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Review Article

Trans-oral incisionless fundoplication vs stretta, two recognized endoluminal anti-reflux therapies; a systematic review and meta-analysis

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ABSTRACT

Gastro-oesophageal reflux disease (GORD) is common with a prevalence of 10-20% in the Western World. During the last two decades, amongst introduced several endo-luminal techniques, evidence has emerged about the efficacy and safety of two treatment modalities for GORD; 'Stretta' procedure and trans-oral incisionless fundoplication (TIF)' or EsophyX. Author in this study aim to conduct a systematic review of published 'level 1' evidence, to evaluate all evidence on the efficacy of Stretta procedure and TIF (EsophyX) for the management of GORD. A robust literature that included RCT trials only, searched on MEDLINE, EMBASE, and Cochrane library was undertaken from January 2007 until January 2017. The outcomes were normalisation of oesophageal pH values, augmentation of lower oesophageal sphincter pressure (LESP), health-related quality of life (HRQOL) score, and ability to stop or reduce PPI after procedure. For quality assurance purposes, two researchers were involved in the data collection process and its analysis. Author collected data from 9 RCT trials, 3 for Stretta and 6 for EsophyX. From the Stretta trials 101 patients were recruited, 92 patients were analyzed. Of the EsophyX trials, 3 of six papers were from single trial. A total of 296 patients were included and 203 were analysed. The pooled results show both stretta and esophyX significantly improved GORD symptoms. In a meta-analysis of trials, author found that both Stretta and EsophyX significantly improves GERD-HRQL score and enables patients to reduce or stop PPI intake compared with sham/PPI therapy alone. The overall quality of evidence is superior for EsophyX than it is for Stretta.

Keywords: EsophyX, Endoluminal, Gastroesophageal reflux disease, Stretta, Trans-oral incisionless fundoplication

INTRODUCTION

Gastro-oesophageal reflux disease (GORD) is one of the most common disorders of the gastrointestinal tract, which has a prevalence of 10-20% in the Western World. GORD is largely caused by repeated exposure of the lower oesophagus to the retrograde flow of gastric contents.[1] Epidemiological studies have shown that reflux is experienced by 3-20% of the population at least weekly.[2,3] The symptoms of GORD are bothersome and most patients report disabling regurgitation and heartburn which affects their jobs and daily way of life. GORD is common in obese adults with an incidence as high as 58%, and with the recent rise in obesity in the West, more people are prone to having the disease.[4] Current management of GORD is mainly lifestyle changes and

drug therapy. Proton Pump Inhibitors (PPI) are widely used in the last 20 years and are considered the most effective for symptom control in GORD, achieving their therapeutic goal in about 60% of patients.[5,6] It is costly (omeprazole 20mg daily costs £30.13/patient/month) to the NHS (1999) and most patients have to take it for a long time. This creates a pill burden for these group of patients, and they get fed up. Furthermore, PPI therapy has been shown to have significant side effects such as clostridium difficile infection, community acquired pneumonia, hip fracture, vitamin B12 deficiency, hypomagnesemia and myocardial infarction in the general population.[7,8]

Open or Laparoscopic anti-reflux surgery which is the gold standard is reserved for patients who have inadequate response to the above treatment, or those who experience complications with PPI therapy, or young patients who do not want to be on lifelong medication, however it has a high failure rate, especially, in obese subjects.[9] Even though GORD patients are dissatisfied with PPI therapy, some patients are reluctant to undergo laparoscopic fundoplication due to the fear of adverse effect such as dysphagia, difficulty in vomiting, and gas bloat.

Table 1: Summaries the inclusion and exclusion criteria of the selected trials.

	Inclusion criteria	Exclusion criteria
Population	Patients with objectively diagnosed gastroesophageal reflux disease (GORD); age >18; on PPI for symptom control; Participants >10	Age <18; Barrett oesophagus; patients with endoscopically diagnosed reflux esophagitis grade C and D by LA classification; Participants <10 Obese patients
Intervention	Stretta procedure/ TIF eg EsophyX 1/2	Patients who has had previous laparoscopic fundoplication
Comparative intervention	Medication therapy for GORD eg PPI, antihistamines, sham intervention	
Outcomes	Primary outcome: GORD HRQL symptom score. QOLRAD questionnaire, GSRS; PPI requirement. Secondary outcome: LES pressure, oesophageal pH monitoring, endoscopic changes (oesophagitis). Studies reporting any 2 of the above outcomes	
Type of studies	Randomised controlled Trials	Non-randomised controlled trials, cohort studies, case series, systematic reviews

Table 2: The keywords used for the internet search.

Population	Intervention	Comparative intervention	Outcome
GORD	Stretta	Proton Pump Inhibitor	Symptom score
GORD	Radiofrequency energy application	PPI	Health-related quality of Life
GORD	Radiofrequency energy delivery	medication	HRQL
GORD	Pulsed radiofrequency treatment	Antihistamines	GERD-HRQL
GERD	Radiofrequency	Laparoscopic fundoplication	GORD-HRQL
Heartburn	EsophyX	Nissen's fundoplication	Acidity
Regurgitation	Transoral Incisionless Fundoplication	Open fundoplication	pH monitoring
	TIF	Operation	Acid reflux
	Natural Orifice Transluminal Surgery		Oesophageal acid exposure
	NOTES		
	Endo-luminal		Lower oesophageal sphincter pressure
	Endoluminal		
Reflux disease	Endoscopic	Surgery	LESP

In the past two decades, several endoscopic modalities for the treatment of GORD in selected patients have been reported in the literature. Most of these modalities were removed from the market due to lack of evidence of their safety and effectiveness, others are still in evolution. Two of these endoscopic techniques that are often mentioned in the literature and in clinical practice in recent years are endoscopic application of radiofrequency ablation to the lower oesophageal sphincter (Stretta), and trans-oral incisionless fundoplication (TIF) using EsophyX device.

In the last decade evidence has emerged about the safety and effectiveness of these two endo-luminal modalities in the treatment of GORD in selected patients. The aim of this study is to conduct a systematic review of published level 1 evidence to identify, critically appraise, and summarise all comparative studies investigating the effectiveness of Stretta and EsophyX.

METHODS

Electronic literature search was undertaken to answer this research question; In patients with GORD, how effective and safe is Stretta procedure or EsophyX technique compared with PPI in the management of their symptoms and improving their quality of life.?

Using the PICO system and their synonyms in various combinations, and using the Boolean operator, extensive electronic search on Medline, Embase, and Cochrane Central Registrar between 2007 and 2017 was undertaken. This is to reflect work done in the last decade since the re-emergence of endoluminal techniques such as Stretta into the market. Conference abstracts and journals from the past meetings including Gastroenterology, Endoscopy and Digestive Disease Week, clinical trials were included in order to identify abstracts of recently completed studies that are not yet published.

All synonyms were searched using 'OR' and then combined the PICO domains using 'AND'.

Data collection and analysis

Two authors independently collected and extracted data on outcomes from all the studies by reviewing titles, abstracts, and selected full text for inclusion. In cases of disagreement between them during the selection is resolved by consensus. Author summarized dichotomous data as the risk ratio along with 95% confidence intervals (i.e. daily PPI requirement) and continuous data (mean % time pH<4 over 24hours, mean LES pressure) as mean difference and standard error along with 95% CI using review manager. Due to the heterogeneity nature of the reporting outcomes of the individual trials, author used a combination of meta-analysis and narrative methodology to report the findings.

RESULTS

The initial electronic search at MEDLINE, EMBASE and Cochrane library retrieved 72 references. The initial review excluded 36 (19 not relevant, 17 duplicate) articles. The remaining 36 references were reviewed by their titles and abstract. A 23 out of 36 studies were excluded because they are not relevant to the above studies. The flow chart Figure 1 shows the summary of the search results and selected studies.

Author read all the remaining 13 articles in full and excluded four articles which did not meet the inclusion criteria for this systematic review. The remaining nine references met the inclusion criteria included three studies for Stretta and six studies for TIF-EsophyX device. No abstracts or unpublished studies met the inclusion criteria.

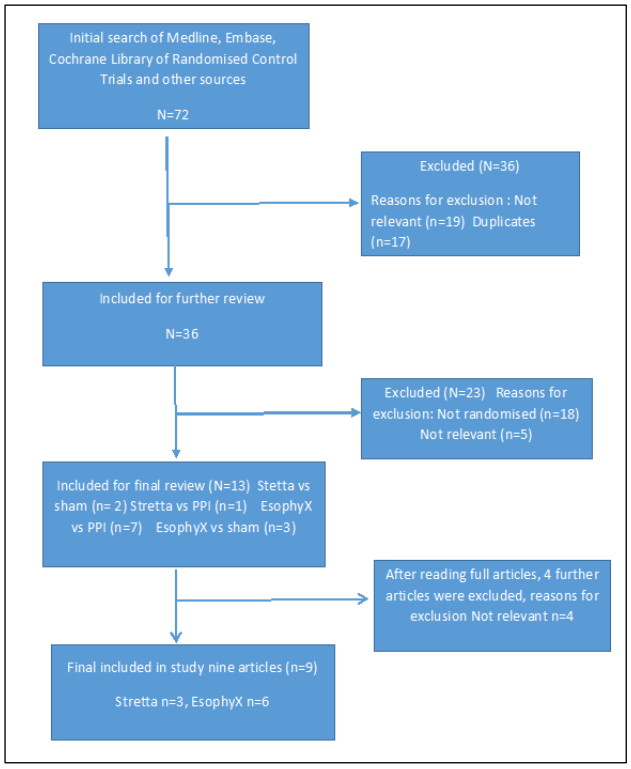

Figure 1: Flow chart showing the selection of studies.

Stretta

The study by Aziz et al, was a multi-arm randomised trial that compares sham treatment versus single-and double-dose Stretta.[10] The primary aim was to evaluate efficacy of Stretta and to show that increasing dose of radiofrequency would further improve the response to this therapy. Total 36 patients were randomised into three groups of 12 each (single Stretta/sham/double Stretta group). Twelve patients (group A) underwent single Stretta, group B underwent sham (endoscopy and passage of Stretta balloon but no deployment of electrodes). Group C had single Stretta and a repeat procedure after 4 months if GERD-HRQL did not improve by 75%. Patients were followed up 6 and 12 months following the intervention. Outcome measures were taken prior to Stretta, six months and twelve months following the procedure. In single Stretta group; there was significant improvement in GORD-HRQL score (baseline 29.6±3.9 dropped to 14.4±4.8) (P<0.01); the mean 24-h total time pH <4.2 also reduced from 9.4±3.4 at baseline to 6.7±2.8 p<0.01; a drop-in esophagitis grade as well as mean LES pressure. Double Stretta group showed further

improvement whereas in the sham group there was no statistically significant improvement.

The study by Arts et al, was a single-centre, double- blind sham- controlled randomised trial that compared Stretta to sham intervention.[11] The secondary outcome was to evaluate the influence of the Stretta procedure on GORD symptoms, oesophageal acid exposure, and distensibility of the GEJ in GORD patients. Twenty-two (22) recruited patients were randomly allocated into the sham group (11) and intervention group (11). Patients had pre-intervention investigations, 3- and 6 months after Stretta. Sham group patients were allowed to crossover to Stretta by their wish. 3 months after Stretta, symptom score significantly improved in intervention group 14.7±1.2 vs. 8.3±1.9 p<0.005, whereas in the sham group, no significant improvement 16.1±2.5 vs. 15.6±2.2. There were no significant differences between the 2 groups in terms of esophagitis grade, oesophageal pH, and PPI dose.

Coron et al performed a multicentre prospective randomized controlled trial to compare Stretta and a PPI strategy in PPI-dependent GORD patients.[12] A 43 patients with GORD were randomized into 2 groups (Stretta n=23, PPI n=20). The primary endpoint evaluated at 6 months, was defined as the possibility for the patient to stop or reduce their daily PPI requirement by 50% of the effective dose required at baseline. Secondary end point included 24h oesophageal acid exposure, and GORD-HRQL score. At 6 months after intervention, in Stretta group18/20 patients stopped (n=3) or decreased (n=15) PPI vs. 8/16 in PPI group (p=0.01). No significant difference in HRQL, or oesophageal acid exposure in both groups before and after intervention. No severe complications reported.

Table 3: Illustrates the mean (%) time oesophageal pH <4 over 24hours for 2 of the studies.

Study	Mean % pH <4	Stretta (SD)	Total	Mean	PPI (SD)	Total	Weight	Mean difference IV, fixed, 95% CI
Aziz et al	6.7	2.8	22	8.2	3.1	12	75.6%	-1.50 (-3.61,0.61)
Coron et al	11.4	6.3	23	8.8	6.1	20	24.4%	2.60 (-1.33,1.33)
Total (95% CI)			45			32	100%	-0.50(-2.33,1.33

Heterogeneity; Chi2=3.54, df=1(P=0.06), I^2=72%, Test of overall effect; Z=0.53 (P<0.059)

Table 4: Illustrating summary of outcome and overall quality of evidence (Stretta).

Outcomes	Sham/PPI	Stretta	Quality of evidence
GERD-HRQL off PPI	NS/NS/	+++	++
Mean % time pH <4 over 24 hours	NS/NS/NS	+/NS/NS	+
Ability to stop PPI	NS/NS/NS	-/+/+	+
Mean LES pressure		-/NS/NS	-
Healed esophagitis	NS	+/NS/NS	-

NS –not significant, +++ strong evidence, ++ moderate evidence, + weak evidence

The Table 3, compares the mean (%) time oesophageal pH <4 over 24hours for 2 of the studies. The mean difference in the (%) time the pH was less than 4 over 24-hours' time was 0.50% lower in favour of Stretta but was not statistically significant. The table 4 summaries outcome with quality of evidence after Stretta therapy.

EsophyX

The study, (TEMPO trial) was a multi-centre open label prospective randomized controlled trial with crossover arm which was performed over a 3- year period.[13-15] The primary aim of the study was to evaluate the efficacy of TIF (EsophyX) versus high dose PPI therapy, and secondarily to assess its durability. The finding of this study was reported at 1st year (2014), 2nd year (2015) and 3rd year (2016). All three studies have been critically appraised in this systematic review. Patients (n=63) were randomized into TIF (n=43) and PPI (n=20). Baseline assessment was undertaken with GERD-HRQL questionnaire, OGD, and oesophageal pH monitoring. At 1st, 2nd and 3rd year follow up, these assessments were repeated. This trial reported significant improvement in GERD-HRQL score 76%, 84%, and 81% of patients in year 1, 2, 3 respectively (p<0.001). A 94% of patient had healed oesophagitis in year 1, 93% in year 2, and 86% in year 3. A 73% of patients were off PPI at year 1, 76% at year 2, and 71% at year 3.

A prospective randomized controlled trial to determine whether or not TIF was better than PPI treatment in troublesome GORD symptoms, particularly regurgitation in the population of chronic PPI-dependent GORD patients.[16] A total 129 patients with GORD randomised into 2 groups: TIF/placebo 87, sham/PPI 43. The primary study aim was the elimination of troublesome

regurgitation. Secondary outcomes include RDQ, GERD-HRQL score, oesophageal acid exposure, mean DeMeester score, and changes in oesophagitis on OGD. At 6 months follow up, elimination of troublesome regurgitation was recorded in 67% in TIF/placebo group vs. A 45% in sham/PPI group (p =0.023). Mean % time pH <4 improved in TIF/placebo from 9.3 to 6.4 after TIF (p<0.001). No significant improvement in the sham group. Reflux esophagitis healed in 77% vs 50% sham/PPI group.

Witteman et al, conducted a randomized controlled trial comparing TIF and PPI for the treatment of GORD.[17] A total of 60 patients (TIF n=40, PPI n=20) were included in the trial. Outcome measurements were taken pre-intervention, 6 and 12 months following intervention. Patients from PPI arm were allowed to crossover after 12 months. Mean HRQL at 6 months significantly improved in TIF from 26.5(8.0) baseline to 12.4(10) vs. 28.2(9.5) to 25.1 (11.2) for PPI group (p<0.001). Significant improvement in PPI use at 6 months for TIF 74% stopped vs 0% in PPI group. No significant difference in healed esophagitis. LESP improved with the median range for TIF baseline 15.2 (8-25) to 18.2 (10-40) at 6 months vs. baseline for PPI 15.5 (6-25) to 13.6 (4-20) p=0.058.

A double-blinded sham-controlled trial performed by Hakansson and Montgomery 18, compared TIF-2 and PPI treatment in chronic GORD patients. A total 44 patients randomized into 2 groups of 22 each. QOLRAD improved significantly for TIF at 6 months from 4.9 (1.96-6.44) at baseline to 6.4 (4.38-7) p=0.0005 vs sham from 4.8 (1.80-6.44) at baseline to 5.2 (4.28-6.88) at 6 months p=0.34, NS. GSRS score improved for TIF from 14 (10-21) to 10 (6-19) p=0.004. No change for sham group. PPI use for TIF 59% off PPI at 6 months vs. 18% for sham (p=0.01). There was significant improvement in total oesophageal acid for TIF group.

Table 5: Illustrates outcomes with EsophyX and PPI/Sham therapy for GORD.

Study	EsophyX events	Total	PPI events	Total	Weight	Odds ratio MH, fixed, 95% CI
Arts et al	0	0	0	0		Not estimable
Aziz et al	0	0	0	0		Not estimable
Coron et al	0	0	0	0		Not estimable
Hakkansson et al	13	22	4	22	91.0%	6.50 (1.64,25.76)
Witterman et al	28	37	0	20	9.0%	123.00 (6.77,2235,21)
Total (95% CI)		59		42	100%	16.94 (5.53,51.88)
Total events	41		4			

Heterogeneity; Chi2=3.65, df=1(P=0.06), I2=73%, Test of overall effect; Z=4.95 (P<0.00001)

Table 6: The summary of all outcomes and quality of evidence for TIF (EsophyX).

Outcomes	Sham/PPI	TIF	Quality of evidence
RDQ	NS/NS	++	++
RSI	NS	+	++
GERD-HRQL	NS/NS/NS/NS	++++	+++
Mean % time pH <4 over 24hours	+NS/NS/NS	+NS++	++
Ability to stop PPI	NS/NS/NS	+++	+
Mean LES pressure	NS/NS	++	++
Endoscopic assessment for esophagitis	NS/NS/NS	+NS+	+

NS –not significant, +++ strong evidence, ++ moderate evidence, + weak evidence

The Table 5, above shows a comparison of EsophyX and PPI/sham for GORD; outcome: inability to stop or reduce PPI. Data on ability to stop or reduce PPI use was extractable and pooled from two randomized controlled trials (n=101). The pooled analysis showed statistical advantage of EsophyX over sham in terms of patients ability for stopping or reduce PPIs. (risk ratio, 16.94; 95% CI 5.53-51.88; p=0.00001). The heterogeneity of the pooled studies was statistically significant. The summary of all the outcomes and overall quality of evidence for TIF (EsophyX) is presented on the Table 6.

DISCUSSION

Author performed a systematic review to evaluate the efficacy of endoluminal methods of treatment of GORD. In the last decade, Stretta and EsophyX have been reported in literature as efficient and safe procedures for GORD patients. These two methods are still at the stage of evolution, and if found to be effective, will go a long way to offer both short and medium-term symptom relief in selected GORD patients. It will fill the so called ‘’therapy gap’’ between PPI and laparoscopic fundoplication in the treatment of these group of patients, whereas in a large majority, it will act as a definitive treatment.

A systematic literature search of randomized controlled trials on Stretta/EsophyX compared with PPI for treatment of GORD in the last 10 years was conducted. This search yielded 9 papers (3 Stretta and 6 EsophyX) that satisfied the inclusion criteria for this systematic review. All nine papers were critically appraised using the McMaster University Critical Appraisal form for quantitative studies. Outcome measures used were GORD-HRQL, QOLRAD, oesophageal pH, ability to stop or reduce PPI medication, grade of esophagitis at endoscopic and LES pressure.

The systematic review finds that both Stretta and EsophyX were effective compared to PPI in the elimination of troublesome GORD symptoms however, evidence was relatively weaker for Stretta than it was for EsophyX device.[18]

The three studies that were included in the review for Stretta had small number of patients in each study which exposes the trial results to a risk of type II error. Moreover, the Stretta studies included in this review have shown non-uniformity in terms of the outcome measures. All three studies used different instruments to assess quality of life, however the results show significant improvement in the quality of life in the intervention group in 2 of the 3 included studies, and 1 study reported significant improvement in dose of PPI requirement after intervention. With regards to safety and tolerability of the Stretta procedure Aziz et al, reported no major complication following the procedure.[10] Some active and sham group patients experienced minor retrosternal discomfort requiring oral analgesia, mild fever, and transient nausea /vomiting, and transient dysphagia. One patient developed aspiration pneumonia which was treated with antibiotics. Arts el al, reported failure of procedure in three patients due technical reasons (difficulty with needle deployment).[11]

In a systematic review and meta-analysis conducted by Lipka et al, the author rejected the fact that Stretta provides any clinical and psychological benefit for patients with GORD, partly due to the reasons given above.[19] Evidence from this study and several others shows that Stretta offers significant symptom relief for GORD patients, as evidenced from patients GORD-HRQL score and patient ability to reduce or stop PPI medication. There have been several cohort studies that have reported the efficacy and safety of Stretta treatment in the last decade. A cohort study by Punnoose et al, conducted in the UK hospital for the first time at the South Tees Institute of Learning, Research and Innovation, Middlesbrough, UK involving 26 patients who underwent the Stretta procedure over a period of 12 months.[20] This study reported significant improvement in GERD-HRQL score from 44 pre-procedure to 6 post procedure. There was overall patient satisfaction of 78%. No reported complications.

Perry et al, conducted a systematic review and meta-analysis of randomised controlled trials and cohort studies to assess the impact of Stretta on GORD symptoms.[21] A total of 1441 patients were included. They found statistically significant improvement in heartburn score, quality of life measured by GORD-HRQL scale, and oesophageal acid exposure after Stretta treatment.

It is quite clear from the review that none of the randomised controlled trials reported a long-term durability of Stretta. Dughera et al, studied a cohort of 158 patients who had Stretta procedure.[22] At 10 years, 51 patients were followed up, 36/51(68.6%) were completely off PPI and there was significant decrease in heartburn and GORD-HRQL score. Only seven patients lost the efficacy of Stretta at 10 years.

In the United States, SAGES guidelines in 2013 and ASGE guidelines 2015 suggests that it is reasonable to offer Stretta as a 'bridge therapy' in selected patients with mild to moderate GORD symptoms. In the United Kingdom, the National Institute for Health and Care Excellence (NICE) overview looked at 2305 patients from 1 systematic review (including 2 randomised controlled trials and 18 cohort series), 2 additional RCTs, 1 non-randomised comparative study and 4 case series. NICE review described Stretta therapy would be for treating GORD symptoms, which cannot be controlled using PPI medication therapy, alongside surgery or before surgery. The key points from the recent NICE review briefing come from 5 studies (n=588). The evidence suggests that Stretta therapy improves symptom scores and reduces PPI medication dependence up to 5 years after treatment when compared with baseline. Today, a few endoscopy centres across the UK have embraced the radiofrequency technology for treating GORD in selected patients and training (including author's centre in UK) is being offered to gastroenterologists and surgeons about its application.

The systematic review also suggests that TIF/EsophyX, offers reasonable symptom relief in selected patients with chronic GORD. Author critically appraised six randomised controlled trials involving 296 patients. Three of the papers (The TEMPO Trial) by Trad et al, assessed the efficacy and durability of EsophyX device in the formation TIF.[13-15] The results showed significant improvement in GERD-HRQL, PPI requirement and healed esophagitis at the end of year 3 follow up. Similar outcomes were achieved for the other three studies at the end of year one.[16-18]

Many case series in the past have reported mixed results in TIF patients but as more experience was gained in the use of EsophyX device outcomes have improved and the number of related complications has reduced with overall patient satisfaction of 72%. 28 None of the studies reported serious adverse events following EsophyX procedure other than transient epigastric pain which was

not statistically significant between TIF and sham in one of the studies.

The review also demonstrates that while TIF is effective in reducing GORD symptoms, improving oesophageal acid exposure and healing of esophagitis, it is also able to improve hiatus hernia (Hill grading). Hunter et al and Hakanson et al reported significant improvement in the Hill grade of hiatal hernias at endoscopy after TIF procedure as high as 96% of patients from Hill grade 2 and 3 to grade 1, compared to sham group.[16,18]

The current result reinforces the outcome of two previously published systematic reviews by Wendling et al who reviewed 15 studies reporting over 550 TIF procedures.[23] There was significant reduction in GERD-HRQL score (21.9 vs. 5.9, p<0.0001) and RSI score (42.5 vs. 5.4, p<0.0001) and overall PPI discontinuation was 67%.

This systematic review has shown more evidence about the efficacy and safety of TIF compared with PPI. What author have not been able to do was to compare the relative efficacy and safety of TIF and Stretta. In literature, no randomised controlled trial has been performed to compare these two techniques. Despite the quality of evidence shown in this systematic review, it bears a few limitations. The total sample size of 397 (Stretta n=101, TIF n=296) is small and this could introduce type 2 error into the study results. Obese patients were excluded from the trial however since obesity is a potent risk factors of GORD and is on the rise in recent years, it would have been interesting to include studies involving patients with high BMI.

CONCLUSION

Author conclude that both Stretta and TIF can fill the therapy gap between PPI medication and laparoscopic fundoplication. Both methods are relatively safe and well tolerated however, based on the evidence author have provided, author can speculate that TIF could be superior to Stretta as endoluminal method of treatment of chronic GORD.

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