Title: A CASE FOR STANDARDIZATION OF CALIBRATION PROCEDURES FOR THERMAL DILUTION CARDIAC OUTPUT COMPUTERS

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Introduction. With the recognition of thermal dilution cardiac output (TDCO) as a useful and an apparently easy-to-perform clinical measurement, there has been a proliferation of manufacturers producing TDCO computers and thermistor containing pulmonary artery catheters. Since the computer user is generally not able to verify the accuracy of a computer with a flow source, the user must rely on the manufacturer's calibration. We recently became suspicious that the two major types of TDCO computers in our institution were providing differing results. We therefore performed an invitro survey of the accuracy of the computers in the clinical flow range using a flowbench.

Methods. The distal 65 cm of the catheter was mounted axially in the 2.54 cm id plexiglass tube of a flowbench. A 3 baffle mixing system was located between the injectate outlet and the thermistor. A continuous flow of saline solution (37°C, 0.9% gm% NaCl) was adjustable to ±0.03 L/M using a Fischer Porter series 10A3500 flowrator meter. Total circuit and reservoir volume was 41 L. Calibration of the flow bench was done by weighing perfusate pumped during a timed period. The weighing system was calibrated with weights traceable to the National Bureau of Standards. Density corrections were made for temperature and electrolyte composition and no measured volume was less than 11 L. No time period was less than 106 seconds in duration. The flowbench and calibration methods were designed so that the hydrostatic presssures in the circuit would be the same during use as during calibration. The flowbench design was provided by Edwards Laboratories. Injections of cold saline (less than 1°C, 10.10±.01 ml) were made with an OMP injector model 3720. In order to optimize performance cold injectate was selected to achieve a greater signal to noise ratio. The output measurements were corrected for the specific heat and specific gravity of the injectate and perfusate solutions used and for the slightly larger injectate volume which our injector delivered.(1) We did attempt to follow the manufacturers instructions precisely. For each type of catheter required, three catheters from different lots obtained over the preceding year were selected. For each of 13 computers, duplicate determinations were made for the 3 catheters at 2, 5 and 8 L/M. At least 1 minute was allowed to elapse between injections. Mean ± standard error of the mean (SEM) are used throughout.

Results. The mean injectate temperature over all determinations was 0.40±.04°C. The mean baseline thermistor temperature over all determinations was 37.17±.02°C. Product A did read consistantly lower than product C, $p<.001$ (figure). Computer A measured low by 15.5±.4%, 13.1±.7% and 12.8±.7% at 2, 5, and 8 L/M respectively. Computer C was 2.0±.6% low at 2 L/M, in agreement with the calibration at 5 L/M (0±.5%, $p<.01$), and 1.4±.5% high at 8 L/M. The products of both major manufacturers were tightly clustered even though the devices were purchased over several years and had received varying use. Computer D was catheter compatible with computer C.

Discussion. Although trend monitoring should make small inaccuracies unimportant, the clinician does frequently respond to specific values of cardiac index and systemic vasular resistance as indications to alter therapy. Powner and Snyder(2) have also reported the variations in accuracy among TDCO computers, but they did not study the two major models presented here. The increasing popularity of leaving an introducer sheath inplace facilitates easy catheter replacement. Where no standardization of equipment exists, this exchange may result in the use of different TDCO computers in the care of a single patient, even though the computers are not catheter compatible. With the increasing number of TDCO computers using electrically compatible catheters, it will be important for the manufactures to assure the same output reading for the same electrical signal. Electrical simulators may satisfactorily meet this need and verify stable computer performance over a period of time. However, calibration with flow will be necessary when circuitry is not compatible. Any flowbench system must make compromises in simulating the biological situation and debate over what set of compromises are most appropriate is probably not valuable. What is necessary is that all manufacturers who calibrate with a flow source in order to define their system's computation constant do so in a standardized manner.

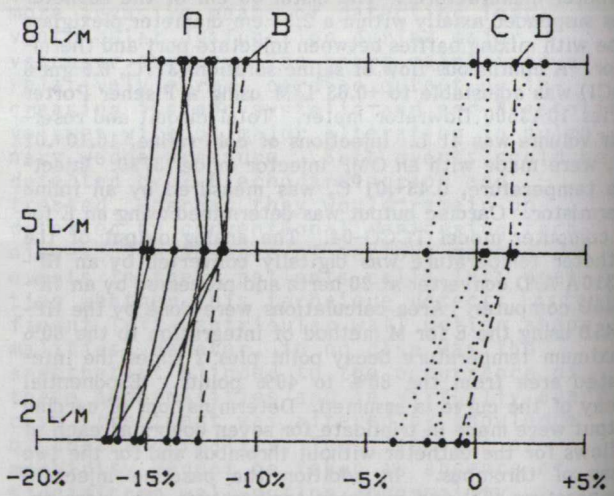

Figure. Each point is the mean of 6 determinations using 3 catheters. Thirteen computers from 4 manufacturers were studied. A. Electronics for Medicine, TCCO-04 (one DTCCO-07). B. Instrumentation Laboratories, 601. C. Edwards Laboratories, 9520A. D. Gould, SP1435.

References.

1. Levett JM, Replogle RL: Thermodilution cardiac output: a critical analysis and review of the literature. J Surg Res 27:392-404, 1979

2. Powner DJ, Snyder JV: In vitro comparison of six commercially available thermodilution cardiac output systems. Med Instrum 12:122-127, 1978