Good guys and practice guidelines: Osteopathic medicine’s role

To the Editor:
The Reverend Billy Graham recently said, “I am now an old man.” While not quite Graham’s age, I too am becoming an old man, preaching quality of care in my chosen profession, osteopathic medicine.

The Institute of Medicine (IOM) of the National Academy of Sciences attracted significant attention with their estimate that between 44,000 and 98,000 patients die annually as a result of medical errors.1 In a later paper, the IOM stated that it takes an average of 17 years for new knowledge generated by randomized, controlled clinical trials to be incorporated into practice and that even then, applications are uneven.2 It is important to note that the IOM did not distinguish between allopathic and osteopathic medicine as separate, culpable entities in this illustration of the disastrous state of American healthcare delivery.

With more than 10,000 clinical trials now in progress and several thousand clinical practice guidelines and consensus recommendations derived from clinical trials now available for implementation by practicing physicians, I wish to share the following two points with my osteopathic brethren:

- Most clinical practice guidelines are not profession-specific (ie, do not distinguish between patients cared for by allopathic and osteopathic physicians) but are disease-specific. Regardless of professional orientation, an osteopathic physician who manages an insulin-dependent diabetic patient would agree with allopathic peers, based on practice guidelines supported by clinical trials, that the patient should receive an annual glycosylated hemoglobin assessment, annual dilated eye examination, annual examination of urine for microalbuminuria, annual measurement of low-density lipoprotein cholesterol levels, etc. There are few, if any, osteopathic practice guidelines related to patients with diabetes.

- There are few, if any, strictly osteopathic practice guidelines for management or treatment of diseases. Only a few consensus recommendations unique to osteopathic medicine exist, and even fewer controlled clinical trials support osteopathic-specific methods for management and treatment.

At the risk of sounding the dour signal of doom, may I suggest the following:

- Osteopathic physicians should be held accountable to demonstrate superior proficiency in implementing all practice guidelines supported by clinical trials, regardless of origin and independent of profession.

- The osteopathic medical profession must invest in clinical trials whose outcomes will support clinical practices unique to osteopathic medicine. Promise resides in such recent osteopathic research initiatives. Let no one be surprised by the enormous financial and professional commitments these initiatives will require.

One and all should support the Osteopathic Research Center of the University of North Texas Health Science Center at Fort Worth as well as initiatives under study by the American College of Osteopathic Family Physicians and the American College of Osteopathic Internists to incorporate mandatory measurement and evaluation of processes of care in the residency accreditation requirement. Implementing this step will advance our profession immeasurably.

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References

More on end-of-life care

To the Editor:
It is gratifying to see the degree of comment generated by your coverage of end-of-life care in the October 2001 issue, particularly the comments of John G. Horton, DO (J Am Osteopath Assoc 2002;102:205-206). As he points out, advocates of physician-assisted suicide make a fine distinction between physician-assisted suicide and euthanasia.

The difference comes down to who administers the lethal dose: physician or patient.

The American Osteopathic Association (AOA) has a firm policy against physician-assisted suicide and euthanasia. Interestingly, however, the recent attempt by Attorney General John Ashcroft to rule the 1994 Oregon Death with Dignity Act illegal brought many physicians to the defense of the Oregon law. This is because Ashcroft’s argument that no drug can be used for off-label, nontherapeutic purposes, such as occurs with physician-assisted suicide, may imply that no drug can be used to ensure adequate pain control, particularly in the situation known as terminal sedation—when a patient may require such a large amount of pain medication to obtain adequate pain relief that the patient succumbs to the disease and dies. This is not considered euthanasia or physician-assisted suicide because the intent was to relieve pain and not to kill the patient—this is known as the principle of secondary effect. The appropriateness of this principle is recognized in the moral, ethical, and religious traditions of the world. The Ashcroft argument did not prevail in the Oregon courts, and physicians may still appropriately treat their patients for pain.

This issue and many others are well covered in the programs being sponsored by the End-of-Life Care (ELC) Advisory Committee of the AOA. The ELC Committee is presenting two workshops providing training in ELC issues. The first workshop was held in June 2002 for invited representatives of each college of osteopathic medicine and osteopathic postdoctoral training institute. The second workshop will be held in June 2003 for invited representatives of each state and specialty society. The purpose of these workshops is to “train the trainer” to provide quality ELC seminars for their respective constituencies.

More information is available from AOA Public Health Manager, Shelley Morrison, at (800) 621-1773, extension 8006.

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Response

To the Editor:
I am pleased that the End-of-Life Care (ELC) Advisory Committee of the American Osteopathic Association will be addressing issues that osteopathic physicians face when treating patients at the end of their lives. This aspect of medicine has been strongly neglected. Osteopathic medical students have been expected to handle these sensitive situations empirically, with little guidance from research or clinical practice.

Moral and spiritual aspects to end-of-life concerns, in addition to ethical and clinical issues, further complicate our approach to such patients. Although the exact parameters for making these decisions are impossible to determine, we must provide guidelines for our students, interns, and residents.

The ELC Advisory Committee provides the beginning of a forum to discuss the formation of such guidelines. Difficulty arises from the effect of building ethics, faith, spirituality, and morals into clinical decisions. Dr Nichols aptly describes the dilemma that is created when we are unable to separate our concerns about physician-assisted suicide from those associated with euthanasia. This dilemma results from the delicate balance that exists in the administration of opioids for pain relief or their lethal dosing to euthanize a patient—a gray area that has been the basis of debate for the legalization of physician-assisted suicide in several states. This is just one example of the serious questions that arise, with no easy answers, around the issue of physician-assisted suicide. As physicians, we cannot continue to be what many perceive as apathetic on this issue. Attorneys may attempt, however unsuccessfully, to legislate objective mandates to direct clinical practice for these highly subjective issues.

It is apparent that we all will benefit from improved education on this sensitive area of clinical practice. Thanks must be given to the ELC Advisory Committee of the American Osteopathic Association and to Dr Nichols for their leadership.

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More on anthrax exposure case report

To the Editor:
Tyler C. Cymet, DO, et al, in their recent case report, “Symptoms associated with anthrax exposure: Suspected ‘aborted’ anthrax” (J Am Osteopath Assoc. 2002;102:41-43), underscore the importance of the community clinician as a potential first responder to patients exposed to biological agents. In addition, their report raises several issues that need to be addressed.

Of concern is the authors’ application of the term aborted anthrax to their patient, as if the scenario represented a new clinical entity. To create such an entity would require proving the patient was infected with anthrax and that he or she had a novel condition or form of the disease that was not previously described in the medical literature. A patient infected with anthrax becomes ill and dies, becomes ill and is treated successfully, or is unsuccessfully treated. Virtually all patients with inhalation anthrax will die if left untreated.1-4 A significant proportion of patients truly infected with anthrax who present with serious symptoms will die even when appropriately treated because of the toxins Bacillus anthracis produces. Death is from profound septicemia, edema, and hemorrhagic pulmonary (hemorrhagic mediastinitis) and central nervous system (CNS) (hemorrhagic meningitis) effects as a result of lethal and edema toxin production. Antibiotics are neither antidotes nor antitoxins. If the bacteria are not killed before producing a critical mass of toxin, the patient will most likely die. The natural history of inhalation anthrax illness is one of mild symptoms (with an incubation time that can be as short as 1 to 6 days) followed by toxin release, escalating symptoms, and rapid death. It is well known that anthrax may have a prolonged incubation period. This is most frequently seen when partial treatment has been given.1 This patient either was initially incompletely treated—if, in fact, he was an anthrax victim—or had other cause(s) of illness. Nowhere in the medical literature is the term abort used as a description of exposure to, or a disease state with any form of, anthrax.

It is unclear in the article if the authors contacted their state health department or the Centers for Disease Control and Prevention (CDC) early in the patient’s presentation at a time when obtaining proper laboratory testing could possibly have supported a diagnosis of anthrax.3

As clinicians, if we suspect our patient has been exposed to a biological agent, we must contact the local state health department or the CDC for guidance as to the appropriate protocols to diagnose, treat, and report the case early in the critical encounter. This is an instance when immediate public health consult is indicated. We may not be accustomed to enlisting the aid of public health departments to provide us with clinical assistance, but in this new era of bioterrorism, it is the public health department that will be our vital link to expertise and a vast network of resources.

The authors state that the patient had a nasal swab, and the results were for epidemiologic purposes only. However, they do not mention the results of the swab, only that some of the patient’s coworkers had positive nasal swabs. Also, use of the term titer culture is unclear. Titers and cultures are not interrelated; they represent entirely different processes and clinical entities.

Unfortunately, the patient did not have blood cultures obtained before antibiotic therapy in the hospital. It was not apparent from the article whether blood smears or other specimens were submitted for evaluation. According to the CDC, this case report may not in fact be a case.3 Because anthrax is relatively rare, it is unlikely anyone would have positive titers unless truly a victim of anthrax.

We wholeheartedly agree with the authors that taking a careful patient history is important. It is a necessary first step in developing an index of suspicion for diagnosing biological weapons, an exigency we clearly have not had to consider in the differential diagnosis until recently. Had it not been for keen clinical acumen, an index of suspicion, and early collaboration with the local health department, the South Florida Sun-Sentinel case in Palm Beach, Florida, may not have been identified early enough to save lives.4 The occupational history is not often given proper attention in the clinical encounter. Clearly the fact that the patient in the present report is working for the US Postal Service could be important to suggesting a strategy for diagnosis and treatment. However, despite the patient’s occupational risk, the authors have not proven a case exists. Their “belief” that this is a case notwithstanding, further evidence is needed.
Although it is estimated that 5% of naturally occurring anthrax cases—most of which are the cutaneous form of the illness—have CNS involvement, approximately 50% of inhalation anthrax cases include CNS involvement ranging from nuchal rigidity to obtundation as a result of complicating anthrax meningitis.1,4 The case in Palm Beach County presented with frank CNS symptoms, not the expected pulmonary complaints.4

After the events of September and October 2001, we need to include bioterrorism in our differential diagnosis. But in doing so, we should not forget that bioterrorism is (like other medical entities) a clinical situation that should be managed in accordance with good medical practices. If the community clinician is going to play an important role as the potential first responder in a biological incident, it is essential that he or she be knowledgeable, and thus prepared, in terms of medical and public health resources. Bioterrorism is a public health issue as well as an emerging field of expertise.

At Nova Southeastern University College of Osteopathic Medicine, we have developed an institute involving medical directors of the county health departments of the three largest counties in Florida, as well as law enforcement and fire rescue personnel, and an interdisciplinary group of medical, psychosocial, and public healthcare experts. The mission of the institute is to act as a resource by providing information on bioterrorism, hazardous materials, and weapons of mass destruction to the healthcare community and community at large. We have provided a variety of training programs, from workshops to videoconferences, town meetings, and weekend symposia to audiences that include first responders, clinicians, law enforcement, and the public. Other training programs are being developed. In addition, we have incorporated into the curriculum a course devoted to teaching future physicians about the role of the community clinician in an era of bioterrorism.

As clinicians, we have a responsibility to coordinate efforts with public health officials and experts in the field to ensure that we perform in a timely manner, obtain the most appropriate diagnostic evaluations, and initiate potentially life-saving interventions. We in the osteopathic medical community have the opportunity to become an important source of leadership in the new challenge of bioterrorism.

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References

Response

To the Editor:
We understand Drs McFee and Howell’s skepticism concerning the case report on symptoms associated with anthrax exposure in which we suggest that an aborted anthrax syndrome may exist. Our contention is that this patient was inadequately or unsuccessfully treated for anthrax exposure. Among his coworkers, at least two inhalational anthrax victims who died never had positive blood cultures, while two others who had cultures that were positive for inhalational anthrax survived. Others exposed to anthrax now report chronic symptoms similar to our patient’s symptoms. We do not believe that our patient had inhalational anthrax, but that an anthrax exposure caused his low Po2, the pleural effusions, and the lesions in his lungs. Other terms to describe the condition, such as unsuccessfully treated anthrax exposure or acute inhalational pneumonitis secondary to anthrax exposure, would also be reasonable.

We disagree that to describe a new clinical manifestation of anthrax exposure would require proving that the patient was infected with anthrax. The proteins secreted by anthrax are what concerned us, as they are responsible for much of the damage to cells in the body, subsequent swelling, and ultimately that which causes death in people with anthrax infection. Acquired immunodeficiency syndrome and legionnaires’ disease were well-known clinical entities even before we were able to test for them.

Anthrax is still rare and not well understood. In particular, it is unclear how the bacterium transforms from a spore to a vegetative cell. We do know that an incredibly small number of spores can cause infection. Exposure to between 2500 and 35,000 spores would kill half of the people exposed to those doses (LD50). Exposure to 100 spores would result in 10% mortality (LD10). Recently published extrapolations from primate data suggest that as few as 1 to 3 anthrax spores may be sufficient to cause infection. With such small numbers involved, cultures and antibody titers may not be positive.

Although anthrax is rare, when the chief complaint of its victims is that “I was inspectsing a filter that had anthrax in it, and I spilled some dust from it on my face; then a few days later I felt sick,” the temporal relationship makes a connection between the two events highly suggestive.

We know that no precautionary measure is 100% effective; prophylaxes may not be effective in persons who have been subjected to a heavy dose of anthrax spores. The importance of involving city, state, and federal health departments needs to be emphasized. We consulted them within hours of the patient’s presentation and thereafter to share ideas and construct plans. It was through these interactions that the term aborted anthrax came to our attention, and we adopted the terminology. Initially, nasal swab results were not shared with clinicians caring for the people exposed; initial reports were that nasal swabs were done for epidemiologic purposes and could not be traced back to specific individuals. We now know that our patient’s nasal swab was negative for anthrax.

Here is a full accounting of cultures done:

- 10/25/01—Blood cultures, negative.
- 10/26/01—Nasal aspirate, negative for virus; also about this time, negative for histoplasmosis, Epstein-Barr virus, and cytomegalovirus titers.
- 10/26/01—Rapid viral antigen panel, negative with no respiratory viral antigen detect-
ed (Virology Department, University of Maryland).

- 10/26/01—Blood cultures and antibody tests sent to the Centers for Disease Control and Prevention (CDC). Verbal report that cultures and antibody negative.
- 12/5/01—Cerebrospinal fluid cultures, negative for fungal, cryptococcal, and bacterial cultures; Gram’s stain negative for white blood cells.
- 12/5/01—Sputum for aflatoxin B, negative (purified protein derivative also negative).
- 12/7/01—CDC recontacted. Blood culture, polymerase chain reaction, and antibody titers performed. Verbal report from CDC was that all were negative.
- 12/9/01—Blood cultures, negative. Urine culture, negative.
- 12/15/01—Stool culture and ova and parasite, negative (Quest Laboratories, San Diego, Calif).
- 12/15/01—Sputum culture, negative.
- 01/03/02—Blood cultures, antibody titers, antispore antibody, and antitoxin antibody tested. Verbal report from CDC was that all were negative.
- 01/20/02—Patient was noted to be anergic to measles and Candida albicans. Epstein-Barr virus, cytomegalovirus, and histoplasmosis titers were also noted to be negative. We conserved sera on two occasions throughout our patient’s hospitalization in the event further testing is recommended.

After publishing the case report and follow-up, we received many productive comments. We looked further for fungal forms of infection, repeated tuberculosis testing, and discovered that our patient was anergic to measles and C. albicans. Constructive input did not change our working diagnosis, however.

Our patients expect us, as primary care physicians, to know why they feel bad and to know what can be done to ease pain and make life more comfortable for them. Before we treat, however, we need a diagnosis. If the treatment is unsuccessful, or the course different than expected, we need to question our diagnosis and look to replace it with another. We were very skeptical ourselves about what caused our patient to become severely ill after his exposure to anthrax. The objective findings of fluid in his lungs, low \( P_{O_2} \), and lung lesions, as well as the subjective findings of severe chest pain and fatigue, eliminated ignoring treatment for anthrax as an option.

We are comfortable stating that anthrax exposure changed our patient’s life in both physiologic and psychologic ways. Good medical practice necessitates that we provide our patient with care, even when we are not able to explain the origin of his condition.

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