Sacroplasty Brings Pain Relief, Cuts Use of Opioids

BY BRUCE K. DIXON

Chicago Bureau

SEATTLE — Percutaneous sacroplasty seems to be a safe, effective therapy for painful sacral insufficiency, according to a multicenter study presented at the annual meeting of the North American Spine

The rate of improvement is rapid, with a 50% or better reduction in pain even before patients left the office. Pain reduction

occurs primarily within the first 3 months and is sustained to 1 year," said Dr. Michael Frey of the Physiatric Association of Spine, Sport, and Occupational Rehabilitation in Fort Meyers, Fla. Sacral insufficiency fractures are a known cause of pain in patients with weakened bone, with a natural history similar to that of vertebral compression fractures. Symptoms gradually resolve, but recovery is slow and patients often resort to opioid analgesics for relief.

Previous studies have shown that injec-

tion of polymethylmethacrylate (PMMA) relieves pain quickly and thoroughly by stabilizing the fracture. However, those studies were small, and their follow-up intervals were 2-16 weeks, Dr. Frey said.

In this prospective, observational cohort study, 25 consecutive sacral insufficiency fracture patients were treated with sacroplasty. There were 17 women and 8 men with a mean age of 74 years and a mean duration of pain of 41 days. Pain level was assessed using the visual analog scale (VAS),

and patient satisfaction and analgesic use were determined. Each procedure was performed under light intravenous conscious sedation and fluoroscopic control, without use of computed tomography. Two bone trocars were inserted between the sacral foramen and sacroiliac joint. About 2-3 cc of PMMA were injected through each trocar under coronal view, Dr. Frey said.

At 1 year, 23 of the 25 patients were available for follow-up. One patient had died from unrelated pulmonary disease. The mean VAS score, which was 7.3 at baseline, plunged to 2.7 immediately post procedure, and at 1 year, was 0.3. Improvement was statistically significant at 1 year and at each follow-up interval (2, 4, 12, and 24 weeks). "We saw a dramatic reduction in the use of opioid analgesics and what we would expect to be an increase in the use of nonopioid pain medications," he said.

Biologic Doesn't

Increase Risk of

Infection in RA

RHODES, GREECE — Adalimumab does not appear to increase the risk of se-

rious infection in patients with rheumatoid arthritis, Dr. J. Kent reported at the 15th

Congress of the European Academy of

There was concern that rheumatoid arthritis (RA) patients, who are more prone to infection than are their healthy peers, would develop more infections while on anti-tumor necrosis factor (anti-TNF) agents like adalimumab (Humira) because of the role these agents play in host defense, Dr. Kent explained in a

However, in a study of more than 2,500 patients who participated in North American and European trials of adalimumab which is also approved for the treatment of psoriatic arthritis and ankylosing spondylitis-there was no increased incidence of serious infections in RA patients,

compared with the reported incidence of

such infections in RA patients naive to anti-

A total of 378 serious infections—most commonly pneumonia (70 patients), septic arthritis (37 patients), urinary tract infection (34 patients), and cellulitis (30 patients)—occurred in 305 patients (4.3 infections per 100 patient-years). The rates were similar to those reported in RA patients prior to availability of anti-TNF agents (3.1-9.6 infections per 100 patientyears), according to Dr. Kent of Abbott Laboratories (the maker of Humira). The rate of serious infections also was

not affected by diabetes status; a total of

23 serious infections occurred in the 146 patients with RA who had diabetes (4.9 infections per 100 patient-years), compared with 355 of 2,358 patients without dia-

betes (4.3 infections per 100 patient-years).

Of note is a finding that 73% of patients

with serious infections were using steroids

at the time of the infection.

Dermatology and Venereology.

poster at the meeting.

TNF therapy.

findings of minimal risk may be related to the use of oral contraceptive formulations containing lower hormonal doses of estrogens and progestogens.

8. Carboydrate and Lipid Metabolic Effects: Oral contraceptives have been shown to cause glucose intolerance in a significant percentage of users. Oral contraceptives notationing greater than 75 micrograms of estrogens cause less ployers for cause glucose intolerance.

Progestogens increase insulin secretion and create insulin resistance, this effect varying with different progestational agents. However, in the nondabetic woman, oral contraceptives appear to have no effect on fasting blood glucose. Because of these demonstrated effects, prediabetic and diabetic women should be carefully observed while taking oral contraceptives. A small proportion of women will have persistent hypertrigh-peridemia while on the pil As discussed earlier (see WARNINGS, 1.a. and 1.d.), changes in serum triglycerides and lipoprotein levels have been reported in oral contraceptive users.

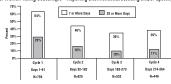
9. Evarled Blood Pressure: Women with significant hypertension should not be started on hormonal contraceptive users.

9. Evarled Blood Pressure: Vomen transfer incomance the service should be monitored closely, and if significant elevation of blood pressure between the progression and succession and contraceptive users.

Women with a history of hypertension or hypertension-related diseases, or renal disease should be encouraged to use another method of contraception. If women with hypertension elect to use oral contraceptives. Should be monitored closely, and if significant elevation of blood pressure occurs, oral contraceptives and even to most or exacershic progression contractance of pressure and pressure and there is no difference in the occurrence of hypertension among ever and never-users.

10. Headacher: The most of exacershicon of migration of contraceptives in memors and bleeding or development of headache with a new pattern that is recurrent, persistent, or severe requires discontinuation o

Figure: Percentage of Women Taking Seasonique™ Reporting Intermenstrual Bleeding and/or Spotting.



As in any case of bleeding irregularities, nonhormonal causes should always be considered and adequate diagnostic measures taken to rule out malignancy or pregnancy. In the event of amenorthea, pregnancy should be ruled out. Some women may encounter post-pill amenorrhea or oligomenorrhea (possibly with anovulation), especially when such a condition was preexistent.

with anouncement, especially miner source commons and product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

1. Sexually Transmitted Diseases: Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

PRECALITIONS

1. Sexually Transmitted Diseases: Patients should be counseled that this product does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

2. Physical Examination and Follow-up: A periodic history and physical examination are appropriate for all women, including women using oral contraceptives. The physical examination, however, may be deferred until after initiation of oral contraceptives. The physical examination however, may be deferred until after initiation of oral contraceptives. The physical examination should include special reference to blood pressure, breasts, abdomen and pelvic organs, including envical cytology, and everal taboratory tests. In case of undiagnosed, persisten for recurrent abnormal variant bleading programs and programs of the product of the product

centrations of acetaminophen and increased clearance of ternazepam, saligivia add, morphine and doffbric acid, due to induction of conjugation have been noted when these drugs were administered with combination or contraceptives.

9. Interactions with Laboratory Tests - See Package Insert for complete information,

10. Carcinogenesis: See WARNINGS. 11. Pregnancy: Pregnancy Category X. See COURTAINDICATIONS and WARNINGS. 12. Nursing Mothers: Small amounts of oral contraceptives steroids and/or metabolites have been identified in the milk of nursing mothers, and a few advierse effects on the child have been reported, including jaundics and breast enlargement. In addition, oral contraceptives given in the postpartum period may interfere with lactation by decreasing the quantity and quality of breast milk. If possible, the nursing mother should be advised not to use oral contraceptives but to use other forms or contraceptive with a beat and present of the properties of Seesonique Wallships warened her child. 3. Pediatric Uses: Seel yand efficacy of Seesonique Wallships warened by the properties of the properties of

OVERDOSAGE: Serious ill effects have not been reported following acute ingestion of large doses of oral contraceptives by young children. Overdosage may cause pauses and withdrawal bleefing may occur in females

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SEASONIQUE™

(levonorgestrel / ethinyl estradiol tablets) 0.15 mg / 0.03 mg and (ethinyl estradiol tablets) 0.01 mg
Brief Summary. See full package brochure for complete information.
Patients should be counseled that this product does not protect against HIV-infection (AIDS) and other sexually transmitted diseases.
CONTRAINDICATIONS: Oral contraceptives should not be used in women who currently have the following conditions: • Thrombophlebitis or thromboembolic disorders • A past history of deep vein thrombophlebitis or thromboembolic disorders • Cerebrovascular or coronary artery disease (current or history) • Valvular heart disease with thrombogenic complications • Uncontrolled hypertension • Diabetes with vascular involvement • Headaches with focal neurological symptoms • Major surgery with prolonged immobilization • Known or suspected carcinoma of the breast or personal history of breast cancer • Carcinoma of the endometrium or other known or suspected estrogen dependent neoplasia • Undiagnosed abnormal genital bleeding • Cholestatic jaundice of pregnancy or jaundice with prior pill use • Hepatic adenomas or carcinomas, or active liver disease • Known or suspected pregnancy . Hypersensitivity to any component of this product

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strong-

VARIANUS:
Ciparette monitori pressase the risk of serious cardiovascular side effects from and contraceptive use. This risk increases with age and with beavy smoking 15 or more ciparettes per day) and is quite marked in women over 25 years of age. Women who use and contraceptives should be strongly advised not be smoke.

The use of ora contraceptives is associated with increased risk of several serious conditions including venous and arterial thrombotic and thromboembolic events (such as mycoardial interdior, infromboembolism, and strole), hypatic recipation, guilbodder desises, and hypertresion. The risk of serious morbid yor morbidly sery result in healthy women without underlying insist factors. The risk of morbidly and morbidly priceases syntimetry in the presence of other underlying risk factors such as certain inherited firmomorbidines, hyperteriscion, bypertipichemics, obesity and diabetes. The risk increases and a certain inherited firmomorbidines with the process of the company in the presence of other underlying risk factors. The risk of the risk of the company is the following inherited price and the process and prospectives in the three for commons use bodies. The relative risk of the risk of a disease, and really a ratio of the originate of a disease and prospective or color studies. See control studies and process of provide information on the actual originate coursease of a disease. Colorist studies provide a measure of artificiate in the information of the actual originate coursease of a disease. Colorist studies provide a measure of administration or the actual originate coursease of a disease. Colorist studies and provides risk originate in the production. For third information, the relative is a control originate or a disease of propose in the risk originate or a disease of a disease or interpretation or a control approach or a disease of a disease or interpretation or the actual originate originate in the risk of the second provides or interpretation or actual originate interpretation or act

least 6 years after discontinuation of and contraceptives, although excess risk was very small. However, both studies were performed with oral contraceptive formulations containing 50 micrograms or higher of estrogens.

2. Estimates of Mordality from Contraceptive users about method of contraception to not smoke, mortality associated with all methods of birth control is less than that associated with children'th. The observation of a possible increase in risk of mortality with age for oral contraceptive users is based on data gathered in the 1970's—but not reported until 1983. However, current clinical practice involves the use of lower estrogen dose formulations combined with careful restriction of oral contraceptive users in which suggest that the risk of cardiovascular disease with the use of and contraceptive users in the saked on data gathered in the 1970's—but not reported until 1983. However, current clinical practice involves the use of lower estrogen dose formulations combined with careful restriction of oral contraceptive users with contraceptive users with such users as the contraceptive users in the contraceptive users with such such that the school contraceptive users with the user of a contraceptive users in the provision of the contraceptive users and the school of the contraceptive users with the user of a contraceptive users in the contraceptive users are designed to the contraceptive users and the contraceptive users are contraceptive. Such women do not have access to effective and acceptable means of contraceptive users user and the productive principal very developed to the provision of the productive principal very developed to the p

Reference: 1. Data on file. Duramed Pharmaceuticals Inc, Pomona, NY.

-Sharon Worcester