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## Nontraumatic Supraspinatus Tears: PT Is Equal to PT Plus Surgery at One Year

### Clinical Question

In adults with nontraumatic supraspinatus tears, is physical therapy (PT) alone as effective as PT plus surgery after one year?

### Bottom Line

In this study, the long-term outcomes of adults with nontraumatic supraspinatus tears who are treated conservatively are similar to those of patients treated with two different surgical approaches. (Level of Evidence = 2b)

### Synopsis

This group of surgeons randomly assigned 180 adults older than 55 years with isolated nontraumatic supraspinatus tears to one of three treatment groups: PT, PT plus acromioplasty, or PT plus acromioplasty plus rotator cuff repair. Although they used intention-to-treat analysis to evaluate the main outcome, the authors do not report if any study personnel (other than the radiologists) were aware of the treatment allocation. The research staff determined the multidimensional Constant score for each patient at baseline and then at three, six, and 12 months after intervention. The authors report that a difference of 10 points on the Constant score is the minimal clinically important difference. Thirteen patients did not complete the study. At three months, the group receiving triple therapy had lower Constant scores than the other

groups, but by six months the scores were comparable. At the end of the study, 87% of patients treated with PT alone were satisfied, compared with 95% and 96% in the other treatment groups. The study was designed to have enough power to detect modest differences in the Constant score. This is one of many studies showing long-term outcomes of various orthopedic interventions are comparable (e.g., steroid injections for shoulder pain vs. conservative treatment).

**Study design:** Randomized controlled trial (nonblinded)

**Funding source:** Unknown/not stated

**Allocation:** Concealed

**Setting:** Outpatient (specialty)

**Reference:** Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of non-traumatic rotator cuff tears: a randomised controlled trial with one-year clinical results. *Bone Joint J.* 2014;96(1):75-81.

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## Suppurative Complications of Sore Throat Uncommon and Unpredictable

### Clinical Question

Which signs and symptoms can clinicians rely on to predict which adult patients will develop sore throat complications?

### Bottom Line

First, the good news. Complications of acute sore throat—peritonsillar abscess, otitis media, sinusitis, and skin infections—occur in only approximately 1% of adults. However, there is no good predictor of which adults will develop these complications. Decision tools that try to predict a response to antibiotics (e.g., Centor criteria) do not identify patients at risk of complications. In this study, antibiotic treatment was not associated with a lower likelihood of, or the severity of, complications. (Level of Evidence = 1b) ▶

## Synopsis

This study was conducted in general practices throughout the United Kingdom in which fewer than 50% of patients with tonsillitis were prescribed antibiotics. The researchers enrolled 14,610 adults presenting with acute sore throat as the main symptom, with an abnormal examination result of the pharynx but without complications at the time of presentation. Overall, 56% of patients were prescribed antibiotics. Complications were assessed in patients who sought additional care within one month with new or unresolved symptoms. The entire cohort was analyzed together (regardless of antibiotic use), with the researchers assuming that antibiotic treatment would attenuate the severity of, but not completely prevent, complications.

Complications—peritonsillar abscess (quinsy), otitis media, sinusitis, impetigo, or cellulitis—occurred in approximately 1% of patients, regardless of whether they received immediate or delayed antibiotics or were not given antibiotics. In multivariate analysis, severe tonsillar inflammation and severe earache were predictive of complications, but not strongly so, and 70% of complications occurred when neither was present. Similarly, a Centor score of at least 4 had a positive predictive value for complications of only 1.7% and the FeverPAIN score was similarly not helpful (positive predictive value = 2.1%). Most complications occurred in patients who had low scores on both predictors or who had bacterial complications. Testing for group A beta-hemolytic streptococcal infection was not performed in most patients. Systemic complications, such as glomerulonephritis and rheumatic heart disease, were not reported.

**Study design:** Cohort (prospective)

**Funding source:** Foundation

**Setting:** Outpatient (primary care)

**Reference:** Little P, Stuart B, Hobbs FD, et al., DESCARTE investigators. Predictors of suppurative complications for acute sore throat in primary care: prospective clinical cohort study. *BMJ*. 2013;347:f6867.

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## Fewer Major Bleeds with Edoxaban Than with Warfarin, but Treatment Benefit Unclear

### Clinical Question

Is edoxaban (Lixiana) as safe and effective as warfarin (Coumadin) for the prevention of thromboembolic events in patients with atrial fibrillation?

### Bottom Line

Edoxaban provides similar effectiveness and a somewhat lower rate of major gastrointestinal and intracranial bleeding than warfarin. It is worth reading the supplemental appendices to this report for a look at the subgroups. For almost all subgroups, low-dose edoxaban caused less major bleeding than warfarin, and was better than high-dose edoxaban. But when you look at the effectiveness outcome, almost every point estimate for low-dose edoxaban in every subgroup favors warfarin. This warfarin advantage was statistically significant for patients who had previously taken a vitamin K antagonist (i.e., warfarin) and for those who were not using aspirin at baseline. Thus, the benefit of edoxaban is much murkier, and is not as clear as the authors claim. (Level of Evidence = 1b)

### Synopsis

Edoxaban is yet another oral direct inhibitor of factor Xa that is awaiting U.S. Food and Drug Administration approval. The researchers identified adults with atrial fibrillation diagnosed within the previous 12 months. They excluded anyone with severely impaired renal function; a high risk of bleeding; moderate to severe mitral stenosis; and acute coronary syndromes, coronary revascularization, or stroke within the 30 days before randomization. The participants were randomized to receive warfarin (international normalized ratio target = 2.0 to 3.0) or one to two doses of edoxaban (30 or 60 mg by mouth once daily). After randomization, patients with a creatinine clearance of 30 to 50 mL per minute per 1.73 m<sup>2</sup> (0.50 to 0.83 mL per second per m<sup>2</sup>); patients taking quinidine, verapamil, or dronedarone (Multaq); and patients weighing 132 lb (60 kg) or less had their dose halved.

Outcomes were adjudicated by a committee masked to the treatment assignment of each patient. Analysis was modified intention to treat (only patients receiving at least one dose of the study drug were included), but included 99.6% of patients originally enrolled in the study. This was a noninferiority trial; that is, it was designed to show that edoxaban was as good as warfarin. Those in the warfarin group spent 68% of their time in range, which is pretty typical for usual practice. The median age of participants was 72 years, 38% were women, and 25% had paroxysmal rather than chronic atrial fibrillation. Approximately 78% had a CHADS<sub>2</sub> (congestive heart failure, hypertension, age 75 years or older, diabetes mellitus, and stroke or transient ischemic attack) score of 3 or less, indicating low risk of venous thromboembolism, whereas the remainder were at higher risk. The primary effectiveness end point was the composite of stroke or systemic embolic event, and the primary safety end point was the occurrence of major bleeding. Patients were followed for a median of 2.8 years, with slightly more than 7,000 persons in each group.

There was also an open-label continuation period, but we will focus on the double-blinded portion of the trial. For the comparison of high-dose edoxaban with warfarin, the former was slightly more

effective regarding the primary outcome (1.18% vs. 1.5% per year;  $P = .02$ ; number needed to treat [NNT] = 312 per year). There was no difference between low-dose edoxaban and warfarin regarding the primary outcome (1.61% vs. 1.5%). Most of the benefit came from a reduction in hemorrhagic (not embolic) stroke, which is actually a complication of anticoagulation rather than a byproduct of the atrial fibrillation. Major bleeding episodes were less common with high-dose edoxaban (2.75% vs. 3.43%;  $P < .001$ ; NNT = 147) and low-dose edoxaban (1.61% vs. 3.43%;  $P < .001$ ; NNT = 55). This benefit was observed for intracranial and gastrointestinal bleeds, as well as any bleed into a critical organ site. Adverse events other than bleeding were similar between groups.

**Study design:** Randomized controlled trial (double-blinded)

**Funding source:** Industry

**Allocation:** Concealed

**Setting:** Outpatient (any)

**Reference:** Giugliano RP, Ruff CT, Braunwald E, et al.; ENGAGE AF-TIMI 48 Investigators. Edoxaban versus warfarin in patients with atrial fibrillation. *N Engl J Med.* 2013;369(22):2093-2104.

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