Reviewer’s report

Title: Decrease in shunt volume in patients with cryptogenic stroke and patent foramen ovale

Version: 2 Date: 29 October 2010

Reviewer: Jill Jesurum

Reviewer’s report:

Major Compulsory Revisions

Background

1. "PFO is permanent" - Clarify meaning. Spontaneous and at rest vs life-long trajectory, chronic. I think you mean physiologic trajectory of PFO throughout life-time.

2. State the hypothesis.

3. Change "study was designed to" to "purpose of the study was..." - determine changes in RLS volume overtime or longitudinally.

Patients and Methods

1. Change to Methods (delete "Patient")

2. Clarify single-center?

3. Clarify non probabability sampling technique.

4. Consecutive enrollment?

5. Throughout manuscript when frequencies are stated need to insert (%) following frequency.

6. Clarify statistical and clinically important change in RLS volume between T0 and T1 and state rationale.

STUDY DESIGN

1. Clarify single group, observational design

2. State rationale for why >= 20 MES was used as operational definition for change in shunt volume?

3. Include section "Setting"

ce-TCD
1. Clarify "consensus read" and operational definition of "evaluations graded differently"?

2. Add section secondary title "Instrumentation" and ceTCD and TEE should go under this section.

STATISTICAL EVALUATION
1. Need to perform post-hoc power analysis
2. Descriptive data should be presented as mean, SD, range and/or 95% CI.
3. State level of significance, 2 tail or 1 tail.
4. Statistical software program used?
5. How were assumptions evaluated? Especially for logistic regression?
6. Were adjustments made for multiple comparisons to avoid Type II error? Bonferroni?

RESULTS
1. Add section "Sample" - include demographics, age, gender, diagnosis.
2. Needs significant reformatting, restructuring, editing and use of secondary titles to improve readability.
3. Add section "Initial RLS Measurements" - divide into TEE and TCD sections. Add details on septal morphology characteristics in TEE section.
4. Need to be consistent throughout manuscript with descriptive data reported. Instead of median, use mean, standard deviation, range, and 95% CI.
5. During follow up, 5 patients had a "recurrent event" - clarify what this means, use diagnosis. Define "recurrence"?
6. Again, frequencies are used but need to include (%) after all references to frequency.
7. Clarify "time delay" - what is the unit of measurement weeks, months from index event???? operational definition.
8. Clarify that with only 5 patients having "recurrent events" - inferences can not be made because of lack of power. Calculate power and report.
9. 12 patients had a small increase in RLS. Report mean, SD, range of MES of these 12 patients.

DISCUSSION
1. Temper statements using "true and accurate" words. Does this study have adequate power to state this degree of evidence. Post hoc power has not been included but should be.

2. Define "time delay" in units of measurement.

3. Change "sustain" to "support".

4. For future research, describe what you recommends from a methodological standpoint.

5. Temper "remarkable result" to "intriguing".

TABLE 2 and 3.

1. Include N in title.

TABLE 4.

1. Report post hoc power of cryptogenic stroke patients and RLS volume change.

2. Define unit of measurement (days, weeks, months) between T0 and T1. Report mean, SD, range, 95% CI. (for Table 5 as well).

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.