SUMMARY

In-Office Balloon Sinus Dilation versus Medical Therapy for Recurrent Acute Rhinosinusitis: A Randomized, Placebo-Controlled Study[1]

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ABSTRACT

BACKGROUND & OBJECTIVE:

A limited number of studies have demonstrated symptomatic improvement for recurrent acute rhinosinusitis (RARS) patients following endoscopic sinus surgery. This randomized, controlled study evaluated 24-week outcomes of balloon sinus dilation (BSD) performed in-office (IO) plus medical management (MM) versus MM only for RARS patients.

METHODS:

Adults diagnosed with RARS were randomized to BSD plus MM (n=29) or MM alone (n=30). Patients who received MM alone also received a sham BSD-IO (non-dilation) procedure to blind patients to group assignment. Patients were followed to 48 weeks post-treatment. The primary outcome was the difference between arms in change in Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks. Secondary endpoints included comparisons of Rhinosinusitis Disability Index (RSDI) score, medication usage, medical care visits, and sinus infections.

RESULTS:

Change in patient-reported quality of life (QOL) as measured by the CSS total score from baseline to 24 weeks was significantly greater in the BSD plus MM group compared to the MM group [37.3±24.4 (n=26) vs. 21.8±29.0 (n=27); p=0.0424]. These results were sustained through 48 weeks of follow-up.

CONCLUSIONS:

Results indicate BSD plus MM is superior to MM alone in enhancing QOL for RARS patients. BSD plus MM should be considered a viable treatment option for properly diagnosed RARS patients.

INTRODUCTION

- Improved quality of life (QOL)/ productivity, reduced medication usage and number of sinus infections have been demonstrated in RARS patients following ESS up to 19 months post-operatively (CRS)[2-4].
- While a growing body of evidence suggests that sinus surgery can be an effective treatment option for RARS patients, the literature lacks prospective controlled studies with design features to minimize bias such as randomization or blinding.
- The present study aimed to compare health outcomes and health care utilization resulting from sinus surgery limited to BSD conducted in-office (IO) plus medical management (MM) versus MM alone for patients with RARS via a patient-blinded, randomized controlled trial.
- This study was designed to provide high quality evidence intended to aid patient and physician evaluation of treatment options for RARS.

METHODS

- This is a prospective, randomized, placebo-controlled study evaluating the effect of BSD plus MM (n=29) compared to MM alone (n=30) on health care outcome and healthcare utilization in patients with RARS.
- Randomization was conducted in block assignments by investigational sites.
- All procedures were conducted using trans-nasal wire-based BSD instruments (Acclarent, Inc., Irvine, CA).
- In order to blind patients to treatment arm assignment, those randomized to MM underwent a sham, IO, non-dilation balloon procedure. A sham procedure was conducted for MM patients in a manner such that no anatomic structures were mobilized and no dilation was performed.

- The primary effectiveness endpoint was comparison of change in patient-reported QOL as measured by total Chronic Sinusitis Survey (CSS) score from baseline to 24 weeks.
- Secondary endpoints included comparisons Rhinosinusitis Disability Index (RSDI) score, medication usage, medical care visits, and sinus infections up to 48 weeks.
- For subjects randomized to the MM arm, open-label cross over to receive a true BSD procedure was allowed after 24 weeks.

RESULTS

- BSD+MM, compared to MM only, resulted in significantly greater improvements in quality of life (QOL) from baseline to 24-week follow-up:
  - Chronic Sinusitis Survey (CSS) total- BSD+MM 37.3±24.4 vs. MM 21.8±29.0; **p=0.0424**]
    - CSS Sinusitis Subscore- BSD+MM 48.7±28.7 vs. MM 27.2±40.1; **p=0.0484**]
  - Rhinosinusitis Disability Index (RSDI) total- BSD+MM -35.6±28.2 vs. MM -18.7±27.4; **p=0.0089**
    - Physical- BSD+MM -15.4±10.8 vs. MM -9.1±12.1; **p=0.0174**
    - Functional- BSD+MM -10.4±9.6 vs. MM -5.7±7.9; **p=0.0363**
    - Emotional- BSD+MM -9.8±9.2 vs. MM -3.9±9.1; **p=0.0037**
- Other outcomes at 24-week follow-up:
  - BSD+MM group had lower mean number of sinus infections through 24-week follow-up: 0.2±0.4 vs. 0.9±0.9; p=0.0015]
  - BSD+MM group demonstrated less severe sinus symptoms: (p=0.0040)
  - BSD+MM group experienced less severe sinus infections: (p=0.0266)
  - BSD+MM made fewer unscheduled medical care visits due to sinusitis: 0.2±0.8 vs. 0.9±1.3; p=0.0035
- The crossover nature of this study limited the ability to perform meaningful comparisons between groups after 24-week follow-up; nonetheless, BSD+MM, compared to MM only, resulted in significantly greater improvements in RSDI from baseline to 48-week follow-up:
  - RSDI total: BSD+MM -36.9±21.1 vs. MM -17.2±14.9; **p=0.0409**
    - Physical- BSD+MM -15.1±9.3 vs. MM -8.5±6.3; **p=0.0823**
    - Functional- BSD+MM -11.4±7.1 vs. MM -5.0±4.9; **p=0.0285**
    - Emotional- BSD+MM -10.4±7.3 vs. MM -3.7±5.6; **p=0.0379**
- Change from baseline to 48-week follow-up in medications usage was significantly lower in the BSD+MM group-
  - Oral antibiotic usage- BSD+MM 0.5±2.1 vs. MM 2.0±3.1; **p=0.0344**
- As crossover was allowed after 24-week follow-up, 21/30 subjects crossed over from the MM to the BSD group (18 at 24-week, 1 at 28-week, 1 at 45-week, and 2 after 48-week).
- Study enrollment was stopped early due to superiority of BSD+MM over MM.
- There were no device- or sinus medication-related adverse events. Three procedure-related or possibly procedure-related adverse events (of which one was considered serious) occurred in the BSD plus MM arm. These were headache, vasovagal response, and eustachian tube dysfunction. The latter two events were considered possibly procedure-related non-serious AE.

CONCLUSION

- RARS patients who have undergone a BSD-IO procedure plus MM demonstrate significantly greater improvement in symptoms, reduced sinus infection frequency and health care utilization compared to patients receiving MM alone, indicating that BSD-IO plus MM is an effective treatment option for RARS patients and these results are sustained through 48-week follow-up.

REFERENCES

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