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Recurrence of reflux after laparoscopic antireflux surgery: reply

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Characteristic	No. With ASD/Total	ASD, % (95% CI) ^a	P Value
Overall	711/30 502 ^b	2.41 (2.17-2.65)	
Age, y			
3-11	403/17 267 ^b	2.42 (2.11-2.72)	.93 ^c
12-17	308/13 235 ^b	2.40 (2.03-2.76)	
Sex			
Male	545/15 727 ^b	3.54 (3.14-3.95)	<.001 ^c
Female	166/14 775 ^b	1.22 (0.98-1.47)	
Race/ethnicity ^d			
Hispanic	140/8111 ^b	1.78 (1.41-2.15)	.01 ^c
Non-Hispanic white	405/14 900 ^b	2.71 (2.36-3.05)	
Non-Hispanic black	89/4038 ^b	2.36 (1.66-3.07)	
Other	77/3453 ^b	2.45 (1.75-3.14)	
Geographic region			
Northeast	145/4742 ^b	3.05 (2.40-3.70)	.11 ^c
Midwest	148/6058 ^b	2.47 (1.93-3.01)	
South	234/10 775 ^b	2.21 (1.81-2.61)	
West	184/8927 ^b	2.24 (1.84-2.65)	
ASD prevalence by year			
2014	237/11 082	2.24 (1.89-2.59)	.23 ^e
2015	240/10 183	2.41 (1.98-2.84)	
2016	234/9237	2.58 (2.14-3.01)	

Abbreviation: ASD, autism spectrum disorder

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- 1. Lyall K, Croen L, Daniels J, et al. The changing epidemiology of autism spectrum disorders. *Annu Rev Public Health*. 2017;38:81-102.
- Christensen DL, Baio J, Van Naarden Braun K, et al; Centers for Disease Control and Prevention (CDC). Prevalence and characteristics of autism spectrum disorder among children aged 8 years: Autism and Developmental Disabilities Monitoring Network, 11 sites, United States, 2012. MMWR Surveill Symm. 2016;65(3):1-23
- **3**. Zablotsky B, Black LI, Maenner MJ, Schieve LA, Blumberg SJ. Estimated prevalence of autism and other developmental disabilities following questionnaire changes in the 2014 National Health Interview Survey. *Natl Health Stat Report*. 2015;(87):1-20.
- **4.** Blumberg SJ, Bramlett MD, Kogan MD, Schieve LA, Jones JR, Lu MC. Changes in prevalence of parent-reported autism spectrum disorder in school-aged US children: 2007 to 2011-2012. *Natl Health Stat Report*. 2013: (65):1-11. 1. 11.
- **5.** Parsons VL, Moriarity C, Jonas K, Moore TF, Davis KE, Tompkins L. Design and estimation for the National Health Interview Survey, 2006-2015. *Vital Health Stat* 2. 2014;(165):1-53.
- **6**. Hansen SN, Schendel DE, Parner ET. Explaining the increase in the prevalence of autism spectrum disorders: the proportion attributable to changes in reporting practices. *JAMA Pediatr*. 2015;169(1):56-62.

COMMENT & RESPONSE

Recurrence of Reflux After Laparoscopic Antireflux Surgery

To the Editor Dr Maret-Ouda and colleagues assessed the outcome of laparoscopic antireflux surgery among 2655 patients who underwent the operation in Sweden between 2005 and 2014. They defined failure as postoperative use of antireflux medications or need for secondary antireflux surgery. The overall failure rate was 17.7%, and female sex, older age, and comorbidities were risk factors. Hospital volume of laparoscopic antireflux surgery was not associated with risk of recurrent reflux. They concluded that the high rate of recurrent reflux diminishes some of the benefits of the operation. The study has significant limitations that raise questions about the validity of the findings and the soundness of the conclusions.

First, many studies have shown that in the absence of Barrett esophagus, preoperative symptoms and endoscopic findings have a sensitivity for gastroesophageal reflux disease of only 58% to 70%.^{2,3} The authors did not provide any information about the preoperative work up in this cohort of patients. Second, the most common indication for laparoscopic antireflux surgery is incomplete relief of symptoms with proton pump inhibitor therapy. Based on this consideration, it is remarkable that 82.3% of patients after surgery had complete control of symptoms without any need for medications.

Third, symptoms are a poor indicator of recurrence of reflux after laparoscopic antireflux surgery, suggesting the need for objective evidence of recurrence of reflux before prescribing acid-reducing medications. ^{4,5} Galvani et al showed that only 39% of patients with recurrent symptoms after laparoscopic antireflux surgery had recurrent reflux when esophageal function tests were performed. ⁴ Furthermore, 68% of patients who were taking acid-reducing medications after surgery had a normal reflux status as determined by pH monitoring. Therefore, assessing failure based

^a Prevalence estimates were weighted.

^b Unweighted number of participants involving all 3 years.

^c *P* value for overall differences in prevalence by strata.

^d Race and Hispanic ethnicity were self-reported and classified based on the 1997 Office of Management and Budget Standards.

e P value for trend.

on the use of antireflux medications overestimates the failure rate. Fourth, for an operation that usually requires a 23-hour stay, surgeon's volume rather than the hospital volume should be assessed.

In conclusion, we think that laparoscopic antireflux surgery, when performed for the proper indications by expert surgeons, is an effective treatment as it offers complete relief of symptoms to the majority of patients.

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- 1. Maret-Ouda J, Wahlin K, El-Serag HB, Lagergren J. Association between laparoscopic antireflux surgery and recurrence of gastroesophageal reflux. *JAMA*. 2017;318(10):939-946.
- 2. Patti MG, Diener U, Tamburini A, Molena D, Way LW. Role of esophageal function tests in diagnosis of gastroesophageal reflux disease. *Dig Dis Sci.* 2001; 46(3):597-602.
- **3**. Bello B, Zoccali M, Gullo R, et al. Gastroesophageal reflux disease and antireflux surgery—what is the proper preoperative work-up? *J Gastrointest Surg*. 2013;17(1):14-20.
- **4.** Galvani C, Fisichella PM, Gorodner MV, Perretta S, Patti MG. Symptoms are a poor indicator of reflux status after fundoplication for gastroesophageal reflux disease: role of esophageal functions tests. *Arch Surg.* 2003;138(5):514-518.
- **5**. Lord RV, Kaminski A, Oberg S, et al. Absence of gastroesophageal reflux disease in a majority of patients taking acid suppression medications after Nissen fundoplication. *J Gastrointest Surg.* 2002;6(1):3-9.

In Reply We do not believe that our view of the use of antireflux surgery is very different from that of Drs Patti and Schlottmann, but we would like to respond to the 4 potential limitations of the study that were brought to our attention

First, it is correct that we had no information about the preoperative workup of each individual in this large cohort of patients. However, it is mandatory to conduct a careful preoperative assessment of each patient considered for antireflux surgery in Sweden, including symptom assessment, endoscopy, and 24-hour manometry and pH measurement. Only patients with objectively verified gastroesophageal reflux disease who have not benefited from medical treatment with proton pump inhibitor are considered for antireflux surgery. Second, we agree that antireflux surgery is often conducted in individuals with particularly severe symptoms or with incomplete relief of symptoms using medical therapy. Considering this, we also agree that the rate of reflux recurrence after antireflux surgery was indeed low in our study, even lower than in most previous studies on this topic, despite the complete follow-up of an unselected cohort.

The third comment concerns our assessment of recurrence of reflux after antireflux surgery. Assessing the presence or absence of gastroesophageal reflux disease is

sometimes difficult, but both endoscopy and 24-hour pH measurement have low sensitivity and specificity to assess this disease. Assessment of reflux symptoms also has a limited specificity, but it has a considerably higher sensitivity. Thus, current guidelines recommend that the diagnosis of gastroesophageal reflux disease is best established using typical reflux symptoms. Based on this, we believe that reflux symptoms and use of antireflux medication are still the best currently available means of defining reflux recurrence after antireflux surgery. Fourth, Patti and Schlottmann suggest that surgeon volume would be a better assessment than hospital volume when evaluating the role of annual antireflux surgery volume. We did not have data on the individual operating surgeon, and hospital volume is still a reliable measure of annual surgery volume. Additionally, surgeon volume and hospital volume usually correlate quite strongly, particularly in Sweden where each department of surgery that conducts laparoscopic antireflux surgery contains very few surgeons specialized in antireflux surgery.

We agree that laparoscopic antireflux surgery is an excellent and probably underused treatment in many patients with gastroesophageal reflux disease, but patients and surgeons should be aware of the risk of recurrence.

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1. Vakil N, van Zanten SV, Kahrilas P, Dent J, Jones R; Global Consensus Group. The Montreal definition and classification of gastroesophageal reflux disease: a global evidence-based consensus. *Am J Gastroenterol*. 2006;101(8):1900-1920.

Self-regulation of the Medical Profession and Maintenance of Certification

To the Editor The Viewpoint¹ regarding maintenance of certification (MOC) requirements and Texas Senate bill (SB) 1148 asked practicing physicians to make a leap of faith that many cannot accommodate. Unfortunately, that leap of faith is central to the author's argument.

As Dr Johnson pointed out, self-regulation is a core attribute of the learned professions. It encompasses the responsibility and authority to establish and enforce standards of education, training, and practice. Physicians routinely defend that responsibility and authority in advocating against the intrusion of all third parties (such as government, private insurers, or hospital administrators) into the practice of medicine.

However, as evidenced by their comments at the Texas Medical Association and American Medical Association House of Delegates and at the committee hearings on SB 1148, many physicians today simply do not acknowledge the certifying boards as "self." They are, instead, profitdriven organizations beholden to their own financial