Objective Outcomes 14 Years After Laparoscopic Anterior 180-Degree Partial Versus Nissen Fundoplication

Results From a Randomized Trial

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Objective: To investigate late objective outcomes 14 years after laparoscopic anterior 180-degree partial versus Nissen fundoplication.

Background: Clinical outcomes from randomized clinical trials suggest good outcomes for anterior 180-degree partial fundoplication, with similar control of reflux symptoms and less side effects, compared with Nissen fundoplication. However, objective outcomes at late follow-up have not been reported.

Methods: A subset of participants from a randomized trial of anterior 180-degree versus Nissen fundoplication underwent stationary esophageal high-resolution manometry and ambulatory 24-hour impedance-pH monitoring at 14 years' follow-up. The subset and other patients in the trial also completed a standardized clinical questionnaire to ensure that they were representative of the overall trial.

Results: Eighteen patients (8 anterior, 10 Nissen) underwent objective testing and had a symptom profile similar to those who did not (n = 59) have testing. Total esophageal acid exposure time and the total number of acid and weakly acidic reflux episodes per 24 hours were higher after anterior fundoplication than after Nissen fundoplication. Proximal, midesophageal and distal reflux were proportionately increased after anterior 180-degree fundoplication. The number of liquid and mixed reflux episodes was also higher after anterior fundoplication, which was accompanied by higher clinical heartburn scores. There were no differences in gas reflux, gastric belches, and supragastric belches, which is in line with the observation that gas-related symptoms were similar for both groups. Mean LES resting and relaxation nadir pressure were lower after anterior fundoplication, which was reflected by lower dysphagia scores. Patient satisfaction was similar after both procedures.

Conclusions: At 14 years after randomization, this study demonstrated that acid, weakly acidic, liquid and mixed reflux episodes are more common after anterior 180-degree fundoplication than after Nissen fundoplication. On the contrary, gas reflux and gastric belching and patient satisfaction are similar for both procedures. Mean LES resting and relaxation nadir pressure are lower after anterior fundoplication. Overall, these findings suggest less effective reflux control after anterior 180-degree partial fundoplication, offset by less dysphagia, leading to a clinical outcome that is equivalent to Nissen fundoplication at late follow-up.

Keywords: anterior fundoplication, gastroesophageal reflux disease, high-resolution manometry, impedance monitoring, laparoscopic antireflux surgery, Nissen fundoplication, objective outcome, pH monitoring, randomized clinical trial

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Laparoscopic fundoplication is commonly used for the surgical treatment of gastroesophageal reflux, with Nissen fundoplication being the most frequently performed operation. However, the Nissen procedure is often followed by troublesome dysphagia and gas-related side effects.[1–3] To reduce the risk of these problems, partial fundoplications have been developed, and these modifications have been tested in randomized clinical trials.[1,4–6] In the absence of late objective outcomes, some have questioned the durability of partial fundoplications,[7–10] although longer term clinical outcomes from the trials actually support the application of anterior 180-degree and posterior 270-degree partial fundoplication techniques.[4,5,11,12] However, no randomized trial of partial versus Nissen fundoplication has reported objective outcome data at late follow-up.

Previous work has demonstrated the utility of objective monitoring of acid reflux, in addition to subjective outcomes, for the assessment of the efficacy of antireflux surgery.[13] In addition, intraluminal impedance monitoring enables quantification of both acid and weakly acidic reflux and proximal reflux events.[14]

In this study, we used high-resolution esophageal manometry combined with pH and impedance monitoring to evaluate late (14-year) objective outcomes in a subset of patients enrolled in a prospective randomized trial of anterior 180-degree partial versus Nissen fundoplication. To ensure that this subset was representative of the overall trial cohort, we assessed clinical outcomes for the whole trial cohort and compared these with the clinical outcomes in the subset who underwent objective assessment.

METHODS

From December 1995 to April 1997, 103 patients with objectively proven gastroesophageal reflux disease were enrolled in a randomized trial of laparoscopic anterior 180-degree partial versus Nissen fundoplication.[6] For this study, all patients enrolled in this trial, who had not undergone a revision operation during follow-up, were invited to complete an objective study protocol to evaluate reflux and belching after fundoplication. All patients were also asked to complete a standardized clinical questionnaire to assess reflux symptoms and postfundoplication side effects. The subset that agreed to undergo the objective tests formed the focus of this study. The outcomes for the clinical questionnaire and the objective tests were compared within this subset. To determine whether the clinical outcome in the patients who underwent the objective tests was similar to clinical

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outcomes in those who did not undergo the tests, the outcomes for the clinical questionnaire were compared for patients undergoing versus not undergoing the objective tests.

The full details of the randomized trial protocol and surgical procedures have been reported previously.[6] Six-month,[6] 5-year,[4,5] and 10-year[11] clinical outcome data have been reported elsewhere. The protocol for the original trial and this study were approved by the Royal Adelaide Hospital Human Research Ethics Committee.

Objective Study Protocol

All patients who had not undergone a revision operation during follow-up were invited to complete the objective study and the clinical symptom assessment. The objective assessment protocol was similar to the protocol described elsewhere by Bredenoord et al.[15] It was comprised of the assessment of reflux and belching using high-resolution manometry and concurrent combined esophageal impedance-pH monitoring initially after a meal and then after provocation by intragastric air inflation, followed by ambulatory assessment using 24-hour impedance monitoring.[15]

Acid-suppressing medication and medication that potentially affects gastrointestinal motility were discontinued 7 days before objective assessment. A manometry catheter was introduced transnasally and a combined impedance-pH monitoring catheter was also positioned transnasally on the basis of the manometric findings (see later). With each subject in the supine position, the manometric response to 10 standardized wet swallows (5 mL water bolus) was studied. Thereafter, subjects were positioned upright and were asked to minimize head movements to avoid axial displacement of the catheters. The subjects then consumed a standardized meal within 30 minutes that was comprised of a 274-g hamburger ("Burger King Whopper" consisting of a bun, beef, tomato, lettuce, mayonnaise, ketchup, pickle, and onion), 116 g of french fries, and 400 mL of orange juice (total 1131 kcal). After the meal, pressure and impedance-pH were recorded for 90 minutes, and at the end of this time a syringe was used to manually infuse 600 mL of air into the stomach through the manometry catheter over a 5-minute period. After air infusion, recording was continued for another 20 minutes. Next, the manometry catheter was removed and 24-hour ambulatory impedance-pH measurement commenced. To minimize the effect of the previously infused air, the first 2 hours of the 24-hour recording were discarded.[15]

Stationary High-Resolution Manometry

High-resolution manometry and impedance-pH monitoring were performed by a single investigator (J.A.B.). A water-perfused system (Medical Measurements Systems; Enschede, The Netherlands) with a multiple-lumen 21-channel catheter was used (Dentsleeve International; Mississuaga, Ontario, Canada). This catheter had 1 gastric channel (0 cm), 12 distal channels (3–14 cm), 4 midesophageal channels (18, 22, 26, and 30 cm), and 4 proximal channels (37, 39, 41, and 43 cm). The catheter was positioned in such a way that its distal 12 side holes, spaced at 1-cm intervals, straddled the esophagogastric junction and the most distal side hole was positioned intragastrically. The gastric baseline pressure was registered and served as the zero reference point.

Combined Esophageal Impedance-pH Monitoring

Combined esophageal impedance-pH monitoring was performed in an identical manner to the methodology described in 2 previous studies.[14,16]

Clinical Assessment Protocol

All clinical data were collected prospectively by a research nurse using a previously described standardized questionnaire that was completed either by telephone interview or by mail.[4]

Analysis of Objective Outcome Data

The classification of belches and reflux characteristics was undertaken in an identical manner to the categorization described in previous studies.[14–16] The 24-hour impedance-pH tracings were manually analyzed using a dedicated software program (Medical Measurements Systems; Enschede, The Netherlands). To minimize observer bias, the investigator (J.A.B.) analyzing these studies was blinded to the patient characteristics and outcomes.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation unless stated otherwise. Differences in age and body mass index between groups were analyzed using an independent t test. All other comparisons of continuous parameters between groups were performed using the Mann-Whitney U test. Ordinal variables were expressed as percentages and differences between groups were analyzed using the χ^2 test. $P < 0.05$ was considered statistically significant. The statistical analysis was performed using SPSS version 15.0 (SPSS Inc., Chicago, IL).

RESULTS

Subjects

The randomized trial originally enrolled 107 patients. During follow-up, 14 patients died of causes unrelated to their original antireflux surgery and 2 were unable to complete an interview due to dementia (Fig. 1). A further 10 patients underwent revision surgery (5 in each arm of the trial). The clinical outcome was available for these patients, but they were excluded from participating in this study. Hence, 81 patients met the eligibility criteria for this study. Of these, a clinical outcome could be determined for 81 patients, and 77 patients (95.1%) completed the clinical assessment protocol. Two patients were lost to follow up and 2 refused participation in this study. More patients underwent surgical reintervention for recurrent reflux in the anterior 180-degree fundoplication group and more for dysphagia

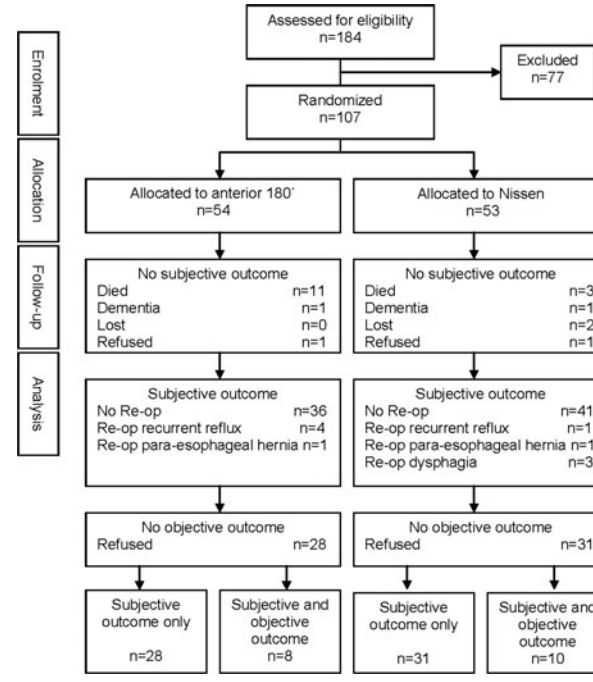

FIGURE 1. Study profile: CONSORT analysis 14-year follow-up.

in the Nissen fundoplication group (Fig. 1). Eighteen patients completed the objective study protocol and the symptom assessment, and 59 patients completed the symptom assessment only.

Clinical Outcome

Baseline characteristics (Table 1) were comparable for patients in the anterior 180-degree partial fundoplication (n = 36) and Nissen fundoplication groups (n = 41). Eight patients in the anterior 180-degree partial fundoplication group and 10 in the Nissen fundoplication group agreed to participate in the objective studies. There were no differences in reflux symptoms, dysphagia scores, gas-related symptoms, and patient satisfaction (Table 2) between participants who completed the objective study protocol (n = 18) and those who did not (n = 59).

Stationary High-Resolution Manometry and Ambulatory 24-Hour Impedance pH Study

The 18 patients completed the full research protocol. The results of these studies are summarized in Tables 3 and 4. Total esophageal acid exposure time was higher after anterior 180-degree fundoplication than after Nissen fundoplication. One out of the 8 patients in the anterior group and 7 out of the 10 patients in the Nissen group had nil esophageal acid exposure. In the patients with acid reflux, individual total esophageal acid exposure times were 5.9%, 6.5%, 7.1%, 7.5%, 16.5%, 20.2%, and 24.3% in the anterior group and 0.9%, 8.7%, and 18.1% in the Nissen group. The total number of acid and weakly acidic reflux episodes was higher after anterior 180-degree partial fundoplication than after Nissen fundoplication. Both liquid and mixed reflux episodes were more frequent in the anterior 180-degree partial fundoplication group (Table 3). The number of proximal, midesophageal, and distal reflux episodes was proportionately increased after anterior 180-degree fundoplication. Mean proximal reflux extent was not different (Table 4). The differences in the number of reflux episodes were reflected by significantly higher heartburn scores in the anterior 180-degree fundoplication group (Table 5), a difference which was also identified in the subgroup analysis of patients who completed the objective tests (Table 6).

In contrast, there were no differences in gas reflux between the 2 groups. In addition, gastric belches and belches experienced by the patient were comparable (Table 3). In line with these observations, there were no differences in gas-related symptoms between the groups for both the whole trial cohort (Table 5) and the subgroup analysis (Table 6). Supragastric belching only occurred in specific patients; it was observed in 4 patients in the anterior 180-degree fundoplication group and 6 patients in the Nissen fundoplication group. The total number of supragastric belches and the number of supragastric belches with and without reflux were similar in both groups (Table 3).

LES resting pressure [16.5 (7.6) mm Hg vs 19.2 (7.3) mm Hg; $P = 0.274$] and LES relaxation nadir pressure [8.3 (7.7) mm Hg vs 10.1 (6.3) mm Hg; $P = 0.460$) were lower after anterior 180-degree partial fundoplication than after Nissen fundoplication, but these differences did not reach statistical significance. The lower LES resting and LES relaxation nadir pressure were accompanied by a lower analog score for dysphagia for solids and the mean 0 to 45 dysphagia score after anterior fundoplication (Table 5). There were no significant differences in these scores in the subgroup that completed the objective study protocol (Table 6).

Postprandial Study

The results of the 90-minute postprandial measurement period were in line with the findings of the ambulatory study.

Intragastric Air Infusion Study

The 20-minute measurement period after intragastric air infusion yielded similar results as those obtained from the ambulatory and postprandial study.

DISCUSSION

Laparoscopic Nissen fundoplication is the most frequently performed operation for reflux disease[13,17] but is often followed by dysphagia and gas-related symptoms. A recent meta-analysis and the pooled results of 2 trials have demonstrated that posterior 270-degree partial[1] and anterior 180-degree partial fundoplication[4] reduce these symptoms and still achieve similar control of reflux symptoms at up to 5 years of follow-up. The first author recently demonstrated that gas reflux and gastric belches are reduced less after posterior partial fundoplication than after Nissen fundoplication, with similar reduction of acid and weakly acidic reflux at 6 months.[16] Cohort studies have raised concerns about the durability of the control of reflux symptoms beyond 5 years after partial fundoplication,[7–10] and such studies might have impeded wider application of these procedures. This study evaluated differences in objective outcomes at very late follow-up, 14 years after randomization, for laparoscopic anterior 180-degree partial versus Nissen fundoplication.

In this study, we have shown that acid, weakly acidic, liquid and mixed reflux episodes are more common after anterior 180-degree fundoplication than after Nissen fundoplication, and that proximal, midesophageal, and distal reflux are proportionately increased after anterior 180-degree fundoplication compared with Nissen fundoplication. These data are consistent with higher clinical heartburn scores occurring after anterior 180-degree fundoplication. In contrast, we observed no differences in gas reflux, gastric belches, and supragastric belches, which is in line with the observation that gas-related symptoms are similar for both groups. On the contrary, mean LES resting and relaxation nadir pressure are lower after anterior 180-degree fundoplication, and this is consistent with lower dysphagia scores after anterior 180-degree partial fundoplication.

Our study demonstrates that the total number of acid and weakly acidic reflux episodes at 14 years (15.0) is similar to results previously reported[16] at 6 months after Nissen fundoplication (7.4). In contrast, the total number of reflux episodes at 14 years is higher after anterior 180-degree fundoplication (40.4), with more liquid and mixed reflux episodes than after Nissen fundoplication. In addition, total esophageal acid exposure time was higher after anterior 180-degree fundoplication than after Nissen fundoplication.

However, differences in the effectiveness of antireflux surgery are determined not only by any reduction in the number of reflux episodes but also by the proximal reflux extent.[18] There were more reflux episodes after anterior 180-degree fundoplication, but mean proximal reflux extent is not higher than after Nissen fundoplication. There were no differences in objective reflux control at 6 months[6] and reflux symptoms at 5 years[4,5] and 10 years[11] between both arms of this trial. However, extension of follow-up to 14 years identified a significantly higher rate of acid and weakly acidic reflux and heartburn after anterior 180-degree fundoplication. In retrospect, mean heartburn scores did not increase from 5-year (1.8)[4,5] to 10-year (1.7)[11] to 14-year follow-up (1.4) after Nissen fundoplication. In contrast, in the anterior 180-degree arm, we observed some increase in mean heartburn scores from 5-year (1.9)[4,5] to 10-year (2.3)[11] to 14-year follow-up (2.7).

Patients with an objective reduction of gastric belches after fundoplication have higher symptom scores for inability to belch and gas bloating than patients who do not have an objective reduction of gastric belches.[19] It has recently been demonstrated that gas reflux and gastric belches are reduced less after posterior 270-degree partial

TABLE 1. Baseline Characteristics for Patients in the Anterior 180-Degree Partial Versus Nissen Fundoplication Group

	Anterior 180 Degrees (n = 36)	Nissen (n = 41)	*P*
Age (range), yr	42.3 (22–74)	46.4 (21–68)	0.169
Male/female sex	25/11	31/10	0.544
Body mass index (kg/m^2)*	27.7 (4.2)	28.7 (4.0)	0.417
Total esophageal acid exposure (%)*	13.4 (11.1)	13.0 (11.8)	0.972
Follow-up interval (yr)*	14.2 (1.0)	14.0 (1.2)	0.432

*Values are given as mean (standard deviation).

TABLE 2. Heartburn Score, Dysphagia, Gas-Related Symptoms, and Patient Satisfaction of Participants Who Completed Both the Objective and Subjective Study Protocols Versus Those Who Participated in the Subjective Study Only

	Objective and Subjective Outcomes (n = 18)	Subjective Outcome Only (n = 59)	*P*
Reflux			
Analog score for heartburn*	2.2 (2.5)	1.9 (2.7)	0.475
Dysphagia			
Analog score for dysphagia for liquids*	0.9 (1.7)	1.4 (2.5)	0.856
Analog score for dysphagia for solids*	2.0 (2.1)	2.5 (2.9)	0.911
0–45 dysphagia score*	9.6 (8.3)	8.2 (9.7)	0.358
Gas-related symptoms			
Inability to belch	2/18 (11.1%)	14/57 (24.6%)	0.225
Gas bloating	11/18 (61.1%)	26/57 (45.6%)	0.252
Inability to relieve bloating	3/18 (16.7%)	13/57 (22.8%)	0.579
Patient satisfaction			
Analog score for satisfaction*	8.4 (2.3)	7.8 (2.6)	0.240
Visick score			0.530
No symptoms	5 (27.8%)	12 (20.7%)	
Mild symptoms	10 (55.6%)	35 (60.3%)	
Moderate symptoms	1 (5.6%)	6 (10.3%)	
Symptoms interfering with life	0	3 (5.2%)	
Symptoms not improved	2 (11.1%)	2 (3.4%)	

*Values are given as mean (standard deviation).

TABLE 3. Total Esophageal Acid Exposure Time, Number of Liquid-Containing Reflux Episodes, Gas Reflux, and Belches per 24 Hours After Anterior 180-Degree Partial Versus Nissen Fundoplication

	Anterior 180 Degrees (n = 8)	Nissen (n = 10)	*P*
Total esophageal acid exposure time (%)	11.0 (8.3)	2.8 (6.0)	0.027
Total reflux episodes	40.4 (38)	15.0 (19)	0.043
Liquid reflux	24.0 (24)	11.4 (17)	0.146
Mixed reflux	16.4 (15)	3.6 (3.2)	0.043
Gas reflux	37.8 (15)	55.8 (50)	0.829
Gastric belches	51.4 (26)	57.0 (50)	0.999
Belches experienced by the patient	4.1 (4.1)	4.0 (4.5)	0.897
Supragastric belches (Anterior, n = 4; Nissen, n = 6)	21.3 (21)	30.3 (25)	0.762
With reflux	5.0 (3.5)	4.3 (9.7)	0.114
Without reflux	16.3 (21)	26.0 (24)	0.476

fundoplication, resulting in fewer gas-related symptoms than after Nissen fundoplication at 6 months.[16]

The long-term results evaluated in our current study were different. The number of gas reflux episodes at 14 years after anterior 180-degree (37.8) and Nissen fundoplication (55.8) was similar to the preoperative numbers described[16] for Nissen fundoplication (36.3). At 14 years, the number of gastric belches after anterior 180-degree (51.4) and Nissen fundoplication (57.0) was also comparable with the preoperative numbers reported[16] for Nissen fundoplication (67.8). These results indicate that short-term differences in gas reflux and gastric belches disappear over time, because gas reflux and belches have increased to preoperative values in both groups at 14 years. This would suggest that with time fundoplications become more compliant to the passage of air. The fact that fundoplication controls reflux

TABLE 4. Extent of Liquid-Containing Reflux Events per 24 Hours and Mean Proximal Reflux Extent After Anterior 180-Degree Partial Versus Nissen Fundoplication

	Anterior 180 Degrees (n = 8)	Nissen (n = 10)	*P*
Proximal reflux	9.4 (10)	2.8 (5.2)	0.021
Midesophageal reflux	25.0 (26)	8.7 (8.5)	0.055
Distal reflux	6.0 (4.1)	3.5 (6.0)	0.068
Mean proximal reflux extent (cm)	8.5 (3.5)	8.7 (1.6)	0.460

TABLE 5. Heartburn Score, Dysphagia, Gas-Related Symptoms, and Patient Satisfaction After Anterior 180-Degree Partial Versus Nissen Fundoplication

	Anterior 180 Degrees (n = 36)	Nissen (n = 41)	*P*
Analog score for heartburn*	2.5 (2.6)	1.5 (2.6)	0.018
Dysphagia			
Analog score for dysphagia for liquids*	1.2 (2.2)	1.3 (2.4)	0.754
Analog score for dysphagia for solids*	1.8 (2.5)	2.9 (2.8)	0.028
0–45 dysphagia score*	5.4 (7.0)	11.3 (10)	0.006
Gas-related symptoms			
Inability to belch	6/35 (17.1%)	10/40 (25.0%)	0.407
Gas bloating	15/35 (42.9%)	22/40 (55.0%)	0.294
Inability to relieve bloating	5/35 (14.3%)	11/40 (27.5%)	0.163
Analog score for satisfaction*	8.3 (2.1)	7.6 (2.8)	0.324
Visick score			0.645
No symptoms	8 (22.2%)	9 (22.5%)	
Mild symptoms	22 (61.1%)	23 (57.5%)	
Moderate symptoms	2 (5.6%)	5 (12.5%)	
Symptoms interfering with life	1 (2.8%)	2 (5.0%)	
Symptoms not improved	3 (8.3%)	1 (2.5%)	

*Values are given as mean (standard deviation).

TABLE 6. Heartburn Score, Dysphagia, Gas-Related Symptoms, and Patient Satisfaction of Participants Who Completed Both the Objective and the Subjective Study Protocols After Anterior 180-Degree Partial Versus Nissen Fundoplication

	Anterior 180 Degrees (n = 8)	Nissen (n = 10)	*P*
Reflux			
Analog score for heartburn*	4.1 (2.4)	0.6 (1.1)	0.001
Dysphagia			
Analog score for dysphagia for liquids*	1.0 (1.9)	0.9 (1.6)	0.762
Analog score for dysphagia for solids*	2.8 (2.4)	1.4 (1.6)	0.203
0–45 dysphagia score*	11.8 (9.0)	7.9 (7.7)	0.360
Gas-related symptoms			
Inability to belch	1/8 (12.5%)	1/10 (10.0%)	0.867
Gas bloating	6/8 (75.0%)	5/10 (50.0%)	0.280
Inability to relieve bloating	1/8 (12.5%)	2/10 (20.0%)	0.671
Patient satisfaction			
Analog score for satisfaction*	7.3 (2.8)	9.4 (1.1)	0.034
Visick score			0.201
No symptoms	1 (12.5%)	4 (40.0%)	
Mild symptoms	5 (62.5%)	5 (50.0%)	
Moderate symptoms	0	1 (10.0%)	
Symptoms interfering with life	0	0	
Symptoms not improved	2 (25.0%)	0	

*Values are given as mean (standard deviation).

without impairing venting of air from the stomach at 14 years can be explained by the observation that the low viscosity of air facilitates passage through a competent esophagogastric junction compared with liquids.[20] In earlier reports of clinical outcomes from our randomized trial, we reported significantly more inability to belch, gas bloating, and inability to relieve bloating at 6 months[6] and 5 years[4,5] after Nissen fundoplication. Our current study demonstrated no differences in these gas-related symptoms at 14 years. Moreover, the rate of gas bloating (42.9% vs 55.0%) and inability to relieve bloating (14.3% vs 27.5%) were similar compared with preoperative rates of gas bloating (51.9% vs 49.0%) and inability to relieve bloating (20.4% vs 18.9%) reported[6] for the anterior 180-degree fundoplication versus Nissen

fundoplication. The finding that gas reflux and gastric belches have returned to preoperative values at 14 years explains why gas-related symptoms return to preoperative rates in both groups. In sharp contrast to gastric belches, supragastric belches are esophageal belches that do not allow air venting from the stomach.[21] Fundoplications alter the belching pattern by reducing gastric belching and increasing supragastric belching at 6 months.[16] Supragastric belches at 14 years after anterior 180-degree (21.3) and Nissen fundoplication (30.3) were similar to the preoperative quantities recorded[16] for Nissen fundoplication (34.2) elsewhere.

A recent meta-analysis found that at 1 year, lower esophageal sphincter relaxation is more likely to be incomplete after posterior than anterior partial fundoplication.[22] This study demonstrates that at 14 years, both lower esophageal sphincter resting and relaxation nadir pressure are reduced after anterior 180-degree fundoplication compared with Nissen fundoplication. It has previously been demonstrated that esophageal sphincter relaxation nadir pressure is the only standard manometry parameter correlated with postfundoplication dysphagia.[23,24] In this study, the reduced esophageal sphincter relaxation pressure after anterior 180-degree fundoplication was also reflected by lower dysphagia scores than after Nissen fundoplication. Overall, patient satisfaction was stable throughout follow-up and similar in the anterior 180-degree and Nissen groups: at 5 years, 8.7 versus 8.0[4,5]; at 10 years, 8.3 versus 8.2[11]; and at 14 years, 8.3 versus 7.6. We can only speculate as to why this might be, given the poorer outcome in terms of reflux control with anterior fundoplication. Perhaps the lower rate of dysphagia complaints, or control of preoperative volume reflux, or ability to control reflux symptoms with less medications than before surgery may all play a role. We did not explore these latter possibilities, however.

A limitation of this study is that most of the patients who completed subjective follow-up would not undergo the extensive objective study protocol. This could lead to selection bias. However, the risk of selection bias was minimized by demonstrating equivalent clinical outcome scores in patients who underwent objective studies versus those who did not. The sample size of the objective study protocol, however, was small, but large differences between both groups were expected after 14 years and, indeed, statistically significant differences were found. We acknowledge that the possibility of both types of statistical error is real in the subgroup of patients who underwent objective testing. However, the differences in objective outcome observed in this subset were confirmed by corresponding differences in subjective outcome recorded for the whole group.

In conclusion, this study demonstrates that at 14 years after randomization, acid, weakly acidic, liquid and mixed reflux episodes are more common after anterior 180-degree fundoplication than after Nissen fundoplication. Proximal, midesophageal, and distal reflux are proportionately increased after anterior 180-degree fundoplication, which is accompanied by higher clinical heartburn scores than that after Nissen fundoplication. In contrast, there were no differences in gas reflux, gastric belches, and supragastric belches, which is in line with the observation that gas-related symptoms were similar for both groups. On the contrary, mean LES resting and relaxation nadir pressure are lower after anterior 180-degree fundoplication, which is reflected by lower dysphagia scores. Patient satisfaction is similar after both procedures. Overall, these findings suggest less effective reflux control after anterior 180-degree partial fundoplication, offset by less dysphagia, leading to a clinical outcome which is equivalent to Nissen fundoplication at late follow-up. No doubt, some may take these findings as strongly supporting the role of a total fundoplication for all patients having antireflux surgery. We take the view that these long-term results support tailoring of fundoplication according to age, performing a total fundoplication in younger patients to ensure durable reflux control and an anterior 180-degree partial fundoplication in older patients to minimize dysphagia. Nevertheless, the similarity in patient satisfaction scores and the small numbers involved in the objectively tested groups mean that we cannot make definitive statements about the best antireflux operation.

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