



Noninvasive Medical Technologies

Comparison of Dissimilar Measurement Methodologies

Issues Related to Cardiac Output Estimation Noninvasive IQ[®] System and Invasive Thermodilution Techniques

Correlation between IQ[®] and Thermodilution techniques indicated that validation studies were not required after 1998.

- All measurement techniques of cardiac output are estimates. Even the true “gold standard” for cardiac output comparisons, the Fick method, is subject to inherent variability and technical inaccuracies.
- IQ[®] System, using thoracic pulsatile impedance changes, directly estimates left ventricular stroke volume from ascending aortic flow and calculates cardiac output (SV x HR). Thermodilution cardiac output (TD CO), using an indicator technique, estimates right ventricular cardiac output as an indicator of left ventricular cardiac output.
- TD CO is user technique dependent, relying on use of:
 1. proper computation constant
 2. accurate injectate volume
 3. accurate injectate temperature measurement
 4. accurate blood temperature measurement
 5. proper injection technique
 6. consistent timing of injections during the respiratory cycle
 7. consistent averaging strategies
- IQ[®] provides nearly real time, continuous data which directly reflects the dynamic nature of left ventricular hemodynamics. TD CO provides “snap shot” of a certain moment in time as opposed to continuous real time hemodynamic monitoring.
- The influence of the respiratory cycle on the cardiovascular hemodynamics may cause significant variability in both TD CO and IQ[®] CO. However this normal physiologic variability negated from the TD CO value recorded, depending on whether the practitioner chooses to inject at end-expiration or randomly through the respiratory cycle.
- The averaging strategies employed directly affect the recorded TD CO value. The average CO value recorded may not represent the patient’s actual hemodynamic status. For example, typically 3 to 5 boluses are obtained until at least 3 are within 10% to 15% of each other, or the high and low values are eliminated, allowing the practitioner to “choose” the CO value to be documented on the flow chart.
- Both risks and benefits need to be considered when replacing any measurement technique with another, when the methods estimate different physiologic events. For example, noninvasive (cuff) blood pressure measurement has poor agreement with invasive (arterial) blood pressure measurement, although the correlation is strong. Agreement (Bland-Altman) evaluates the mean differences between two variables, on the average how well the methods agree. Correlation (r) assesses the strength of a linear relationship between two variables and the ability to trend each other.



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Comparison of Cardiac Output Estimates (Thoracic Electrical Bioimpedance (TEB), Thermodilution (TD), Fick Method, Dye Dilution, Esophageal Doppler, Angiography)

Source	Comparison	Population	n	# of data points	r	Bland - Altman
Yelderman, 1992, J CT Vasc Anes	<ul style="list-style-type: none"> • TD Bolus • TD CCO 	ICU	54	222	0.94	Bias 0.02 L/min., 95% conf. Limits 1.07 and -1.03 L/min.
Medin, 1997, CCM	<ul style="list-style-type: none"> • TD Bolus • TD CCO 	Conv. Sample	20	306	0.93	NR
Burchell, 1997, CCM	<ul style="list-style-type: none"> • TD Bolus • TD CCO 	Crit. ill surg	21	202	NR	Bias 0.49 L/min. Precision 1.01 L/min.
Hillis, 1985, Am J Card	<ul style="list-style-type: none"> • Fick • Indicator Dilution (TD/green dye) 	High/Low CO states, Left sided regurgitation	808	808	NR	Authors report excellent agreement < 20% difference in 90% of patients
Reddy, 1976, J Lab Clin Med	<ul style="list-style-type: none"> • Fick • Indicator dye 	Various CV diseases	105	NR	NR	84% agreed within 10% of the line of identity, 98% were within 25% of the line of identity
Davies, 1986, CCM	<ul style="list-style-type: none"> • Cont. Fick • TD Bolus 	Ventilates, S/P Card. Surg.	21	237	0.86	NR
Van Grondelle, 1983, Am J Physiol	<ul style="list-style-type: none"> • Fick • TD Bolus 	ICU	26	57	NR	TD values > in all cases where Fick < 3.5L/min. Suggests TD overestimates in low Co range.
Yu, 1996, CCM	<ul style="list-style-type: none"> • Fick • TD Bolus 	Group (1) sepsis, Septic shock, ARDS Group (2): hemorrhagic shock	13 9	82 65	0.68 0.60	(1) Bias -0.54 ± 1.99 L/min. 95% Conf. Limits -4.44, 3.35 (L/min.) (2) Bias 0.60 ± 1.75 , 95% Conf. Limits -4.02, 2.83 (L/min.)
Sorohan, 1997, CCM	<ul style="list-style-type: none"> • Esoph Dop. CO • TD Bolus 	CABG	50	354	0.91	Bias = 0.2 L/min. Precision 0.5 L/min.

NR (Not Reported); TEB (Thoracic Electrical Bioimpedance); TD (Thermodilution); CCO (Continuous Cardiac Output)



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Source	Comparison	Population	N	#of data points	r	Bland-Altman
Wo, 1995 Curr. Science	• TD Bolus • TEB-IQ®	Critically ill	68	842	0.86	Bias -0.06 ± 0.62 L/min./m2
Shoemaker, 1997, submitted for publication	• TD Bolus • TEB-IQ®	Ed: Severely injured/ hemorrhaging (139), Medial (129), High risk surgical (274), ICU (138)	680	2192	0.85	Bias -0.12 = 0.72 L/min/m2
Roessler, 1996, CCM	• TD Bolus • TEB-IQ®	High risk OR	28	234	0.89	NR
Marik, 1997, CCM	• TD Bolus • TEB-IQ®	CAD	24	24	0.80	Limits of agree -0.41 to 3.5 L/min., 95% CL -2.7 to -5.5 L/min., 2.1 to 4.9 L/min.
Shoemaker, 1996, CCM	• TD Bolus • TEB-IQ®	Ed: Severely injured, hemorrhaging	75	NR	0.75	NR
Van De Water, 1995, J Clin Engineer	• TD Bolus vs. • TEB-Kubicek • TEB- Bernstein • TEB-IQ® • TEB-IQ®	• Critically ill • Critically ill • Critically ill • CABG	21 21 87 17	21 21 87 17	0.74 0.45 0.83 0.93	NR
Grayce, 1997, CCM	• TD Bolus • TEB	ICU	76	414	0.57	NR
Pianosi, 1996, Am J Card	• Indirect Fick • TEB	Healthy children during exercise	30	NR	0.82	Bias 0.14 ± -1.05 L/min. 95% CL -0.12 to 0.44 L/min.
Wong, 1996, Acta Anes Sin	• TD Bolus • TEB	CABG	18	128	0.86	Bias 0.66 ± 0.915 L/min., 95% CL 0.12 to 0.98 L/min. Limit of Agree -2.49 to 1.17 L/min.
Belardinelli, 1996, Am J Card	• TD Bolus • Fick • vs. TEB	CAD, hx MI, During exercise	25	45	TD 0.90 Fick 0.93	NR
Fuller, 1991, Clin. Inv. Med	• TD Bolus • Dye Dilution • Fick • Angiography • vs. TEB	Meta-analysis (28 studies)	NR	2688	TD 0.82 Dye 0.83 Fick 0.80 Ang. 0.65 Mean 0.81	NR

NR (Not Reported); TEB (Thoracic Electrical Bioimpedance); TD (Thermodilution); CCM (Critical Care Medicine)



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Headquarters: 6412 S. Arville St. • Las Vegas, NV. 89118

888-466-8552 Fax: 702-614-4170