### **Cochrane for Clinicians**

### **Putting Evidence into Practice**

## Acromioclavicular Joint Dislocation: Surgical vs. Conservative Interventions

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### **Clinical Question**

Is surgical intervention for acromioclavicular (AC) joint dislocation superior to conservative interventions in adults?

### **Evidence-Based Answer**

Surgical treatment for AC joint dislocation of the shoulder does not appear to be superior to conservative management in adults. Both strategies resulted in similar quality of life, function, and return to previous activities after one year. Surgical therapy increases the risk of hardware complications, infection, and continued discomfort. (Strength of Recommendation: B, based on inconsistent or limited-quality patient-oriented evidence.)

#### **Practice Pointers**

Dislocation of the AC joint accounts for about 9% of shoulder injuries in the general population and increases to 40% among elite athletes participating in highly competitive impact sports.<sup>2</sup> Dislocation of the AC joint involves injury to the AC ligament with or without coracoclavicular ligament disruption. It most commonly occurs in sports such as football, boxing, martial arts, and cycling and results from a direct impact or fall onto the superior aspect of the shoulder. The most widely accepted classification of AC joint injuries is the Rockwood classification, which grades the

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injury from I to VI. Types I and II are generally considered nonsurgical, and grades IV through VI are surgical. Treatment of type III injuries is controversial and is outside the scope of this review. The authors of this Cochrane review sought to determine if surgical management of AC joint dislocation was superior to conservative management.

The review included six randomized or quasirandomized controlled trials and 357 participants.1 Most participants were male with a mean age of 32 years. All studies were determined to be at high risk of bias; blinding was impossible, and sham surgeries are unethical. Although not all studies specified the severity of injury, by description they all seemed to include type III, and some also included types IV through VI. Primary outcomes were shoulder function, pain level, and treatment failure leading to unplanned surgical intervention, with most studies assessing the need for additional surgical intervention over the subsequent one to four years. A number of secondary outcomes were examined, including return to activity and adverse effects.

The Disabilities of the Arm, Shoulder and questionnaire (https://www.myoptum healthphysicalhealth.com/Documents/Forms/ DASH.pdf) is a validated self-reporting tool that assesses the ability to perform upper limb movements. For the primary outcome of shoulder function, low-quality evidence in studies that used this tool favored conservative (i.e., nonsurgical) treatment within the first three months (mean difference = 8.38 points; 95% CI, 2.62 to 14.14). However, there were no significant differences in shoulder function by one year in studies that included any validated shoulder function assessment tool. No significant differences occurred between treatment groups in level of pain or episodes of treatment failure, although these outcomes had only very lowquality evidence.

Return to previous activities tended to occur earlier or was more successful in those who were managed conservatively, although this secondary outcome was assessed with very low-quality evidence and was measured in a variety of ways that could not be consolidated for meta-analysis. Most adverse effects were reported in the surgical

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group and included infection, problems with hardware, and restricted range of motion.

It should be noted that this Cochrane review encompassed at least 35 conservative treatments and 150 distinct surgical methods for treating AC joint dislocation; further study on specific techniques is warranted because newer methods may have more success. Surgical management may also be warranted for cases in which the shoulder injury is more extensive, such as a co-occurring coracoclavicular ligament strain. However, at least one other systematic review of 14 studies that included 646 patients found no significant difference in outcomes for patients with more severe AC joint dislocations, further suggesting that conservative therapy may be warranted initially for most patients.<sup>3</sup>

**The practice** recommendations in this activity are available at http://www.cochrane.org/CD007429.

**The views** expressed in this publication are those of the authors and do not necessarily reflect the official policy of the Department of Defense, the Department of the Army, the U.S. Army Medical Department, or the U.S. government.

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# Rapid Point-of-Care Antigen and Molecular Tests for Diagnosis of SARS-CoV-2 Infection

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### **Clinical Question**

What are the sensitivity and specificity of point-of-care antigen and molecular-based tests for detecting SARS-CoV-2?

### **Evidence-Based Answer**

SARS-CoV-2 antigen tests have an average sensitivity of 68.9% (95% CI, 61.8% to 75.1%) and an average specificity of 99.6% (95% CI, 99.0% to 99.8%). Accuracy depends on symptom status, time from symptom onset, and test brand. The Standard Q COVID-19 antigen test (SD Biosensor) has a sensitivity of 85.8% (95% CI, 80.5% to 89.8%) and specificity of 99.2% (95% CI, 98.2% to 99.6%).¹ (Strength of Recommendation [SOR]: B, based on inconsistent or limited-quality patient-oriented evidence.)

SARS-CoV-2 rapid molecular tests have an average sensitivity and specificity of 95.1% (95% CI, 90.5% to 97.6%) and 98.8% (95% CI, 98.3% to 99.2%), respectively. The Xpert Xpress SARS-CoV-2 test (Cepheid) has a sensitivity and specificity of 100% (95% CI, 88.1% to 100%) and 97.2% (95% CI, 89.4% to 99.3%), respectively. (SOR: B, based on inconsistent or limited-quality patient-oriented evidence.)

### **Practice Pointers**

Rapid and accurate point-of-care SARS-CoV-2 tests are valuable tools to slow the spread of the virus and safely return people to work and school. To be widely useful, these tests need to be portable and easy to perform, require less operator expertise and only a minimal amount of extra equipment, be inexpensive, and provide results in less than two hours. The authors of this Cochrane review looked at the evidence for SARS-CoV-2 tests meeting these criteria.<sup>1</sup>

This review has been updated once already and includes studies released through November 2020.¹ It involves 64 reports with 78 studies of antigen or molecular tests suitable for point-of-care testing with 24,087 samples, 7,415 of which were confirmed by traditional polymerase chain reaction (PCR) testing to have SARS-CoV-2. Most studies were conducted in Europe and North America.

Included studies evaluated 16 commercial antigen tests, most of which targeted the nucleocapsid protein. Overall, the average sensitivity was 68.9% (95% CI, 61.8% to 75.1%) and the average specificity was 99.6% (95% CI, 99.0% to 99.8%; 21,614 samples; 6,136 confirmed SARS-CoV-2 cases). Accuracy was impacted by symptom status, time from symptom onset, and test brand. On average, sensitivity was greater in those who had symptoms (72%; 95% CI, 63.7% to 79.0%; 37 studies, 15,530 samples, 4,410 cases) than in those without symptoms (58%; 95% CI, 40.2% to 74.1%; 12 studies, 1,581 samples, 295 cases). Sensitivity was also greater in those who had symptoms for less than one week (78.3%; 95% CI, 71.1% to 84.1%; 26 studies, 5,769 samples, 2,320 cases) vs. those in their second week of symptoms (51.0%; 95% CI, 40.8% to 61.0%; 935 samples, 692 cases).

The Standard Q COVID-19 antigen test was one of the best performing tests. When used in the recommended manner, the test had a sensitivity of 85.8% (95% CI, 80.5% to 89.8%) and specificity of 99.2% (95% CI, 98.2% to 99.6%) overall (four studies, 2,522 samples, 421 cases). When broken down by subgroup, the test performed better in symptomatic than in asymptomatic patients. This trend of improved accuracy in symptomatic patients was also evident in another test that performed well, the Panbio COVID-19 rapid antigen test (Abbott). When used according to manufacturer instructions, it had a sensitivity of 72.0% (95% CI, 56.5% to 83.5%) and specificity of 99.2% (95% CI, 98.5% to 99.5%) overall (five studies, 1,776 samples, 362 cases).1

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As the prevalence of COVID-19 rises, the positive predictive value (PPV) of antigen tests improves. In a symptomatic population at 5%, 10%, and 20% COVID-19 prevalence, the Standard Q COVID-19 antigen test PPV is 84%, 92%, and 96%, respectively, with a slight decrease in negative predictive value (NPV; 99.4%, 98.7%, and 97.1%, respectively). This means that with 10% prevalence, if 1,000 people were tested, there would be 88 true-positives, eight false-positives, 892 true-negatives, and 12 false-negatives. For the Panbio COVID-19 rapid antigen test, at 5%, 10%, and 20% prevalence in a symptomatic population, the PPV is 89%, 94%, and 97%, respectively, with a slight decrease in NPV (98.7%, 97.2%, and 94.1%, respectively). This means that with 10% prevalence, if 1,000 people were tested, there would be 75 true-positives, five false-positives, 896 true-negatives, and 25 false-negatives.1

Other studies in the review examined the performance of rapid molecular tests for diagnosing SARS-CoV-2 infection. These tests work similarly to traditional PCR assays by amplifying RNA, but they are automated, require less handling and expertise to process, and typically produce results faster than traditional PCR tests. Average sensitivity and specificity were 95.1% (95% CI, 90.5% to 97.6%) and 98.8% (95% CI, 98.3% to 99.2%), respectively (4,351 samples, 1,781 confirmed SARS-CoV-2 cases). The two most studied tests were the ID NOW COVID-19 test (Abbott) and the Xpert Xpress SARS-CoV-2 test. When used in accordance with the manufacturer's instructions, ID NOW had a sensitivity and specificity of 73.0% (95% CI, 66.8% to 78.4%) and 99.7% (95% CI, 98.7% to 99.9%), respectively (four studies, 812 samples, 222 cases). The Xpert Xpress test had a sensitivity and specificity of 100% (95% CI, 88.1% to 100%) and 97.2% (95% CI, 89.4% to 99.3%), respectively (two studies, 100 samples, 29 cases). In a symptomatic population at 5%, 10%, and 20% prevalence, the ID NOW test PPV is 93%, 96%, and 98%, respectively, with a slight decrease in NPV (98.6%, 97.1%, and 93.6%, respectively). This means that with 10% prevalence, if 1,000 people were tested, there would be 73 true-positives, three false-positives, 897 true-negatives, and 27 false-negatives. For the Xpert Xpress test, at 5%, 10%, and 20% prevalence, PPV is 65%, 80%, and 90%, respectively, with 100% specificity. With 10% prevalence, if 1,000 people were tested, there would be 100 true-positives, 25 falsepositives, 875 true-negatives, and 0 false-negatives.1

The authors acknowledge that diagnoses of SARS-CoV-2 infections in these studies were made on the basis of one positive traditional PCR assay result, which would miss people who become PCR-positive *after* their initial testing. They also point out that methodologies varied widely between studies. These included different populations tested (asymptomatic people tested as part of contact

tracing or routine surveillance, biorepository samples from before the emergence of COVID-19, symptomatic people in different settings, people with known SARS-CoV-2 infection), different sites of sampling, different personnel (self, non-health care worker, health care worker, laboratory technician) conducting sampling, different mediums and methods of handling samples, different intervals between sample collection and analysis, and different sites of analysis (most rapid molecular tests were analyzed in commercial laboratories). As a result of these study limitations, the authors caution that anyone using these tests in a clinical environment should balance these reported results with the place in which these tests would actually be conducted, the local prevalence of disease, the implications of falsepositives and false-negatives in their population, and the availability of traditional follow-up laboratory-based COVID-19 PCR testing.1

Use of these tests must be informed by the wide variance in accuracy among commercially available antigen tests and the lack of evidence for actual point-of-care application of rapid molecular tests. Additionally, sensitivity for antigen tests appears to decrease in asymptomatic people and one week after symptom onset. Until there are more comparative studies that evaluate commercial tests against each other and studies that evaluate molecular tests in actual point-ofcare settings, the best application of these tests might be in contact tracing, outbreaks, or as initial screening for people to determine if they require further testing with the recommended laboratory PCR. The Centers for Disease Control and Prevention supports these limited applications. It notes that the best use of these tests may be in communities without readily accessible laboratory testing or during an emerging outbreak.2

**The practice** recommendations in this activity are available at http://www.cochrane.org/CD013705.

### **Editor's Note:** Dr. Saguil is a contributing editor for AFP.

**The views** expressed are those of the authors and do not reflect the official policy or position of the U.S. Army, U.S. Navy, Uniformed Services University of the Health Sciences, Department of Defense, or the U.S. government.

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