

Novel System for Detection of Right-to-Left Shunts

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Introduction

The current gold standard for detection of right-to-left shunts (RLS) is transesophageal echocardiography (TEE). The Flow Detection System (FDS) (Cardiox Corporation, Columbus, Ohio) is a new, minimally invasive diagnostic test, based on transdermal detection of indocyanine green (ICG) dye (Pulsion Medical Systems, Munich, Germany) (Figures 1-3). The current study was conducted to determine the optimum dosing and injection timing protocols as well as the system's accuracy in the detection of RLS.

Methods

Various ICG doses and injection timing protocols were evaluated in eight patients with known RLS to determine the optimal dose and injection timing. An additional 20 patients had testing with power M-mode transcranial Doppler (TCD) and FDS. Ten patients with large RLS (Spencer grades IV or V by TCD) were selected for the study group; 10 additional patients with Spencer grades 0 or I by TCD were selected for the control group. All patients were evaluated 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, New Brunswick, New Jersey) performed during the catheterization.

Results

All 10 study patients with TCD-proven RLS exhibited a Shunt Conductance Index (SCI) > 0, reflecting the presence of a RLS (Table 1). Sensitivity: 100%. FDS was also in agreement with ICE results in all 10 patients (Table 2). Nine of 10 patients with TCD-negative RLS had SCI = 0. False Positive vs. TCD = 1.

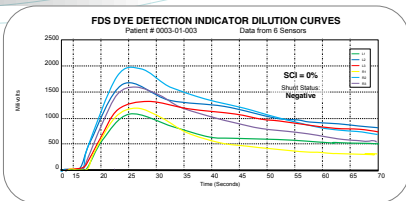


Figure 1

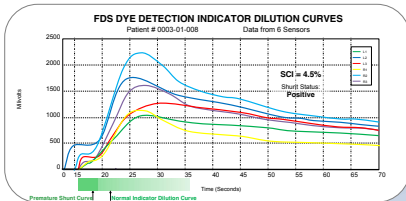


Figure 2

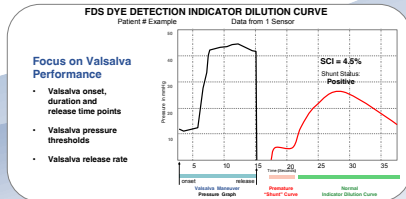



Figure 3

Conclusion

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 good negative predictive value.

| FDS Pilot Study | FDS vs TCD | FDS vs ICE |
|---------------------------|------------|------------|
| n = | 20 | 10 |
| Sensitivity / PPA | 100% | 100% |
| Specificity / NPA | 90% | 100% |
| Positive Predictive Value | 90% | 100% |
| Negative Predictive Value | 100% | 100% |
| Accuracy | 95% | 100% |
| True Positives | 10 | 10 |
| False Positives | 1 | 0 |
| True Negatives | 9 | 0 |
| False Negatives | 0 | 0 |

Disclosure – 

Employment: David Dobson, Andrew Eggers
Stock ownership: David Dobson, Andrew Eggers, Eric Eggers
Family employment: Andrew Eggers, Eric Eggers
Consultant: Robert Sommer, Eric Eggers