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**Is Radiofrequency Energy a Safe and Effective Treatment for
Reducing Symptoms of Gastroesophageal Reflux Disease in Patients
18 Years or Older?**

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective evidence based medicine review is to determine whether or not “Is radiofrequency energy a safe and effective treatment for reducing symptoms of gastroesophageal reflux disease in patients 18 years or older?”

STUDY DESIGN: Review of two double-blind, randomized control trials and one double-blind, randomized cross-over study published between 2003 and 2012. All studies were published in the English language in peer reviewed journals.

DATE SOURCES: Two randomized control trials and one randomized cross-over study were found using PubMed.

OUTCOMES MEASURED: The outcomes measured include changes in GERD symptom scores for fourteen symptoms, improvement of GERD symptoms based on a GERD HRQL questionnaire, decrease in heartburn based on a 6 point Likert scale, and GERD health related quality of life based on a 6 point Likert scale.

RESULTS: Arts et al (2012) demonstrated a significant reduction in GERD symptom scores after treatment with radiofrequency energy with a p value of < 0.005 . Aziz et al (2010) demonstrated a significant reduction in GERD symptoms after treatment with radiofrequency energy with a p value of < 0.05 . Corley et al (2003) demonstrated a significant decrease in both heartburn and GERD health related quality of life after treatment with radiofrequency energy with a p value of 0.05 and 0.03, respectively. A noted side effect in two of the studies include chest pain.

CONCLUSIONS: Results of the three studies demonstrate that radiofrequency energy is an effective treatment for reducing the symptoms of gastroesophageal reflux disease. Two studies assessing chest pain following radiofrequency energy demonstrated that the safety of radiofrequency energy is inconclusive and requires further investigation.

KEY WORDS: gastroesophageal reflux disease, GERD, radiofrequency energy, Stretta

INTRODUCTION

Gastroesophageal reflux disease, commonly known as GERD, is a chronic condition that occurs when the lower esophageal sphincter inappropriately relaxes or is weakened. This defect allows stomach contents and acid to flow back into the esophagus.⁷ The irritation from the acid and stomach contents on the esophageal lining is what causes the symptoms of GERD, which can greatly impact a person's quality of life. GERD is a common condition. It is estimated that GERD affects 15% to 20% of adults in the United States.⁴ There are approximately 8.9 million ambulatory healthcare visits and 4.7 million hospitalizations due to GERD with an annual health care cost of 9.8 million dollars.^{3,5}

The relaxation or weakening of the lower esophageal sphincter can be caused by numerous things such as increased abdominal pressure (obesity, pregnancy), medications (calcium channel blockers, antihistamines, sedatives, antidepressants, asthma medications), smoking, and hiatal hernias.³ The most common symptoms of GERD include substernal heartburn and regurgitation. Other symptoms include chest pain, nausea, vomiting, abdominal pain, dysphagia, dental erosions, and a chronic cough.^{4,7} There are numerous complications of GERD including esophagitis, esophageal strictures, respiratory problems, and Barrett's metaplasia.⁷ Barrett's metaplasia can progress to esophageal adenocarcinoma, which occurs at a yearly development rate of 0.1% to 0.3% per year.⁴

GERD is treated with both lifestyle modifications and medications. Lifestyle modifications include avoiding foods and beverages that exacerbate heartburn and further weaken the lower esophageal sphincter (fried and fatty food, chocolate, peppermint, alcohol, coffee, vinegar, tomato sauce, citrus, etc.), avoiding aspirin and NSAIDs, eating smaller portions, not eating before bedtime, raising the head of the bed, losing weight, and smoking cessation.⁶

Medications include antacids, H₂ receptor antagonists, and proton pump inhibitors. Antacids and H₂ receptor antagonists are used for mild symptoms of GERD. Proton pump inhibitors are the treatment of choice for moderate to severe symptoms of GERD.^{4,6} Unfortunately, patients with GERD may not have a sufficient response to high dose PPI medications.¹ These medications can cause unbearable side effects and are also expensive, ranging anywhere between \$2,000 to \$3,000 per year.^{3,9} Using radiofrequency energy, which is called the Stretta procedure, is an alternative treatment option for patients with symptoms of GERD. It is conducted via a minimally invasive procedure with an endoscope that applies controlled radiofrequency energy to the lower esophageal sphincter.^{1,2,3} It promotes symptom relief and decreases the need of PPI medication in patients with GERD by improving the antireflux barrier and augmenting the lower esophageal pressure.^{1,2}

OBJECTIVE

The objective of this selective evidence based medicine review is to determine whether or not “Is radiofrequency energy is a safe and effective treatment for reducing symptoms of gastroesophageal reflux disease in patients 18 years or older?”

METHODS

Criteria: This selective evidence based medicine review evaluates two double-blind, randomized control trials and one double-blind, cross-over study chosen based on population, intervention, comparison group, and outcomes measured. The selected population of interest was patients 18 years or older with a diagnosis of GERD. The intervention in these three studies was radiofrequency energy delivered to the lower esophageal sphincter and gastroesophageal junction. The treatment group receiving radiofrequency energy was compared to a group receiving a sham procedure. The outcomes measured in these three studies included a decrease in

heartburn, improvement or changes in GERD symptoms after radiofrequency energy, and the effect on GERD health related quality of life.

Data Sources: The key words “gastroesophageal reflux disease,” “GERD,” “radiofrequency energy,” and “Stretta” were searched on PubMed to find articles both relevant to the clinical question and ones that included patient oriented outcomes. All articles were published in the English language between 2003 and 2012 in peer reviewed journals. The inclusion criteria included double-blind studies published after 2000 and exclusion criteria included patients under 18 years old. The statistics used and reported in this selective evidence based medicine review include p-values, numbers needed to harm (NNH), numbers needed to treat (NNT), change in mean from baseline, and confidence intervals.

Table 1 – Demographics & Characteristics of Included Studies

| Study | Type | # Pts | Age (years) | Inclusion criteria | Exclusion criteria | W/D | Interventions |
|----------------|---|-------|--|--|---|-----------|---|
| Arts, 2012 (1) | Double-blind, randomized cross-over study | 22 | 47 ± 12 | Long standing history of GERD, typical GERD symptoms, response to high dose PPI, pathological esophageal pH monitoring | < 18 y/o, hiatal hernia, Barrett’s, erosive esophagitis, absent peristaltic contractions on manometry, coagulation disorders | Not noted | Radiofrequency energy delivered through four needle electrodes to the region of the LES |
| Aziz, 2010 (2) | Double-blind, randomized control trial | 36 | Sham: 32.0 ± 8.3 (22 to 48) Tx: 36.7 ± 9.5 (24 to 50) | > 18 y/o, heartburn or regurgitation > 6 months, GERD HRQL score >18 when medication stopped, HRQL score of ≤ 10 on | Hiatal hernia, pregnancy, poor surgical candidate, esophagitis, Barrett’s metaplasia or dysplasia, collagen vascular disease, | Not noted | Single session Stretta procedure (radiofrequency energy) |

| | | | | | | | |
|------------------|--|----|------------------------------|---|--|---|---|
| | | | | medication, normal LES relaxation, abnormal acid exposure, no esophagitis | autoimmune disease, severe dysphagia, previous esophageal or gastric surgery | | |
| Corley, 2003 (3) | Double-blind, randomized control trial | 64 | Sham: 52 ± 15 Tx: 45 ± 12 | Heartburn or regurgitation, responsive to daily medication, >18 y/o, abnormal esophageal acid, normal esophageal peristalsis, normal sphincter relaxation | Hiatal hernia, erosive esophagitis, Barrett's, extraesophageal manifestations of GERD, coagulation disorders, mechanical prostheses, prominent dysphagia, unstable disorders | 8 | Radiofrequency energy delivery to the GEJ |

OUTCOMES MEASURED

All of the outcomes measured in this selective evidence medicine based review include patient oriented evidence. These outcomes include change in GERD symptom scores, improvement of GERD symptoms, improvement in the symptom of heartburn, and effect on GERD health related quality of life. The Arts et al double-blind, randomized cross-over trial measures changes in GERD symptom scores prior to and three months after the radiofrequency energy treatment. Fourteen typical and atypical symptoms (heartburn, food regurgitation, acid regurgitation, nausea, vomiting, chest pain, dysphagia, odynophagia, coughing, choking, dyspnea, wheezing, hoarseness, and throat ache) were scored by the patient on a scale from zero to three. Rating the symptom a three indicated that it interfered with daily activities and rating it a zero meant the symptom was not present. All of the symptom scores were added together for a

maximum cumulative score of 24. The data was reported as a mean change in baseline with a standard deviation.¹

The Aziz et al double-blind, randomized control trial measured improvement of GERD symptoms. This was assessed based on a GERD health related quality of life (HRQL) questionnaire. The baseline GERD HRQL scores were compared with scores both 6 and 12 months after radiofrequency energy treatment. The data was reported as a mean change in baseline with a standard deviation.²

The Corley et al double-blind, randomized control trial measured a decrease in the symptom of heartburn and GERD health related quality of life for multiple different symptoms. Both were measured based via a six point Likert scale ranging from no symptoms to incapacitating symptoms. The data was reported as both a mean change in baseline with standard deviation and dichotomous data.³

RESULTS

This selective evidence based medicine review evaluates radiofrequency energy as a treatment for GERD. The results of these studies were presented in both continuous and dichotomous data: Arts et al presented continuous data, Aziz et al presented continuous and dichotomous data, and Corley et al presented continuous and dichotomous data. All three studies were randomized with concealment to randomization. All of the patients, clinicians, and study workers were kept blind to which patients were in the treatment group for the duration of the study.

Arts et al is a double-blind, randomized cross-over study that assesses the efficacy of radiofrequency energy applied to the region of the gastroesophageal junction and lower esophageal sphincter in adults who are 18 years or older with a long-standing history of GERD.

The treatment group was compared to a sham procedure. This study involved twenty-two patients divided evenly into two groups of eleven participants. One group was placed in the radiofrequency energy group initially and the other group placed in the sham procedure first. To qualify as a cross-over study, the participants received the opposite procedure three months after the initial procedure. Symptom scores of the participants were evaluated both before and 3 months after the initial procedure for improvement. The symptom scores were obtained via patient reports for fourteen typical and atypical symptoms (all scored on a scale from 0 to 3 for a maximum score of 24) and continuous data was reported as mean change from baseline. The mean change from baseline for the radiofrequency energy treatment group was 14.7 +/- 1.5 before the procedure to 8.3 +/- 1.9 at three month follow up. The mean change from baseline for the sham procedure group was 16.1 +/- 2.5 before procedure to 15.6 +/- 2.2 at three month follow up. At the conclusion of the study, it was determined there was a significant decrease in symptom scores of GERD with a statistically significant p-value of < 0.005.¹

Table 2 – GERD Symptom Scores at Baseline and 3 Month Follow Up

| | Baseline | 3 Month Follow Up |
|---------------------------------|--------------|-------------------|
| Radiofrequency Energy Procedure | 14.7 +/- 1.5 | 8.3 +/- 1.9 |
| Sham Procedure | 16.1 +/- 2.5 | 15.6 +/- 2.2 |

Aziz et al is a double-blind, randomized control trial that assesses the efficacy and safety of radiofrequency energy to the gastroesophageal junction in adults who are 18 years or older. The treatment group was compared to a sham procedure. Thirty-six participants were placed into one of three groups: twelve patients in a single radiofrequency energy procedure group, twelve patients in a sham procedure group, and twelve patients in a two-series radiofrequency energy group. For the purpose of this selective evidence based medicine review, the single radiofrequency energy and the sham groups will be focused on. The study measured

improvement of GERD symptoms based on a GERD related health quality of life questionnaire at 6 and 12 months after the procedure. Only the twelve month follow up results were presented as mean change from baseline. The mean change in baseline for the single radiofrequency energy treatment group was 29.6 +/- 3.9 before treatment to 14.7 +/- 4.8 at twelve month follow up. The mean change from baseline for the sham group was 30.3 +/- 3.8 before the procedure to 24.8 +/- 4.9 at twelve month follow up. At the conclusion of the study, it was determined there was a significant decrease in GERD symptoms with a statistically significant with a p-value of < 0.05.²

Table 3 – Improvement of GERD Symptoms at Baseline and 12 Month Follow Up

| | Baseline | 12 Month Follow Up |
|--|--------------|--------------------|
| Single Radiofrequency Energy Procedure | 29.6 +/- 3.9 | 14.7 +/- 4.8 |
| Sham Procedure | 30.3 +/- 3.8 | 24.8 +/- 4.9 |

Corley et al is a double-blind, randomized control trial that assesses efficacy and safety of radiofrequency energy to the gastroesophageal junction in adults who are 18 years or older. The treatment group was compared to a sham procedure. Sixty-four patients with GERD were randomly assigned to a radiofrequency energy group (35 patients) or a sham group (29 patients). The study measured a decrease in the symptom of heartburn based on a 6 point Likert scale ranging from no symptoms to incapacitating symptoms. The decrease in the symptom of heartburn was reported as both continuous and dichotomous data at 6 month follow up. The mean change in baseline for patients in the radiofrequency energy group was -1.6 (95% confidence interval of -1.1 to -2.2) compared to a mean change in baseline of -0.6 (95% confidence interval of 0.1 to -1.2, p = 0.01) in the sham procedure group. At six month follow up, 61% of patients in the radiofrequency energy group and 33% of patients in the sham procedure group were without heartburn symptoms. This was determined to be statistically significant with a p-value value of 0.05.³ The RBI was determined to be 85% and the ABI was

determined to be 28%. Numbers needed to treat was determined to be 4. Table 4 displays the effectiveness of radiofrequency energy in decreasing the symptom of heartburn for this study.

Table 4 – Effectiveness of Radiofrequency Energy at Reducing Symptom of Heartburn

| | Sham Procedure (CER) | Radiofrequency Energy Procedure (EER) | Relative Benefit Increase (RBI) | Absolute Benefit Increase (ABI) | Number Needed to Treat (NNT) |
|---------------|----------------------|---------------------------------------|---------------------------------|---------------------------------|------------------------------|
| Corley (2003) | .33 | .61 | .61-.33=.28 | .61-.33=.28 | 1/.28=3.57 = 4 |

Corley et al also evaluated improvement of GERD health related quality of life scores for multiple symptoms based off of a 6 point Likert scale ranging from no symptoms to incapacitating. The improvement of GERD health related quality of life was reported as both dichotomous and continuous data at 6 month follow up. The mean change in baseline for patients in the radiofrequency energy group was -13 (95% confidence interval of -9 to -17) compared to a mean change in baseline of -3 (95% confidence interval of -8 to 2, $p = 0.003$) in the sham procedure group. At six month follow up, 61% of patients in the radiofrequency energy group and 30% of patients in the sham procedure group had more than a 50% improvement in their GERD health related quality of life score. This was determined to be statistically significant with a p-value of 0.03.³ The RBI was determined to be over 100% and the ABI was determined to be 31%. Numbers needed to treat was determined to be 4. Table 5 displays the effectiveness of radiofrequency energy in improving GERD health related quality of life scores.

Table 5 – Effectiveness of Radiofrequency Energy on GERD Health Related Quality of Life

| | Sham Procedure (CER) | Radiofrequency Energy Procedure (EER) | Relative Benefit Increase (RBI) | Absolute Benefit Increase (ABI) | Number Needed to Treat (NNT) |
|---------------|----------------------|---------------------------------------|---------------------------------|---------------------------------|------------------------------|
| Corley (2003) | .30 | .61 | .61-.30=.31 | .61-.30=.31 | 1/.31=3.22 = 4 |

For this selective evidence based medicine review, the common side effect of chest pain was evaluated. Aziz et al and Corley et al evaluated chest pain after treatment with single radiofrequency energy or sham procedure. Aziz et al determined that 58% of patients had chest pain following radiofrequency energy procedure and 16.6% of patients had chest pain following sham procedure.² Corley et al determined that 11% of patients had chest pain following radiofrequency energy procedure and 0% of patients had chest pain following sham procedure.³ Table 6 indicates the number of patients who had chest pain after receiving treatment with either the radiofrequency energy or the sham procedure.

Table 6 – Safety of Radiofrequency Energy from Selected Studies: NNH

| Study | Patients with Chest Pain following Sham Procedure (CER) | Patients with Chest Pain following Radiofrequency Energy Procedure (EER) | Relative Risk Increase (RRI) | Absolute Risk Increase (ARI) | Numbers Needed to Harm (NNH) |
|---------------|---|--|------------------------------|------------------------------|------------------------------|
| Aziz (2010) | .166 | .58 | $.58-.166/.58 = .71$ | $.58-.166 = .41$ | $1/.41 = 2.43 = 3$ |
| Corley (2003) | 0 | .11 | $.11-0/.11 = 1$ | $.11 - 0 = .11$ | $1/.11 = 9.09 = 10$ |

DISCUSSION

The radiofrequency energy procedure that is offered in the United States is called the Stretta system. This system was approved by the Food and Drug Administration in 2000.⁹ According to Vanderbilt University Medical Center, this endoscopic procedure may cost anywhere from \$7,500 to \$10,000.⁹ Unfortunately, there is no frank answer as to whether insurance will cover the Stretta procedure. However, Aetna determined that the Stretta procedure was experimental and investigational based on a review of the current clinical information. Aetna also states that the patient's medical claim determines whether or not a particular medical procedure is covered.¹⁰

The Stretta System is specifically used to coagulate tissue in the region of the lower esophageal sphincter and gastroesophageal junction for the treatment of gastroesophageal reflux disease.⁸ Contraindications to the Stretta System include patients younger than 18 years old, pregnancy, patients that do not have GERD, patients with a hiatal hernia larger than 2 centimeters, patients with achalasia, patients who have incomplete lower esophageal sphincter relaxation after swallowing, and patients who are poor surgical candidates.⁸ The Stretta System has not been studied in patients who have an implant that might be conductive with the radiofrequency energy near the lower esophageal sphincter, patients with a normal twenty-four hour pH study, patients with GERD symptoms that are unresponsive to proper anti-secretory medication, Barrett's metaplasia, active esophagitis that is grade three or four by Savary-Miller criteria, patients who have risk factors for endocarditis, patients with esophageal bleeding or dysphagia, patients who have untreated or unstable hypertension, diabetes mellitus, heart disease, or collagen vascular disease, patients on steroids, patients who are immunosuppressed, patients with a cardiac pacemaker, and patients who have coagulation abnormalities or are on anticoagulation therapy.⁸ There are complications that may occur with radiofrequency energy when treating GERD including bleeding, bloating, chest pain, difficulty belching, dysphagia, epigastric pain, laceration of the esophageal mucosa, fever, perforation, pharyngitis, vomiting, achalasia, prolonged gastric emptying, dental injury, dyspnea, infection, injury to the larynx, and worsening of GERD.⁸

All three studies included in this selective evidence based medicine review demonstrated limitations. Sample size was the main limitation. Arts et al had a sample size of twenty-two, Aziz et al had a sample size of thirty-six, and Corley et al had a sample size of sixty-four.^{1,2,3} Corley et al also had a considerable difference in the number of patients in the treatment group (35

patients) and the number of patients in the sham group (29 patients).³ Another limitation was a moderate dropout rate. For instance, Corley et al began their study with sixty-four patients and ended with fifty-six.³

CONCLUSIONS

All three studies successfully demonstrated that there is a significant decrease in symptoms of gastroesophageal reflux disease following treatment with radiofrequency energy. Therefore, radiofrequency energy is an effective alternative treatment for reducing the symptoms of GERD in patients who are 18 years or older. However, the two studies that assessed chest pain following radiofrequency energy yielded inconclusive results. Due to this inconsistency, further studies are warranted to assess the potential side effect of chest pain following treatment with radiofrequency energy. It is also important to follow these patients for a longer period of time in order to assess whether or not symptoms of GERD will return or if radiofrequency energy could potentially be curative for patients with GERD. Since these three studies compared radiofrequency energy to a sham procedure, it would be important to create a study comparing radiofrequency energy to another treatment modality, such as long term proton pump inhibitors or a surgical anti-reflux procedure, to see which method of treatment would be superior for treating symptoms of GERD.

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