

## Iatrogenic Spinal Accessory Nerve Injury

BRIAN CAMAZINE, MD

**editor's note:** Welcome to "Scalpel & Gavel," a new feature that analyzes court verdicts and settlements in surgical malpractice cases. Brian Camazine, MD, a general surgeon and expert witness consultant, provides commentary and cases. Dr Camazine is assistant professor of surgery at Texas A&M Health Science Center and staff surgeon in general surgery and thoracic oncology at Central Texas Veterans Health Care System, Temple, TX. The editors also select cases from *Medical Malpractice Verdicts, Settlements & Experts*, with permission of the editor, Lewis Laska, Nashville, TN ([www.verdictslaska.com](http://www.verdictslaska.com)). □

The patient required physical therapy after the surgery, but residual biomechanical dysfunction persisted until the trial.

During trial, the patient claimed the surgeon who performed the biopsy was negligent, and failed to inform the patient about the risk to the spinal accessory nerve. The patient said the surgeon informed him of generic risks to the nerves and blood vessels. Additionally, the patient claimed the

surgeon did not obtain informed consent.

**VERDICT:** The patient, a retiree, was awarded \$275,000 in Pennsylvania. This included an award for loss of consortium for the patient's spouse.

**CONTEXT** | Injury to the spinal accessory nerve is not uncommon, nor is it trivial. It causes significant pain and decreased range of motion of the shoulder, and can result in permanent disability. Iatrogenic injury is the most common injury of the spinal accessory nerve, and lymph node biopsy is the most implicated procedure.<sup>1-3</sup> The following cases illustrate that the medicolegal implications of iatrogenic spinal accessory nerve injury are quite significant for the surgeon.

**CASE 1** | A general surgeon performed an excisional right neck lymph node biopsy on a male patient. The patient had local anesthesia with intravenous sedation during the 20-minute procedure.

After surgery, the patient complained of extreme discomfort in his upper right chest, neck, shoulder, and back. A neurologist diagnosed spinal accessory nerve injury. The patient then had exploration of the right spinal accessory nerve and reanastomosis to repair the nerve.

**CASE 2** | A general surgeon treated a 43-year-old male construction worker for an infected sebaceous cyst in the right posterior triangle of the neck. Initially, the surgeon prescribed antibiotics, but excised the cyst after 1 week because the abscess had not resolved. The surgery was performed under general anesthesia without use of a nerve stimulator.

The specimen showed an infected epidermoid cyst, measuring 4.1X1.5 cm with severe surrounding inflammation.

After surgery, the patient had severe pain in the right shoulder with sagging and decreased range of movement, which prevented him from returning to work. At a follow-up visit, the surgeon noted the patient could shrug his shoulders, and told the

# BEXTRA®

(valdecoxib tablets)

Brief summary of prescribing information.

## INDICATIONS AND USAGE

For relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis. For the treatment of primary dysmenorrhea.

## CONTRAINDICATIONS

BEXTRA should not be given to patients who have demonstrated allergic-type reactions to sulfonamides, patients with known hypersensitivity to valdecoxib or those who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or NSAIDs. Severe, rarely fatal, anaphylactoid-like reactions to NSAIDs are possible in such patients (see WARNINGS - Anaphylactoid Reactions, and PRECAUTIONS - Pre-existing Asthma).

## WARNINGS

**Gastrointestinal (GI) Effects - Risk of GI Ulceration, Bleeding, and Perforation:** Serious GI toxicity (bleeding, ulceration and perforation of the stomach, small intestine or large intestine) can occur at any time with or without warning symptoms in patients treated with NSAIDs. Minor GI problems such as dyspepsia are common and may also occur at any time during NSAID therapy. Therefore, physicians and patients should remain alert for ulceration and bleeding even in the absence of previous GI tract symptoms. Inform patients about the signs and symptoms of serious GI toxicity and the steps to take if they occur. Only 1 in 5 patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding or perforation caused by NSAIDs occur in about 1% of patients treated for 3 to 6 months and 2-4% of patients treated for one year. These trends continue, thus increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk. Prescribe NSAIDs with extreme caution in patients with a prior history of ulcer disease or GI bleeding. Most spontaneous reports of fatal GI events are in elderly or debilitated patients and therefore special care should be taken in treating this population. For high risk patients, consider alternate therapies that do not involve NSAIDs. Studies have shown that patients with a prior history of peptic ulcer disease and/or GI bleeding and who use NSAIDs, have a greater than 10-fold higher risk for developing a GI bleed than patients with neither of these risk factors. Pharmacoeconomic studies have identified several other co-therapies or co-morbid conditions that may increase the risk for GI bleeding such as: treatment with oral corticosteroids, or anticoagulants, longer duration of NSAID therapy, smoking, alcoholism, older age, and poor general health status.

**Serious Skin Reactions:** Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported through postmarketing surveillance in patients receiving BEXTRA (see ADVERSE REACTIONS-Postmarketing Experience). As these reactions can be life-threatening, BEXTRA should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

**Anaphylactoid Reactions:** In postmarketing experience, cases of hypersensitivity reactions (anaphylactoid reactions and angioedema) have been reported in patients receiving BEXTRA (see ADVERSE REACTIONS-Postmarketing Experience). These cases have occurred in patients with and without a history of allergic-type reactions to sulfonamides (see CONTRAINDICATIONS). BEXTRA should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs (see CONTRAINDICATIONS and PRECAUTIONS - Pre-existing Asthma). Seek emergency help in cases where an anaphylactoid reaction occurs.

**Advanced Renal Disease:** Treatment with BEXTRA is not recommended in patients with advanced kidney disease, but if it is used, close monitoring of the patient's kidney function is advisable.

**Pregnancy:** Avoid BEXTRA in late pregnancy because it may cause premature closure of the ductus arteriosus.

## PRECAUTIONS

**General:** BEXTRA Tablets cannot be expected to substitute for corticosteroids or to treat corticosteroid insufficiency. The pharmacological activity of valdecoxib in reducing fever and inflammation may diminish the utility of these diagnostic signs in detecting complications of presumed noninfectious, painful conditions.

**Hepatic Effects:** Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs, and notable elevations of ALT or AST (about three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials with NSAIDs. These lab abnormalities may or may not change with continuing therapy. Rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis and hepatic failure (some with fatal outcome) have been reported with NSAIDs. In controlled clinical trials of valdecoxib, the incidence of borderline (defined as 1.2- to 3.0-fold) elevations of liver tests was 8.0% for valdecoxib and 8.4% for placebo, while approximately 0.3% of patients taking valdecoxib, and 0.2% of patients taking placebo, had notable (defined as greater than 3-fold) elevations of ALT or AST. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be monitored carefully for evidence of the development of a more severe hepatic reaction while on therapy with BEXTRA. Discontinue BEXTRA if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash).

**Renal Effects:** Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, NSAIDs may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this action are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state. Use caution when initiating treatment with BEXTRA in patients with considerable dehydration. Rehydrate patients first and then start therapy with BEXTRA. Use caution in patients with pre-existing kidney disease. (See WARNINGS - Advanced Renal Disease.)

**Hematological Effects:** Anemia is sometimes seen in patients receiving BEXTRA. Patients on long-term treatment with BEXTRA should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia. BEXTRA does not generally affect platelet counts, prothrombin time (PT), or partial prothrombin time (PTT), and does not appear to inhibit platelet aggregation at indicated dosages.

**Fluid Retention and Edema:** Fluid retention and edema have been observed in some patients taking BEXTRA. Use BEXTRA with caution in patients with fluid retention, hypertension, or heart failure.

**Preexisting Asthma:** Due to the potential for cross reactivity, do not use BEXTRA in patients with aspirin-sensitive asthma because of the risk of severe bronchospasm, which can be fatal. Use with caution in patients with preexisting asthma.

**Information for Patients:** Inform patients that BEXTRA can cause GI discomfort and, rarely, more serious GI side effects, which may result in hospitalization and even fatal outcomes; to be alert for the signs and symptoms of ulcerations and bleeding, and seek medical advice should these be observed; to promptly report GI ulceration or bleeding, skin rash, weight gain, or edema; to stop therapy and seek immediate medical attention if they experience the warning signs and

symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness, and flu-like symptoms); to seek immediate emergency help in the case of an anaphylactoid reaction; and to avoid BEXTRA in late pregnancy due to potential premature closure of the ductus arteriosus.

**Laboratory Tests:** Physicians should monitor for signs and symptoms of GI bleeding.

**Drug Interactions:** Drug interaction studies with valdecoxib were performed both with valdecoxib and a rapidly hydrolyzed intravenous prodrug form. **General:** Valdecoxib metabolism is predominantly mediated via CYP 3A4 and 2C9 with glucuronidation being a further (20%) route of metabolism. In vitro studies indicate that valdecoxib is a moderate inhibitor of CYP 2C19, and a weak inhibitor of both 3A4 and 2C9. In view of the limitations of in vitro studies and high valdecoxib IC50 values, the potential for such metabolic inhibitory effects in vivo at therapeutic doses of valdecoxib is low. **Aspirin:** Concomitant administration of aspirin with valdecoxib may result in an increased risk of GI ulceration and complications compared to valdecoxib alone. Because of its lack of anti-platelet effect valdecoxib is not a substitute for aspirin for cardiovascular prophylaxis.

**Methotrexate:** Valdecoxib 10 mg BID did not show a significant effect on the plasma exposure and renal clearance of methotrexate. **ACE-inhibitors:** NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. **Furosemide:** NSAIDs can reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis.

**Anticonvulsants:** Anticonvulsant drug interaction studies with valdecoxib have not been conducted. Routine monitoring should be performed when therapy with BEXTRA is either initiated or discontinued in patients on anticonvulsant therapy.

**Dextromethorphan:** Dextromethorphan is primarily metabolized by CYP 2D6 and to a lesser extent by 3A4. Coadministration with valdecoxib (40 mg BID for 7 days) resulted in a significant increase in dextromethorphan plasma levels suggesting that, at these doses, valdecoxib is a weak inhibitor of 2D6. Dextromethorphan plasma concentrations in the presence of high doses of valdecoxib were almost 5-fold lower than those seen in CYP 2D6 poor metabolizers. **Lithium:** Valdecoxib 40 mg BID for 7 days produced significant decreases in lithium serum clearance (25%) and renal clearance (30%) with a 34% higher serum exposure compared to lithium alone. Closely monitor patients on lithium when initiating or changing therapy with BEXTRA. Lithium carbonate (450 mg BID for 7 days) had no effect on valdecoxib pharmacokinetics. **Warfarin:** In healthy subjects, coadministration of BEXTRA 40 mg BID with warfarin (1-8 mg/day) for 7 days caused a statistically significant increase in plasma exposures of R-warfarin and S-warfarin (12% and 15%, respectively), and in the pharmacodynamic effects (prothrombin time, measured as INR) of warfarin. While mean INR values were only slightly increased with coadministration of valdecoxib, the day-to-day variability in individual INR values was increased. Monitor anticoagulant activity, particularly during the first few weeks, after initiating therapy with BEXTRA in patients receiving warfarin or similar agents.

**Fluconazole and Ketoconazole:** Concomitant single dose administration of valdecoxib 20 mg with multiple doses of ketoconazole and fluconazole produced a significant increase in exposure of valdecoxib. Plasma exposure (AUC) to valdecoxib was increased 62% when coadministered with fluconazole and 38% when coadministered with ketoconazole. **Glyburide:** Coadministration of valdecoxib (10 mg BID for 7 days) with glyburide (5 mg QD or 10 mg BID) did not affect the pharmacokinetics (exposure) of glyburide.

**Carcinogenic, mutagenesis, impairment of fertility:** Valdecoxib was not carcinogenic in rats given oral doses equivalent to approximately 2- to 6-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub> or in mice given oral equivalent to approximately 0.6- to 2.4-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub> for two years. Valdecoxib was not mutagenic in an Ames test or a mutation assay in Chinese hamster ovary (CHO) cells, nor was it clastogenic in a chromosome aberration assay in CHO cells or in an in vivo micronucleus test in rat bone marrow. Valdecoxib did not impair male rat fertility at oral doses equivalent to approximately 3- to 6-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub>. In female rats, a decrease in ovulation with increased pre- and post-implantation loss resulted in decreased live embryos/fetuses at doses equivalent to approximately 2-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub> for valdecoxib. The effects on female fertility were reversible. This effect is expected with inhibition of prostaglandin synthesis and is not the result of irreversible alteration of female reproductive function.

**Pregnancy: Teratogenic Effects:** Pregnancy Category C. The incidence of fetuses with skeletal anomalies such as semi-bipartite vertebrae centra and fused sternbrae was slightly higher in rabbits at an oral dose equivalent to approximately 72-fold human exposures at 20 mg QD as measured by the AUC<sub>(0-24h)</sub> throughout organogenesis. Valdecoxib was not teratogenic in rabbits up to an oral dose equivalent to approximately 8-fold human exposures at 20 mg QD as measured by the AUC<sub>(0-24h)</sub>. Valdecoxib was not teratogenic in rats up to an oral dose equivalent to approximately 19-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub>. There are no studies in pregnant women. However, valdecoxib crosses the placenta in rats and rabbits. Use BEXTRA during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Non-Teratogenic Effects:** Valdecoxib caused increased pre- and post-implantation loss with reduced live fetuses at oral doses equivalent to approximately 19-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub>, in rats and an oral dose equivalent to approximately 72-fold human exposure at 20 mg QD as measured by the AUC<sub>(0-24h)</sub> throughout organogenesis and lactation period. No studies have been conducted to evaluate the effect of valdecoxib on the closure of the ductus arteriosus in humans. Therefore, avoid use of BEXTRA during the third trimester of pregnancy. **Labor and Delivery:** The effects of BEXTRA on labor and delivery in pregnant women are unknown. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because of the potential for adverse reactions in nursing infants from BEXTRA, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother and the importance of nursing to the infant. **Pediatric Use:** Safety and effectiveness of BEXTRA in pediatric patients below the age of 18 years have not been evaluated. **Geriatric Use:** No overall differences in effectiveness were observed between elderly patients and younger patients.

## ADVERSE REACTIONS

**Adverse events occurring in >2.0% in controlled arthritis trials of three months or longer regardless of causality at doses of 10 mg (N=1214) and 20 mg (N=1358) respectively:** Hypertension 1.6%/2.1%, Back pain 1.6%/2.7%, Edema peripheral 2.4%/3.0%, Influenza-like symptoms 2.0%/2.2%, Injury accidental 4.0%/3.7%, Dizziness 2.6%/2.7%, Headache 4.8%/8.5%, Abdominal fullness 2.1%/1.9%, Abdominal pain 7.0%/8.2%, Diarrhea 5.4%/6.0%, Dyspepsia 7.9%/8.7%, Flatulence 2.9%/3.5%, Nausea 7.0%/6.3%, Myalgia 2.0%/1.9%, Sinusitis 2.6%/1.8%, Upper Respiratory Tract Infection 6.7%/5.7%, Rash 1.4%/2.1%. 7.5% of arthritis patients receiving valdecoxib 10 mg daily, 7.9% of patients receiving valdecoxib 20 mg daily and 6.0% of patients receiving placebo discontinued due to adverse events in placebo and active controlled clinical trials. In the seven controlled OA and RA studies, the following adverse events occurred in 0.1-1.9% of patients treated with BEXTRA 10-20 mg daily, regardless of causality: **Application site disorders:** Cellulitis, dermatitis contact. **Cardiovascular:** Aggravated hypertension, aneurysm, angina pectoris, arrhythmia, cardiomyopathy, congestive heart failure, coronary artery disorder, heart murmur, hypotension; **Central, peripheral nervous system:** Cerebrovascular disorder, hypertension,

hypoaesthesia, migraine, neuralgia, neuropathy, paresthesia, tremor, twitching, vertigo; **Endocrine:** Goiter; **Female reproductive:** Amenorrhea, dysmenorrhea, leukorrhea, mastitis, menstrual disorder, menorrhagia, menstrual bloating, vaginal hemorrhage; **Gastrointestinal:** Abnormal stools, constipation, diverticulosis, dry mouth, duodenal ulcer, duodenitis, eructation, esophagitis, fecal incontinence, gastric ulcer, gastritis, gastroenteritis, gastroesophageal reflux, hematemesis, hematochezia, hemorrhoids, hemorrhoids bleeding, hiatal hernia, melena, stomatitis, stool frequency increased, tenesmus, tooth disorder, vomiting; **General:** Allergy aggravated, allergic reaction, asthma, chest pain, chills, cyst NOS, edema generalized, face edema, fatigue, fever, flu flushes, hemiparesis, malaise, pain, periorbital swelling, peripheral pain; **Hearing and vestibular:** Ear abnormality, earache, tinnitus; **Heart rate and rhythm:** Bradycardia, palpitation, tachycardia; **Hemic:** Anemia; **Liver and biliary system:** Hepatic function abnormal, hepatitis, ALT increased, AST increased; **Male reproductive:** Impotence, prostatic disorder; **Metabolic and nutritional:** Alkaline phosphatase increased, BUN increased, CPK increased, creatinine increased, diabetes mellitus, glycosuria, gout, hypercholesterolemia, hyperglycemia, hyperkalemia, hyperlipemia, hyperuricemia, hypocalcemia, hypokalemia, LDH increased, thirst increased, weight decrease, weight increase, xerophthalmia; **Musculoskeletal:** Arthralgia, fracture accidental, neck stiffness, osteoporosis, synovitis, tendonitis; **Neoplasm:** Breast neoplasm, lipoma, malignant ovarian cyst; **Platelets (bleeding or clotting):** Echinomysis, epistaxis, hematoma NOS, thrombocytopenia; **Psychiatric:** Anorexia, anxiety, appetite increased, confusion, depression, depression aggravated, insomnia, nervousness, morbid dreaming, somnolence; **Resistance mechanism disorders:** Herpes simplex, herpes zoster, infection fungal, infection soft tissue, infection viral, moniliasis, moniliasis genital, cystitis media; **Respiratory:** Abnormal breath sounds, bronchitis, bronchospasm, coughing, dyspnea, emphysema, laryngitis, pneumonia, pharyngitis, pleurisy, rhinitis; **Skin and appendages:** Acne, alopecia, dermatitis, dermatitis fungal, eczema, photosensitivity allergic reaction, pruritus, rash erythematous, rash maculopapular, rash psoriasisform, skin dry, skin hypertrophy, skin ulceration, sweating increased, urticaria; **Special senses:** Taste perversion; **Urinary system:** Albuminuria, cystitis, dysuria, hematuria, micturition frequency increased, pyuria, urinary incontinence, urinary tract infection; **Vascular:** Claudication intermittent, hemangioma acquired, varicose vein; **Vision:** Blurred vision, cataract, conjunctival hemorrhage, conjunctivitis, eye pain, keratitis, vision abnormal; **White Cell and RES Disorders:** Eosinophilia, leukopenia, leukocytosis, lymphadenopathy, lymphangitis, lymphopenia.

**Other serious adverse events that were reported rarely (estimated <0.1% in clinical trials, regardless of causality, in patients taking BEXTRA: Autonomic nervous system disorders:** Hypertensive encephalopathy, vasospasm; **Cardiovascular:** Abnormal ECG, aortic stenosis, atrial fibrillation, carotid stenosis, coronary thrombosis, heart block, heart valve disorders, mitral insufficiency, myocardial infarction, myocardial ischemia, pericarditis, syncope, thrombophlebitis, unstable angina, ventricular fibrillation; **Central, peripheral nervous system:** Convulsions; **Endocrine:** Hyperparathyroidism; **Female reproductive:** Cervical dysplasia; **Gastrointestinal:** Appendicitis, colitis with bleeding, dysphagia, esophageal perforation, gastrointestinal bleeding, ileus, intestinal obstruction, peritonitis; **Hemic:** Lymphoma-like disorder, pancytopenia; **Liver and biliary system:** Cholelithiasis; **Metabolic:** Dehydration; **Musculoskeletal:** Pathological fracture, osteomyelitis; **Neoplasm:** Benign brain neoplasm, bladder carcinoma, carcinoma, gastric carcinoma, prostate carcinoma, pulmonary carcinoma; **Platelets (bleeding or clotting):** Embolism, pulmonary embolism, thrombosis; **Psychiatric:** Manic reaction, psychosis; **Renal:** Acute renal failure; **Resistance mechanism disorders:** Sepsis; **Respiratory:** Apeur, pleural effusion, pulmonary edema, pulmonary fibrosis, pulmonary infarction, pulmonary hemorrhage, respiratory insufficiency; **Skin:** Basal cell carcinoma, malignant melanoma; **Urinary system:** Pylonephritis, renal calculus; **Vision:** Retinal detachment.

**Postmarketing Experience:** The following reactions have been identified during postmarketing use of BEXTRA. These reactions have been chosen for inclusion either due to their seriousness, reporting frequency, possible causal relationship to BEXTRA, or a combination of these factors. Because these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**General:** Hypersensitivity reactions (including anaphylactoid reactions and angioedema)

**Skin and appendages:** Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis

## OVERDOSAGE

Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions may occur following an overdose. Manage patients by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. Dialysis is unlikely to be useful in overdose. Forced diuresis, alkalization of urine, or hemoperfusion may not be useful.

## DOSAGE AND ADMINISTRATION

**Osteoarthritis and Adult Rheumatoid Arthritis** - 10 mg once daily.

**Primary Dysmenorrhea** - 20 mg twice daily, as needed.

## HOW SUPPLIED

BEXTRA Tablets 10 mg are white, film-coated, and capsule-shaped, debossed "10" on one side with a four pointed star shape on the other, supplied as:

NDC Number	Size
0025-1975-31	Bottle of 100
0025-1975-51	Bottle of 500
0025-1975-34	Carton of 100 unit dose

BEXTRA Tablets 20 mg are white, film-coated, and capsule-shaped, debossed "20" on one side with a four pointed star shape on the other, supplied as:

NDC Number	Size
0025-1980-31	Bottle of 100
0025-1980-51	Bottle of 500
0025-1980-34	Carton of 100 unit dose

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature]

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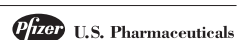


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patient the symptoms were secondary to healing and would resolve with time.

Over the next 6 months, the patient saw the surgeon twice for the same symptoms. No further studies were performed. The patient continued to be disabled, and the surgeon suspected malingering.

After 8 months, the patient saw a neurologist. Electromyography showed denervation of the trapezius. At this visit, the right trapezius was wasted and significant drooping of the right shoulder was evident. The patient had severe weakness of shoulder abduction (*Figure*).

A plastic surgeon re-explored the wound and determined a 3-cm segment of the spinal accessory nerve never was missing. Despite a sural nerve graft, trapezius function remained significantly impaired. The patient could not return to work.

**VERDICT:** The surgeon was found negligent for injuring the nerve and failing to diagnose the problem. The patient was awarded \$350,000 in Texas.

**EDITOR'S COMMENT** | The accessory nerve (cranial nerve 11) is one of the 12 paired cranial nerves, which arise directly from the brain. The cranial nerves are distinguished from the 31 paired spinal nerves that originate from the spinal cord. The accessory nerve is unique because it is formed by the fusion of cranial and spinal root components. The two components are viewed as a cranial nerve.<sup>4</sup>

The joined components exit the skull through the jugular foramen, and then separate. The cranial component joins the vagus nerve, and the spinal component becomes the spinal accessory nerve.<sup>4</sup>

In the neck, the spinal accessory nerve descends close to the internal jugular vein. It passes through or posterior to the sternocleidomastoid muscle, which it innervates. The spinal accessory nerve then enters the posterior triangle of the neck where the upper and middle thirds of the sternocleidomastoid muscle meet. It travels obliquely on the surface of the levator scapulae until it reaches the trapezius at the junction of its middle and lower thirds.<sup>1-3</sup>

In the posterior triangle, the nerve comes within 1–1.5 cm of the skin surface, where it is most susceptible to iatrogenic injury.<sup>2</sup> The most common cause of iatrogenic injury is lymph node biopsy.<sup>2</sup>

**PREVENTIVE MEASURES** | Before and after any procedure in the posterior triangle, the surgeon must eval-

**FIGURE** Limited Abduction



The patient could not abduct his arm beyond 90 degrees. The scar appears in the posterior triangle where the spinal accessory nerve was injured.

uate spinal accessory nerve function. However, a patient's ability to shrug an affected shoulder is not an adequate assessment of accessory nerve and shoulder function because the levator scapulae can elevate the shoulder without a functioning trapezius. Rather, the arm should be abducted at 90° so that the humerus is fixed on the acromion. Movement beyond this point requires a functioning trapezius.<sup>1-3</sup>

Early recognition of spinal accessory nerve injury is critical. Studies have shown that repair within 3 months yields good results, but longer delays are associated with poor outcomes.<sup>1,2</sup>

Iatrogenic injury to the spinal accessory nerve is preventable. Surgeons must exercise caution with any procedure in the posterior triangle. A nerve stimulator can help identify and avoid injury to the spinal accessory nerve. When injuries occur, physical examination and EMG studies can help make an early diagnosis, which can lead to successful outcomes.<sup>1-3</sup>

*Disclosure: Dr Camazine reports no affiliation with any company associated with any products mentioned or their competitors.*

#### References

1. London J, London NJ, Kay SP. Iatrogenic accessory nerve injury. *Ann R Coll Surg Engl.* 1996;78:146-150.
2. Donner TR, Kline DG. Extracranial spinal accessory nerve injury. *Neurosurgery.* 1993;32:907-911.
3. Nason RW, Abdulrauf BM, Stranc MF. The anatomy of the accessory nerve and cervical lymph node biopsy. *Am J Surg.* 2000;180:241-243.
4. Gray H, Williams PL, Bannister LH. *Gray's Anatomy: The Anatomical Basis of Medicine & Surgery.* 38<sup>th</sup> ed. New York: Churchill Livingstone; 1995:1081-1083.

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