

LETTERS TO THE EDITOR

SSRIs IN PREGNANCY

To the Editor:

Pregnancy is a period of stress for women and can be a risk factor for depressive illness. The decision to prescribe an antidepressant medication during pregnancy needs to be made on a case-specific basis. The risks and benefits of the medication should be evaluated with patient participation and informed consent should be obtained. Once a decision has been made to use antidepressant therapy, the selective serotonin reuptake inhibitors (SSRIs) are a safe choice because of their side-effects profile and safety in overdose.

Fluoxetine (Prozac) is the only SSRI for which there is existing human data regarding safety in pregnancy. Pastuszak et al¹ compared 128 women taking fluoxetine during the first trimester with two matched groups of women who were exposed to either nonteratogens (eg, penicillin, acetaminophen) or tricyclic antidepressants (TCAs). They found no differences in rates of major birth defects in babies exposed to fluoxetine compared with those exposed to nonteratogens (2% vs 1.8%). In a second comparison reported in the same study, no significant differences were found between the fluoxetine group, nonteratogen-exposed controls, and TCA-exposed controls.¹

These findings are backed by two other studies by Goldstein² and Chambers et al.³ Goldstein reported postnatal complications unrelated to malformations in 15 of 112 identified pregnancies. This study did not find a consistent pattern or a dosage rela-

tionship. Chambers and associates studied a large sample of 228 pregnant women taking fluoxetine who were prospectively identified. In comparing the fluoxetine group with controls, they found no significant differences in pregnancy loss (10.5% vs 9.1%), nor was the rate of major structural abnormalities any different (5.5% vs 4.0%). Infants exposed to fluoxetine in the third trimester had a higher rate of perinatal complications such as premature delivery, admission to special care, and lower birth-weight. This study did not control for coexisting diseases and did not correct for the severity of depression among women requiring pharmacotherapy during pregnancy. These data suggest that fluoxetine should be the physician's first-choice SSRI in pregnancy.

Sertraline (Zoloft) has been reported in animal studies to cause transient aggressiveness at the start of treatment and to reduce body weight. Delay in ossification of the fetuses was noted and appeared to be related to low fetal weights (product monograph). Paroxetine (Paxil), though safe in animal studies, lacks human data (package insert). In the case of fluvoxamine (Luvox), there were 63 reports of pregnancy during the use of this drug. Of these, approximately half the births were considered normal. There were eight therapeutic and eight spontaneous abortions.

The Food and Drug Administration (FDA) system of rating drugs for use in pregnancy places fluoxetine, sertraline, and paroxetine in category B, whereas fluvoxamine is in category C. Once a decision has been

made to use medication treatment we believe fluoxetine to be the best choice because its safety in pregnancy and lack of problems in infants born to mothers taking fluoxetine have been demonstrated in studies.

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RADIOLOGICAL MAXILLARY SINUSITIS IN PATIENTS WITH COMMON COLD

To the Editor:

We have noticed that *The Journal of Family Practice* has published a great deal of research on infections of the upper airway. We thought a recent study from our clinic would be of interest to your readers. As you know, upper respiratory tract infections (URIs) are the leading cause of antibiotic prescription.¹ It is commonly accepted that patients with URI and radiological maxillary sinusitis may benefit from antibiotic treatment. Computerized tomography (CT) scans have shown, however, that sinus abnormalities are present in more than 80% of patients with a common cold.² We wanted to assess, by using sinus radiographs, the fre-

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TABLE

Radiographic Maxillary Sinuses Findings (Occipitontental View) Among Patients with Common Cold (N = 283) Compared with Controls Without Respiratory Tract Infection (n = 80)

	Mucosal Thickening ≥ 6 mm	Sinus Opacity	Air Fluid Level	Any Signs of Sinusitis	Normal Sinuses
Patients, No (%)	44 (15)	19 (7)	20 (7)	71 (25)*	212 (75)
Controls, No (%)	1 (1)	1 (1)	0	2 (3)*	78 (97)

* $P \leq 0.001$

quency of maxillary sinus abnormalities among patients who seek treatment for the common cold but who have no clinical signs or symptoms of sinusitis.

Patients who presented at our walk-in medical clinic with a common cold during the winter season were eligible for participation. Inclusion criteria were a history of acute nasal congestion or rhinorrhea and evidence on clinical examination of a URI with nasal congestion, rhinorrhea, or pharyngitis. We excluded all patients with facial pain, maxillary toothache, tenderness of the maxillary or frontal sinuses, as well as patients with an overall clinical impression in favor of sinusitis and patients with chronic sinus disease. Eighty healthy volunteers without respiratory tract infections were recruited as control subjects. A sinus radiograph (occipitontental view) was performed in all patients and controls at the time of enrollment. The radiographs of the controls and the patients were mixed, and two experienced radiologists, blinded to all clinical symptoms, interpreted these films separately. The diagnosis of maxillary sinusitis was considered if at least one maxillary sinus had an air-fluid level, a complete opacity, or a mucosal thickening ≥ 6 mm.

Two hundred eighty three patients were included in the study; 152 men and 131 women (average age 31 years). The median duration of symptoms was 3 days. Approximately half of the patients had taken over-the-

counter medication at the time of enrollment.

The radiological appearance of maxillary sinuses was considered normal on both sides in 212 of the 283 patients (75%), even though mucosal thickening (<6 mm) in one or both sinuses was present in 37 patients (13%). Polyps in one or both of the maxillary sinuses were present in 32 cases (11%) and in 6 controls (8%) ($P = .36$).

Radiological maxillary sinusitis was present in 71 (25%) patients with a common cold. The radiological signs were an air-fluid level ($n=20$, 7%), a complete opacity ($n=19$, 7%), and a mucosal thickening ≥ 6 mm ($n=44$, 15%). The radiographic maxillary sinuses findings for patients with a common cold compared with the controls as shown in the Table. The mucosal thickening was bilateral in 15 patients and was associated with an air-fluid level or a total opacity in 12. Among the 566 maxillary sinuses (left and right) that were examined in the 283 patients enrolled, radiological sinusitis was present in 104 sinuses (18%). Only two controls had a radiological maxillary sinusitis; one with total sinus opacity and another with a mucosal thickness >6 mm. Thus, 25% of study subjects and 3% of controls had sinusitis confirmed by radiology ($P \leq 0.001$).

The clinical distinction between the common cold and acute bacterial sinusitis among patients with community-acquired URI is a frequent dilemma. Although antral

puncture is the gold standard,^{3,4} sinus radiology remains the reference because it is much easier to perform.⁵ In our study we took care to exclude patients with signs or symptoms suggesting acute sinusitis. Nonetheless, 25% of these patients had maxillary sinusitis demonstrated by radiology. Such findings, however, were very rare among controls without URI. The use of CT scans has shown that sinus abnormalities are frequent among patients with a common cold, but there were no data available that made use of radiographs.² Our findings confirm, using a larger population and a less sensitive imaging tool, that early in the course of a common cold there is maxillary mucosal lesions and radiological sinusitis. Patients with a common cold have a rhino-sinusitis. Therefore, in patients with URIs, maxillary radiographs are unlikely to be a good criterion by which to judge the necessity of antibiotic treatment. Nevertheless, sinus radiography is the reference test in many clinical studies on acute sinusitis.⁶

Our findings are confirmed by a recent study among patients who had a URI and sinusitis confirmed by radiography.⁷ In this office-based study, 214 patients were randomized to placebo or antibiotic treatment. Despite radiologically confirmed sinusitis, the clinical cure and the rate of complications were similar in both treatment groups. This study and our

results strongly suggest that maxillary radiographs should not be used in the initial evaluation of patients with community-acquired URI.

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WESTERN ALLOPATHIC VS ALTERNATIVE MEDICINE

To the Editor:

Dr Gillette wrote a letter to the editor¹ in the December issue of the *Journal* critiquing the editorial by Dr Wayne Jonas² on the subject of complementary and alternative medicine (CAM). Dr Gillette pointed out the lack of good scientific data to substantiate the claims made for many CAM therapies. He further stated that it would be hazardous to the intellectual integrity of "science-based" physicians to endorse these unsubstantiated claims since they may, in fact, be based on placebo effects or entrepreneurial zeal. He noted that objective reality is verifiable and correctly states that this standard applies equally to all unbiased observers. Lastly, he stated that it may be appropriate to "tolerate" patient use of CAM if the therapies are harmless and paid for out of pocket.

The long overdue move toward evidence-based medicine places all parties on an equal playing field. There are many examples from the recent medical literature that make it painfully obvious that much of what we do in western allopathic medicine (WAM) has not been substantiated by our own standards. For instance, the use of digoxin in the treatment of heart failure for more than 200 years was finally "validated" last year in a study of 7788 patients reported at the annual meeting of the American College of Cardiology.³ The study showed a 14% reduction in death rate because of worsening heart failure and a 25% reduction in death rate of first hospitalizations for heart failure. The same study also showed a 12% increase in death because of presumed arrhythmias and a 26% increase from presumed myocardial infarctions. The routine treatment of both acute maxillary sinusitis⁴ and acute otitis media⁵ with antibiotics has not been proved to consistently improve outcomes. Even the common practice of treating fever with

antipyretics has been brought into question with evidence suggesting this may increase the duration or severity or both of certain infections.⁶ An unflattering report from the government Office of Technology Assessment estimates that well over half of what we do in WAM has not been proved.⁷ It seems more and more as if the self-proclaimed emperor (WAM) has very few clothes, and tattered clothes at that.

Would Dr Gillette have us stop using digoxin for heart failure, antibiotics for sinusitis and otitis media, and antipyretics for fever for the sake of "intellectual integrity"? I for one am unwilling to categorically dispense with these powerful clinical tools. In real life, the art of medicine requires us to routinely use therapies that have not been scientifically proved (or disproved).

There are many therapies in both WAM and CAM that appear to be effective clinically and yet, as with the case of digoxin, it may take 200 or more years to come up with even equivocal proof of their efficacy or lack thereof. Neither we nor our patients can afford to do nothing for the next 200 years while we wait for academicians to try to prove the obvious, or not so obvious. In the gap between practice and proof, we need to curiously inquire, keenly observe, and cautiously balance the risks and benefits of all therapies while we humbly admit we do not have all the answers. The stance Dr

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Gillette is taking could be perceived as interfering with inquiry, impairing observation, and discouraging humility. If patients perceive that we are simply "tolerating" their unscientific delusions, they will tend to become secretive, which is a disservice to all involved.

As physicians who practice both a science and an art, we cannot afford to let science crowd out humility. Intellectual integrity requires that we apply the same standards of proof to WAM as to CAM and that we not assume a stance that alienates those patients who choose to use CAM.

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The preceding letter was referred to Dr Gillette, who responds as follows:

Dr Hammerly raises a number of important issues, and I thank him and the *Journal* for the opportunity to address them. It might be helpful to highlight a relevant philosophical point before responding to his specific questions and assertions. Dichotomous value judgments (good or bad, arrogant or humble, and so forth) can interfere with clear thinking about complicated issues. It is often more productive to cogitate in

terms of a continuum between poles. For example, Dr Hammerly's hyperbolic assertion that Western allopathic medicine is as flawed as the mythical emperor was naked represents a four-plus estimation of a one-plus problem. Our system is less than perfect, but that is inevitable given the inherent complexity of the human body and the disorders that may afflict it. Our present level of knowledge reflects decades of brilliant and diligent work by countless clinical and bench researchers, and progress continues at a mind-numbing rate. The same statement cannot now be made for "complementary and alternative medicine," although some of the latter may provide valid over time.

Intellectual integrity is a necessary ingredient of appropriate patient care, and so is the ability to change clinical practice standards as new information becomes available. For example, the use of digitalis and related compounds represented a major therapeutic advance when they appeared in the late 18th century, a time when today's cardiac drugs were unknown. Proper indications for prescribing them have diminished in recent years as our understanding of congestive heart failure has expanded and new pharmaceutical agents have appeared, but digoxin is still useful in certain clinical situations. It should be neither embraced blindly nor abandoned, but utilized selectively in line with current knowledge of its value and limitations.

Dr Hammerly observes correctly that there is a problem with overtreatment of sinusitis and otitis media. This may, in part, reflect pressure on clinicians to "do something" to meet the psychological needs of patients or families, or perhaps our own need to be in control and to be seen as competent and proactive. There is an old cartoon that shows two little boys sitting on the steps of one child's home. One says to the other, "You look hungry. Why don't you ask your mother to

fix us two peanut butter sandwiches?" Which child is really hungry? By analogy, whose needs are met when antibiotics are prescribed for a viral infection? The patient's? The parent's? Or perhaps the doctor's? The answer to the question about fever treatment is more straightforward: the evidence indicates that we should treat the patient, not the numbers on a thermometer. A dose of acetaminophen is appropriate if a child's temperature is 99° and he or she feels miserable, but not if it is 103° and the youngster is happily watching television.

I consulted some dictionaries and other reference works in response to Dr Hammerly's call for "humility" in scientific observation and clinical practice. The noted semanticist S.I. Hayakawa has noted of the related word "humble" that it "has...acquired a patronizing tone when used of other people and an air of sanctimonious piety when used of oneself."¹ In my view it is good to have humility in the sense of modesty and courteous respect, but that self-perceptions of incompetence, of spinelessness, or of deserving low professional status are inappropriate. Between the polar opposites of arrogance and excessive humility there is an appropriate middle ground of confidence that most of our professional knowledge is valid and worth sharing with our patients and their families. A small fraction of what we have been taught will fall by the wayside in time, but we can be openminded and flexible enough to change our thinking and professional practices as the need to do so becomes manifest. As William James put it, "We have to live today by what truth we can get today and be ready tomorrow to call it falsehood."

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