


Laparoscopic fundoplication performed in community hospital settings

A protocol for systematic review

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Abstract

Background: Laparoscopic fundoplication (LF) is well-established as the surgical intervention of choice for management of refractory gastro-esophageal reflux disease. Much of its success lies in the reported benefits in symptom control outlined by the postoperative patient. It is unclear whether patient-reported outcomes differ according to the institution type providing care. This review aimed to address this knowledge gap by reviewing the available evidence examining patient-reported outcomes of LF in non-metropolitan centers.

Objectives: To investigate patient-reported outcomes of LF performed in regional or community-based hospitals.

Data sources: Four electronic databases, and citations of relevant articles.

Study eligibility criteria: Only studies that separately reported patient-reported outcomes of LF performed in regional or community hospitals were included; papers deemed to be unclear about the type of facility in which LF surgeries were performed, or in which data from LF surgeries performed in regional/community hospitals was combined with data from major metropolitan hospitals, were excluded.

Study appraisal: Only studies that were graded as fair or good using Quality Assessment Tool for Observational Cohort and Cross-sectional studies were eligible for inclusion in this review. Seven studies were then eligible for inclusion, all of which were observational cohort studies with 6 of the studies reporting on a single intervention arm.

Results: Seven observational cohort studies were included in the review, with a combined total of 1071 patients who underwent LF at non-metropolitan centers. Of these, data was collected for 742 patients, yielding an overall response rate of 69.3%. All 7 studies assessed patients' post-operative outcomes through questionnaires that were based on a modified Likert scale or a similar tool. Overall patient satisfaction was high (86%) and a significant majority of patients stated they would recommend the procedure to others (93.3%). Post-operative prevalence of reflux and dysphagia compared favorably to rates generally reported in the literature (11.9% and 17.6% respectively). Further research is required to ascertain the safety of performing these procedures in non-metropolitan hospitals.

Conclusion: Current evidence suggests that patient-reported outcomes are favorable for patients undergoing LF in community settings, and are broadly comparable to those undergoing LF in tertiary-level centers.

Abbreviations: GORD = gastro-esophageal reflux disease, LF = laparoscopic fundoplication, SIGN = Scottish intercollegiate guidelines network.

Keywords: community hospital, hiatal hernia repair, laparoscopic fundoplication, regional hospital

1. Introduction

The Montreal consensus defines gastro-esophageal reflux disease (GORD) as “a condition which develops when the reflux of stomach contents causes troublesome symptoms and/or complications.”^[1] Symptoms are classified as troublesome if they

negatively impact patients' quality of life and well-being.^[2] The prevalence of GORD in western countries is approximately 20%, indicating a large burden of disease.^[3]

Management of GORD differs from patient to patient according to their symptom profile. Lifestyle modifications and pharmacological interventions form the basis of initial

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treatment.^[4,5] Patients with refractory gastro-intestinal symptoms or atypical symptoms (such as chest pain, cough, hoarse voice, asthma, bloating and diarrhea) may benefit from operative management.^[4] Surgical intervention with laparoscopic fundoplication (LF) is a well-established management option, with a body of research spanning more than 25 years supporting its efficacy.^[4,5]

Although a large number of studies have examined LF in the setting of GORD management, with the majority focusing on patient-reported outcomes, most of this research has been undertaken in tertiary-level hospitals. These facilities are seen as setting the benchmark for LF due to their higher volume of cases and well-established capacity for undertaking major upper gastrointestinal surgical procedures.^[6,7] However, many regional and non-metropolitan centers also offer LF. There is evidence to suggest that non-metropolitan service provision is currently in the midst of a surge, with Colavita et al reporting a steady increase in the number of LF surgeries performed in regional and community hospitals.^[8] A key reason for this increase may be that patients from areas with populations of less than 2,50,000 are more likely to undergo LF within their own community, indicating a preference for utilizing local services.^[8]

Despite the significant body of literature regarding the role of LF in the management of GORD, there has been no systematic review published to date on the performance of LF within non-metropolitan hospital settings. We aim to address this gap by systematically reviewing the available literature concerning the efficacy of LF performed in regional or community-based hospitals, focusing on patient-reported outcomes. Given that we have chosen to conduct a systematic review, ethics approval was deemed unnecessary.

2. Methods

2.1. Literature search strategy

This systematic review was performed according to the preferred reporting items for systematic reviews and meta-analyses statement.^[9] To be eligible for inclusion, studies had to meet the population, intervention, control, outcomes, and study length criteria outlined in Table 1. There were no restrictions placed on participant age. Only primary research studies published in peer-reviewed journals were eligible for inclusion and reviews, case reports, conference abstracts, and case series including less than 10 patients were ineligible.

A literature search was performed in MEDLINE (1966 to January 2020), EMBASE (January 1974 to January 2020), PubMed, and The Cochrane Library (1996 to January 2020) using combinations of the following medical subject headings terms; *anti-reflux surgery*; *hiatal hernia repair* “AND” *regional hospital*; *community hospital*; or *hospital/low-volume*. Studies were restricted to those published in English from years 2000 to 2020. There were no further restrictions placed. Reference lists from relevant articles were hand searched for additional potentially relevant studies. The literature search was performed

by N.F., with the most recent search undertaken on the 6th of February, 2021. As all information gathered for the systematic review remains available in the public domain and is completely anonymized as such, ethics approval was not required nor sought for this project.

2.2. Study selection

Study evaluation was performed by 2 reviewers (N.F. and A.G.). Studies were entered into an electronic management system and duplicates removed. All identified studies were screened firstly by title, and then, if potentially eligible, by abstract. The full text of all studies deemed potentially eligible on abstract screening was thoroughly reviewed. Studies from which a decision could not be made based upon the abstract were also reviewed. Only studies that separately reported patient-reported outcomes of LF performed in regional or community hospitals were included; papers deemed to be unclear about the type of facility in which LF surgeries were performed, or in which data from LF surgeries performed in regional/community hospitals was combined with data from major metropolitan hospitals, were excluded. When multiple publications reporting on identical or overlapping study populations were identified, only the most complete or recent publication was included.

The quality of papers was assessed using the previously validated Quality Assessment Tool for Observational Cohort and Cross-sectional Studies.^[10] Based on these guidelines, the overall quality of each study was rated as being good, fair or poor. Only studies that were graded as fair or good were eligible for inclusion in this review. Risk of bias was assessed for all studies using the Scottish intercollegiate guidelines network (SIGN) checklist.^[11] Only studies that were ranked as low or acceptable risk of bias were included.

2.3. Data extraction

Data from included studies were extracted independently by 2 reviewers (N.F. and A.G.) using a preformed data extraction tool. Intervention data collected included pre-operative investigations and results as well as a description of the operative technique. There were 3 main categories of data collected for postoperative patient-reported outcomes, and these comprised the primary summary measures for this review. These categories were: post-operative symptoms, such as dysphagia and reflux, and use of anti-secretory medications; level of patient satisfaction; and whether patients would recommend the procedure to others. Discrepancies were resolved by consensus. Given that the majority of studies selected were retrospective observational studies, the SIGN checklist for case-control and cohort studies was used to assess each study's risk of bias.^[12] Studies were ranked as being high quality, acceptable or unacceptable on the basis of criteria addressing selection bias, detection bias and attrition bias. Owing to the heterogeneity present amongst the selected studies, a meta-analysis could not be performed. Furthermore, the current work was a systematic review so ethical approval was not necessary.

3. Results

3.1. Study selection

219 titles were initially identified, of which 39 were selected for abstract review (Fig. 1). Of the 11 articles selected for full text review, 4 were excluded, all due to not meeting the population, intervention, control, outcomes, and study length eligibility criteria. The Quality Assessment Tool for Observational Cohort and Cross-sectional Studies was applied to all articles selected for inclusion in this review^[10]; no articles were excluded on the basis of being poor quality. Risk of bias was assessed for all

Table 1

PICOS restrictions for study selection.

PICOS	Restrictions
Population	Patients in regional or community hospitals i.e., low volume settings
Intervention	Laparoscopic fundoplication
Control	No control or comparison group required
Outcomes	Post-operative symptoms. Efficacy of the procedure. Patient satisfaction
Study design	No restriction placed on study design

PICOS = population, intervention, control, outcomes, and study length.

studies included in final review using the SIGN checklist.^[12] All studies were ranked as either low or acceptable risk of bias and were therefore included.

3.2. Study characteristics

Seven studies were eligible for inclusion, all of which were observational cohort studies with 6 of the studies reporting on a single intervention arm. Two studies, Hwang (2012)^[13] and Ranson et al (2007)^[14] were prospective, and the remaining 5 were retrospective. Sandbu et al (2009) was the only study to compare outcomes of patients undergoing LF in regional centers to those undergoing LF in metropolitan centers.^[15]

Of the combined total of 1071 patients who underwent LF in low volume settings, data was collected for 742 patients,

yielding an overall response rate of 69.3%. Response rates ranged from 44% to 98% across the studies. Follow-up periods ranged from 4 to 120 months amongst the 7 studies. Baseline characteristics extracted from included studies are presented in Table 2.

All 7 studies assessed patients' post-operative outcomes through questionnaires that were based on a modified Likert scale or a similar tool. Responses from the Likert scales were then converted into binary outcomes for analysis. Results from individual studies are presented in Table 3.

All 7 studies reported on typical GORD symptoms, namely heartburn, reflux and dysphagia. Pooled results from the included studies are presented in Table 4. Three studies reported on atypical symptoms such as bloating, chest pain, coughing, hoarse voice, asthma, nausea, and diarrhea.^[14-16]

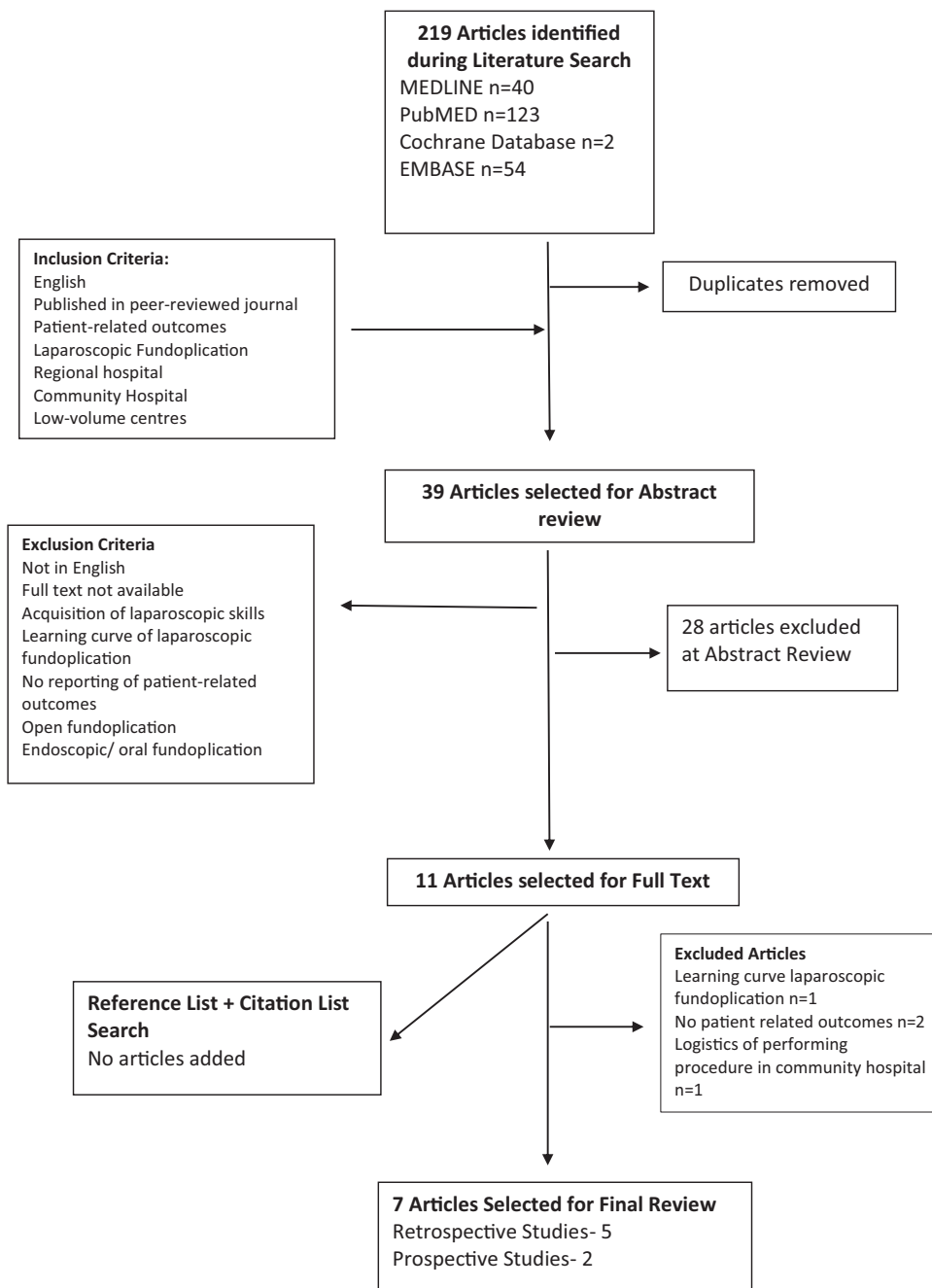


Figure 1. Flowchart of article selection.

Table 2**Baseline characteristics extracted from the included studies.**

Baseline characteristics	Number
Total number of patients eligible to participate in the included studies	1071
Total patients included in studies	742
Male	427
Female	487
Gender not reported	157
Overall response rate	69.3%
Median age of patients	51.8 yr
Median follow-up period	53 mo
Study design	
Retrospective cohort study	5
Prospective cohort study	2

3.3. Post-operative symptoms

All studies except for Neuoven et al (2014) reported the prevalence of reflux post-operatively.^[17] Estimates ranged from 5% to 20.4%, with a pooled prevalence of 11.9%.^[13–16,18,19]

Six studies reported the prevalence of dysphagia post-operatively, with estimates ranging from 2 to 37%.^[13–16,18,19] The pooled prevalence of dysphagia (of any severity) postoperatively was 17.6%. The 2% prevalence of dysphagia postoperatively reported by Althar et al (1999) was substantially lower than in the other 5 studies reporting this outcome.^[19] In all 6 studies that reported both outcomes (reflux and dysphagia), the post-operative prevalence of dysphagia was higher than that of reflux.^[13–16,18,19]

Five studies reported on the prevalence of anti-secretory medication use post-operatively, which ranged from 6.7% to 48%, with a pooled prevalence of 23.5%.^[13,15–18] None of the studies distinguished between different classes of anti-secretory medication.

Three studies investigated the prevalence of atypical symptoms in the post-operative period.^[14–16] These include gas-bloat syndrome, chest pain, sore throat, nausea and diarrhea. Ranson (2007) reported on the difference between the pre- and post-operative prevalence of chest pain, cough, hoarseness, sore throat, asthma, nausea, bloating and diarrhea following LF and found that the prevalence of all symptoms decreased post-operatively, including a 31% decrease in

Table 3**Data extraction tool.**

Study	Population characteristics	Pre-operative investigations	Operation	Follow-up period	Post-operative outcomes	Implication
Tucker et al 2005 USA[19]	n = 119 (76% response rate) Mean age = not reported Male = not reported Female = not reported	Gastroscopy, + esophageal motility +/- pH measurements	Description provided	17–104 mo	Reflux – 5% Dysphagia – 37% Meds – 48.7% Satisfaction – 73.2% Recommend procedure – 88%	In terms of patient satisfaction, laparoscopic fundoplication is an acceptable alternative to long-term medical therapy.
Neuonen et al 2014 Finland[18]	n = 64 (59.8% response rate) Mean age 61.9 yr Male = 40 Female = 26	Gastroscopy + 24 hr pH monitoring OR Oesophageal manometry	No description provided	10 yr	Reflux – not reported Dysphagia – not reported Meds – 36% Satisfaction – 82.8% Recommend procedure – not reported	Using quality of life measures suggest that fundoplication can be subjectively successful even 10 years post-op. Suggest further direction of research such as prospective, randomized trial with long term follow-up in terms of quality of life measures
Althar 1999 USA[20]	n = 98 (98% response rate) Mean age 48.8 yr Male = 30 Female = 70	Gastroscopy + Oesophageal manometry + 24 pH monitoring	Description provided	4–33 mo	Reflux – 18% Dysphagia – 2% Meds – not provided Satisfaction – 98% Recommend procedure – 99%	Results suggest high patient satisfaction. There was no long term dysphagia suggesting that laparoscopic fundoplication is safe and effective when performed in a community hospital setting.
Prassas et al 2017 Germany[17]	n = 166 (44% response rate; high lost to follow-up rate) Mean age 51.8 yr Male = 153 Female = 223	Gastroscopy + esophageal manometry + barium meal + CXR	Description provided	8.8 yr	Reflux – 20.4% Dysphagia – 18.7% Meds – 22.9% Satisfaction – 85% Recommend procedure – not reported	Highlights the need to assess the long-term efficacy of laparoscopic fundoplication especially in terms of safety, symptoms and patient quality of life in low volume/regional setting.
Ranson 2007 USA[14]	n = 69 (75.8% response rate) Mean age 46.8 yrs Male = 35 Female = 46	Gastroscopy ± esophageal manometry ± pH monitoring	Description provided	2 yr	Reflux – 9% Dysphagia – 33% Meds – not reported Satisfaction – 98% Recommend procedure – not reported	Data from long term follow-up from 24–46 mo, suggests durability of patient satisfaction with on-going significant improvement in both typical and atypical symptoms.
Hwang 2012 Canada[13]	n = 26 pre-op n = 18 post-op (94% response rate) Mean age 50.6 yr Male = 9 Female = 17	Gastroscopy ± barium oesophagogram ± esophageal manometry + pH monitoring	No description provided	21 mo	Reflux – 7.7% Dysphagia – 3.8% Meds – 7.7% Satisfaction – 58% Recommend procedure – not reported	Out of 342 patients referred during the study period for laparoscopic fundoplication only 26 underwent fundoplication with good post-operative outcomes. Rates for post-operative symptoms are lower than those reported in literature suggesting good outcomes with stringent patient selection.
Sandbu et al 2009 Sweden[15]	n = 208 (97% response rate) Mean age 51.5 yr Male = 133 Female = 81	Not provided	No description provided	Median follow-up 4 yr	Reflux – 6.8% Dysphagia – 9.1% Meds – 6.7% Satisfaction – 86.1% Recommend procedure – 90%	In comparison with patient-related post-operative outcomes, low volume centers had higher rates of successful procedures. This suggests that volume is not indicative of patient outcomes.

Table 4**Combination of post-operative outcomes from included studies.**

Post-operative Outcomes	Reported pool	Not reported	Number of patients	Percentage
Symptoms				
Reflux	678	64	81	11.9
Dysphagia	678	64	119	17.6
Anti-secretory medication	575	167	135	23.5
Overall satisfaction	742	0	638	86
Recommend procedure	417	325	389	93.3

bloating and 50% decrease in diarrhea.^[14] Prassas et al (2017) reported an increase in gas-bloating syndrome with 61.4% of patients reporting bloating post-operatively.^[16] Sandbu et al (2002) reported a similar prevalence of gas-bloat (53.8%) post-operatively.^[15]

3.4. Overall satisfaction

All studies included in this review measured overall patient satisfaction following LF, with the proportion of patients satisfied ranging from 58% to 98%.^[13-19] The pooled overall proportion satisfied was 86%. Most studies reported patient satisfaction of greater than 75%, with only Hwang (2012) reporting a proportion (58%) which was substantially lower than the other included studies.^[13] Only Sandbu et al (2002) asked patients to comment on reasons for dissatisfaction, the most common of which were side-effects (34.5%), relapse (31%) and lack of improvement of pre-operative symptoms (20.1%).^[15]

3.5. Recommendation of procedure

Three studies reported on whether patients would recommend LF to their friends and family, with estimates ranging from 88% to 99% of patients who agreed that they would recommend the procedure.^[15,18,19] Of the combined total of 417 patients in these studies that were asked whether they would recommend the procedure, 389 (93.3%) agreed.^[15,18,19]

4. Discussion

This systematic review identified 7 studies reporting on patient-related outcomes after LF performed in regional centers. These studies reported postoperative symptom prevalence estimates ranging from 5% to 20.4% for reflux,^[13-16,18,19] 2% to 37% for dysphagia^[13-16,18,19] and 6.7% to 48% for use of antisecretory medications^[13,15-18] Patient satisfaction estimates ranged from 58% to 98%^[13-19] and 88% to 99% of patients stated that they would recommend the procedure to their friends and family.^[15,18,19]

Our finding of post-operative reflux, with prevalence estimates ranging from 5 to 20.4%, following LF performed in regional centers is comparable to studies reporting on patient outcomes for LF in metropolitan centers. For example, Dassinger et al (2004) reported that 12% of patients experienced post-operative reflux.^[20] Long-term studies in tertiary centers such as Robinson et al (2014) and Campanello et al (2019) found rates of post-operative reflux of 19.6% and 26% respectively with patients followed-up for up to 20 years following LF^[21,22]

Dysphagia is common in the early post-operative period and has been reported to affect nearly half of all LF patients. This is most likely due to mucosal edema or hematoma associated

with the wrap itself. The pooled prevalence of post-operative dysphagia of 17.6% found in our study is similar to results reported from high volume centers with Dassinger et al (2004) and Contini et al (2002) both reporting a post-operative dysphagia prevalence of 16%.^[20,23]

It is noteworthy that the pooled prevalence of post-operative dysphagia in this review was higher than that of reflux. In many ways this is an expected relationship, as if the general trend was to perform the fundoplication more tightly, then it would be expected that the rates of dysphagia from this would increase, whilst the rates of reflux would proportionally drop. Adding to this trend however, may be the fact multiple included studies included both intermittent dysphagia with daily symptoms under a single banner, but reflux severity and frequency was not assessed, therefore potentially leading to a higher reported rate of dysphagia.^[13-16,18,19]

Studies included in this review reported post-operative anti-secretory medication use prevalence estimates ranging from 6.7% to 48%.^[13,15-18] The prevalence of post-operative anti-secretory medication use is also notably higher than the prevalence of reflux. Although this might seem unusual, other studies have also reported a relatively high prevalence of anti-secretory medication use post-operatively. Campanello et al (2019) reported that 32% of patients were using medication at 20 years post LF^[22] whereas Dassinger et al (2004) reported a rate of 21%.^[20] This wide range is also seen across the literature with Luketich et al (2000) reporting a prevalence of 10%^[24] whereas Robertson et al (2015) reported a prevalence of 48% of patients.^[25] It is reasonable to surmise that the use of anti-secretory medication does not correlate directly with symptoms of post-operative reflux and may in fact be masking the true prevalence of post-operative reflux. Furthermore, the wide range is likely a reflection of the subjective nature of reflux pain, with symptomatology often not correlating well to either physiological testing scores or endoscopic findings.

Importantly, the use of antisecretory medication, presence of post-operative reflux and dysphagia does not necessarily equate to overall patient dissatisfaction. The pooled overall satisfaction rate in our study was 86% with most studies reporting a satisfaction rate greater than 75%.^[13-19] Long term studies from metropolitan centers reported comparable satisfaction. Dassinger et al (2004) and Robinson et al (2015) reported that greater than 90% of patient were satisfied.^[20,21] Campanello et al (2019) found that 84% of patients would recommend the procedure with data collected 20 years postoperatively.^[22]

A component of LF that is difficult to conceptualize is how patient selection affects outcomes. Although we were not able to fully develop a framework for how patient selection influenced outcomes across our review, a stringent patient selection process was highlighted by Hwang (2012).^[13] Sandbu et al (2002) also commented on the need for restricted patient selection in low-volume centers particularly if facilities for specialization and high care are not available.^[15] Although there is a suggestion that community hospitals may be required to have a more restricted patient selection process overall, ultimately there is insufficient data to effectively answer this question. Future research in this area needs to consider patient selection in the overall assessment of LF being performed in regional settings. In-depth exploration on the implications of the learning curve in performing LF in regional areas is another component that would benefit from further research.

Whilst the studies included commented on the pre-operative investigations and the majority provided a description of the operation, analysis of these factors was beyond the scope of this review. As such, there can be no comparison made between the different types of LF and patient-related post-operative outcomes. This may be a area for further research in either regional or metropolitan settings.

The empirical results discussed in this review should be viewed in light of certain limitations. Owing to the heterogeneity in study design, definition and measurement of outcomes, including the variability in the questionnaires utilized, results were pooled in this study with prevalence estimates made for outcome measures based on ranges reported in individual studies. Performing crude unweighted pooling of results in this study is a statistical limitation and highlights a need for further research in this area. In addition, there is risk of publication bias in this study as only 7 studies were identified on reporting patient related outcomes for LF performed in non-metropolitan centers. In order to counteract this risk of bias, both published studies and gray literature was searched.

5. Conclusion

A total of 7 studies provided data on post-operative patient-related outcomes for LF performed in non-metropolitan settings and were included in this systematic review. Pooled data suggests favorable outcomes for patients in community settings with a high rate of patient satisfaction and comparable rates of post-operative symptoms such as reflux and dysphagia, and use of anti-secretory medication. Further research into the safety and objectively-measured efficacy of performing these procedures in community hospitals is required. Further research into patient selection for LF in these centers would also be of benefit.

Author contributions

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