Title: VALIDATION OF A RIGHT VENTRICULAR EJECTION FRACTION CATHETER UTILIZING THE JARVIK-7 ARTIFICIAL HEART

Authors: R. F. Feinstein, Ph.D., M.D., R. K. Parker, D.O., C. I. Weiss, M.D., S. M. Poler, M.D., D. G. Lappas. M.D.

Affiliation: Department of Anesthesiology
Washington University School of Medicine
Barnes Hospital
St. Louis, MO 63110

Introduction: The use of thermodilution techniques to estimate performance parameters of the left side of the heart and circulation have become well accepted adjuncts to modern anesthesia care. Recently there have appeared in the literature studies employing specially modified thermodilution catheters capable of measuring right ventricular ejection fraction (RVEF) and cardiac output (CO). Many of these studies were performed in animals, and only recently has the technique been extended to humans. The purpose of this study is to validate data obtained from a rapidly responding thermodilution catheter under controlled conditions in a pulsatile artificial perfusion device, namely a Jarvik-7 artificial heart.

Methods: Elecath (tm) pulmonary artery (PA) catheters were used in conjunction with an Elecath cardiac output computer. These catheters differ from standard thermodilution PA catheter in two respects. Firstly, the time constant of the thermistor is much shorter (average response time $\leq$ 100 msec.) than in normal PA catheters, and secondly, the injection port is closer to the thermistor than in conventional PA catheters, such that it lies within the RV. Use of two catheters was required because of the mechanical valve in the Jarvik heart RV. One of these catheters was inserted into the inflow tract of the RV of the Jarvik-7 artificial heart for injection. Another catheter was placed with its thermistor in the outflow tract of the Jarvik's RV. The separation of the injection port and the thermistor was maintained at the same distance as their separtion on a single catheter. The Jarvik-7 mock circulation was maintained at 37^{o}C and cardiac output control data readings were made at heart rates ranging from 35 beats per minute to 105 beats per minute using room temperature and iced injectates. The cardiac output of the Jarvik-7 was measured using a turbine flowmeter placed inline in the flow tube between the aortic and right atrial pressure chambers of the mock circulation.

The end-diastolic volume for the Jarvik-7 is approximately 150 ml. and the stroke volume is 100 ml. with a nominal ejection fraction of 67%. The Elecath computer was synchronized to the driveline pressure waveform of the Jarvik-7, and readings were taken of cardiac output, stroke volume, ejection fraction, end-systolic volume and end-diastolic volume. Measurements were made at heart rates ranging form 35 to 105 beats per minute using room temperature and iced injectates.

The Elecath measures cardiac output by the thermodilution method. Cardiac output is computed by the Stewart-Hamilton equation. The Elecath computer is also capable of measuring ejection fraction. Ejection fraction is described as the right ventricular fraction of blood at end diastole ejected by end systole. Ejection fraction is derived by the difference in temperature of the injectate versus blood between successive diastoles. End-diastolic volume is then calculated by the computer using stroke volume and ejection fraction. Stroke volume and end-diastolic volume are then used to calculate end-systolic volume.

Results were analyzed by linear regression and analysis of variance. Between group comparisons used Bonferroni's correction for multiple comparisons. $P < 0.05$ was accepted as the level of statistical significance.

Results: The Elecath consistently underestimated the Jarvik-7 measurements of cardiac output (-0.67 l/m, average underestimate), stroke volume (-18.6 ml, average underestimate), and ejection fraction (-34%, average underestimate). Table I illustrates the dependence of the results on injectate temperature. The magnitude of error for cardiac output was influenced by the temperature of the injectate ($P < 0.0003$) but was not influenced by heart rate. The estimation of Jarvik-7 cardiac output by the Elecath with iced injectate has a error of 0.13 ± 0.55 which is statistically indistinguishable from the known cardiac output of the Jarvik-7 heart. Because stroke volume is a calculated value, the temperature of the injectate also influences the magnitude of error ($P < 0.037$). The stroke volume with iced injectate underestimated the Jarvik-7 by -3.7 ± 0.5 ml.($n = 13$). Neither the heart rate nor the temperature of the injectate had a predictive value in estimating the Jarvik-7 ejection fraction. Due to the underestimation of ejection fraction and stroke volume, the calculated value of end-diastolic volume would be expected to be overestimated. This expectation was confirmed. The Jarvik-7 end-diastolic volume was consistently overestimated by the Elecath by an average of 84.2 ml.

TABLE I: MEASUREMENT ERRORS

	INJECTATE TEMPERATURE	
mean $\pm$ s.d.(n)	Iced	Room T
SV (ml.)	$-3.7 \pm 0.5(13)$	$-20 \pm 0.1(38)$
EDV (ml.)	$126 \pm 45(9)$	$72 \pm 26(30)$
EF (%)	$32.3 \pm 7.1(10)$	$36.4 \pm 7.9(30)$
CO (l/m.)	$0.13 \pm 0.55(9)$	$-0.90 \pm 0.71(30)$

Discussion: Our results indicate that the Elecath RVEF thermodilution catheter provides an accurate measure of cardiac output in the model used when the injectate solution is iced. The accuracy of cardiac output with iced injectate allows a reasonable approximation of stroke volume, but room temperature injectate does not. The results from this study indicate that ejection fraction as measured by the Elecath is inaccurate and unreliable in this model. We were unable to show a predictable or reproducible ejection fraction measurement in our model system. Due to the inaccuracy of ejection fraction determinations, the Elecath computer calculations of end-diastolic volume and end-systolic volume were also inaccurate. The intermediate location of the mechanical valve between the injection port and thermistor may systematically perturb the output of the Elecath catheter and computer. An argument can be made that the situation as studied in the Jarvik-7 is not a suitable model. However, the stroke volume estimates under one condition, using iced saline, are very close to the nominal stroke volume of the Jarvik heart. This supports the validity of the model. Additionally, water was used as the circulatory fluid in the Jarvik-7 instead of blood, thus the specific heat and specific gravity differences between blood and water were eliminated in this model. In spite of these differences, we would expect this controlled environment to produce reproducible results with a consistent change with changing conditions. This was not the case for ejection fraction measurements. In conclusion, the ejection fraction data and resulting volume calculations produced by the Elecath must be viewed with skepticism. Most of the recent studies with ejection fraction catheters have utilized the American Edwards catheter; this study does not apply to that catheter.