

Safety and litigation update for shoulder pain pumps

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It's time to stop using intra-articular pain pumps

Several modalities have emerged for postoperative pain control to facilitate outpatient surgery. For shoulder arthroscopy, these modalities include regional nerve blocks and pain pumps. Regional anesthetic procedures such as interscalene blocks, however, may not be available or desirable because they typically require a trained anesthesiologist and their administration can significantly delay the start of the procedure.



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Pain pumps are self-contained units that dispense medications through tubing to the surgical site. They can be filled with any medication, but typically they dispense a local anesthetic, such as bupivacaine, with or without opiate medications. Many pain pumps provide continuous infusion at a controlled release rate; they may also have patient-administered bolus options. Pain pumps for postoperative pain control in the shoulder can be inserted by the anesthesiologist at the site of the regional anesthetic block, or the surgeon can place it in the intra-articular or the subacromial space.

The problem with pain pumps

As surgeons began to use the pain pumps in the glenohumeral joint, a unique complication

called post-arthroscopic glenohumeral chondrolysis (PAGCL) developed. According to Hansen and associates in 2007, PAGCL diagnostic criteria include increased shoulder pain, shoulder stiffness, shoulder crepitus independent of range of motion, and radiographic joint space narrowing. Of the reported 12 cases of PAGCL, all had arthroscopic shoulder stabilization with use of an intra-articular pain pump using bupivacaine and epinephrine (Fig. 1). This and several other reports found a clear clinical association between PAGCL and pain pump use. A similar clinical picture has also been reported with the use of intra-articular radiofrequency devices.



Fig. 1 Radiograph of PAGCL in a 19 year-old patient more than 18 months after arthroscopic surgery for instability was performed with use of an intra-articular pain pump. The patient later had a hemiarthroplasty with biologic resurfacing. Note the metal anchors placed from the index procedure and the loss of articular surface with bony erosions. Courtesy of Laura B. Kalur

Several basic science studies have confirmed the chondrotoxicity of both bupivacaine and epinephrine. The effects of bupivacaine have been shown to be time- and dose-dependent. Of particular interest are the rabbit studies.

Rabbits were administered a solution of saline solution (control) or 0.25 percent bupivacaine with or without epinephrine into the shoulder via a pain pump over a 48-hour period. At 3 weeks, sacrificed bupivacaine rabbits had significant chondrotoxicity compared with the control group. When the same study was repeated with animal sacrifice at 3 months, however, no permanent cartilage impairment was found. Although there was an increased sulfate uptake in the bupivacaine pain pump groups, this response was thought to be reparative.

Many in vitro studies confirm the chondrotoxicity of local anesthetics, so these studies showing differing effects are puzzling.

Treatment options

Several options for treating PAGCL exist, including arthroscopic débridement, humeral head replacement with or without biologic resurfacing, total shoulder arthroplasty, mosaicplasty, and microfracture. Many reports are case series with short-term follow-up and no reported outcome measures. Because these treatment options do not allow for long-term success in a young athlete, avoiding the complication is the better option. For this reason, intra-articular pain

pumps should not be used in the shoulder.

Subacromial shoulder pain pumps

Although long-term data have not been reported, using pain pumps in the subacromial space appears to be safe and effective. In the initial study associating intra-articular pain pump use and PAGCL, 104 patients were treated with subacromial pain pumps without any chondrolysis. A short-term study of 583 patients with subacromial pain pumps found only 1 complication (external catheter breakage upon removal).

Longer term follow-up is necessary to definitively determine that PAGCL does not occur with subacromial pain pump use. Reasons for the apparent safety of subacromial use may include an increased surface area for absorption, lack of direct cartilage exposure with an intact rotator cuff and joint capsule, and use in a patient population with the primary surgical site in the subacromial space rather than the glenohumeral joint.

Pain pump litigation status

By early August 2009, more than 300 personal injury lawsuits had been filed across the country in federal and state courts by patients with shoulder chondrolysis following the use of intra-articular pain pumps. These lawsuits name the manufacturers and distributors of the pain pumps as well as pharmaceutical companies whose medications were used in the pain pump.

- The lawsuits allege, in part, the following:
- The pain pump manufacturer/defendants knew or should have known, prior to placing the product on the market, that continuous intra-articular infusion of local anesthetics such as lidocaine and bupivacaine, with or without epinephrine, for extended periods of time, results in chondrocyte death and thus, chondrolysis in shoulder surgery patients.
- The defendants failed to adequately warn the orthopaedic community of the danger posed by intra-articular placement of pain pump catheters.
- The defendants failed to adequately warn—through labeling or education of their sales force—the orthopaedic community that such a use had been specifically denied multiple times by the U.S. Food and Drug Administration (FDA).

This last point is significant in determining liability. Since 1998, several manufacturers had applied to the FDA for approval to place the pain pump catheter in the synovial cavity and the applications had been denied. Instead of informing orthopaedic surgeons that the FDA had considered and rejected intra-articular use, sales representatives either directly told surgeons to use the pump intra-articularly or simply left it up to the doctor to figure out what “intra-operative site,” as listed in the general *Instructions for Use* for the pain pumps, meant.

Legally, a manufacturer of medical devices is held to the standard of an expert in the field of medical devices they manufacture and market. Orthopaedic surgeons are not legally held to that same standard and reasonably rely on information provided by the manufacturers through sales representatives, labeling, and other documents provided by a manufacturer of medical devices. Despite this legal standard, many of the defendants argue that orthopedic surgeons are at fault for the injuries sustained by their patients after the use of intra-articular pain pumps.

Next steps

Orthopaedic surgeons who have used intra-articular pain pumps in patients in the past should immediately contact those patients and tell them to seek a follow-up visit immediately. Physicians have an ethical and legal obligation to advise their patients of an adverse event or potential injury that could have resulted from their treatment. This is important as the onset of PAGCL is typically delayed several months from the surgical procedure. Patients have the right to know if a product has caused them harm, and doctors have a duty to advise them of that harm.

Orthopaedic surgeons should immediately discontinue use of intra-articular pain pumps in joints following surgery. The growing body of literature has changed the standard of care, given the association with the devastating complication of PAGCL. Those doctors still using intra-articular pain pumps may face medical liability claims if chondrolysis develops in patients so treated.

Links to the studies cited in this article can be found in the online version available at www.aaosnow.org

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Note: *The information contained in this article is intended for general information purposes and should not be considered legal advice. Individuals who need legal advice should contact a duly licensed professional.*

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