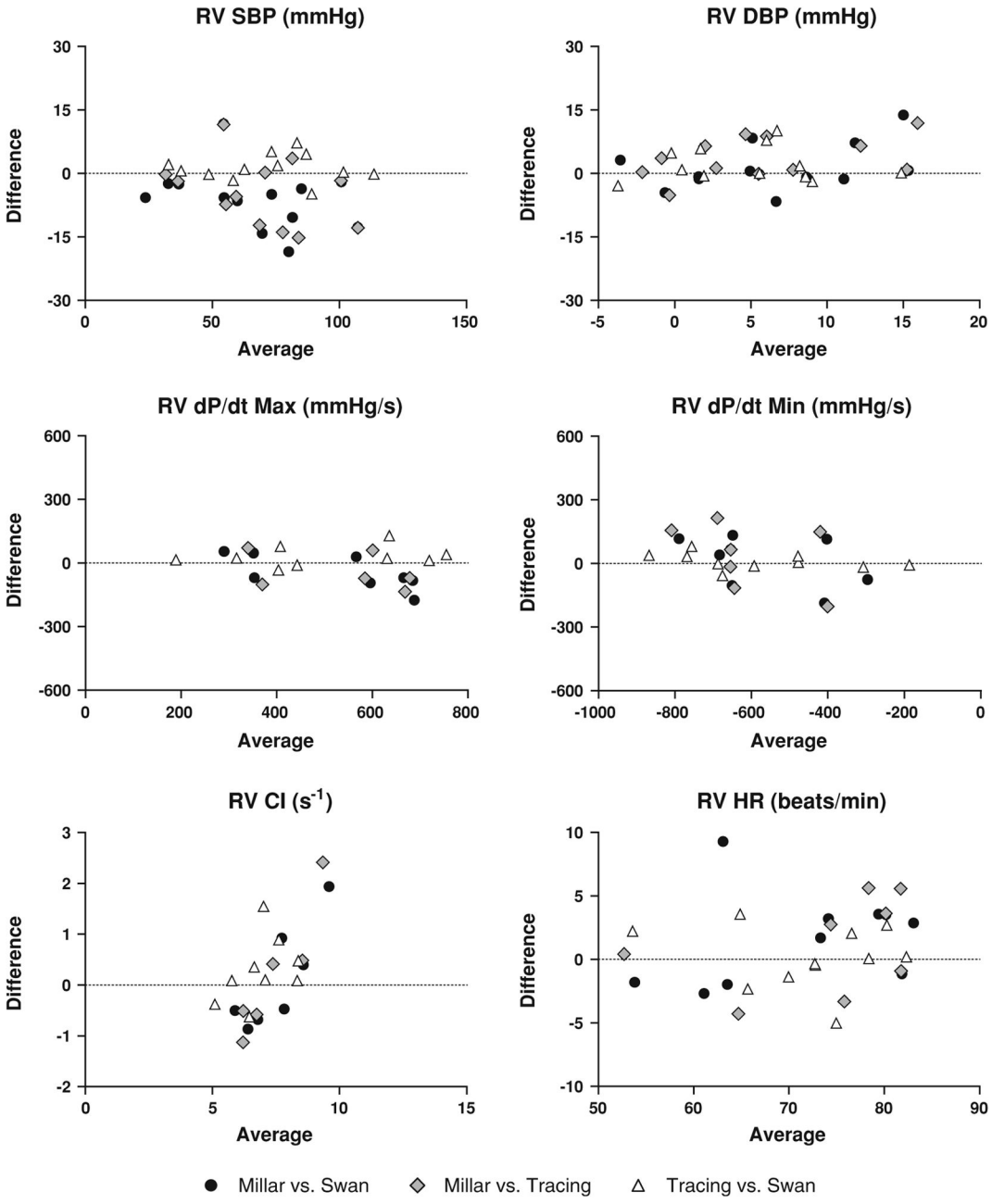

FIGURE 4.

Bland–Altman analyses comparing the hemodynamic parameters obtained via Millar, Swan, and tracing in the RV.

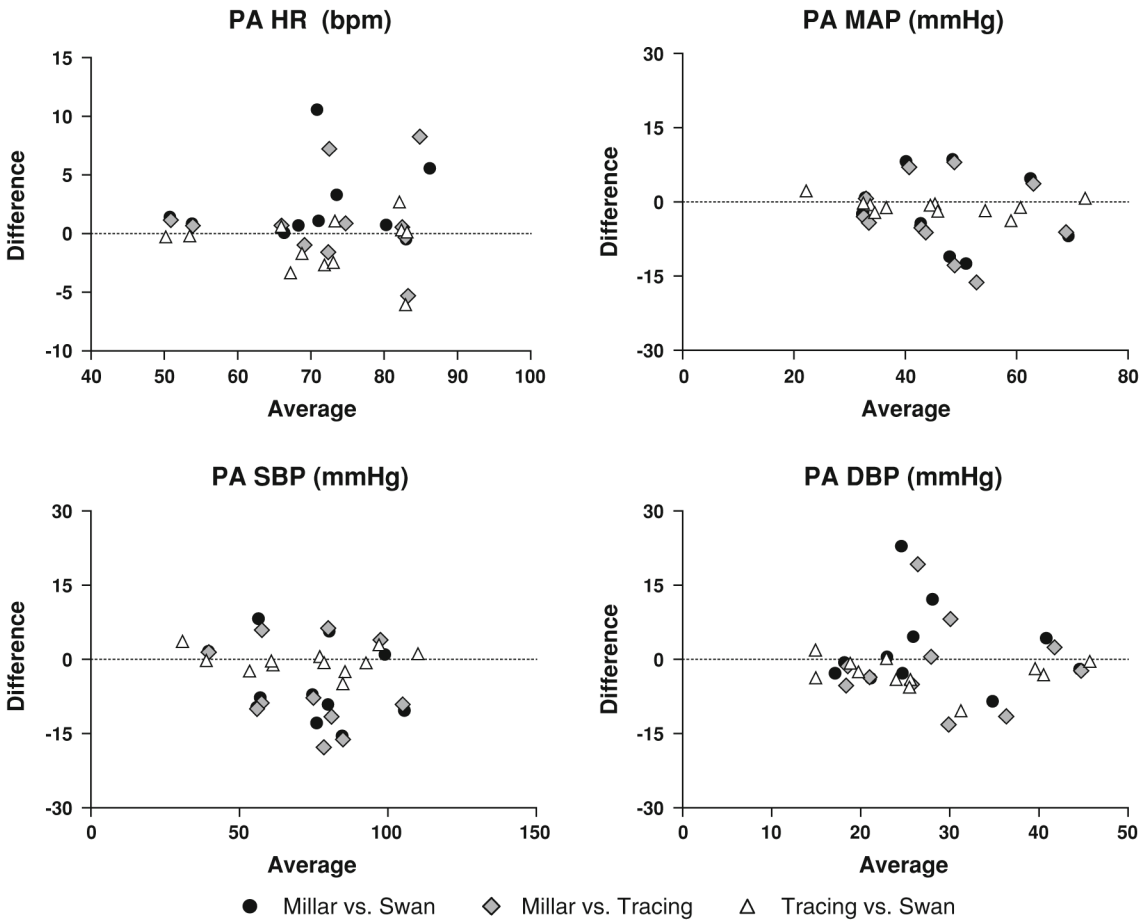

FIGURE 5.

Bland–Altman analyses comparing the hemodynamic parameters obtained via Millar, Swan, and tracing in the PA.

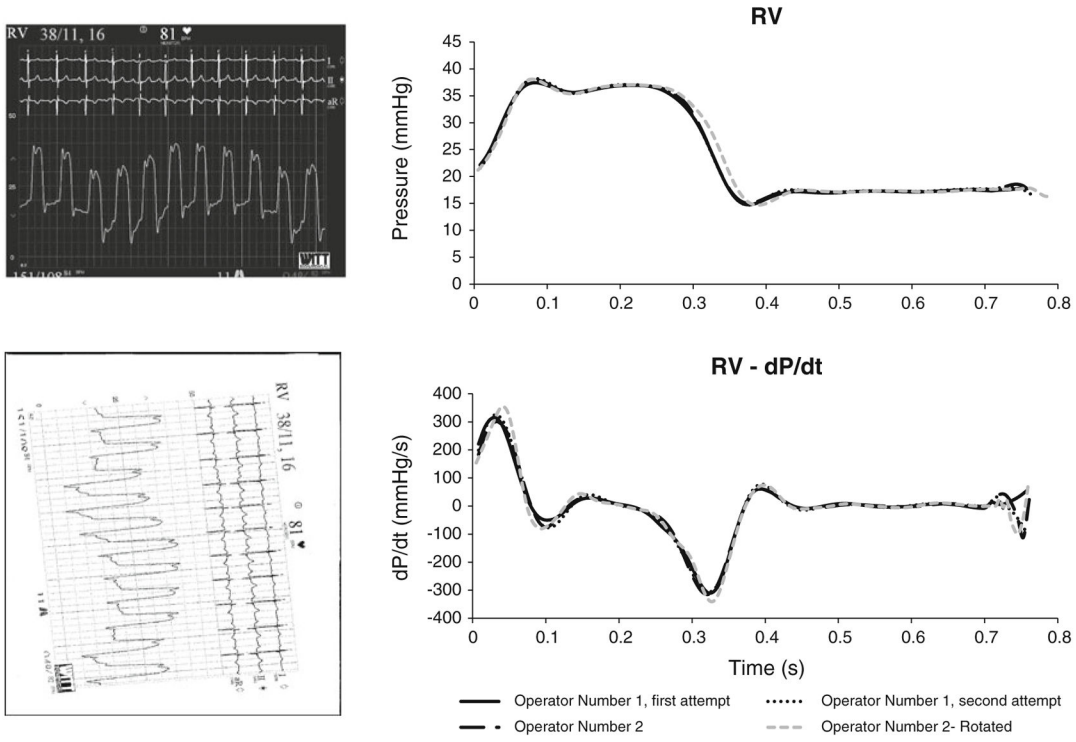

FIGURE 6.

Representative plots from interoperator and intraoperator variability assessment of RV tracing. (Top left) Original capture. (Bottom Left) Manually scanned and arbitrarily rotated printout of same capture. (Top Right) Resulting average beats from capture. (Bottom Right) Derivative of average pressure waveforms.

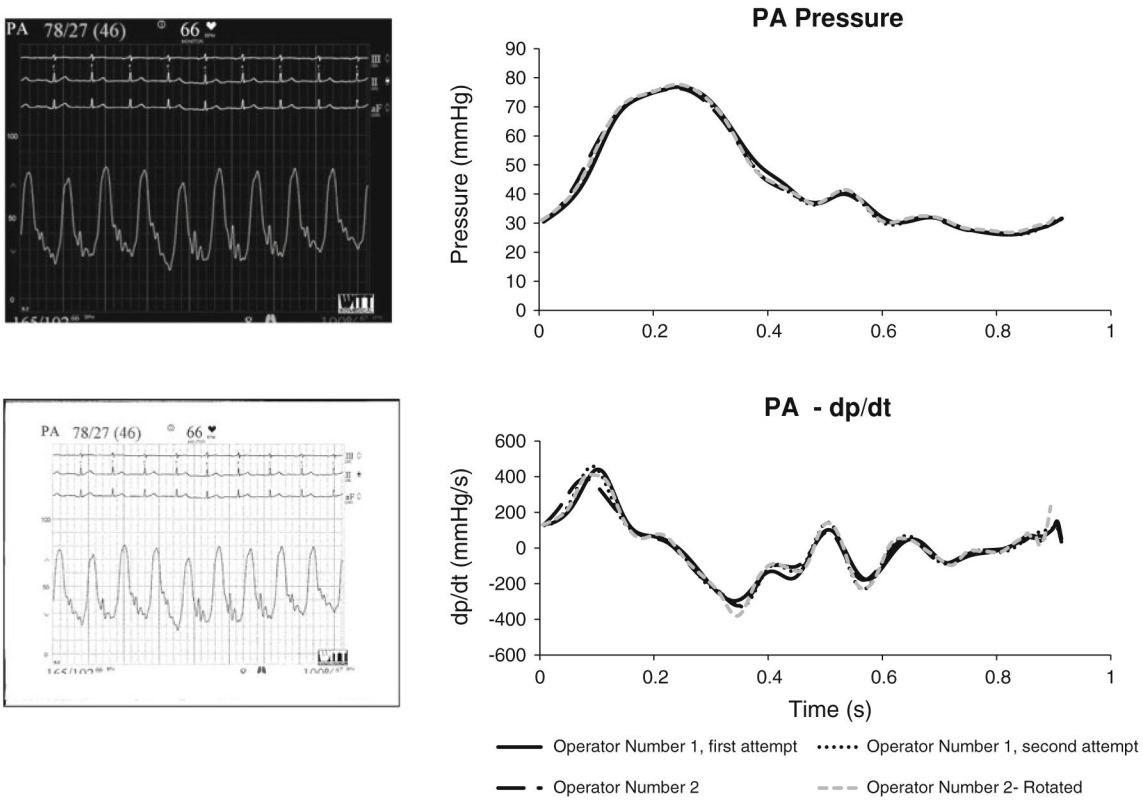

FIGURE 7.

Representative plots from interoperator and intraoperator variability assessment of PA tracing. (Top left) Original capture. (Bottom Left) Manually scanned and arbitrarily rotated printout of same capture. (Top Right) Resulting average beats from capture. (Bottom Right) Derivative of average pressure waveforms.

TABLE 1

Correlation between the measurement techniques and the number of comparisons.

	Millar vs. swan			Swan vs. tracing			Millar vs. tracing		
Parameter	***R***	***R*²**	***p***	***R***	***R*²**	***p***	***R***	***R*²**	***p***
RV HR	0.942	0.887	<.001	0.956	0.914	<.001	0.942	0.887	<.001
RV SBP	0.964	0.929	<.001	0.992	0.984	<.001	0.949	0.901	<.001
RV DBP	0.666	0.444	0.013	0.721	0.520	0.008	0.756	0.572	0.004
RV dP/dt_{max}	0.939	0.882	0.001	0.972	0.945	<.001	0.862	0.027	0.012
RV dP/dt_{min}	0.823	0.677	0.012	0.987	0.974	<.001	0.614	0.377	0.142
RV CI	0.892	0.796	0.007	0.860	0.740	0.003	0.908	0.824	0.012
PA HR	0.961	0.924	<.001	0.977	0.955	<.001	0.948	0.899	<.001
PA SBP	0.929	0.863	<.001	0.995	0.990	<.001	0.908	0.824	<.001
PA DBP	0.614	0.377	0.045	0.954	0.910	<.001	0.585	0.342	0.059
PA MAP	0.844	0.712	<.001	0.995	0.990	<.001	0.844	0.712	<.001
	N = 7–13			*N* = 8–12			*N* = 6–12		

TABLE 2

Bias and standard deviation results from Bland–Altman analysis of measurement techniques.

	Millar vs. swan		Swan vs. tracing		Millar vs. tracing	
Parameter	**Bias**	**SD**	**Bias**	**SD**	**Bias**	**SD**
RV HR	1.67	3.66	0.12	2.54	1.19	3.83
RV SBP	−5.931	7.353	1.35	3.209	−4.603	8.082
RV DBP	1.41	5.53	2.14	4.10	3.73	4.91
RV dP/dt_{max}	−44.22	80.86	30.94	48.00	−40.84	85.87
RV dP/dt_{min}	13.55	120.00	9.61	37.68	36.07	154.10
RV CI	0.11	1.03	0.28	0.65	0.18	1.26
PA HR	2.20	3.26	−0.98	2.36	1.03	3.80
PA SBP	−5.04	7.88	−0.34	2.33	−5.74	8.70
PA DBP	−1.94	7.06	−2.83	3.18	−1.06	8.99
PA MAP	−2.86	7.24	−0.86	1.52	−3.09	7.60

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