

# ONE-YEAR RESOURCE USE FOR MEDICATION REFRACTORY GASTROESOPHAGEAL REFLUX DISEASE PATIENTS TREATED WITH LAPROSCOPIC NISSEN FUNDOPLICATION OR LINX REFLUX MANAGEMENT SYSTEM: A SURVEY OF 99 U.S. CLINICIANS

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## Introduction

- In the U.S., the prevalence of gastroesophageal reflux disease (GERD) ranges from 18-27% with an annual economic burden of \$15-20 billion.<sup>1,2</sup>
- Patients with persistent and intense symptoms of GERD (i.e. refractory GERD) experience a decreased health-related quality of life (HRQL), lower productivity at work and in daily activities, and higher healthcare and employer costs.<sup>3</sup>
- Treatment of medication-refractory GERD may involve surgery with laparoscopic Nissen fundoplication (LNF), a non-reversible procedure with adverse side-effects, including gas-bloat syndrome, dysphagia, diarrhea, and recurrent heartburn.<sup>4</sup>
- Technologies such as the LINX Reflux Management System which uses magnetic sphincter augmentation (LINX) have emerged with demonstrated clinical benefits, however, treatment patterns and healthcare resource use data are limited.<sup>5-10</sup>

## Objective

- A clinician survey sought to assess treatment patterns and healthcare resource use associated with LINX, and how this compares to LNF over a 1-year time period.

## Methods

- A survey was developed to capture resource use with LINX and LNF including: procedure utilization/setting, diagnostic tests, consumables, drugs, lab tests, readmissions, reoperations, and follow-up visits.
- Survey development utilized published literature and input from 2 key opinion leaders (i.e., U.S. one gastroenterologists (GI) and one surgeon that have experience with GERD procedures).
- After development, a larger sample of GI and surgeon candidates were recruited through large physician and surgeon databases to identify qualified respondents.
- Screening questions were asked of potential participants to ensure that they had appropriate qualifications and experience to answer survey questions.
- Inclusion for surgeons required:
  - Performed 12+ GERD surgeries in the past 6 months
  - Performed 5+ LINX procedures in the past 6 months
- Inclusion for GI required:
  - Treated/managed 250+ GERD patients in previous year
  - Referred 30+ GERD patients to a surgeon for GERD surgery
  - Performed or managed diagnostic work-ups of patients referred for GERD surgery
- Administration of the survey was conducted via an online survey instrument.
- Following completion of the survey, participants were asked a series of questions on demographics, the size/setting of the institution at which they practice, and their involvement in purchasing decisions and evaluation of new technologies.
- Survey questions asked of participants are summarized in **Table 1**.

**Table 1. Clinician survey questionnaire.**

Utilization of LINX and LNF in medication-refractory, mechanical GERD patients	
1.	A) Currently what percentage of your GERD surgical cases are performed as LINX, LNF, or other procedures? B) Currently, what percentage of your procedures for medication-refractory, mechanical GERD patients receiving LINX or LNF are being billed for Medicare as inpatient vs. outpatient procedures?
2.	A) What do you predict will be the percentage breakdown of your GERD surgical cases in 3 years? B) In 3 years, what percentage of your procedures for medication-refractory, mechanical GERD patients receiving LINX or LNF would you anticipate being billed for Medicare as inpatient vs. outpatient procedures?
Diagnostic tests prior to surgery	
3.	A) What percentage of your LNF patients require the following diagnostic tests prior to the procedure? B) Would you expect the percentage of your patients requiring diagnostic tests prior to the procedure to be different for LINX vs. LNF patients? C) What percentage of your LINX patients require the following diagnostic tests prior to the procedure?
Intra-operative consumables	
4.	Aside from the LINX device itself, please indicate if the type and quantity of consumables (e.g., sponges, swabs, dressings) used in a LINX procedure is more than, less than or the same amount used during a LNF procedure.
Intra- and post-operative resources	
5.	In your experience, what is the average amount of time a patient would spend under anesthesia for a LINX or LNF procedure?
6.	Please indicate if the type and dosage of intra-operative drugs used during an average LINX procedure is higher than, lower than or the same as the dosage used during an LNF procedure.
7.	Please indicate if the type and dosage of post-operative drugs used following a LINX procedure, during the hospitalization period on a per-day basis, is higher than, lower than or the same as the dosage following an LNF procedure.
8.	During the post-operative hospitalization period, how many of each of the following laboratory tests and/or procedure work-ups are completed per hospital day for a patient after a typical GERD-related surgical procedure (i.e. LINX or LNF)?
Reoperations	
9.	What proportion of reoperations after a LINX procedure are for device removals vs. revisions?
Readmissions	
10.	Based on your experience, what would you estimate the 90-day and one-year readmission rates to be for LINX and LNF procedures?
11.	For readmissions that occur within 30-days or 90-days post- LINX or LNF procedures, do providers typically receive a separate reimbursement payment, or is this cost absorbed by hospitals through the index procedure payment?
12.	Considering the overlap between reoperations and readmissions, what would you estimate is the proportion of 90-day and one-year readmissions that are due to reoperations only for each procedure?
13.	When considering readmissions that are not reoperations, what length of hospital stay (in hours) is appropriate for a typical patient readmission for LINX or LNF procedures?
Healthcare Visits	
14.	Based on your experience, what are the estimated number of physician office, hospital outpatient, and emergency room visits for LINX patients in first year post-procedure?
15.	Are you typically involved with the management of patients' one-year post-operative follow-up?
16.	Please estimate the percentage of LINX and LNF patients who receive procedures and tests, apart from diagnosis, up to one-year post-procedure.

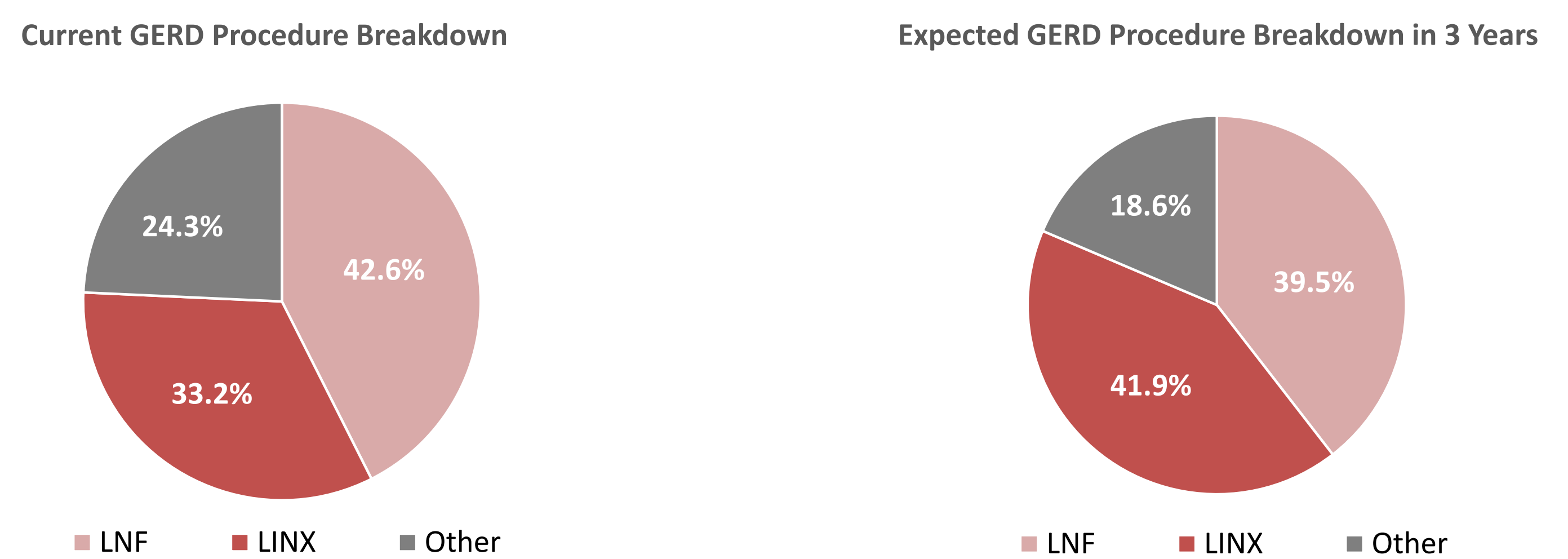
## Results

- In total, 99 clinicians completed the survey (50 GIs and 49 surgeons).

### Current and Future Usage of LINX and LNF

- Surgeons anticipate the usage of LINX to increase by 8.7% over the next three years, whereas LNF and other surgical procedures will decrease by 3.1% and 5.7%, respectively (**Figure 1**).
- Respondents indicated they anticipated a shift from inpatient procedures to outpatient over the next 3 years, with LINX driving a larger proportion of this shift compared to LNF.

**Figure 1. Clinicians reported increased use of LINX in the future compared to current practice.**



### Diagnostic Testing Prior to the Procedure

- Overall, the type of GERD procedure (LNF or LINX) was anticipated to have very little impact, if any, on the diagnostic tests required by GIs or surgeons prior to surgery.
- For both procedures, GIs reported a significantly higher portion of EGD tests than surgeons and surgeons reported a significantly higher proportion of esophagrams than GIs.

### Surgical Consumable Use

- Surgeons reported using each consumable during LINX and LNF procedures (range 83% to 96%).
- In most cases, consumables used during LINX procedures was thought to be similar to less than LNF (**Figure 2**) with the relative reduction in consumables being approximately half that of LNF (range 47%-64%).

### Intra- and Post-Operative Hospital Resource Use

- LINX patients are under anesthesia for less time than LNF (66 min vs. 86 min, respectively).
- Surgeons reported using each type of intra-operative drug during LINX and LNF procedures (range 90% to 100%).
- Surgeons reported similar or less intra-operative drugs used with LINX vs. LNF procedures (**Figure 3**), with the relative reduction in intra-operative drugs with LINX ranging from 25%-37%.
- Surgeons reported using each type of post-operative drug during LINX and LNF procedures (range 88% to 100%).
- Surgeons reported similar or less post-operative drugs used after LINX vs. LNF procedures (**Figure 4**), with the relative reduction in post-operative drugs with LINX ranging from 35%-37%.
- After a LINX or LNF procedure, most tests are anticipated to be given once daily: basic metabolic panel (1.4), comprehensive metabolic panel (1.1), chest X-rays (0.9), esophagrams (0.8), and electrocardiograms (0.8).

### Readmissions and Reoperations

- Both surgeons and GIs anticipate 90-day and 1-year readmission rates to be lower for LINX than LNF (**Figure 5**).
- For readmissions that do not involve reoperations, both groups anticipated the length of hospital stay would be shorter with LINX vs. LNF (28.2 hrs vs. 34.5 hrs, respectively).
- For readmissions that would be due to reoperations:
  - Surgeons reported a smaller proportion of readmissions would be due to reoperations, with LINX vs. LNF at 90-days. GIs did not report this difference.
  - At 1-year, both groups anticipated the proportion of readmissions due to reoperations would equal for both LINX and LNF.
- When a reoperation following a LINX procedure is required, roughly 2/5 for device removal, while the remaining are revisions.
- Both GIs and surgeons anticipated reductions in readmissions would help hospitals reduce costs. Most hospitals absorb the costs of LINX and LNF readmissions if they occur within 30-days. At 90-days most readmissions were reported to receive a separate payment.

### Healthcare Resources Over 1 Year

- GIs and surgeons anticipated use of LINX would be associated with fewer physician office and hospital outpatient visits and more emergency room visits vs. LNF or medication only patients (**Table 2**).
- Visits for LNF and medication only patients were informed by the literature.<sup>11</sup>
- Surgeons reported significantly higher of physician office and hospital outpatient visits after LINX compared to GIs.

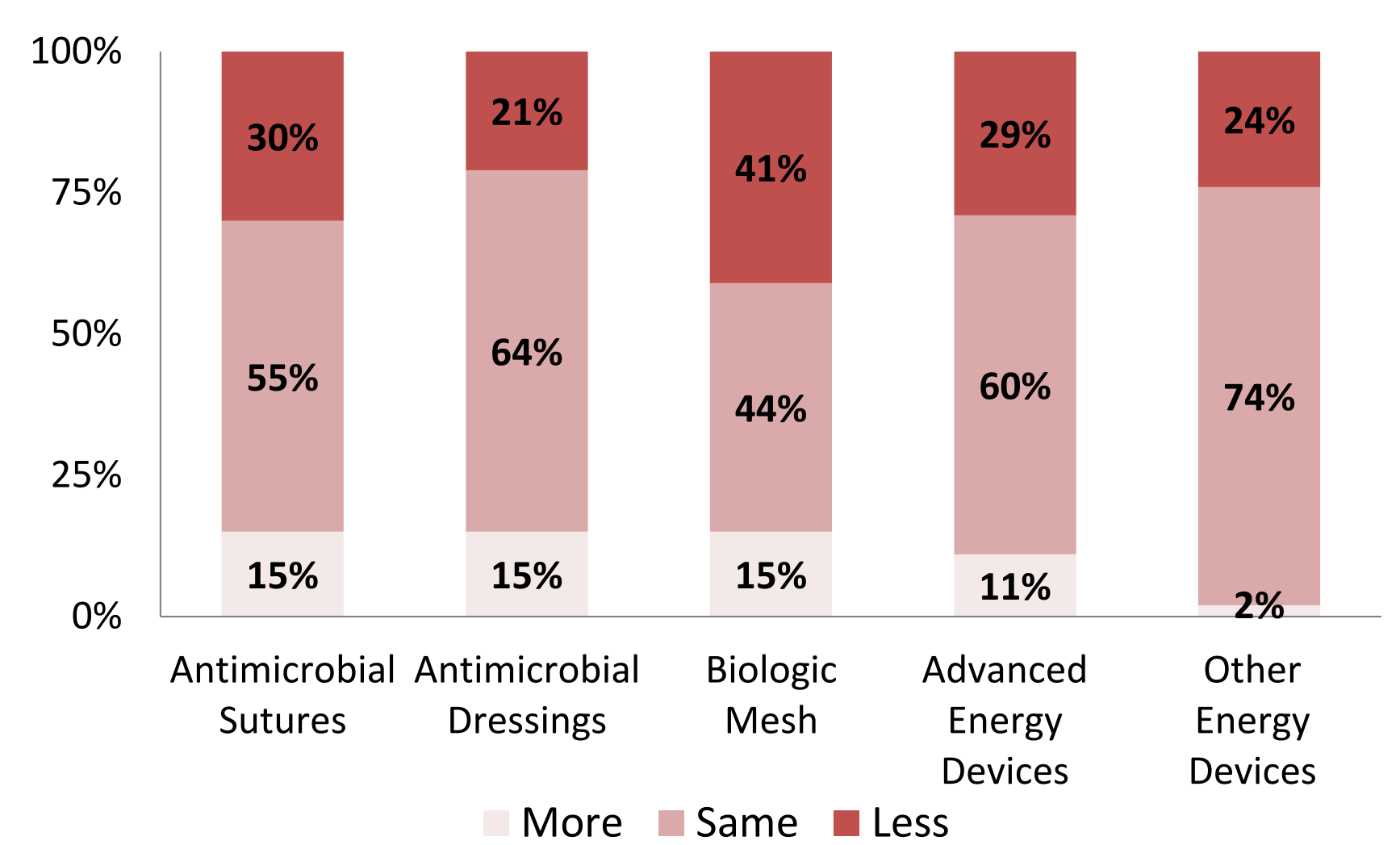
## Conclusions

- Both surgeons and GIs anticipate the treatment of medication refractory GERD patients with LINX to result in reduced overall healthcare resource use compared to LNF.
- Use of LINX was anticipated to have the largest benefit on longer term healthcare resources, including lower readmissions and physician/outpatient visits, and similar or slight reductions in procedural resources compared to LNF.
- These findings may have important economic implications for the healthcare system given the costs associated with the various resources captured.
- Further study using real-world data is warranted to help confirm the findings of this study.

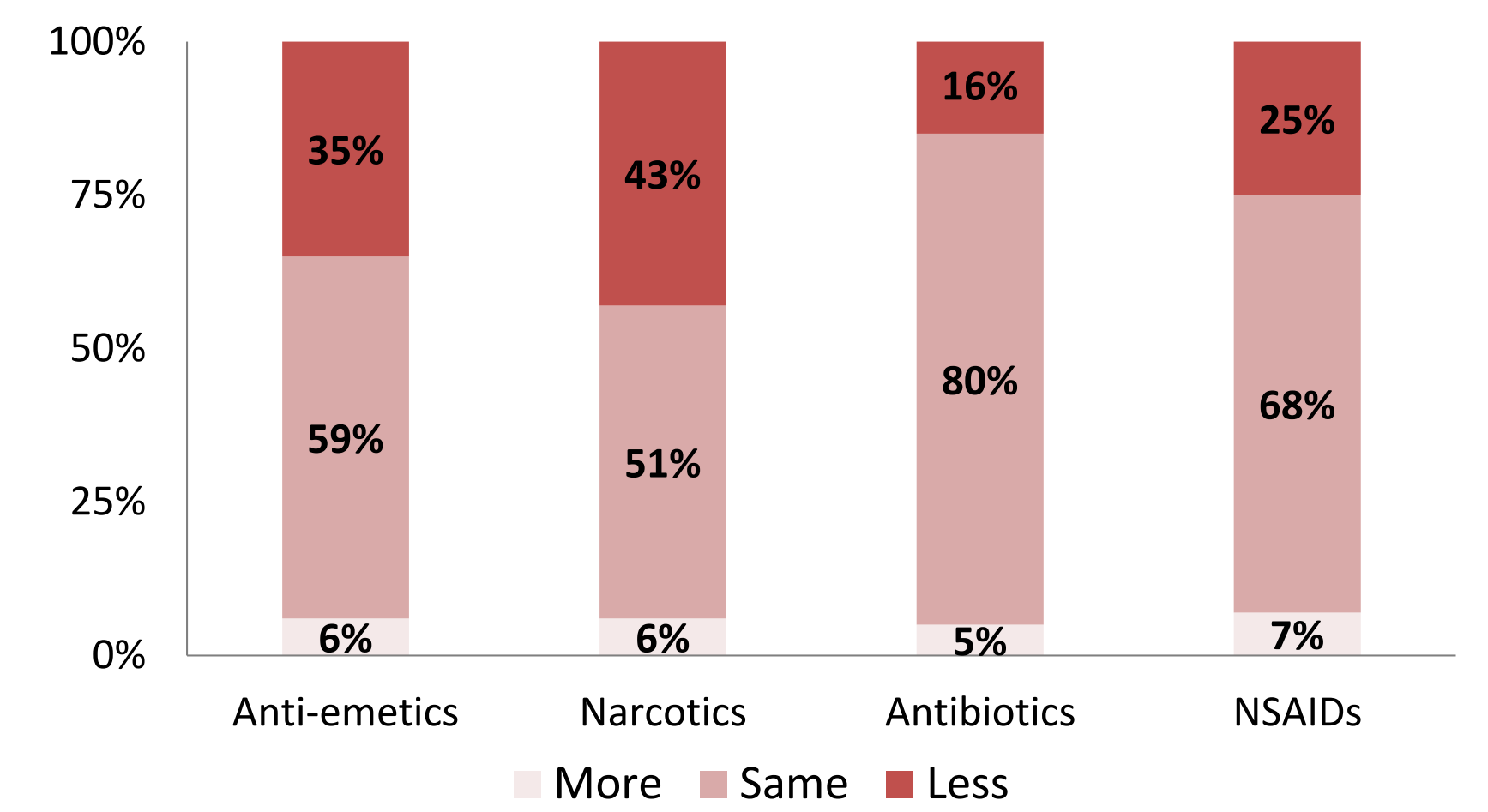
## References

- Gawron AJ, French DD, Pandolfino JE, Howden CW (2014) Economic evaluations of gastroesophageal reflux disease medical management. *Pharmacoeconomics* 32 (8): 745-758.
- El-Serag HB, Sweet S, Winchester CC, Dent J (2013) Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut* 62(12):1701-1709.
- Togiani S, Johnson DA, Stalhammar N-O, Zeribib F (2011) Burden of gastro-oesophageal reflux disease in patients with persistent and intense symptoms despite proton pump inhibitor therapy. *Clinical drug investigation* 31 (10): 703-715.
- Richter JE (2013) Gastroesophageal reflux disease treatment: side effects and complications of fundoplication. *Clinical Gastroenterology and Hepatology* 11 (5): 465-471.
- Warren HF, Reynolds JL, Lipham JC, Zehetner J, Bildzukevicz NA et al. (2016) Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surgical endoscopy* 30 (8): 3289-3296.
- Reynolds JL, Zehetner J, Wu P, Shah S, Bildzukevicz N et al. (2015) Laparoscopic magnetic sphincter augmentation vs laparoscopic nissen fundoplication: a matched-pair analysis of 100 patients. *Journal of the American College of Surgeons* 221 (1): 123-128.
- Riegler M, Schoppang SF, Bonavina L, Ashton D, Horbacht T et al. (2015) Magnetic sphincter augmentation and fundoplication for GERD in clinical practice: one-year results of a multicenter, prospective observational study. *Surgical endoscopy* 29 (5): 1123-1129.
- Reynolds JL, Zehetner J, Nieh YB, Bildzukevicz N, Sandhu K et al. (2016) Charges, outcomes, and complications: a comparison of magnetic sphincter augmentation versus laparoscopic Nissen fundoplication for the treatment of GERD. *Surgical endoscopy* 30 (8): 3225-3230.
- Skubleny D, Switzer NJ, Dang J, Gill RS, Shi X et al. (2017) LINX® magnetic esophageal sphincter augmentation versus Nissen fundoplication for gastroesophageal reflux disease: a systematic review and meta-analysis. *Surgical endoscopy* 31 (8): 3078-3084.
- Chen MY, Huang DY, Wu A, Zhu YB, Zhu HP et al. (2017) Efficacy of Magnetic Sphincter Augmentation versus Nissen Fundoplication for Gastroesophageal Reflux Disease in Short Term: A Meta-Analysis. *Can J Gastroenterol Hepatol* 2017:9596342.
- Gregory D, Scotti D, Buck D, Triadaflopoulos G (2016) Budget Impact Analysis to Estimate the Cost Dynamics of Treating Refractory Gastroesophageal Reflux Disease With Radiofrequency Energy: a Payer Perspective. *Managed care (Langhorne, PA)* 25 (5): 42-50.

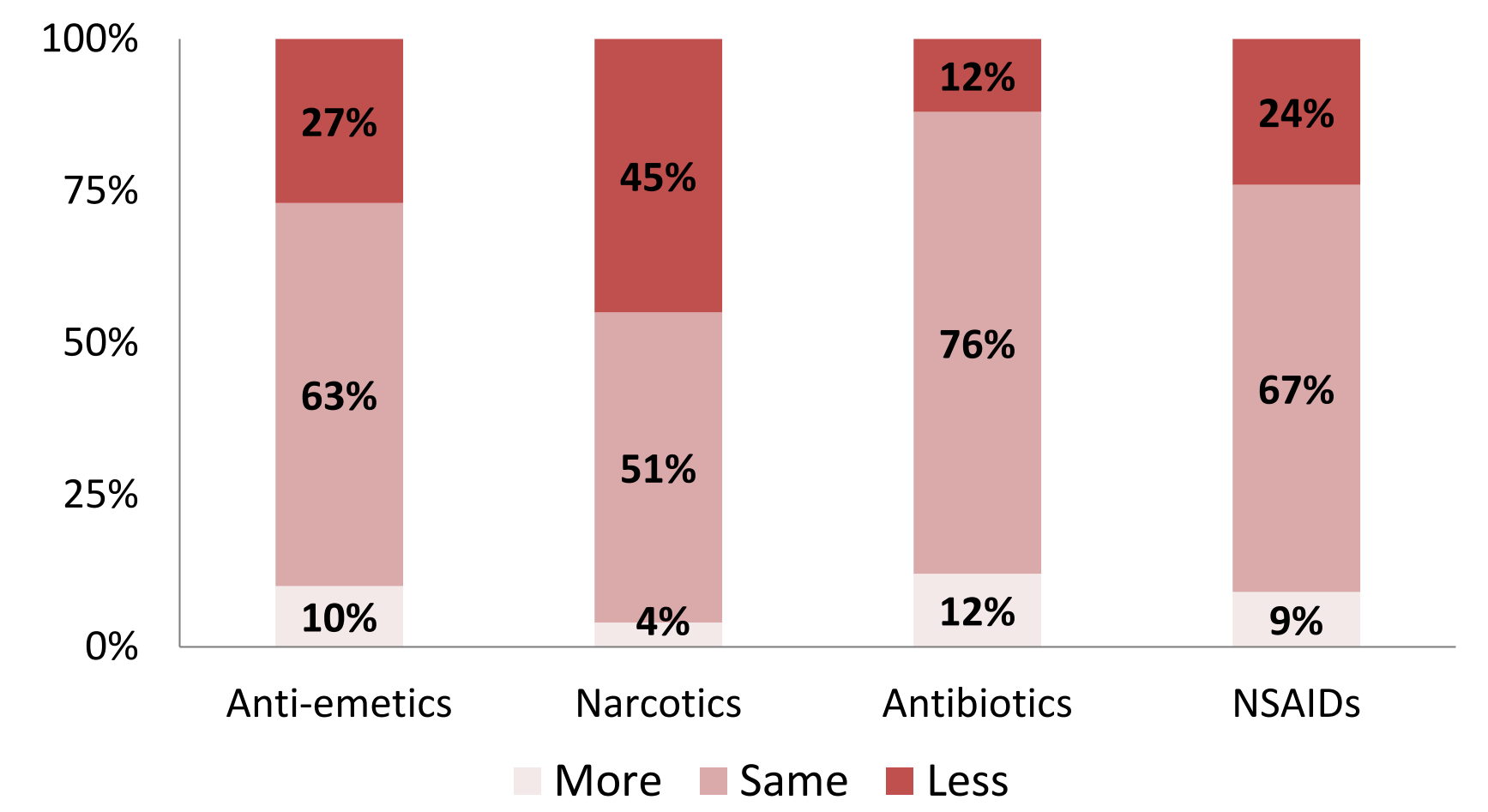
**Figure 2. Surgeons reported similar or less consumable use with LINX vs. LNF.**



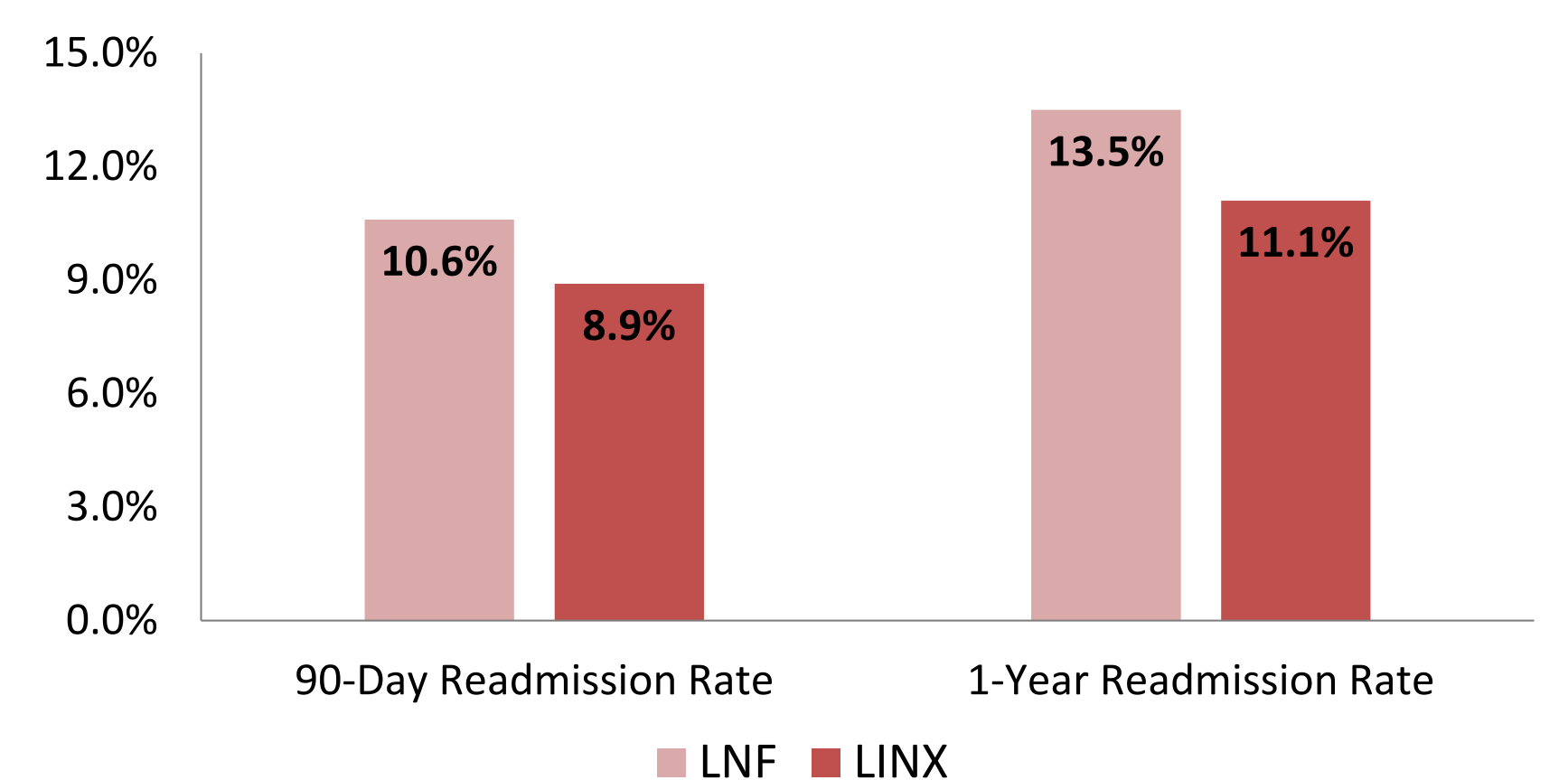
**Figure 3. Surgeons reported similar or less intra-operative drug use with LINX vs. LNF.**



**Figure 4. Surgeons reported similar or less post-operative drug use with LINX vs. LNF.**



**Figure 5. Clinicians expected lower readmission rates (excluding reoperations) with LINX vs. LNF.**



**Table 2. Clinicians expected lower healthcare visits with LINX vs. LNF and medication only over 1 year.**

	LINX	LNF <sup>11</sup>	Medication Only <sup>11</sup>
Physician's Office	4.7	7.0	8.0
Hospital Outpatient	2.1	2.5	3.4
Emergency Room	1.0	0.5	0.5