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Ankle Position During the Swing Phase of Gait is a Factor in Recurrent Ankle Sprains

ABSTRACT & COMMENTARY

Synopsis: The 2 hypothesized causes of chronic ankle instability are mechanical instability and functional instability.

Source: Tropp H. Functional ankle instability revisited: Special communications/commentary. *Journal of Athletic Training*. 2002;37(4):512-515.

THIS COMMENTARY WAS PROVIDED BY HANS TROPP, MD, PHD, FOR a *Journal of Athletic Training* special issue on chronic ankle stability. Tropp, a pioneer in ankle instability research, explains that mechanical instability and functional instability are the 2 hypothesized causes of chronic ankle instability. He defines mechanical instability as ankle movement beyond the physiologic limit of ankle range of motion, and functional instability as the subjective feeling of ankle instability or the presence of recurrent, symptomatic ankle sprains.

Tropp presents the functional biomechanics of ankle instability and emphasizes that while the talocrural joint is often considered the “ankle joint,” the subtalar joint has greater relevance to this malady. Stability of the foot underneath the center of gravity occurs from postural corrections at the subtalar joint as rotations around the center of pressure. The effect of external loads (torques) on the ankle is dependent on the line of action of the ground-reaction force upon the subtalar joint axis. Tropp explains that the ground-reaction force usually acts lateral to the subtalar joint axis and anterior to the talocrural joint axis, and consequently external loads usually evert and dorsiflex the ankle.

Hyperinversion and “giving way” occurs when the inverted, weight-bearing ankle is subjected to an external load that further forces the foot into inversion. This mechanism is exacerbated if a shear force is added, with the evertor muscles unable to withstand the lever produced by the body-weight load. The potential for hyperinversion is compounded with the wearing of a shoe, since the shoe

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increases the length of the lever arm, and the friction between the shoe and the ground can add a shear force component.

■ COMMENT BY DAVID H. PERRIN, PhD, ATC

Tropp challenges the theory that damage to the lateral ankle ligaments during hyperinversion disrupts the mechanoreceptor system arising from the sensory receptors in these ligaments. He explains that anesthetizing the lateral ligaments has little effect on ankle joint proprioception and that the wearing of an ankle brace improves ankle joint position sense. He deduces from this information that a variety of receptor sources, including cutaneous, joint, and muscular sources, are likely necessary for motor control.

Tropp also explains the importance of neuromuscular preparation for weight-bearing during the swing phase of gait. He postulates that inappropriate positioning of the lower limb before heel strike likely increases the potential for injury, since the line of action of the reaction force is determined when the foot reaches the ground.

Clinicians typically use a battery of proprioception

and strengthening exercises for the rehabilitation of ankle instability. Tropp suggests that the main factor in functional instability is a change in coordination, mainly due to a transition from ankle synergy to hip synergy during postural corrections. It is this transition that might also affect the tendency to invert the foot during the swing phase of gait. Consequently, he recommends including coordination training activities that provoke ankle inversion and eversion in the rehabilitation protocol. ■

A Link Exists Between Deficiency in Ankle Position Sense and Repeated Ankle Inversion Injury

ABSTRACT & COMMENTARY

Synopsis: Measurable deficits in kinesthesia and ankle position sense are present in subjects with chronic ankle instability.

Source: Konradsen L. Factors contributing to chronic ankle instability: Kinesthesia and joint position sense. *Journal of Athletic Training*. 2002;37(4):381-385.

KONRADSEN DISCUSSES THE LITERATURE AND HIS own work related to deficits in kinesthesia and joint position sense in chronic ankle instability and presents a pathogenic model that connects a deficit in position sense to an increased risk of stumbling with a resultant lateral ankle sprain. He first explains that kinesthesia (joint motion detection) and joint position sense are precise sensorimotor functions that require sophisticated instrumentation for measurement. Joint position sense requires the matching of a set of angles set by the researcher and can be assessed passively or actively. He suggests that passive assessment isolates the proprioceptive ability of the ankle receptors and that active assessment tests proprioceptors in the muscle-tendon unit. He supports this theory with his own work showing that an anesthetic ankle block increased ankle position error when the ankle was moved passively to the index angle by the researcher, yet did not increase error when subjects were allowed to actively move their own ankles.

Konradsen also discusses kinesthesia and position sense deficits in chronic ankle instability vs acute inversion injury. Most studies of chronic ankle instability report deficits in kinesthesia and position sense, and he

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Customer Service E-Mail Address:

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Editorial E-Mail Address: christie.messina@ahcpub.com

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attributes inconsistency in these findings to the definition of chronic instability and to differences in testing protocols. With acute inversion injury, he cites research that shows significant deficits in position sense from a single sprain. He questions whether the deficits in kinesthesia and position sense seen in chronic instability are the result of a predisposition, a single inversion injury, or a single event that was inadequately rehabilitated.

Konradsen's pathogenic model attempts to make a link between deficits in position sense and the swing phase of stride. He explains that the swing phase requires very accurate sensorimotor control and that the lateral border of the foot passes just 5 mm above the surface of the ground during this phase. With this small margin for error, loading of the ankle complex with the body weight at unanticipated heel contact can lead to inversion torque, resulting in further forced inversion of the ankle and susceptibility to injury. Konradsen makes an experimental link between increased ankle position replication error following inversion injury and increases in rotational error that drop the lateral border of the foot and engage the ground during the late swing phase. He postulates that small differences in replication error can have substantial clinical impact in the form of chronic ankle instability.

■ COMMENT BY DAVID H. PERRIN, PhD, ATC

Konradsen correctly points out that measurement of kinesthesia and position sense requires sophisticated instrumentation. He proposes that clinical tests of postural stability and agility may be superior, yet these tests fail to isolate the components of the sensorimotor system that might be involved in chronic ankle instability. Additional research is needed to establish the efficacy of these and other tests to clinicians who do not have access to sophisticated laboratory instrumentation.

Konradsen's pathogenic model of unprovoked ankle sprain and the importance of adequate sensorimotor control during the swing phase of stride seems consistent with Tropp's suggestion that inappropriate positioning of the lower limb before heel strike likely increases the potential for injury.¹ If the lateral border of the foot passes just 5 mm above the ground during level-surface walking, one can imagine the challenges uneven ground and externally induced forces and perturbations present to the athlete with chronic ankle instability. Tropp recommends rehabilitation that includes coordination training activities that provoke ankle inversion and eversion. Konradsen points out that the effect of these activities on kinesthesia and joint position sense is not exactly known. However, rehabilitation programs concerned with balance, coordination, and strength are known to reduce postural sway and increase peroneal muscle

strength. These programs continue to be recommended for patients with chronic ankle instability while research seeks to find the best protocols for restoration of kinesthesia and ankle joint position sense. ■

Reference

1. Tropp H. Functional ankle instability revisited: Special communications/commentary. *Journal of Athletic Training*. 2002;37(4):512-515.

Don't Give Me a Complex!

ABSTRACT & COMMENTARY

Synopsis: *Patients with normal anatomic variants of the anterosuperior labrum, including a sublabral hole or a Buford complex, were 5-7 times more likely, respectively, to have SLAP lesions at arthroscopy.*

Source: Ilahi OA, et al. Variants of the anterosuperior glenoid labrum and associated pathology. *Arthroscopy*. 2002; 18(8):882-886.

VARIANTS OF THE ANTROSUPERIOR LABRUM HAVE been relatively recently described as shoulder arthroscopy and MRI techniques have improved. The anterosuperior labrum can have a normal sublabral hole or foramen from the 1 to 3 o'clock position that is not pathological or associated with instability. Alternatively, the labrum can be absent in this area with a bare glenoid rim, termed a Buford complex. In about 75% of these cases, the middle glenohumeral ligament is thickened or cord-like. Beyond this, little is known about these variants.

Ilahi and colleagues add to our understanding of these anatomic variants as they report their arthroscopic findings in a prospective series of 108 consecutive shoulders. They found an incidence of 18.5% for sublabral foramens and 6.5% for Buford complexes. Most of these patients also had absent superior glenohumeral ligaments in association with a thickened middle glenohumeral ligament. In fact, a discernable superior glenohumeral ligament could only be found in less than half of all shoulders.

The vast majority of patients were scoped for rotator cuff or impingement problems, with only 5% diagnosed preoperatively and 23% intraoperatively with a significant SLAP lesion (type I excluded). Interestingly, they found a strong correlation between anterosuperior labral variants and SLAP lesions. Of the 25 patients with a significant SLAP lesion, 40% had a sublabral foramen and 20% had a Buford complex. If the numbers are turned around, 50% of patients with a sublabral foramen and 71% of patients

with a Buford complex had a SLAP lesion, compared to a 12% incidence in all other shoulders.

■ COMMENT BY DAVID R. DIDUCH, MS, MD

The superior labrum can be a difficult area to diagnose pathology on MRI and even at arthroscopy. Not only is there variability in attachments and mobility of the biceps and labrum, but also we have these anatomic variants to sort out. Ilahi et al help us by supplying good numbers that provide warning signs for SLAP tears. In their series, patients with sublabral holes or Buford complexes were at least 50% likely to have a SLAP tear if they presented with shoulder pain requiring arthroscopy. In fact, they were at 5- to 7-fold greater risk than other patients to have a SLAP lesion.

Clearly, this risk factor can aid in diagnosis. But why does this association exist? Ilahi et al theorize that a less-than-stable anterosuperior labrum puts more stress on the superior labrum and biceps attachment, thereby putting it at risk to pull off with trauma or twisting during throwing activities. They do not call these anatomic variants pathologic or associate them with patterns of instability. Thus, one should not treat the sublabral foramen or Buford complex by any type of reattachment if recognized at arthroscopy. Indeed, patients can lose rotational motion if the anterosuperior labrum is attached where it never was before.

The weakness of this study is that the accurate diagnosis of SLAP lesions can be in question even at arthroscopy, possibly affecting Ilahi et al's numbers. However, the clear benefit of this study is that it provides us a warning sign and a possible correlation as we try to determine normal vs pathological bicep attachment on MRI and at arthroscopy. ■

Arthroscopic Access to the Inferior Shoulder Capsule and Axillary Pouch

ABSTRACT & COMMENTARY

Synopsis: *This descriptive, anatomic, cadaveric study evaluates and confirms the safety of a low-posterior arthroscopy portal to access the inferior capsular recess of the glenohumeral joint.*

Source: Davidson PA, Rivenburgh DW. The 7-o'clock posteroinferior portal for shoulder arthroscopy. *Am J Sports Med.* 2002;30:693-696.

DAVIDSON AND RIVENBURGH STUDIED THE 7-o'clock posterior-inferior portal for safety with

regard to proximity of the axillary and suprascapular nerves in addition to the risk of injury to the articular cartilage. They evaluated the relationship of the 2 closest nerves in 6 paired cadaveric shoulders using both the outside-in and inside-out techniques. They used an anterosuperior portal for passing the inside-out Wissinger Rod. They studied the distance in millimeters and the angle of divergence necessary to injure the nerves.

Davidson and Rivenburgh showed that the suprascapular nerve (28 mm) and the axillary nerve (39 mm) are sufficiently far from the posteroinferior portal to be considered safe. The inside-out technique resulted in a portal approximately 5 mm further from either nerve than the outside-in technique. There was no significant difference in the distance between both nerves and the posterior-inferior portal with varying arm position: flexion-extension or abduction-adduction. The angle of divergence from the intended portal path necessary to injure the axillary nerve was 47° and 33° to injure the suprascapular nerve.

Davidson and Rivenburgh showed that the portal penetrated the teres minor muscle in all cases. They note that with the inside-out technique, it is essentially impossible to injure the suprascapular neurovascular structures since they are medial to the glenoid. However, with a tight shoulder, the Wissinger Rod may cause iatrogenic injury to the articular surface.

■ COMMENT BY MARC R. SAFRAN, MD

Accessory portals for arthroscopy of any joint are helpful to gain access to areas that may otherwise be difficult or impossible to reach. The safety of a posterior inferior shoulder portal is important to establish and have the information disseminated for several reasons. First, the anterior inferior portal for shoulder arthroscopy has been shown to not be entirely safe for routine use. Access to the inferior capsular recess is important, however, to help remove loose bodies from the axillary pouch and for arthroscopic shoulder stabilization and capsulorrhaphy procedures.

There is the concern for crowding with 2 posterior portals; however, not any more so than with 2 anterior portals, which is routinely performed with shoulder stabilization. However, with a 9-o'clock posterior portal, these 2 portals may be too close for easy manipulation of instrumentation. Thus, it would be recommended to have a 10:30 posterior portal in addition to the 7-o'clock posterior portal.

It would be advisable for the arthroscopic surgeon to practice this posterior-inferior portal in cadavers and in

patients with loose shoulders using the inside-out technique before attempting the outside-in technique. Using the inside-out technique in a tight shoulder risks injury to the articular surfaces and thus should be reserved for those without a tight shoulder. The surgeon not familiar with this portal should not begin with the outside-in technique until he is familiar with the correct angle of portal insertion. Knowing the correct path of the portal helps reduce divergence from the appropriate path, as divergence may result in neurologic injury. Once familiar with the correct angle of inclination of the trocar and sheath, using the outside-in technique appears to be safe, provided the trocar is blunt. Arthroscopic identification of the proposed portal with a spinal needle can also be helpful. ■

Two-Bundle ACLs

ABSTRACT & COMMENTARY

Synopsis: *Anatomic 2-bundle reconstruction may produce a better biomechanical outcome than single-bundle reconstruction.*

Source: Yagi M, et al. Biomechanical analysis of an anatomic anterior cruciate ligament reconstruction. *Am J Sports Med.* 2002;30(5):660-666.

REPLACEMENT OF THE ANTEROMEDIAL BUNDLE, NOT the posterolateral bundle, is the focus of most anterior cruciate ligament reconstructions. The present study evaluates an anatomic reconstruction that approximates both functional bundles of the ACL.

In this controlled laboratory study, 10 fresh-frozen cadaveric knees were subjected to various external loading conditions: 134-N anterior tibial load at 0°, 30°, 60°, and 90° of knee flexion, and combined rotary load of 5 nm internal tibial torque and 10 nm valgus torque at 15° and 30° of knee flexion to reproduce a pivot shift force. Through the use of a robotic/universal force-moment sensor testing system, highly accurate measurements of knee kinematics and *in situ* forces in grafts were taken for knees that were intact, ACL deficient, single-bundle reconstructed, and (anatomically) reconstructed with 2 bundles.

Under the 134-N anterior tibial load, anterior tibial translation for the anatomic reconstruction was significantly ($P < 0.05$) closer to that of the intact knee than was the single-bundle reconstruction. The magnitude of the *in situ* force in the ACL and the ACL graft for the anatomic reconstruction did not differ significantly

from the intact ACL at all flexion angles and was significantly higher than those for the single-bundle reconstruction ($P < 0.05$). The *in situ* force normalized to the intact ACL for the anatomic reconstruction was $97\% \pm 9\%$, whereas the single-bundle reconstruction was only $89\% \pm 13\%$.

Under the combined rotary load, the coupled anterior tibial translation of the anatomic reconstruction was significantly greater than that of the intact knee but significantly less than that of single-bundle reconstruction. The forces on the graft itself were greatest in the intact knee, followed by the 2-bundle and then the single-bundle reconstructions ($P < 0.05$). The normalized *in situ* force for the single-bundle and anatomic reconstructions at 30° of flexion was 66% and 91%, respectively.

■ COMMENT BY BRIAN J. COLE, MD, AND NINA SHERVIN

Surgical reconstruction of the ACL is a common procedure to restore knee stability with good-to-excellent clinical results and high success rates. Most ACL reconstruction procedures have focused only on replacing the anteromedial bundle; however, recent reports describe the outcomes of more anatomically correct ACL reconstructions designed to reconstruct both the anteromedial and posterolateral bundles of the ACL.^{1,2} The findings of this study suggest that anatomic reconstruction may produce a better biomechanical outcome than does single-bundle reconstruction, especially during rotary loads. It appears as though anatomic ACL reconstruction more closely restores normal knee kinematics and more closely resembles the *in situ* forces seen in an intact ACL than single-bundle reconstruction. The use of the robotic/universal force-moment sensor testing system allowed Yagi and colleagues to obtain measurements directly from the same specimen, thereby minimizing the interspecimen variation and increasing the statistical power. Despite the promising results of this study, as noted by Yagi et al, further investigation and long-term clinical trials are required to determine the potential functional advantages of anatomic ACL reconstruction procedures. ■

References

1. Muneta T, et al. Two-bundle reconstruction of the anterior cruciate ligament using semitendinosus tendon with endobuttons: Operative technique and preliminary results. *Arthroscopy.* 1999;15:618-624.
2. Pederzini L, et al. Double tibial tunnel using quadriceps tendon in anterior cruciate ligament reconstruction. *Arthroscopy.* 2000;16:E9.

Pump Up the Pain Relief

ABSTRACT & COMMENTARY

Synopsis: *Continuous bupivacaine infiltration using a portable outpatient pump resulted in less pain and less narcotic usage following ACL reconstruction.*

Source: Hoenecke HR Jr, et al. The efficacy of continuous bupivacaine infiltration following anterior cruciate ligament reconstruction. *Arthroscopy*. 2002;18(8):854-858.

IT IS GENERALLY CONSIDERED STANDARD OF CARE NOW to perform ACL reconstructions on an outpatient basis. Pain control is the limiting factor in the success of this. Autograft patellar tendon reconstruction is a painful procedure, especially regarding donor site morbidity. Various methods have been used to improve pain relief for the patient and optimize this as an outpatient experience, including femoral nerve blocks, intra-articular anesthetics, and various pain medication cocktails. Hoenecke and colleagues provide the first prospective, randomized, placebo-controlled, double-blind study that explores the efficacy of disposable pumps to administer continuous local anesthetic.

The study design involved 26 patients randomly assigned to either receive saline as a placebo or bupivacaine for 48 hours after ACL reconstruction. At the conclusion of the case, a small catheter was tunneled under the skin and placed into the patellar tendon defect and partially into the knee joint. Both groups received an initial bolus of 35 mL of 0.25% bupivacaine and 5 mg of Morphine intra-articularly at the conclusion of surgery. The experimental group then received an infusion of 2 mL per hour of bupivacaine while the control group received saline. Patients and evaluators were blinded.

The study group showed a statistically significant difference in visual analogue pain scores as well as pain relief scores at all time points. They also consumed 37% less narcotics than the placebo group. All other surgical and demographic variables were comparable between groups. Hoenecke et al conclude that the technique to provide continuous local anesthetic with the disposable pump on an outpatient basis was effective and safe.

■ COMMENT BY DAVID R. DIDUCH, MS, MD

Although we have numerous ACL studies regarding surgical variables, this is a welcome addition to the literature as it addresses the important issue of pain control in the perioperative period and is carefully designed and executed. A prospective, randomized, double-blind, placebo-controlled study offers little room for criticism.

Their findings were convincing and consistent at each time point. Basically, the study group showed less pain, improved pain relief, and less narcotic use, all desirable outcomes for ACL surgery on an outpatient basis. Furthermore, they found that the system was safe on an outpatient basis and that either the patient or the physical therapist could effectively remove the catheter without any problems at the end of the 48-hour infusion period. The pump is designed such that the rate of anesthetic administration is controlled and foolproof. It would be interesting to determine if higher rates of administration above 2 mL per hour would be even more effective. Their total bupivacaine dose, including the 35 mL bolus at the conclusion of the case, was just 182.5 mg, still well below the published recommended limit of 400 mg over 24 hours.

Other strengths of the study include that they used a dose equivalency system to convert all narcotics to a single scale, both p.o. and IV, for more direct comparisons. They also measured recovery room time and noted that the study group left more than one-half hour sooner on average than the placebo group. Certainly on all fronts the addition of this pump system improved patient outcomes of having outpatient ACL surgery. The only negative to the approach remains cost for the disposable pump system. This is certainly something that surgeons and patients have to weigh in decision making. It may also be something that is variable according to insurance reimbursement and geographic region. This type of paper also helps provide insurance companies with supportive evidence to reimburse this therapy in the interests of patient pain control and overall cost savings by keeping the patients out of the hospital. ■

Bone Sticks for OCD

ABSTRACT & COMMENTARY

Synopsis: *This study examined both fixed and grafted unstable OCD lesions using autologous bone sticks made from the ipsilateral tibia with 90% success.*

Source: Navarro R, et al. The arthroscopic treatment of osteochondritis dissecans of the knee with autologous bone sticks. *Arthroscopy*. 2002;18(8):840-844.

TREATMENT OF SYMPTOMATIC, UNSTABLE OCD fragments in patients at or near completion of growth generally involves drilling across the fragment and some form of (usually) absorbable fixation. Bone grafting with more aggressive curettage facilitates heal-

ing if joint fluid is tracking behind the fragment. Navarro and associates used autologous bone sticks to accomplish all 3 tasks: drilling, fixation, and bone grafting. They report their experience with 11 patients who did not improve with nonoperative treatment and had unstable lesions by exam and radiographic evaluation, including MRI.

Three or 4 bone sticks each 2 cm in length were obtained using a micro-saw from the tibial metaphysis. After drilling across the lesion with a Steinmann pin, these were delivered using a cannula and trocar so that the bone sticks were recessed below the articular surface. At a mean follow-up of 4 years, all patients but 1 had good or excellent results according to a scoring system popularized by Hughston. That 1 “poor” patient had some flattening of the condyle due to collapse with effusions. All OCD lesions healed.

■ COMMENT BY DAVID R. DIDUCH, MS, MD

OCD can be a challenge to treat, frequently requiring open bone grafting for larger, unstable lesions once the growth plates have closed and the potential for spontaneous healing diminishes. Although absorbable pins are commonly used to fix the fragment, Navarro et al present an interesting and very affordable alternative. These autologous bone sticks appear to both fix and graft the lesion, while the antegrade drilling with the large pin helps to provide vascular access to the fragment.

Unfortunately, the details of how they prepared the bone sticks and mean time to healing are not provided in this somewhat-loose study. Fashioning these sticks with a hand held, micro-sagittal saw from a chunk of cortical bone and forcing them inside a delivery cannula could be problematic, I would imagine. However, they do present an interesting new approach to an old clinical problem. It would be appealing to develop instruments that allowed harvest of these sticks percutaneously with arthroscopic delivery. That approach would parallel the technique of osteochondral plug transfer at a smaller diameter with no real limit on graft availability. More studies with both approaches are needed to better evaluate the potential of this treatment for a difficult and not uncommon problem. ■

CME Questions

1. **Successful treatment of OCD requires:**
 - a. drilling to provide vascular access.
 - b. stable fixation.
 - c. bone grafting for larger, unstable lesions.
 - d. All of the above

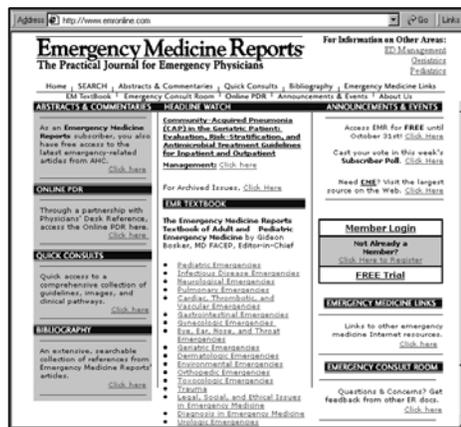
2. **Anesthetizing the lateral ligaments of the ankle is known to:**
 - a. reduce ankle joint proprioception.
 - b. have little effect on ankle joint position sense.
 - c. increase postural instability.
 - d. confirm chronic ankle instability.
3. **The deficits in kinesthesia and position sense seen in chronic instability are the result of a:**
 - a. single inversion injury.
 - b. predisposition.
 - c. single event that was inadequately rehabilitated.
 - d. disruption of the somatosensory system.
4. **Sublabral foramen and Buford complexes are:**
 - a. normal anatomic variants.
 - b. best left unattached to the anterior glenoid.
 - c. highly associated with SLAP tears.
 - d. associated with thickened middle glenohumeral ligaments.
 - e. All of the above
5. **Structures at risk with the postero-inferior arthroscopy portal of the shoulder include:**
 - a. suprascapular nerve.
 - b. axillary nerve.
 - c. articular surface of the humeral head.
 - d. posterior circumflex humeral artery.
 - e. All of the above
6. **Which of the following is false?**
 - a. Most ACL reconstructions focus on replacing the anteromedial bundle only.
 - b. Anatomic 2-bundle ACL reconstruction restores knee kinematics more closely to normal than single-bundle reconstruction.
 - c. Anatomic 2-bundle ACL reconstruction has a long and established clinical track record of superiority over single-bundle reconstructions.
 - d. The in situ force in ACL grafts is closer to an intact ACL in anatomic 2-bundle reconstructions as compared to single-bundle reconstructions.
7. **The continuous administration of local anesthetic through a pump system after ACL surgery resulted in:**
 - a. lower pain relief scores.
 - b. lower levels of pain.
 - c. equivalent use of narcotics.
 - d. longer stays in the recovery room.

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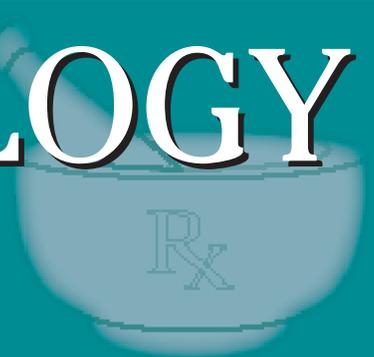
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PHARMACOLOGY WATCH



FDA Approves Claritin For OTC Use For Seasonal Rhinitis

After years of legal wrangling, the FDA has approved loratadine (Claritin, Schering-Plough) as an over-the-counter (OTC) product for the treatment of seasonal rhinitis. Loratadine is considered a nonsedating antihistamine, and its OTC approval was linked with the FDA's work with the National Transportation Safety Board to improve public awareness about the concerns of drowsiness while driving associated with older antihistamines. The OTC switch also comes within months of loss of patent protection for loratadine and the entry into the market of generic equivalents. The OTC switch applies to all 5 formulations of Claritin, and at least 1 generic house plans to market "Reditabs." Meanwhile, Schering-Plough continues to aggressively market desloratadine, the active metabolite of loratadine under the trade name Clarinex, in an attempt to protect its \$3 billion Claritin market.

Simpler Atrial Fibrillation Management

Management of atrial fibrillation (AF) may be simpler in the future based on the results of 2 studies published in the December 5, 2002, *N Engl J Med*. The larger of the 2 studies (AFFIRM) enrolled more than 4000 patients in the United States and Canada with AF and at least 1 other risk factor for stroke such as hypertension, coronary artery disease, diabetes, congestive heart failure, or age older than 65. Patients were randomized to a rhythm control strategy with cardioversion followed by amiodarone, sotalol, propafenone, or older antiarrhythmics such as procainamide or quinidine; or a rate control strategy with digoxin, beta-blockers, and/or calcium channel antagonists. All patients in both groups were anticoagulated with warfarin. The primary end point was overall mortality. The 5-year death

rate was 23.8% in the rhythm control group and 21.3% in the rate control group ($P = 0.08$). Rhythm control was associated with more hospitalizations and more adverse drug effects. In the second study from The Netherlands, 522 patients with persistent AF after electrical cardioversion were randomized to treatment aimed at rate control or rhythm control. Both groups received oral anticoagulation, and the composite end point was death from cardiovascular causes as well as bleeding, implantation of a pacemaker, or severe adverse effects of drugs. After a mean duration of nearly 2.5 years, the primary end point occurred in 44 patients in the rate control group (17.2%) and 60 patients in the rhythm control group (22.6%) ($P = 0.11$). Although both studies showed trends toward adverse outcomes with rhythm control, neither study reached statistical significance. The authors of both studies suggest that a rate control strategy for the treatment of AF is at least as good as the rhythm control strategy. In an accompanying editorial, Michael D. Cain, MD, states that "on the basis of these data, rate control can now be considered a primary approach to the treatment of atrial fibrillation." He also suggests that nonpharmacologic treatments for AF will still be pursued with the goal toward maintaining

This supplement was written by William T. Elliott, MD, FACP, Chair, Formulary Committee, Kaiser Permanente, California Division; Assistant Clinical Professor of Medicine, University of California-San Francisco. Telephone: (404) 262-5517. E-mail: robin.mason@ahcpub.com. In order to reveal any potential bias in this publication, we disclose that Dr. Elliott reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study.

sinus rhythm (*N Engl J Med.* 2002;347:1825-1833; 1834-1840; 1883-1884).

Oral Anticoagulation Vs Aspirin in AF

In a related study, oral anticoagulation was found to be superior to aspirin in preventing stroke in patients with atrial fibrillation (AF) or paroxysmal AF. The study was a pooled analysis of 6 trials of more than 4000 patients who were randomized to receive therapeutic doses of oral anticoagulant or aspirin with or without low-dose oral anticoagulants. Patients receiving oral anticoagulation were significantly less likely to experience stroke (2.4 vs 4.5 events per 100 patient years; hazard ratio [HR], 0.55), ischemic stroke (HR, 0.48), or cardiovascular events (HR, 0.71) but were more likely to experience major bleeding (2.2 vs 1.3 events per 100 patient years; HR, 1.71). Anticoagulant therapy also showed benefit on all-cause mortality but only after 3 years of therapy. Interestingly, more benefit was seen for anticoagulation vs aspirin in patients younger than 75 compared to those 75 years or older. A lesser benefit was also seen for women compared to men. The authors suggest that oral anticoagulation is more effective than aspirin in decreasing the risk of stroke and other cardiovascular events in patients with nonvalvular AF (*JAMA.* 2002;288:2441-2448).

Immunization Does Not Cause Autism

A new study should put an end to concern regarding the MMR (measles, mumps, and rubella) vaccine and its possible link to autism. Researchers in Denmark looked at the records of all children born between January 1991 and December 1998, representing a cohort of almost 540,000 children. Of those, 82% (440,655) received the MMR vaccine. In the cohort, 316 children were diagnosed with autism and 422 were diagnosed with other artistic spectrum disorders. After adjustment for potential confounders, the relative risk for artistic disorder in the vaccinated children compared to the unvaccinated was 0.92 (95% CI, 0.68 to 1.24). The relative risk for other artistic spectrum disorders was 0.83 (95% CI, 0.65 to 1.24). The authors also looked for a possible association between age at the time of vaccination, the time since vaccination or the date of vaccination, and development of artistic disorder and found no relationship. They also found no temporal clustering of cases of autism at any time after immunization (*N Engl J Med.* 2002;347:1477-1482).

Statins May Lower CRP Levels

C-reactive protein (CRP), an inflammatory marker, has shown to be a strong predictor of cardiovascular events, perhaps even more predictive than LDL cholesterol levels (*N Engl J Med.* 2002; 347:1557-1565). Most physicians have looked at these studies with interest but have been unsure what to do with an elevated CRP level in an individual patient. Perhaps even more importantly, it is unclear whether lowering CRP affects cardiovascular outcomes. Until an answer is found to this important question, an increasing body of evidence is suggesting that statins may lower CRP levels.

Simvastatin Reduced CRP Plasma Levels

A recent study reviewed the use of simvastatin in 130 patients with mixed hyperlipidemia and 195 patients with hypertriglyceridemia in a placebo-controlled, double-blind trial. After 6 weeks of treatment with simvastatin 20, 40, and 80 mg, significant reductions in CRP plasma levels were noted vs placebo ($P < 0.05$) (*Am J Cardiol.* 2002;90:942-946). CRP lowering by statins appears to be a class effect with multiple reports of benefit with various statins in the last 2 years.

FDA Actions

Roche's pegelated interferon alfa-2a (Pegasys) has been approved for use in combination with a ribavirin for the treatment of hepatitis C. The drug was approved in October 2002, but Roche has been eagerly awaiting the approval for combination treatment in order to compete with Schering-Plough's Peg-Intron/ribavirin combination for the same indication.

Eli Lilly has received approval to market atomoxetine (Strattera) for the treatment of attention deficit hyperactivity disorder (ADHD). Unlike other drugs for this indication, atomoxetine is not a stimulant and is not listed as a controlled substance. Rather, the drug is a selective norepinephrine reuptake inhibitor, which seems to play a role in regulating attention, impulsivity, and activity levels. Strattera is approved for treatment of ADHD in children, adolescents, and adults.

Eli Lilly has also received approval to market teriparatide injection (Forteo) for the treatment of osteoporosis in postmenopausal women who are at high risk for fracture. Teriparatide is a portion of human parathyroid hormone, which stimulates new bone formation in the spine and hip. The drug is given by daily injection in the thigh or abdomen. ■