ORIGINAL ARTICLE

Endoscopic day case antireflux radiofrequency (Stretta) therapy improves quality of life and reduce proton pump inhibitor (PPI) dependency in patients with gastro-oesophageal reflux disease: a prospective study from a UK tertiary centre

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ABSTRACT

Background Endoscopic antireflux radiofrequency treatment (Stretta) offers a therapeutic alternative for patients suffering from refractory gastro-oesophageal reflux disease (GORD). Current evidence suggests that the treatment may improve symptoms of GORD and decrease requirement for proton pump inhibitor (PPI) therapy.

Methods Prospective assessment of patients undergoing Stretta, between October 2014 and February 2016, in a UK tertiary referral centre was carried. All patients were assessed for suitability using endoscopy, contrast studies, and pH and manometry studies. The Gastro-oesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL) was used to evaluate symptoms along with PPI dependency, pre-Stretta and post-Stretta treatment. Patients were followed up by outpatient clinic appointment and telephone consultation.

Results Fifty consecutive patients were followed up for a median of 771 days (range 499–1162) following treatment with Stretta. The average GERD-HRQL score improved from 46.2/75 (± 14.2) preprocedure to 15.2/75 (± 17.3) postprocedure. Dissatisfaction with GORD as measured in the GERD-HRQL decreased from 100% to 10% with three patients showing no improvement (non-responders) at follow up and two late failures at the time of this review. There were no complications and all cases were carried out as day cases.

Conclusion There are currently few effective therapeutic alternatives to antireflux surgery for refractory GORD. This series corroborates the value and safety of Stretta as a viable option for selected patients who are unwilling or unable to undergo an operation. Stretta improves quality of life and decreases PPI dependency in selected patients with GORD.

INTRODUCTION

Gastro-oesophageal reflux disease (GORD) is a common disorder with an estimated prevalence of 15% in the European population.¹ The condition is characterised by reflux of gastric contents which can result in a range of symptoms from heartburn and acid regurgitation, to more atypical symptoms of non-cardiac chest pain, chronic cough, chronic asthma, laryngitis or dental erosions.² Treatment options for GORD include lifestyle modification, pharmacological, endoscopic and surgical therapy.³ Laparoscopic fundoplication remains the gold standard operative treatment for GORD.^{4,5} Indications for surgery include GORD which is refractory to medications but has been demonstrated objectively, and those who respond favourably to medical therapy, however, are unwilling, or unable to take long-term proton pump inhibitors (PPIs).^{3,6} The failure rate for

laparoscopic anti-reflux surgery is reported to be between 3%–30% with a reoperation rate of 3%–6%.⁷ The risks of abdominal surgery alongside the potential for developing post fundoplication symptoms such as dysphagia, gas bloat, rectal flatulence and the inability to vomit have led to the emergence of endoscopic therapies for reflux.

The Stretta procedure⁸ offers a therapeutic alternative for patients suffering from GORD. The device uses radiofrequency (RF) energy delivered to several levels around the lower oesophageal sphincter (LES) and gastric cardia. The aim of the treatment is to augment the LES musculature in order to enhance the antireflux barrier function. Current evidence suggests that the treatment may improve symptoms of GORD, improve quality of life and decrease requirement for PPI therapy.^{9–12} The use of Stretta in the UK is regulated by the National Institute for Health and Care Excellence (NICE) and the body recommends further evidence required on the long-term safety and efficacy of the device.¹³ Stretta is however currently recommended by Society of American Gastrointestinal and Endoscopic Surgeons for those patients aged ≥ 18 years with GORD: who have had symptoms of heartburn, regurgitation or both for >6 months duration who have at least partially responded to medication and have refused laparoscopic fundoplication.¹⁴ The primary objective was to assess the quality of life scores and PPI dependency. We report our experience of the first 50 patients undergoing Stretta therapy¹⁵ in a UK-based tertiary referral centre.

METHODS

Analysis of a prospectively maintained database of patients undergoing treatment with Stretta between October 2014 and February 2016, in a UK tertiary referral centre. Inclusion criteria were patients with reflux symptoms, refractory to PPIs or do not wish to remain on PPI, erosive oesophagitis, non-erosive reflux disease (NERD) with pathological acid reflux on pH studies and hiatus hernia <2 cm.

All patients were assessed for suitability using a combination of clinical assessment, endoscopy, contrast studies, and pH and manometry studies. The pH impedance was done in eight patients who were referred from South of England and in the remaining, 24-hour ambulatory pH test was attempted, where four patients could not tolerate or failed. In this cohort, we recorded only the presence of pathological acid reflux with DeMeester scores without other parameters such as symptom index (SI) and symptom association probability as detailed reports were not accessible. There were 22 patients who were tertiary and referred from outside South Tees region, from all over the UK. Contrast X-rays were obtained to ascertain the size of hiatus hernia as the endoscopic assessment of small hiatus hernia is variable and subjective. This enabled to carefully select suitable patients. The

Gastro-oesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQL) was used to evaluate symptoms and in addition recorded PPI with other antacid medication pre and post treatment.¹⁶

Exclusion criteria included patients <18 years of age, pregnancy, hiatal hernia >2 cm, patients with cardiac pace makers, Achalasia or incomplete LES relaxation and severely unfit patients (classified as American Society of Anaesthesiologists classification IV). All patients were aware of ongoing audit and were provided with written information regarding the procedure in clinic alongside potential side effects and complications.

Stretta procedure

At Stretta therapy, a thermocouple-controlled RF energy is delivered via electrodes proximal, at and below the gastro-oesophageal junction (GOJ) at six levels using a disposable using a balloon-tipped four-electrode catheter.

Procedures were carried out in a dedicated endoscopy department or theatre dependent on whether patient had opted for sedation versus general anaesthetic. The sedation regimen consisted of an initial 2 mg of midazolam followed by 50 μ g of fentanyl, this was repeated at 'level 4 RF delivery' (half time) during the procedure to allow for maximal patient comfort. All patients had Lidocaine throat spray in addition to sedation at the start of the procedure. Patients were monitored with oxygen saturations, heart rate and blood pressure monitoring and received 2 L oxygen via nasal cannula. A trained nurse was present to maintain and assess airway. The procedure was carried out according to a set protocol by a consultant upper gastrointestinal surgeon. Standard upper gastrointestinal endoscopy was initially performed to confirm pre-procedural findings and to assess the distance from incisors to GOJ, this was recorded and a guidewire is then passed into the stomach. The endoscope is withdrawn and the RF delivery catheter is passed over the guidewire to a position 1 cm above the GOJ. Four-needle electrodes are deployed from the delivery system into the muscle and energy is then delivered to reach a target temperature for a predetermined time period. This is repeated following rotation of the device and then RF energy is applied to a further five levels distally. In summary, at initial four levels, RF energy was delivered via a wire-guided Stretta catheter and continued at two further distal to GOJ at the cardia without a guidewire. A check endoscopy is performed following removal of the device to assess the mucosa. The procedure typically takes 50 min and the patients are discharged the same day.

Follow-up

Patient and procedural data were held in accordance with *The Data Protection Act 1998* on a secure National Health Service (NHS) server. Patients were advised to

Table 1 Preprocedure and postprocedure GERD-HRQL scores

GERD-HRQL score	Pre-Stretta score	Post-Stretta score	Maximum score	P values
Heartburn	21.8	5.1	30	<0.001
Regurgitation	20.0	6.1	30	<0.001
Total score	46.9	14.6	75	<0.001

Note: Medication affecting the daily life, pain on swallowing and associated dysphagia are graded 0–5 each, taking the total score to 75. GERD-HRQL, Gastro-oesophageal Reflux Disease-Health-Related Quality of Life.

continue their antacid medications for up to 6 weeks following the procedure and then steadily wean off. Patients were again counselled regarding dietary and lifestyle modification. Follow-up was by way of an outpatient clinic appointment between 3 and 6 months and routine telephone consultations. At 3 months, the outcomes were recorded in the clinic, and at 6 months, telephone appointments subsequently.

Statistics

Continuous data are described as mean ($\pm$ SD) and median (range) as appropriate. We have used χ^2 test for categorical data and Wilcoxon-matched pairs signed rank test for non-parametric data. P value was taken to be significant when <0.05 .

RESULTS

Demographics

The mean age of the cohort was 52.3 years (± 13.9) and the majority were women (70%). Fifty consecutive patients were followed up for a median of 25.3 months (771 days (range 499–1162)) following Stretta procedure for treatment of GORD. All patients were taking at least one antacid medication prior to the procedure

(49 on PPIs and 1 on ranitidine), 16 patients were taking both PPI, a histamine (H₂) receptor antagonist with or without gaviscon.

Patient's presentation

Thirty-five (35) patients presented with only GORD symptoms, 14 with GORD and extraoesophageal symptoms (laryngopharyngeal reflux (LPR)) and one with only LPR. Four patients (4/50) in the cohort had previously undergone antireflux surgery in the form of either open or laparoscopic Nissen Fundoplication and experienced recurrence of GORD symptoms. Thirty-four (34) patients had erosive oesophagitis at index endoscopy and remaining 16 had NERD, and 9 with NERD had LPR symptoms.

Length of stay and complications

Thirty-five (70%) patients underwent conscious sedation for the procedure and the remainder opted general anaesthetic. All were day cases (100%) with median stay of 2 hours after the procedures. There were no immediate or delayed complications observed in this cohort. Two patients required 1000mg paracetamol in recovery following the Stretta procedure for chest discomfort and discharged after 3–4 hours. There were no readmissions within 30 or 90 days following the procedure.

Preprocedure and postprocedure GERD-HRQL scores

The mean total heartburn scores improved from 21.8 (± 6.5) to 6.7 (± 7.5) and regurgitation scores from 20.0 (± 8.3) to 6.7 (± 7.7) out of a possible 30 score following application of RF energy using the Stretta device. The average GERD-HRQL score improved from 46.2/75 (± 14.2) preprocedure to 14.6/75 (± 17.3) postprocedure (table 1/figure 1). Dissatisfaction with GORD as measured in the GERD-HRQL

Figure 1 GERD-HRQL scores pre-Stretta and post-Stretta. GERD-HRQL, Gastro-oesophageal Reflux Disease-Health-Related Quality of Life.

Table 2 NRs and LF

	Patient 1 (NR)	Patient 2 (NR)	Patient 3 (NR)	Patient 4 (LF)	Patient 5 (LF)
Age	66	64	57	46	64
Sex	Female	Male	Female	Male	Female
Pre-Stretta therapy	Omeprazole 20 mg BD	Esomeprazole 20 mg BD and gaviscon	Lansoprazole BD, gaviscon	PPI, antacids, 10 years+history of GORD	PPI, antacids, prokinetics volume regurgitation
Atypical symptoms	Cough	Nil	Cough, choking, odynophagia better, dysphagia, chest pains	No atypical symptoms, recurrent reflux, 18-month Stretta, initial good outcome	Cough, atypical chest pains
Comorbidities	Obese, personality disorder, smoker Cocodamol, ibuprofen, pregabalin, trazadone, buscopan, citalopram, prochlorperazine	Stroke, renal cancer, prostate cancer, 3 lumbar spine surgeries, depression, mirtazapine, statins, ramipril, solifenacin, amlodipine, tamsulosin	Respiratory/ENT review Takes citalopram (can cause reflux, chest pains)	Nil	Previous fundoplication with HH repair in another hospital
Endoscopic findings	Oesophagitis	Gastritis, patulous GOJ, previous oesophagitis	<2 cm HH, oesophagitis	Lax GOJ, dilated hiatus, small sliding HH (2–3 cm) with refluxing bile on post-Stretta endoscopy (18 months later)	Bile reflux, recurrent HH (2–3 cm), lax GOJ
Barium swallow	Reflux++ on barium study	Normal barium study	Mild transient cricopharyngeal spasm. Possible small HH, delayed coating of marsh mallow and delayed gastric emptying of barium, 80% normal peristalsis, 20% low-amplitude simultaneous contractions	Pre-Stretta barium swallow (2015) okay Subsequent barium swallow (2018), small sliding HH, prolapsing stomach (dilated hiatus)	Reflux+no wrap displacement Small hiatal hernia
pH/Manometry	Manometry; dysmotility, low resting tone LES, sliding HH, pH study; patient could not complete	Not tolerated	Small HH De Meester score 54.6, SI 70% Manometry ok	De Meester score 30.4, SI 93%, Manometry ok	Not tolerated
Procedure under sedation/GA	Sedation	GA	GA	Sedation	Sedation
Post-Stretta therapy	Omeprazole 20 mg BD	Esomeprazole 20 mg and gaviscon	Lansoprazole BD	Lansoprazole b.d. started after recurrence of symptoms	Lansoprazole did not stop
Electrodes (n=56)	51	54	53	55	52
Pre-Stretta GERD-HRQL score	5	65	53	44	42
Post-Stretta GERD-HRQL score	0	60	50	65	38

GA, general anaesthesia; GERD-HRQL, Gastro-oesophageal Reflux Disease-Health-Related Quality of Life; GOJ, gastro-oesophageal junction; LES, lower oesophageal sphincter; LF, late failure; NR, non-responder; SI, symptom index.

decreased from 100% to 10% with three patients showing no improvement (non-responders (NRs)) at initial or delayed follow-up and two late failures (LFs (table 2)) at the time of this review. All patients with combination of GORD and LPR symptoms showed improvement in scores, however one patient with

LPR symptoms only, showed no improvement who remained symptomatic with cough.

The majority of patients were taking PPI medication prior to being referred for Stretta (99.5%). PPI formulation and dosage varied widely (omeprazole, lansoprazole, esomeprazole, pantoprazole and rabeprazole).

Table 3 PPI and antacid medication usage before and after Stretta therapy

	Pre-Stretta	Post-Stretta	P values
Number of patients taking at least one medication (PPI) for reflux (%)	49/50 (99.5%)	27/50 (54 %)	<0.001
Number of patients taking at least two medications for reflux (%)	16/50 (32%)	11/50 (22%)	Not significant

PPI, proton pump inhibitor.

One-third of patients (32%) were also taking at least one additional medication, most often ranitidine and alginate containing antacids such as gaviscon. Following Stretta therapy, the percentage of patients prescribed PPI reduced from 99.5% to 54% and 10% of patients went on to monotherapy from dual therapy (table 3).

DISCUSSION

GORD is a common condition which impacts adversely on health-related quality of life.¹⁷ Currently the treatment of GORD in the UK involves an escalation through dietary modifications, medications (primarily PPIs) and ultimately to laparoscopic fundoplication as required. Endoscopic options remain attractive for patients, surgeons and gastroenterologists as they avoid the requirement for general anaesthetic, risks of abdominal surgery and postfundoplication complaints such as dysphagia and gas bloat. Stretta also offers an alternative to re-do fundoplication following failed Nissen's¹⁸ and a potential alternative to further surgery in patients with obesity suffering from reflux following sleeve gastrectomy.¹⁹

Stretta has been shown to remodel the LES, improve LES function and decrease transient relaxations of this muscle, thereby reducing the frequency and amount of gastric contents refluxing into oesophagus.^{8–11}

In 2013, for the first time, NICE²⁰ published guidance on endoscopic RF therapy for GORD. The initial recommendations were based on systematic review of 1441 patients. A second NICE²¹ review was published in 2016, where evidence of further five studies (n=588) evaluated. NICE recommended that endoscopic RF therapy is indicated in patients with GORD, when PPI medication therapy fail, alongside surgery, or before surgery. The evidence suggests that Stretta Therapy improves symptom scores and reduces PPI medication dependence up to 5 years after treatment when compared with baseline. NICE also recommended that, because of uncertainty over longer term safety and inconclusive efficacy evidence, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

In our institute, the introduction of endoscopic RF ablation for GORD was discussed in clinical effectiveness and governance committees chaired by the medical director in 2014. Following the approval of the committee, we commenced offering the RF therapy to all suitable and carefully selected NHS patients as ongoing prospective audit. Furthermore, we have shared our outcomes in the trust's committee and acknowledged by the governance committee in 2018.

Treatment with the Stretta RF device has previously been demonstrated to reduce symptoms scores and reduce medication dependency.⁹ Uncertainties remain regarding objective evidence of efficacy. Fass *et al* published a recent systematic review and meta-analysis randomised control trials and cohort studies of patients undergoing treatment with Stretta, (n=2468 patients) and found no statistical significance in LES basal pressure; however, incidence or erosive oesophagitis was reduced by 24% (p<0.001). The study also found significant improvement in health-related quality of life, heartburn scores and reduction in patients requiring PPIs from baseline.¹⁰ This is in contrast to a previous systematic review and meta-analysis of randomised control trials by Lipka *et al* (2015) which no significant difference between Stretta and sham (n=153 patients).²² Despite this conflicting evidence, more recent studies and long-term follow-up have shown that in short and medium term, the device is an effective therapeutic option in the treatment of GORD.^{9 10 18}

This is the first UK series of 50 consecutive patients confirming Stretta as a safe and well-tolerated procedure which in the majority of cases can be performed as an outpatient under sedation. Except 1 patient (a renal patient with kidney failure), all were taking PPIs and 16 of them were on dual therapy (PPI+ranitidine). We noted, 27 (54%) patients stopped PPI at median follow-up of 25.4 months. Two of 50 patients (4%) developed chest pain soon after the procedure requiring 1000mg of intravenous paracetamol before discharge and there were no unplanned readmissions after discharge. All patients (100%) were day cases with average stay around 2 hours. Three out of four carefully selected patients, who developed recurrent GORD after previous fundoplication surgery, benefitted with Stretta therapy. We believe that there is a case to consider Stretta when medical therapy fails in this subgroup of patients, instead of a further revisional antireflux surgery. The later is fraught with more morbidity. We believe, NICE should take this factor into consideration furthering the guidance in future.

NON-RESPONDERS AND LATE FAILURES

There were three NRs who did not improve either at initial review or delayed follow-up and two patient's (LFs) who presented with recurrence symptoms 8 months and 18 months after Stretta therapy (table 2). Two among three NRs carried comorbidity

Significant of this study

What is already known on this topic

- ▶ Stretta therapy is an endoscopic minimally invasive endoscopic procedure that has shown to be effective in reducing the gastro-oesophageal reflux disease (GORD) symptoms and decrease or eliminate proton pump inhibitor (PPI) medication dependency in selective patients.

What this study adds

- ▶ The current series is the first reported outcomes from a cohort of patients with GORD in the UK with a median follow-up of 25.3 months. We have shown that STRETTA therapy is a useful tool in recurrent GORD after previous antireflux (fundoplication) in selected patients.

How might it impact on clinical practice in the foreseeable future

- ▶ This study bears a certain impact on the management of selected patients with GORD via endoscopic least invasive antireflux (Stretta) therapy.

and were taking multiple medications as summarised in table 2. Whether they had visceral hypersensitivity with functional oesophageal pain causing reflux dyspepsia require further assessments, as the triggering factors are multitude ranging from emotional to mechanical stimuli. This may enable us to determine factors which may further improve criteria for patient selection. One NR patient (column 1 table 2) presented with suspected reflux-induced cough as the main symptom with mild dyspepsia, explaining the pre-Stretta low score of 5. The fourth and fifth patients who were LFs, on repeat contrast and endoscopic examination, had a sliding hiatus hernia (2 cm+) with refluxing bile. One LF patient had previous fundoplication with a recurrent small hiatus hernia and the other did not have hiatus hernia at initial pre-Stretta assessment.

Limitations of this study include its small numbers and pre-Stretta assessments were carried out by various teams from all over the UK prior to the original referral. In summary, our experience to date has shown that Stretta offers a safe, alternative therapeutic option in the management of GORD in selected patients improving quality of life and reducing PPI dependency.

Contributors All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing or revision of the manuscript. YKSV: involved in planning, drafting, editing and submitting the manuscript. NM: drafting and data analysis. R-BO: data collection and telephone assessment. AD: assisted in planning and advised towards preparation of manuscript. SP: data collection and data analysis.

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Author note All authors confirm that this work 'conform to the guidelines set forth in the Helsinki Declaration of 1975, as revised in 2000, concerning human and Animal Rights, and that they followed the policy concerning Informed Consent'. The data analysed in this article are anonymised without any patient identifiable information.

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