Clinical Studies

References on Impedance Cardiography

With the increasing incidence of catheter related sepsis, and recognition of increased mortality and cost of care with pulmonary artery catheters, the need for a safe, cost-effective, and clinically accurate means of obtaining hemodynamic data has become evident. The problems faced by companies who earlier marketed unproven systems with arbitrary results left many a cardiologist apprehensive of such systems. The Haemotron System has proved itself in clinical trials both in Europe and South Asia in terms of accuracy and reliability. It is believed that the system will again prove itself in the United States.

Impedance Cardiography (ICG) forms a vital part of our system. Over eighty peer reviewed articles have been published on ICG since 1993. So the theory and the practicality of the system is well accepted no matter what system was used for the measurements. Summaries of significant clinical studies and articles are given below. These are listed as a professional courtesy and in no way constitute an endorsement of products or services by the authors of the referenced studies.

TITLE : NORMATIVE DATA ON EXERCISE STROKE VOLUME BY IMPEDANCE CARDIOGRAPHY IN CHILDREN

Canadian Cardiovascular Congress 2001

AUTHOR : P Pianosi. Dalhousie University, Halifax, NS*

Impedance cardiography (ICG) offers a simple, inexpensive, unobtrusive, and non-invasive means of measuring SV (and cardiac output) during exercise. The purpose of this study was to measure these parameters to develop normative reference data. One hundred and eighteen healthy children performed a progressive exercise test to voluntary exhaustion with power increments every minute on a cycle ergometer. Oxygen uptake (VO2) was measured breath by breath on a Collins CPX plus system. SV was measured with an ICG-M501 impedance cardiograph, which employs a tetrapolar lead system placed on the neck and lower rib cage. It was expressed as SVI to normalize data across subjects, whose ages ranged from 7-19 yrs, and BSA from 0.90 to 2.08 m2. Cardiac output was regressed on oxygen uptake. Prediction equations for SVI vs oxygen uptake were computed using linear modeling with SAS, considering potential confounders such as age and sex. Cardiac output increased linearly with oxygen uptake in all subjects. Individual slopes and intercepts ranged from 2.45 to 7.77 l/min per l/min VO2, and 1.82 to 10.6 l/min, respectively. SVI rose by a mean (SD) of 29±17% from rest to exercise. Maximum SVI was 52 ml/m2 in boys and girls. Sex influenced the course of SV recruitment during exercise. Girls increased SVI more on the first workload and then at a slower rate as VO2 rose; whereas boys increased SVI less at the onset of exercise, but to a greater extent with increasing VO2. There was no significant effect of age on this relationship. Though most subjects demonstrated a plateau or gentle rise in SV during exercise, a minority showed decreasing SV despite rising oxygen uptake and cardiac output. ICG is a useful clinical and research tool in pediatric cardiology and work physiology. These results will now be used as a reference standard against which children with cardiac disorders can be compared.

Authors: Yung, GL, Fletcher, CC, Fedullo, PF, Johnson, FW, Kinninger, K, Knowlton, KU, Channick, RN
Title: "Comparison of Impedance Cardiography and Direct Fick Cardiac Output Measurements in Pulmonary Hypertension Patients," Presented at the American Thoracic Society Annual Meeting, April 26, 1999.

"Cardiac Index (CI) is the most important determinant of outcome in patients with pulmonary hypertension. Traditional methods of cardiac index measurement are either invasive, time consuming, operator dependent, or costly. Thoracic Electrical Bioimpedance (ICG) offers a simple and convenient method of determining CI."

Thirty-three patients undergoing cardiac catheterization were measured simultaneously with ICG and direct Fick methods.

Results:

- Bias: -0.14 l/min/m^2
- Precision: 0.44 l/min/m^2
- Correlation: 0.84

The authors concluded that: "Impedance Cardiography appears to be a clinically acceptable method of determining cardiac output in patients with pulmonary hypertension."

Authors: Speiss, B., Muhammad, A., Soltow, L., et al.
Title: "Thoracic Electric Bioimpedance Cardiac Output Compared to Pulmonary Artery Catheter Monitoring in Patients Undergoing Coronary Artery Bypass Graft Surgery," Presented at the Society for Cardiovascular Anesthesiologists' 20th Annual Meeting, April 28, 1998.

The Pulmonary Artery Catheter (PAC) is routinely used to measure cardiac output by thermodilution method for patients undergoing coronary artery bypass graft surgery. PACs are associated with complications, and data has shown up to a 22% margin of error. This study compares cardiac output obtained via Thoracic Electrical Bioimpedance (ICG) with PACs during Coronary Artery Bypass Grafting (CABG).

Thirty-one patients undergoing first time CABG were studied. After induction of anesthesia, a PAC was inserted and electrodes for ICG were placed.

Simultaneous measurements of CO were performed after induction, sternal retraction, before and after cardiopulmonary bypass, and after the closure of the chest. Data was

compared for the entire study at specific time points using the Pearson's R correlation and Bland-Altman technique.

Results:

- Post-induction correlation with thermodilution was r = 0.939

The researchers concluded, "...the correlation between the two measurements is highly significant, and that ICG provides an alternative noninvasive and benign method of monitoring cardiac output. In the current climate of cost containment this method may prove to be a valuable alternative."

Authors: DeMaria, A., Belott, P., Spiess, B., Williams, B., Sageman, S., Diaco, N., Raisinghani, A.and Ohmori, K.
Title: "The COST Study: A Multicenter Trial Comparing Measurement of Cardiac Output by Impedance Cardiography with Thermodilution," Presentation at the American College of Cardiology 47th Annual Scientific Session, April 1, 1998.

One hundred and ninety-one patients undergoing Swan-Ganz™ Heart Catheterization and Thermodilution (TD) measurement of cardiac output, for a variety of clinical indications, including diagnostic catheterization, CHF, shock, and post CABG. The study was performed at seven medical centers.

The authors stated, "Measurement of cardiac output is of fundamental importance in assessing pathophysiology and determining therapy in patients with heart disease. Recent developments have enabled refinement of instrumentation for measurement of Thoracic Electrical Bioimpedance (ICG)."

Results:

- Cardiac output by TD ranged from 2.2 to 9.1 L/min (mean 5.2, +/- 1.5), cardiac output via ICG ranged from 2.0 to 9.9 L/min (mean 5.3, +/- 1.6).
- Mean variability was 50% greater with TD measurements as compared to ICG measurements.
- Bland-Altman analysis revealed a bias of - 0.13 L/min with a precision of 1.15 L/min.

The researchers concluded, "...reliable cardiac output can be obtained by both TD and ICG," and, "...measurement of cardiac output using refined ICG instrumentation shows good correlation with TD."

Authors: Verhoeve, P., Cadwell, C. and Tsadok, S.

Title: "Reproducibility of Noninvasive Bioimpedance Measurements of Cardiac Function," Presented at the second annual meeting of the Heart Failure Society of America, Boca Raton, FL. September 13 - 16, 1998.

The purpose of this study was to determine reproducibility in a steady state using Impedance Cardiography measurements in patients with known cardiovascular disease, and to determine normal ranges of cardiac indices in this patient population to provide a baseline for evaluation of responses to therapeutic interventions.

Stroke index, cardiac index, systemic vascular resistance, thoracic fluid content, and other indices of cardiac function were measured prospectively in a convenience sample of 96 men and women enrolled in a cardiac rehabilitation program.

Results:

- Strong intra-day correlation between measures of cardiac index, systemic vascular resistance index and thoracic fluid content were found (SI: $r = 0.99$ and 0.95, CI: $r = 0.96$ and 0.92, SVRI: $r = 0.97$ and 0.84, TFC: $r = 0.99$ and 0.97; $p<0.001$)
- High inter-day correlation was also found, with a degree of variability showing device sensitivity. (SI: $r = 0.86$, CI: $r = 0.79$, SVRI: $r = 0.76$, TFC: $r = 0.80$; $p<0.001$).

The researchers concluded, "...the patient with cardiopulmonary disease can be reliably monitored noninvasively for quantifiable hemodynamic measurements. The availability of expected ranges provides valuable information for objective determination of responses to therapy."

Authors: Littman, L, Lasater, M.
Title: "Cost Effectiveness of Noninvasive Hemodynamic Monitoring as a Screening Tool Prior to Initiation of Inotrope Infusion." The Journal of Cardiovascular Management, March/April 1999: pp 29-30.

"Noninvasive hemodynamic monitoring, through the technology of Impedance Cardiography, provides an excellent screening tool prior to the initiation of costly intravenous inotrope therapy."

" It can be used to guide therapeutic decisions, such as diuresis, in a patient who is acutely decompensated. It is extremely cost-effective, and poses no risk to the patient."

Authors: Connors, A.F., Speroff, T., Dawson, N., Thomas, C., Harrell, F., Wagner, D., Desbiens, N., Goldman, L., Wu, A., Califf, R., Fulkerson, W., Vidallet, H., Broste, S., Bellamy, P., Lynn, J. and Knaus, W.

The objective of the study was to examine the association between the use of right heart catheterization during the first 24 hours of care in the intensive care unit and subsequent survival, length of stay, intensity of care, and cost of care. The study was performed at five U.S. teaching hospitals and a group of 5,735 critically ill patients was retrospectively studied.

By case-matching analysis, patients with a PAC had an increased 30-day mortality (odds ratio, 1.24), higher mean cost of treatment ($49,300 vs. $35,700, a $13,600 difference), higher length of stay in the ICU (14.8 days vs. 13.0 days, a 1.8 day difference).

Impedance Cardiography (ICG) is a method for measuring cardiac performance, which is noninvasive, continuous, has minimal technical requirements and no patient risk. Cardiac output measurements were compared from a ICG monitor with those from thermodilution via a pulmonary artery catheter (PAC).

- Cost analysis demonstrated that the use of ICG for the initial cardiac assessment was approximately $600 less than the use of thermodilution via a PAC. However, the significant potential associated costs of invasive monitoring through additional days in the ICU and complications as a result of invasive monitoring were not considered in the cost analysis.
- The mean difference between the two cardiac output measurements was small (0.23, +/- 0.56) and was not affected by the magnitude of the cardiac output readings.
- There was a strong correlation between cardiac output via thermodilution and cardiac output via ICG (r=0.91).

The researchers concluded, "There is no patient risk associated with ICG, while thermodilution is associated with cardiac arrhythmia, pneumothorax, and infection, all of which may affect cost, morbidity, and mortality. ICG is easier to use than thermodilution. The ICG device takes only minutes to apply and requires one technician. Frequent thermodilution monitoring is time consuming, labor intensive for nurses, and provides only a snapshot perspective of dynamic cardiovascular changes. The data profile from ICG is continuous, allowing earlier intervention. ICG may become a valuable alternative for hemodynamic monitoring in critically ill and injured patients because it offers potential opportunities consistent with our contemporary cost conscious and noninvasive

approach to sick patients. ICG provides dynamic, accurate data at lower costs without the associated morbidity of thermodilution."

Authors: Hayes, D., Hayes, S. and Hyberger, L.
Title: "Atrioventricular Interval Optimization Technique: Impedance Measurements vs. Echo/Doppler," Presented at the North American Society for Pacing and Electrophysiology 19th Annual Scientific Session, May 9, 1998.

Optimization of the atrioventricular interval (AVI) may be critical for some patients with dual-chamber pacemakers and left ventricular dysfunction. The most widely used technique for AVI optimization, Echo/Doppler, is operator dependent, requires multiple carefully obtained measurements, and may be time consuming and costly.
In this study, 14 patients with dual chamber pacemakers were monitored simultaneous with Impedance Cardiography (ICG) as Echo/Doppler measurements were obtained. Twelve patients were tested at three AV intervals, two patients with limited programmability were tested at two AV intervals.
Results:

- When optimal AV interval by Echo/Doppler criteria was compared to optimal AV interval by highest cardiac output by bioimpedance, there was exact correlation in 10 out of 14 patients.
- In two patients, there was no clear difference at any AV interval as measured by the two methods. In the remaining two patients, although the optimal AV interval as measured by the two methods did not correlate exactly, the difference was very slight.
- Average time to assess three AV intervals by Echo/Doppler was 25 minutes vs. 15 minutes by impedance technique.

The researchers concluded, "This study demonstrates feasibility and greater ease of this new impedance technique to determine Cardiac Output (CO) with excellent correlation to Echo/Doppler values. Impedance derived CO values may be adequate for AVI optimization more efficiently and potentially at a lower cost."

Authors: Weinhold, C., Reichenspurner, H., Fulle, P., Nollert, G., and Reichart, B.
Title: "Registration of Impedance Cardiography for Early Diagnosis of Rejection After Heart Transplantation," The Journal of Heart and Lung Transplantation. Sept/Oct. 1993: pp. 12:832-6.

In this study, Impedance Cardiography (ICG) was used for early detection of acute rejection after heart transplantation. Thirty-five heart transplant recipients were monitored during the immediate postoperative period, and during the outpatient follow-up. At the same time, endomyocardial biopsy specimens were taken. In addition to

cardiac stroke volume index and ejection fraction, acceleration index was obtained. Acceleration index describes the acceleration of blood volume and represents a function parameter of myocardial inotropy.

Results:

- Seventeen acute rejection episodes were diagnosed during the follow-up period. The average acceleration index value during the 17 episodes was 92.5 sec. -2, +/- 11.7, significantly lower when compared with the nonrejection levels ($p < 0.05$).
- The acceleration index values decreased during acute rejections by an average of 36.4 sec. -2, +/- 19.3. The sensitivity of this diagnostic parameter in the examined patients was 71% and the specificity was 100%.

The researchers concluded that, "Thoracic Electrical Bioimpedance and calculation of the acceleration index represents a quick, and noninvasive monitoring technique and can ideally be used in the outpatient clinic as a supplement of invasive endomyocardial biopsies."

Authors: Alsabrook, G., Lazio, L. and Lasater, M.
Title: "Non-Invasive Assessment of Hemodynamic Characteristics in a Sustained Narrow-Complex Tachycardia Episode," American Journal of Critical Care, Oct. 2, 1998.

This case study describes a patient with a history of ischemic cardiomyopathy who was being simultaneously monitored, non-invasively, via Impedance Cardiography (ICG) during a right heart catheterization procedure. During the procedure, the patient experienced sustained narrow complex tachycardia. During this episode, hemodynamic parameters were continuously monitored via ICG, allowing the clinician to assess the therapeutic effects of intravenous adenosine and lidocaine doses. The patient returned to a stable hemodynamic state solely with medication.

Authors : Paul Pianosi, MD, and Daniel Garros, MD
Title : Comparison of Impedance Cardiography With Indirect Fick (CO_2) Method of Measuring Cardiac Output in Healthy Children During Exercise

Electric bioimpedance has been used to measure cardiac output for decades. Improvements in modeling and microprocessor technology have spawned newer generations of such devices. This method would be especially useful in children, in whom the use of invasive methods is limited. We tested a device (ICG-M401, ASK Ltd.) in 30 healthy children at 2 levels of exercise (0.5 and 1.5 W/kg), and compared

impedance measurements of cardiac output (Qicg) with carbon dioxide (CO2) rebreathing measurements of cardiac output (Qrb). The Qicg-oxygen uptake (VO2) relation was expressed by Qicg= 3.8 + 4.6 VO2; r2= 0.68. Mean +/- SD bias (Qicg-Qrb) was 0.14+/- 1.05 L/min, not significantly different from zero (95% confidence interval -0.12 to +0.44 L/min). All Qicg results were within +/- 15% of the hypothetical mean value (Bland and Altman analysis). The largest deviation of Qicg from Qrb was +30%, found in 1 of 57 paired determinations. Eighty percent of Qicg values were within +/- 20% of the Qrb result. We conclude that impedance cardiography with the ICG-M401 provided realistic and reliable estimates of cardiac output in healthy children during exercise. This, along with its ease of operation and utility at rest and during exercise, make it both useful and attractive for clinic and research purposes. **(Am J Cardiol 1996;77:745-749)**

Authors : Paul T. Pianosi, MD
Title : Impedance Cardiography Accurately Measures Cardiac Output During Exercise in Children With Cystic Fibrosis

Objectives: After validation of impedance cardiography (ICG) in healthy children, this same device was tested in children with cystic fibrosis (CF) to validate its capability of measuring cardiac output (Q) in this population.
Design: Comparative study of ICG vs the indirect Fick (CO2) method.
Setting: Tertiary care children's teaching hospital.
Patients: Twenty-one CF children with mean FEV1 of 77+/-21% predicted.
Measurements: ICG results were compared with CO2 rebreathing (RB) measurements of Q with sampling of capillary blood gases at two levels of exercise (0.5 and 1.5 W/kg). ICG measurements were made each minute, and duplicate RB measurements from 6 to 8 min at each workload. Q was regressed against oxygen uptake and results by each method were compared.
Results: Mean bias (Qrb-Qicg) was -0.09+/-0.94 L/min. The largest deviation of Qicg from Qrb was +33%, and 83% of corresponding Qicg values were within +/- 20% of Qrb results.
Conclusions: This device gives rapid, accurate, noninvasive Q measurements in children with CF.
(CHEST 1997; 111:333-37)

Authors : I Horváth, I Juricskay, B Mezey, Á Vincze, G Mózsik, First Department of Medicine, Medical University of Pécs, Ifjúság u. 13. H-7643 Pécs, Hungary

Title : Effect of the cold pressor test in healthy and hyperacid subjects

Summary: The aim of this study was to estimate the effects of the cold pressor test (CPT) on hemodynamic changes and to analyze the differences in the changes between

normal and hyperacid subjects. Twelve healthy volunteers and 12 hyperacid patients were studied. The different hemodynamic parameters (basic impedance, Zo; heart rate, HR; systolic and diastolic blood pressure, RRs and RRd; ventricular ejection time, VET; stroke volume, SV; cardiac output, CO; rate-pressure-product, RRP) were measured and calculated with the impedance cardiographic method (ICG).The changes of hemodynamic parameters (HR, RRs, RRd, VET, SV, CO, RPP) were well-recorded by this method. The data were analyzed with unpaired t-tests and the multivariate statistical method, pattern recognition by independent multicategory analysis (PRIMA). There were significant differences in changes of Zo, HR ($P < 0.05$), RRs, RRd, SV, CO and VET ($P< 0.01$) and subjects in the normal and hyperacid groups could be well separated by the PRIMA method.