

Novel System for Detection of Cardiac Right to Left Shunts

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Columbia University Medical Center**Background:**

The current "gold standard" for detection and quantification of right-to-left shunts (RLS) is transesophageal echocardiography (TEE). The Flow Detection System (FDS) (Cardiox Corp., Columbus, OH) is a new, minimally invasive, diagnostic test, based on transdermal detection of Indocyanine Green (ICG) dye (Pulsion Medical Systems AG, Munich, Germany). The present study was performed to determine optimum ICG dosing and injection timing protocols, as well as the system's accuracy in the detection of RLS.

Methods:

Various ICG dosages and injection timing protocols were evaluated in eight (8) patients, with known RLS, to determine the optimal dose and injection timing to facilitate detection of RLS with FDS. 20 additional patients underwent testing with power m-mode transcranial Doppler (TCD) and subsequent FDS. Ten (10) patients with large RLS, (Spencer grades IV or V by TCD) were selected to comprise the study group. Ten (10) additional patients with Spencer grades 0 or I shunt by TCD were selected to comprise a control group. All patients were evaluated just prior to a scheduled catheterization, with both TCD and FDS using the dosing and timing parameters developed in the initial cohort of eight patients. In the study group, results were also compared with RLS assessment by intra-cardiac echocardiography (ICE - Johnson & Johnson, NJ) performed during the catheterization.

Results:

All ten study subjects with TCD-proven RLS exhibited a Shunt Conductance Index (SCI) > 0, reflecting the presence of a RLS (sensitivity = 100%). FDS was also in agreement with ICE results in all ten. Nine (9) of ten (10) patients with TCD-negative RLS, had SCI = 0.

Conclusions:

The Cardiox FDS, with the established dosage of ICG dye and timing protocols, provided consistent detection of significant RLS (Spencer Grades IV or V), with a good negative predictive value.

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