

efforts and pay-for-performance initiatives. Considering the burden of revisits to patients and hospitals following ambulatory operations, our study highlights the importance of expanding health policy and clinical interventions to include ambulatory surgery and complications assessed in the ED.

Future work should determine associated risk factors and which complications are potentially preventable.

**Claudia A. Steiner, MD, MPH**  
**Melinda Maggard-Gibbons, MD, MSHS**  
**Susan Oehme Raetzman, MSPH**  
**Marguerite L. Barrett, MS**  
**Greg D. Sacks, MD, MPH**  
**Pamela L. Owens, PhD**

**Author Affiliations:** Center for Delivery, Organization and Markets, Agency for Healthcare Research and Quality, Rockville, Maryland (Steiner, Owens); RAND Corporation, Santa Monica, California (Maggard-Gibbons); Truven Health Analytics, Bethesda, Maryland (Raetzman); M. L. Barrett Inc, Del Mar, California (Barrett); Department of Surgery, University of California David Geffen School of Medicine, Los Angeles (Sacks).

**Corresponding Author:** Claudia A. Steiner, MD, MPH, Agency for Healthcare Research and Quality, 540 Gaither Rd, Rockville, MD 20850 ([claudia.steiner@ahrq.hhs.gov](mailto:claudia.steiner@ahrq.hhs.gov)).

**Author Contributions:** Drs Steiner and Owens had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Steiner, Raetzman, Barrett, Sacks, Owens.

**Acquisition, analysis, or interpretation of data:** All authors.

**Drafting of the manuscript:** Steiner, Maggard-Gibbons, Raetzman, Barrett, Owens.

**Critical revision of the manuscript for important intellectual content:** Steiner, Raetzman, Barrett, Sacks, Owens.

**Statistical analysis:** Steiner, Maggard-Gibbons, Barrett, Owens.

**Obtained funding:** Steiner.

**Administrative, technical, or material support:** Steiner, Raetzman, Sacks, Owens.

**Study supervision:** Steiner, Owens.

**Conflict of Interest Disclosures:** The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

**Funding/Support:** This study was funded by the Agency for Healthcare Research and Quality (AHRQ) under a contract to Truven Health Analytics for developing and supporting the Healthcare Cost and Utilization Project (HCUP). Dr Sacks' time was supported by the Robert Wood Johnson Clinical Scholars Program at the University of California, Los Angeles.

**Role of the Funder/Sponsor:** The AHRQ had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Disclaimer:** The views expressed in this article are those of the authors and do not necessarily reflect those of AHRQ or the US Department of Health and Human Services.

**Additional Contributions:** We thank the following HCUP partner organizations that provided the data: California Office of Statewide Health Planning and Development, Florida Agency for Health Care Administration, Georgia Hospital Association, Missouri Hospital Industry Data Institute, Nebraska Hospital Association, New York State Department of Health, and Tennessee Hospital Association. In addition, we thank the following Truven Health Analytics staff members, who were compensated for their contributions: Minya Sheng, MS, for the statistical programming; Lauren Hughey, MPH, and Christine Walsh, BA, for reviewing data tables; and Linda Lee, PhD, for editorial assistance.

1. National Center for Health Statistics, Centers for Disease Control and Prevention. Health, United States, 2012: with special feature on emergency care. <http://www.cdc.gov/nchs/data/atus/atus12.pdf>. Accessed December 1, 2014.

2. Perron-Burdick M, Yamamoto M, Zaritsky E. Same-day discharge after laparoscopic hysterectomy. *Obstet Gynecol*. 2011;117(5):1136-1141.

3. Morton JM, Winegar D, Blackstone R, Wolfe B. Is ambulatory laparoscopic Roux-en-Y gastric bypass associated with higher adverse events? *Ann Surg*. 2014;259(2):286-292.

4. Coley KC, Williams BA, DaPos SV, Chen C, Smith RB. Retrospective evaluation of unanticipated admissions and readmissions after same day surgery and associated costs. *J Clin Anesth*. 2002;14(5):349-353.

5. Owens PL, Barrett ML, Raetzman S, Maggard-Gibbons M, Steiner CA. Surgical site infections following ambulatory surgery procedures. *JAMA*. 2014;311(7):709-716.

6. Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project (HCUP): HCUP Databases: December 2014. <http://www.hcup-us.ahrq.gov/databases.jsp>. Accessed May 12, 2015.

## Extended Follow-up of a Randomized Clinical Trial of Open vs Endoscopic Release Surgery for Carpal Tunnel Syndrome

In the United States, carpal tunnel release (open or endoscopic) was performed more than 577 000 times in 2006.<sup>1</sup> A survey of hand surgeons found 52% used only open release, 36% used mostly endoscopic release, and 12% used both in 2011.<sup>2</sup> Randomized trials have shown these methods have similar short-term efficacy, but no previous studies have adequate follow-up beyond 5 years.<sup>3</sup> Longer-term follow-up is important because disease progression or scar formation could occur.

We conducted a randomized trial comparing open and endoscopic release and found modestly lower postoperative pain following endoscopic surgery, but no differences in symptom and function scores up to 5 years.<sup>4,5</sup> This extended follow-up compared outcomes 11 to 16 years after surgery.

**Methods |** Patients aged 25 to 60 years with carpal tunnel syndrome (CTS) were randomized in the operating room of a regional hospital in Sweden to conventional open or 2-portal endoscopic release (surgeons were experienced in both techniques).<sup>4</sup> The trial and follow-up were approved by the regional ethical review board of Lund University. Participants provided written informed consent. Evaluations were performed the week before surgery and again at 3, 6, 12, and 52 weeks' postsurgery as well as 5 years after surgery.

In this extended follow-up, a questionnaire, which included the validated Levine-Katz 11-item CTS symptom severity scale and 8-item functional status scale,<sup>6</sup> also used at baseline, 1 year, and 5 years, was mailed to the patients (score range, 1 [best] to 5 [worst]). The questionnaire also included (1) a pain scale (used in prior evaluations), (2) the 11-item disabilities of the arm, shoulder and hand (DASH) scale, (3) the treatment satisfaction visual analog scale, and (4) questions about height and weight, smoking, medical conditions, and subsequent surgery on the hands (verified through medical records). Patients reporting current numbness and/or tingling were interviewed by a blinded researcher via telephone.

The primary outcome was change in symptom severity score from baseline and 1 year. The secondary outcomes

Table 1. Symptom Severity and Functional Status Scores in the 2 Carpal Tunnel Surgery Groups

	Mean (SD)			Adjusted Mean Between-Group Difference in Change From Baseline to 11-16 y (95% CI)	P Value	Adjusted Mean Between-Group Difference in Change From 1 y to 11-16 y (95% CI)	P Value
	Baseline	At 1 y	At 11-16 y				
Symptom severity score <sup>a</sup>							
Open CTR group (n = 61)	3.1 (0.6)	1.4 (0.5)	1.4 (0.7)	−0.03 (−0.25 to 0.19)	.79	−0.03 (−0.23 to 0.17)	.76
Endoscopic CTR group (n = 63)	3.2 (0.6)	1.4 (0.6)	1.4 (0.6)				
Functional status score <sup>b</sup>							
Open CTR group (n = 61)	2.4 (0.8)	1.2 (0.4)	1.3 (0.5)	0.11 (−0.09 to 0.31)	.27	0.09 (−0.10 to 0.27)	.35
Endoscopic CTR group (n = 63)	2.4 (0.6)	1.3 (0.5)	1.4 (0.6)				

Abbreviation: CTR, carpal tunnel release.

<sup>b</sup> Score range: 1 (no activity limitations) to 5 (most severe activity limitations).<sup>a</sup> Score range: 1 (no symptoms in the study hand) to 5 (most severe symptoms in the study hand).

Table 2. Secondary Outcomes at Follow-up in the Carpal Tunnel Surgery Groups

	Open CTR (n = 61)	Endoscopic CTR (n = 63)	Unadjusted Mean Between-Group Difference (95% CI) <sup>a</sup>	P Value
Pain score <sup>b</sup>				
Mean (SD)	5.1 (16)	3.5 (11)	1.5 (-3.5 to 6.5)	.54
Median (range)	0 (0 to 79)	0 (0 to 68)		
11-item DASH Scale score <sup>b</sup>				
Mean (SD)	9.7 (15)	10.4 (18)	-0.7 (-6.6 to 5.2)	.82
Median (range)	2.3 (0 to 75)	2.3 (0 to 75)		
Satisfaction score, mean (SD) <sup>c</sup>	87.8 (22)	90.1 (16)	-2.3 (-9.1 to 4.5)	.51
	No. (%)		RR (95% CI)	
Numbness and/or tingling				
None	41 (67)	41 (65)	0.94 (0.57 to 1.54)	.80
Mild	11 (18)	15 (24)		
Moderate	5 (8.2)	6 (9.5)		
Severe	4 (6.6)	1 (1.6)		
Median nerve distribution <sup>d</sup>	11 (18)	10 (16)	1.14 (0.52 to 2.48)	.75
Pain in scar or proximal palm	5 (8.2)	6 (9.5)	0.86 (0.28 to 2.67)	.80
Satisfaction score <80 <sup>c</sup>	8 (13)	9 (14)	0.92 (0.39 to 2.22)	.85
Subsequent surgery on study hand	3 (4.9) <sup>e</sup>	4 (6.3)	0.77 (0.18 to 3.32)	.73

Abbreviations: CTR, carpal tunnel release; DASH, disabilities of the arm, shoulder and hand; RR, relative risk.

<sup>a</sup> Unless otherwise indicated.<sup>b</sup> Score range: 0 (no pain or disability) to 100 (most severe pain or disability).<sup>c</sup> Treatment satisfaction visual analog scale score range: 0 (dissatisfied) to 100 (very satisfied).<sup>d</sup> Current numbness and/or tingling of any severity involving at least 1 of the 3 radial fingers (based on telephone interview).<sup>e</sup> Medical records of the 3 deceased patients and the 1 patient who refused to participate showed no further surgery after the trial.

were change in functional status score from baseline and 1 year, current pain, DASH scale and satisfaction scores, and repeat surgery. The sample was adequate to detect a between-group symptom severity score difference (absolute) of 0.4; smaller differences are unlikely to be clinically important.

We compared the 2 groups regarding changes in symptom severity and functional status scores with analysis of covariance (adjusting for age, sex, study hand dominance, and baseline scores), other scores with the *t* test, and categorical outcomes with the  $\chi^2$  test (relative risks were calculated). We used Stata version 13.0 (StataCorp) and a 2-sided threshold of .05 for statistical significance.

**Results** | Of 128 patients originally randomized (65 to the open group and 63 to the endoscopic group), 3 died and 1

refused participation (all 4 were in the open group). From October 2013 through September 2014, 124 patients (97%) provided complete data for all outcome measures between 11.3 and 15.7 years after surgery (mean [SD], 12.8 [1.2] years). Patient characteristics at follow-up were similar between groups (mean age, 57 years; 75% were women; body mass index [calculated as weight in kilograms divided by height in meters squared] of 27.5; 15% were smokers). Six percent had undergone further surgery on the same hand and 40% on the contralateral hand.

Improvement in symptom severity score (similar in the 2 groups at 1 year) was maintained at follow-up (Table 1). In the open group, the symptom severity score was 3.1 at baseline, 1.4 at 1 year, and 1.4 at follow-up (mean [SD] change from baseline, 1.7 [0.7]; from 1 year, 0.04 [0.5]); in the endoscopic group, it was 3.2 at baseline, 1.4 at 1 year, and 1.4 at

follow-up (mean [SD] change from baseline, 1.8 [0.8]; from 1 year, -0.003 [0.6]). Adjusted mean between-group difference in change from baseline was -0.03 (95% CI, -0.25 to 0.19;  $P = .79$ ) and from 1 year was -0.03 (95% CI, -0.23 to 0.17;  $P = .76$ ). No between-group differences were found in the secondary outcomes (Table 2).

**Discussion** | To our knowledge, this is the first randomized trial to evaluate long-term outcomes of CTS surgery. After a mean follow-up of 12.8 years after CTS surgery, there were no significant differences between open and endoscopic carpal tunnel release. The large symptom and functional improvements and high level of patient satisfaction achieved with surgery were durable and few patients had undergone further surgery.

Study limitations include a single institution in Sweden and unknown generalizability. Our long-term follow-up was limited to patient-reported outcomes, which are central in CTS and were consistent across several measures with established reliability and validity. The results should help clinicians and patients in making treatment decisions.

Isam Atroshi, MD, PhD  
Manfred Hofer, BSc  
Gert-Uno Larsson, MD  
Jonas Ranstam, PhD

**Author Affiliations:** Department of Orthopedics Håssleholm-Kristianstad, Lund University, Lund, Sweden (Atroshi); Department of Physical and Occupational Therapy, Kristianstad Hospital, Kristianstad, Sweden (Hofer); Department of Orthopedics, Håssleholm Hospital, Håssleholm, Sweden (Larsson); Department of Clinical Sciences Lund-Orthopedics, Lund University, Lund, Sweden (Ranstam).

**Corresponding Author:** Isam Atroshi, MD, PhD, Department of Orthopedics Håssleholm-Kristianstad, Clinical Sciences, Lund University, SE-22100 Lund, Sweden (isam.atroshi@med.lu.se).

**Author Contributions:** Dr Atroshi had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Atroshi.

**Acquisition, analysis, or interpretation of data:** All authors.

**Drafting of the manuscript:** Atroshi.

**Critical revision of the manuscript for important intellectual content:** All authors.

**Statistical analysis:** Atroshi, Ranstam.

**Obtained funding:** Atroshi.

**Administrative, technical, or material support:** Atroshi, Hofer, Larsson.

**Study supervision:** Atroshi.

**Conflict of Interest Disclosures:** The authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

**Funding/Support:** This research was supported by grants from Region Skåne.

**Role of the Funder/Sponsor:** Region Skåne had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Trial Registration:** clinicaltrials.gov Identifier: NCT01887145

**Additional Information:** The trial protocol is available upon request from the authors.

1. Jain NB, Higgins LD, Losina E, Collins J, Blazar PE, Katz JN. Epidemiology of musculoskeletal upper extremity ambulatory surgery in the United States. *BMC Musculoskelet Disord*. 2014;15:4.

2. Leinberry CF, Rivlin M, Maltenfort M, et al. Treatment of carpal tunnel syndrome by members of the American Society for Surgery of the Hand: a 25-year perspective. *J Hand Surg Am*. 2012;37(10):1997-2003.e3.

3. Louie D, Earp B, Blazar P. Long-term outcomes of carpal tunnel release: a critical review of the literature. *Hand (N Y)*. 2012;7(3):242-246.

4. Atroshi I, Larsson GU, Ornstein E, Hofer M, Johnsson R, Ranstam J. Outcomes of endoscopic surgery compared with open surgery for carpal tunnel syndrome among employed patients: randomised controlled trial. *BMJ*. 2006;332(7556):1473.

5. Atroshi I, Hofer M, Larsson GU, Ornstein E, Johnsson R, Ranstam J. Open compared with 2-portal endoscopic carpal tunnel release: a 5-year follow-up of a randomized controlled trial. *J Hand Surg Am*. 2009;34(2):266-272.

6. Levine DW, Simmons BP, Koris MJ, et al. A self-administered questionnaire for the assessment of severity of symptoms and functional status in carpal tunnel syndrome. *J Bone Joint Surg Am*. 1993;75(11):1585-1592.

## COMMENT & RESPONSE

### Treatment of Uncomplicated Acute Appendicitis

**To the Editor** The use of a noninferiority design in the Appendicitis Acuta (APPAC) trial allowed for the assessment of primary outcomes specific to each treatment.<sup>1</sup> However, we believe that the chosen outcomes were not equally patient-centric, leading to the erroneous conclusion that antibiotics did not meet the prespecified criterion for noninferiority compared with appendectomy.<sup>1</sup>

The primary end point in the antibiotic-treated group of “discharge from the hospital without the need for surgery and no recurrent appendicitis during a 1-year follow-up period” was patient-centric and answers the patient’s question: “If I choose to be treated with antibiotics, what is the chance that I will eventually need an appendectomy?” However, the primary end point for the surgical group of “successful completion of an appendectomy” is irrelevant to patients who rightfully assume that an appendectomy will successfully remove the appendix.<sup>1</sup> Patients undergoing an appendectomy are typically concerned with the risk of postoperative complications and the extent of postoperative disability.

Therefore, a more patient-centric end point would have been development of a postoperative complication, which answers the patient’s question: “If I choose to be treated with an appendectomy, what is the chance I will have a complication from surgery?” When applying this outcome, antibiotics were within the predetermined noninferiority margin (24%) because there was a 20% complication rate in the appendectomy group and a 27% failure rate in the antibiotic group. In addition, consistent with previous randomized clinical trials, the APPAC trial confirmed the safety of nonoperative management by demonstrating no difference in rates of complicated or perforated appendicitis between the 2 groups.<sup>2</sup>

Applying the results of the APPAC trial in the United States will be difficult because the surgical group underwent open appendectomies and the antibiotic group received 3 days of intravenous antibiotics. The standard of care in the United States for patients with uncomplicated appendicitis is to undergo a laparoscopic appendectomy with either same-day discharge or discharge on the first postoperative day. Early results from a US study in children demonstrated the feasibility of nonoperative management of uncomplicated appendicitis using 24 hours of intravenous antibiotics with improved quality of life and fewer disability days compared with laparoscopic appendectomy.<sup>3</sup>