

A Novel Endoscopic Assessment Score which Predicts Long Term Outcome Following Stretta; Early Results

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Abstract

Background: Endoscopic anti-reflux radio-frequency therapy (STRETTA) is a NICE approved treatment for gastro-esophageal reflux disease (GERD). To obviate poor outcomes, there is a need for clinicians to select suitable patients who are likely to benefit. There are no published endoscopic scores, for use before endoscopic anti-reflux therapy, which predicts an outcome. This study aims to produce an endoscopic score which predicts good outcome following STRETTA for GERD.

Materials and Methods: All patients undergoing STRETTA therapy between July 2017 and January 2018 were scored at the time of their pre-STRETTA endoscopy by an expert endoscopist. The following criteria make up the score: Crural insufficiency; z line displacement; prolapse of the stomach; preservation of angle of His; depth of the fundus from GOJ on retroversion; erosive esophagitis. Patients were then independently scored by a specialist Upper GI trainee to ensure reproducibility. GERD Health-Related Quality of Life Questionnaires were obtained before STRETTA, and again at 12 months. Statistical analysis was performed comparing pre-STRETTA endoscopic scores and patients reported outcomes.

Results: A total of 19 patients were analysed, 15 patients reported improvement in the symptom scores and 12 of then expressed full satisfaction at 12 months. There was no significant difference between scores produced by both endoscopists ($p > 0.05$), confirming reproducibility. No single endoscopic criteria were predictive of good outcome ($p > 0.05$). However, group A (completely satisfied) patients had significantly lower total scores than group B (improved and non-improved) patients, 3.42 vs 6.43 ($p = 0.012$). ROC curve analysis demonstrates a score less than or equal to 5 is likely to produce a good outcome (92% sensitivity, 71% specificity).

Conclusion: This is a novel endoscopic assessment score which may predict a successful outcome in patients undergoing STRETTA for GERD. This requires prospective validation in a new cohort of patients; this is ongoing.

Keywords: STRETTA; Outcomes; Prediction of the Outcome; Endoscopic Management; GERD; Endoscopic Evaluation

Introduction

Gastro-esophageal reflux disease (GERD) has an estimated prevalence of 10 - 20% [1]. First-line treatment for GERD, in conjunction with lifestyle modification, is medical therapy. Life-long treatment is often required. However, as many as 42% of patients fail to achieve

benefit from PPIs [2]. Surgical therapies for GERD reduce the need for life-long treatment, though the traditional laparoscopic Nissen fundoplication requires a general anaesthetic and carries long-term risk of dysphagia and gas-bloat syndrome [3].

Endoscopic anti-reflux radiofrequency therapy (STRETTA) has been approved by NICE, in the UK, for GERD which is refractory to medication [4]. STRETTA has also been recommended by the Society of American Gastrointestinal and Endoscopic Surgeons [5]. This system is minimally invasive and proven to improve reflux symptoms, reduce PPI dependency, and lower the need for surgical management of GERD. STRETTA results in lower esophageal sphincter augmentation, resulting in a stronger anti-reflux barrier, which improves GERD symptoms [6].

Complicated GERD (defined as stricture, ulcerative esophagitis, scarring, a hiatus hernia of greater than 2.5 cm, a dilated crura of greater than 2.5 cm, a Schatzki’s ring or Barrett’s metaplasia) is associated with poor outcomes following STRETTA therapy [6]. The published outcomes of STRETTA for uncomplicated GERD are variable [7-15] this in part, maybe due to heterogeneous patient cohorts. There are no published validated assessment tools, or scores, which aim to predict a good outcome from endoscopic anti-reflux therapies, such as STRETTA, for patients with uncomplicated GERD.

Aim of the Study

This study aimed to identify pre-procedure, prospectively documented, endoscopic findings which can identify patients with GERD who are likely to benefit from STRETTA.

Materials and Methods

Patients with uncomplicated GERD who had failed standard medical anti-reflux therapy were considered for STRETTA. Uncomplicated GERD is defined as the absence of ulcerative esophagitis, scarring, stricture, a hiatus hernia of greater than 2.5 cm, a dilated crura of greater than 2.5 cm, a Schatzki’s ring or Barrett’s metaplasia. All patients had a pre-procedural endoscopy, contrast x-ray, pH and manometry studies before being considered for STRETTA.

All patients undergoing STRETTA therapy between July 2017 and January 2018 were scored at the time of their pre-STRETTA endoscopy by an expert endoscopist. This data was stored on a prospectively maintained database, this is registered with the Research Registry (researchregistry5576). Ethical approval was not required for the anonymized observational data collection. The score included the following criteria: Crural insufficiency; z line displacement; prolapse of the stomach; preservation of angle of His; depth of the fundus from Gastro-Esophageal Junction (GEJ) on retroversion; erosive esophagitis. These criteria are further described in table 1 and 2, figure 1. The criteria were chosen by our expert endoscopist (YKSV) through observations over 6 years, having performed more than 200 Stretta procedures. It was felt these criteria were likely to be predictive of a good outcome. Patients were independently scored by a specialist Upper GI trainee to ensure scores were reproducible, where there was a conflict, a consensus was reached.

Criteria	Definition
Crural insufficiency	The space around the endoscope at GEJ on retroversion, indication laxity at GEJ. Scores were given depending on the accommodating space. E.g. the number of scopes which could be passed via the dilated crurae [6] (Figure 2).
Z line displacement	Z line normally syncs with the crural impression, identifiable both on antegrade and retrograde assessment of GEJ. Absence of the synchronisation with proximal displacement of Z Line in relation to crural impression.
Prolapse of stomach	The mucosa of the proximal stomach can intermittently prolapse via a lax GEJ. This is observed on antegrade and on retroversion.
Preservation of angle of His	Acute angle at cardia with esophageal axis, it is completely obliterated in patients with hiatus hernia [22].
Depth of the fundus from GEJ on retroversion	The estimated distance from GEJ to the highest point of fundus, an ancillary marker of the length of intraabdominal esophagus.
Erosive esophagitis	Esophageal mucosa showing inflammatory changes.

Table 1: Definitions of each pre-STRETTA endoscopic criteria.

Criteria	Score
Crural insufficiency	1 point per scope diameter
z line displacement	1 point per cm displacement
Prolapse of stomach	1 point if yes
preservation of angle of His	1 point if no
depth of the fundus from GOJ on retroversion	0 points for 4 cm or more, 1 point for 3 cm, 2 points for 2 cm, 3 point for 1 cm.
Erosive esophagitis	1 point if yes.

Table 2: Proposed pre-STRETTA endoscopic score.

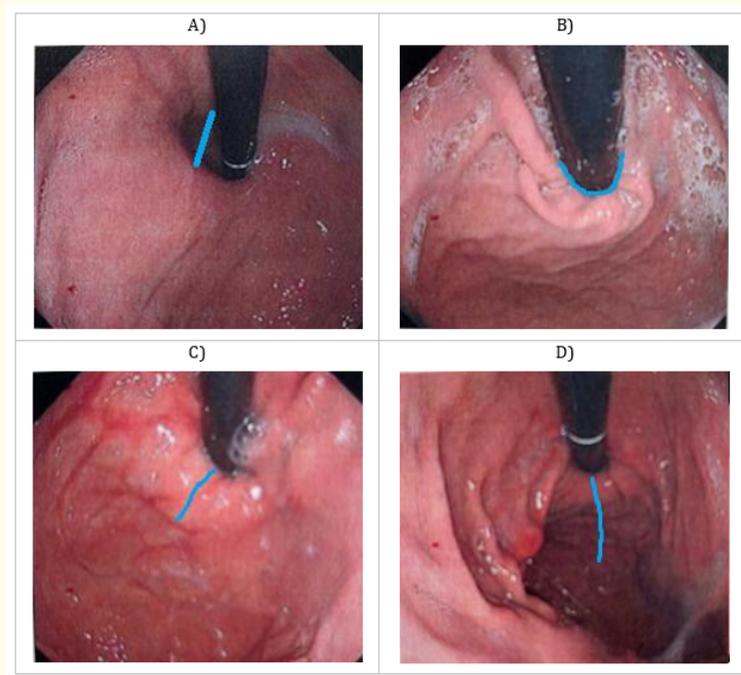


Figure 1: A photographic example of pre-STRETTA endoscopic GEJ findings. A) Crural insufficiency, B) No crural insufficiency, C) Depth of fundus measuring approximately 1 cm from GEJ, D) Depth of fundus measuring at least 3 cm from GEJ.

GERD-HRQL (Health-Related Quality of Life Questionnaire) [16] and GSAS (Gastroesophageal Reflux Disease Symptom assessment scale) were obtained before STRETTA, and at 12 months after STRETTA. The outcomes of these validated questionnaires from patients undergoing STRETTA in our institution have previously been published [7]. GERD-HRQL is a 16 point questionnaire which grades the severity of GERD on a scale of 0 - 75, and GSAS is a 15 point questionnaire which aims to assess severity on a scale of 0 - 45.

Statistical analysis (Microsoft Excel 2016) was performed comparing pre-STRETTA endoscopic scores and patients reported outcomes. Continuous and categorical variables were compared against outcomes using T-test and Chi-squared tests respectively.

Results

There were no complications related to STRETTA. A total of 19 patients were analysed. 15 patients reported improvement in the symptom scores on their GERD-HRQL and GSAS. 12 of them expressed complete satisfaction at 12 months. There was no significant difference between pre-STRETTA scores produced by both endoscopists ($> p.0.05$), confirming the reproducibility of scoring. No single endoscopic criteria were predictive of good outcome ($p > 0.05$). However, group A (completely satisfied) patients had significantly lower mean scores (+/- SD) than group B (improved and non-improved) patients, 3.42 (+/- 1.68) vs 6.43 (+/- 2.30) ($p = 0.012$). The scores in group A ranged from 1 - 6, and those in group B ranged from 4 - 10.

ROC curve analysis demonstrates a score less than or equal to 5 is likely to produce a good outcome (92% sensitivity, 71% specificity) (See figure 2).

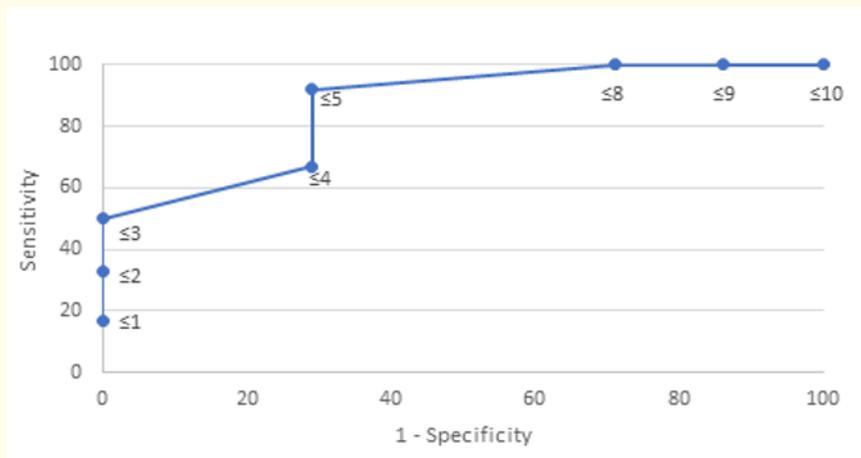


Figure 2: ROC curve analysis of pre-STRETTA endoscopic score.

Discussion

STRETTA is a novel therapy which aims to increase the resting tone of the lower oesophageal sphincter and reduce transient relaxation, by lower esophageal sphincter augmentation. There is evidence that STRETTA improves patients quality of life and reduces dependence on medical therapy [7-10,13,17]. However, there are several publications which have suggested that STRETTA has failed to provide improvement for some patients [14]. In light of this, there is a need for clinicians to identify who is likely to benefit from STRETTA. This is the first study which looks to identify factors which predict a good outcome from STRETTA therapy. We have developed a pre-STRETTA endoscopic evaluation of the GEJ which predicts good outcome in patients undergoing STRETTA therapy. This score is simple to perform at the time of pre-procedure diagnostic endoscopy.

Importantly, STRETTA has been demonstrated to be more cost effective than surgical management of GERD [18-21]. However, there is conflicting evidence as to which is more cost effective when comparing STRETTA to medical therapy [18-20].

Assuming this pre-procedure score helps identify patients that will have good outcome, this will improve cost-effectiveness of STRETTA by not performing it on patients who are unlikely to benefit.

There are a number of limitations to this study. We have only used a small number of patients, and the score has not yet been prospectively validated (this is ongoing). However, this is the first study aiming to establish pre-procedure predictive factors as to who is likely to benefit from STRETTA therapy in order to improve outcomes and cost-effectiveness.

Conclusion

We have identified the first simple endoscopic score which may predict successful outcome in patients undergoing STRETTA for GERD. This pre-STRETTA endoscopy score requires further prospective validation in a new cohort of more number patients; this is ongoing.

Highlights

This proposed endoscopic evaluation of the gastro-esophageal junction may help clinicians to predict which patients will benefit from STRETTA for GERD.

Conflicts of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

YKSV concept idea, data collection, manuscript evaluation and revision. EJN data collection, analysis, manuscript drafting. All authors approved the manuscript before submission.

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