

Consider a Contract for Pain Patients on Opioids

BY SHARON WORCESTER

EXPERT ANALYSIS FROM THE ANNUAL MEETING OF THE AMERICAN COLLEGE OF RHEUMATOLOGY

ATLANTA – Treating chronic pain poses unique challenges in this age of abuse and litigation, but using contracts can help improve the chances that patients get the relief they need from opioid therapy – safely and without legal ramifications, according to Dr. Allan Gibofsky.

Before you get to the point of discussing a contract, however, it is important to assess a patient's risk for problematic medication use and substance abuse. Several validated measures exist for this purpose (although none are in widespread use), and other methods can also be used to help predict potential problems, said Dr. Gibofsky, professor of medicine and public health at Weill Cor-

nell Medical College and an attending rheumatologist at the Hospital for Special Surgery, New York.

For example, prior history of problematic use, requests for increased dosage, a preference for a specific route of administration, patient focus on opioids during a visit, multiple calls from the patient regarding prescriptions are all signs of trouble, he noted.

A determination should be made as to whether the patient should be treated or referred to a pain management or addiction specialist for care, Dr. Gibofsky said, suggesting that if the choice is to treat, then the patient should be categorized into a low or high perceived-risk category, and therapy should be structured from that perspective.

"That will help your ability to monitor the patient and help a patient who may have some vulnerability maintain

control," he said.

A contract should be considered as a way for the physicians and patients to achieve those goals.

It is reasonable to request all medical records and to contact all other health care providers to obtain prescribing and other histories, as well as to suggest, or even require, that a patient receive a consultation with a specialist if there is concern about abuse or potential risk of abuse.

The contract can also spell out what is expected of both the patient and the provider, and it can provide for penalties on both sides for violations. For example, a contract can require that a patient be seen on a certain schedule, and it can state that only small amounts of medication will be given and that toxicology screens must be performed.

A contract could also require that concomitant nonpharmacologic modalities –

that could limit the required dosing of pain medications – be used, and that others, such as a spouse or significant other, be allowed to contact you regarding the patient's compliance, he said.

Such contracts are recommended by many pain management specialists, and they have been widely adopted, but they remain controversial. While they can be educational and can provide clarification of roles, patients may perceive them as stigmatizing and punitive. They can limit flexibility and – ironically – can increase liability for providers who don't live up to their own responsibilities as specified in the contract.

However, they can also provide a good framework from which to provide safe and effective pain management.

Dr. Gibofsky reported that he had no financial conflicts of interest relevant to this presentation. ■

Bystander-Given Naloxone May Reverse Opioid Overdose

BY BRUCE JANCIN

FROM THE ANNUAL MEETING OF THE AMERICAN PUBLIC HEALTH ASSOCIATION

DENVER – A novel program of bystander-administered intranasal naloxone shows promise for the treatment of potentially fatal opioid overdoses.

The program was implemented in response to a greater than sixfold increase in the annual number of opioid-related fatal overdoses in Massachusetts from 1990 to 2006. Among 25- to 34-year-olds in the state, mortality from opioid overdose is greater than that attributable to motor vehicle accidents, Courtney E. Pierce observed at the meeting.

This is a national problem fostered by the ready availability of relatively low-cost, high-purity heroin along with the marked growth in opioid prescriptions, some of which are diverted for recreational use as street drugs. That's why the Centers for Disease Control and Prevention is funding the ongoing 2-year Intranasal Naloxone and Prevention Education's Effect on Overdose (INPEDE OD) study. The study is comparing opioid overdose rates, fatal and nonfatal, in those high-risk Massachusetts communities that have implemented bystander-administered intranasal naloxone to rates in other high-risk communities that have not, explained Ms. Pierce of the section of general internal medicine at Boston Medical Center.

Bystander-given intranasal naloxone for reversal of opioid overdoses was implemented by the Boston Health Commission in August 2006. Based upon the favorable Boston experience over a 15-month period, the state health department implemented a structured program of overdose education and

distribution of intranasal naloxone kits in seven additional sites across the state.

The program is implemented by community-based HIV risk-reduction programs or public health agencies. It entails 1 hour of training in how to recognize signs of overdose, administer intranasal naloxone, and contact emergency medical services. Participants are then given a two-dose kit and encouraged to keep it on their person.

To date nearly 8,000 potential bystanders have been enrolled. These are



The program entails 1 hour of training in how to recognize overdose, give naloxone, and contact EMS.

MS. PIERCE

individuals considered particularly likely to encounter overdoses. They have been enrolled mostly at detox centers, methadone clinics, needle exchange sites, emergency departments, shelters, and drop-in centers. Among the enrollees are 5,351 individuals in treatment for, recovery from, or current active users of illicit drugs and 2,589 nonuser family members and professionals. At enrollment, 78% of people in the active- or past-use group and 47% of the nonusers had previously witnessed an overdose.

At last follow-up, 755 overdoses were reversed through bystander-administered intranasal naloxone. In two-thirds of cases, the naloxone was administered by a friend, in 14% by a partner or family member, and in 9% by a stranger.

Ms. Pierce declared she has no relevant financial interests. ■

OTC Painkillers Linked to Undescended Testes

BY JENNIE SMITH

FROM HUMAN REPRODUCTION

Women taking over-the-counter painkillers during pregnancy have an increased risk of having sons born with undescended testes, according to a study that also incorporates rat models to show why this might be.

Using data from a birth cohort study of singleton sons born to 1,463 women in Finland and 834 in Denmark, all of whom completed either written questionnaires or telephone interviews or both, the researchers, led by Henrik Leffers, Ph.D., of Rigshospitalet in Copenhagen, found the risk of cryptorchidism to increase sevenfold in boys born to women who used more than one of three over-the-counter painkillers – aspirin (acetylsalicylic acid), acetaminophen (paracetamol), or ibuprofen – simultaneously during their pregnancies. Exact doses of the painkillers were not recorded.

The findings, published online (doi: 10.1093/humrep/deq323), also showed that any of these painkillers used for any duration during the second trimester more than doubled the risk of cryptorchidism, though the association for acetaminophen did not reach significance.

The highest risk was among women who used more than one compound simultaneously for more than 2 weeks in the second trimester (adjusted odds ratio, 21.7 [1.83-258]).

A possible mechanism for this effect, Dr. Leffers and his colleagues hypothesized, was demonstrated by some of the study's coauthors, who found in a linked investigation that intrauterine exposure to acetaminophen, at three times the recommended dose for humans, led to a reduction in anogenital distance among

fetal rats, and also reduced testosterone production by about half in fetal rat testes.

Aspirin was also tested in rats, but the results were not conclusive. "A particular strength of this study is the use of two complementary rat models to support the contention that the association between analgesic use and cryptorchidism seen in our cohort study may result from a reduction in androgen production," Dr. Leffers and his colleagues wrote.

Their study adds to findings (Epidemiology 2010;21:779-85) from a cohort of 47,000 boys born in Denmark, 980 of whom were identified in childhood as having cryptorchidism. That study, which also looked at acetaminophen, ibuprofen, and acetylsalicylic acid during pregnancy through telephone interviews and questionnaires with mothers, saw exposure to acetaminophen during both the first and second trimesters associated with increased cryptorchidism (hazard ratio = 1.33). However, no association was found for ibuprofen or aspirin.

Dr. Leffers and his colleagues found all but one of their significant associations in the Danish part of their cohort, and speculated that differences in design of the Finnish and Danish cohort studies may have been partly responsible.

In a press release accompanying the study, Dr. Leffers said: "A single paracetamol tablet (500 mg) contains more endocrine disruptor potency than the combined exposure to the 10 most prevalent of the currently known environmental endocrine disruptors during the whole pregnancy."

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