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The Journal of the American Osteopathic Association

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Prolotherapy: An Effective Adjunctive Therapy for Knee Osteoarthritis

To the Editor:

The November 2012 article by Van Manen and colleagues¹ on the management of knee osteoarthritis (OA) provides a useful update of several therapies. However, numerous complementary and alternative therapies also exist that are supported by varying degrees of evidence-based data. Among these, prolotherapy is particularly well suited to the osteopathic community, appears to be effective for knee OA, and deserves mention.

Prolotherapy is an injection therapy for chronic musculoskeletal injury, including knee OA.²⁴ Small volumes of an irritant solution are injected during several treatment sessions at painful tendon and ligament insertions and in adjacent

joint spaces.² Although the mechanism of action is unclear, inflammatory and neural effects have been suggested.² Because sources of pain in knee OA include intra-articular and supportive extra-articular structures,^{5,6} prolotherapy injections targeting multiple potential pain generators in and around the knee joint may be well suited to address the multifactorial etiologic process of knee OA pain.

An early report documented the use of prolotherapy 75 years ago, when the technique was referred to as sclerotherapy because of the scar-forming properties of early injectants.⁷ Current injection protocols were formalized in the 1950s, when the more commonly used term *prolotherapy* (from proliferant therapy) was adopted on the basis of the observation that ligamentous tissue exhibited a larger cross-sectional area after prolotherapy injection in animal models.⁸ Early scientific literature of generally low methodologic

rigor documented positive clinical outcomes from the 1930s to the early 2000s.⁹

Our group has conducted an open-label trial¹⁰ and a blinded randomized controlled trial^{11,12} (Clinical Trial number NCT00085722) assessing prolotherapy for patients with knee OA. In the open-label trial, we compared pain and disability in participants receiving prolotherapy to their baseline levels;¹⁰ in the randomized controlled trial, we compared the effects of prolotherapy with blinded saline control or at-home exercise therapy.^{11,12} Outcomes in both studies were assessed by the validated Western Ontario McMaster University Osteoarthritis Index (WOMAC; 100-point scale) at 52 weeks.

Participants in the open-label study¹⁰ reported improvement in overall WOMAC scores at as early as 4 weeks progressing through 52 weeks (mean [standard deviation (SD)] point improvement, 15.9 [2.5]; $P < .001$). Interestingly, while participants reported less severe baseline knee OA in uninjected contralateral knees compared with injected knees, they reported small but statistically significant improvements in pain severity and frequency ($P < .001$) and severity alone (43%; $P = .001$) at 52 weeks as well, suggesting a compensatory mechanism associated with prolotherapy.¹⁰

In the randomized controlled trial,^{11,12} WOMAC scores among prolotherapy recipients improved more at 52 weeks than did scores among saline control and at-home exercise participants (mean [SD] score change, 15.3 [3.5] vs 7.6 [3.4] and 8.2 [3.3], respectively; $P < .05$). In both studies,¹⁰⁻¹² the improvement in WOMAC scores exceeded the minimal clinically important difference for the WOMAC of

12 points, satisfaction with prolotherapy was high, and no adverse events occurred.

Definitive determination of the clinical utility of prolotherapy for knee OA will require confirmation in a larger effectiveness trial that includes biomechanical and imaging outcome measures to assess potential disease modification. Additional reports now in preparation or review will address long-term (3-year) qualitative and magnetic resonance imaging findings. However, our findings suggest that prolotherapy is clinically appropriate before total knee arthroplasty for carefully selected patients with knee OA in whom conservative therapy has been unsuccessful.

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Osteoarthritis Guidelines: A Progressive Role for Topical NSAIDs

To the Editor:

Osteoarthritis (OA) is a potentially debilitating disorder that can place serious limitations on patient functionality and overall quality of life.¹ Traditionally considered a disease of the elderly, more recent perceptions of OA reveal a broad spectrum of age and disease severity among patients.^{2,3} Because there are no curative or disease-modifying therapies for patients with OA at present, current approaches to management strive to relieve pain and increase functionality while minimizing the potential for adverse effects.²⁻⁷ Osteopathic physicians are particularly well positioned to achieve these goals, in light of their focus on manipulative treatment and their emphasis on total patient care.⁸

Current evidence-based approaches to the management of OA include both phar-

macologic and nonpharmacologic therapies.^{4-7,9} Nonpharmacologic approaches include patient education, exercise, weight loss, physical therapy, braces, and lateral heel wedges.⁴ Although effective, these approaches typically need to be paired with pharmacologic treatments, which are discussed herein, to adequately address a patient's OA symptoms (*Figure*).

Oral NSAIDs

Choosing the specific course of pharmacologic management for a patient with OA can be overwhelming given the number of options currently available. Acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), selective cyclooxygenase-2 (COX-2) inhibitor NSAIDs, opioid analgesics, and various topical therapies have been shown to be efficacious in the management of OA pain.^{4-6,8} Oral NSAIDs are commonly prescribed because of their established anti-inflammatory effects, clinical efficacy, and lack of addictive potential compared with opioids.⁴⁻⁷ However, growing awareness of the gastrointestinal and cardiovascular adverse effects of oral NSAIDs and selective COX-2 inhibitors has raised the question of where these agents belong in the overall OA treatment paradigm, especially for patients with established cardiovascular disease or an elevated risk of gastrointestinal adverse events.¹⁰⁻¹⁴

The dose-related gastrointestinal adverse events associated with oral nonselective NSAIDs occur as a result of the inhibition of the COX-1 enzyme, which is responsible for normal gastroprotective processes.¹⁵ Common gastrointestinal adverse events observed with these agents include dyspepsia (3% to 26%), abdomi-

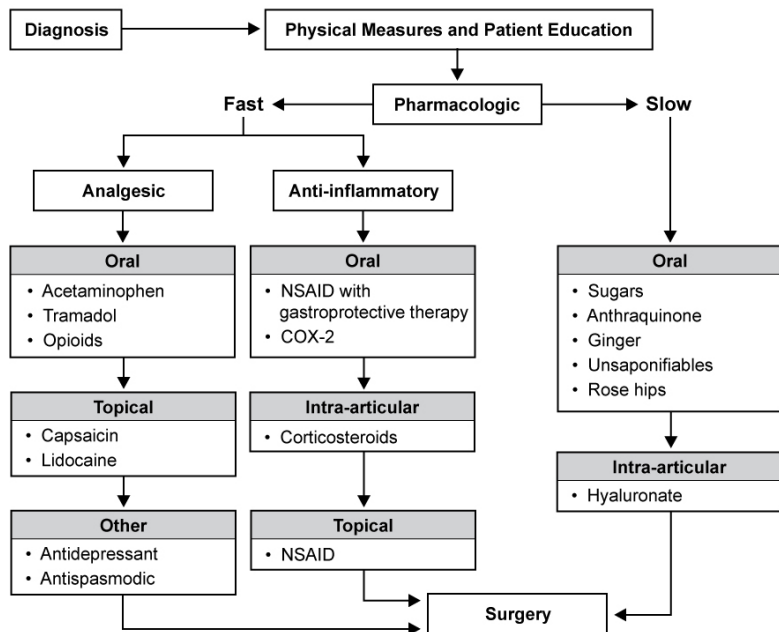


Figure.

Approach to the pharmacologic management of osteoarthritis. Once the diagnosis of osteoarthritis is confirmed, a nonpharmacologic program is initiated. If not effective, a pharmacologic program is initiated that is most often multimodal in its execution. Adapted with permission of the *American Journal of Managed Care* from Altman RD. Practical considerations for the pharmacologic management of osteoarthritis. *Am J Manag Care*. 2009;15(8 suppl):S236-S243.³¹ Permission conveyed through Copyright Clearance Center, Inc. Abbreviations: COX-2, cyclooxygenase-2; NSAID, nonsteroidal anti-inflammatory drug.

nal pain (3% to 22%), and nausea (2% to 13%).¹⁶ However, more serious adverse events can occur, including upper gastrointestinal bleeding, ulcerations, and death.¹⁷ Oral nonselective NSAIDs have been shown to increase the risk of gastrointestinal complications in individuals already at high risk, including those older than 70 years, those with certain comorbid medical conditions (such as a history of peptic ulcer disease, gastrointestinal bleeding, or active *Helicobacter pylori* infection), and those who take certain concurrent medications (such as corticosteroids and antiplatelet agents).^{17,18}

Oral nonselective NSAIDs are known to cause an increase in blood pressure, but until recently their impact on cardiovascular outcomes was not known. It is now well established that both oral nonselective and COX-2 selective NSAIDs increase the incidence of myocardial infarction, stroke, and death.^{12,13,19} This risk

can be compounded by the multitude of risk factors for cardiovascular disease, including cigarette smoking, increased age, and comorbid conditions (eg, diabetes mellitus, hyperlipidemia, hypertension).²⁰ The American Heart Association's guidelines on NSAID use suggest that the cardiovascular risks are associated only with chronic use or with higher doses of drugs in this class.¹⁹ More recent evidence, however, suggests that the increase in risk is more rapid: a study of patients taking oral NSAIDs demonstrated that the risk of myocardial infarction increases after the first dose of certain oral nonselective NSAIDs and after 30 days for COX-2 selective NSAIDs.¹³

Topical NSAIDs

With the increased gastrointestinal and cardiovascular risks associated with oral nonselective NSAIDs, there is a need to establish a first-line therapy plan that

maintains the established efficacy profile of these drugs while producing a lower incidence of systemic adverse events. Topical NSAIDs may provide a solution to this challenge for osteopathic physicians.

Topical NSAIDs have an established role in the pharmacologic management of OA in Europe and were first approved in the United States in 2007.^{1,5,6,21-23} Globally, topical preparations are available for diclofenac, eltenac, felbinac, ibuprofen, ketoprofen, and piroxicam.²⁴ Topical NSAIDs approved in the United States, however, are limited to 3 diclofenac formulations: diclofenac epolamine topical patch 1.3% (Flector Patch, King Pharmaceuticals Inc), diclofenac sodium topical gel 1% (Voltaren Gel, Endo Pharmaceuticals Inc), and diclofenac sodium topical solution 1.5% w/w (Pennsaid, Mallinckrodt Inc).²¹⁻²³ Of these, both diclofenac sodium topical gel 1% and diclofenac sodium topical solution 1.5% w/w are ap-

proved by the US Food and Drug Administration for the management of OA.^{21,22}

Treatment Guidelines for Topical NSAIDs

The recommended use of topical NSAIDs varies among OA management guidelines.^{4-7,9} Citing the safety and general effectiveness of topical NSAIDs, international organizations, including the European League Against Rheumatism (EULAR), the Osteoarthritis Research Society International (OARSI), and the National Institute for Health and Clinical Excellence (NICE), have incorporated topical NSAIDs into their OA management guidelines.^{1,5,6} The OARSI recommendations state that NSAIDs be used adjunctively or as alternatives to oral analgesic or anti-inflammatory agents in knee OA,⁵ and EULAR recommends their use both in knee OA and preferentially over systemic treatments for hand OA, especially when pain is mild to moderate and affects only a few joints.^{6,25} Regarding adjunctive use, it should be noted that current evidence shows that combining a topical NSAID with an oral NSAID confers no additional therapeutic benefit over either agent used alone, but it does increase the number of adverse events.²⁶

The NICE guidelines go further than both the EULAR and OARSI guidelines by recommending that topical NSAIDs be considered first-line therapy (ie, before oral NSAIDs, COX-2 inhibitors, or opioids) in all patients with localized OA (such as in the knee), regardless of gastrointestinal or cardiovascular risk. Acetaminophen is given the same recommendation. Under the NICE guidelines, all other pharmacologic options, including

oral nonselective NSAIDs, COX-2 selective NSAIDs, and opioids, are considered adjunctive treatments if either a topical NSAID or acetaminophen is insufficient in providing pain relief.⁴

Guidelines based in the United States include those issued by the American Academy of Orthopaedic Surgeons, the American College of Rheumatology, and the American Geriatrics Society.^{4,7,9} As in the European guidelines, all of these organizations generally agree that topical NSAIDs are safe and may be effective in the management of OA.^{4,7,9} However, only the American Academy of Orthopaedic Surgeons⁴ specifically identifies topical NSAIDs as a first-line pharmacologic option in those at increased gastrointestinal risk. These include patients who are using corticosteroids or anticoagulants, are aged 60 years or older, have comorbid medical conditions, or have a history of peptic ulcer disease or gastrointestinal bleeding.⁴ American College of Rheumatology guidelines conditionally recommend topical NSAIDs for the initial management of hand or knee OA and recommend the use of topical rather than oral NSAIDs for patients aged 75 years or older who have hand or knee OA.⁹

Conclusion

Of the topical NSAIDs approved in the United States, both diclofenac gel and diclofenac solution have demonstrated efficacy in the management of OA of the knee. In this indication, diclofenac gel has been shown to be more effective than placebo in the management of OA of the knee;²⁷⁻²⁹ topical diclofenac solution has demonstrated efficacy similar to that of oral diclofenac.^{26,30}

Current guidelines for the management of OA recognize that the consideration of disease progression, level of functional impairment, and coexisting conditions that increase risk of adverse events is vital to the treatment of all patients with OA.^{4-7,9} As shown in the *Figure*, this approach is aligned with the focus of osteopathic medicine on individualizing therapy to the specific patient and avoiding unnecessary adverse effects of therapy.³¹ The recognition of topical NSAIDs in current OA guidelines provides osteopathic physicians with a treatment option that offers pain relief and functional improvement for many patients with OA while avoiding the potential systemic adverse effects of oral formulations.

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Health Care as a “Right”

To the Editor:

Recently, a colleague told me he feels that health care is a “right.” This was not a novel idea: for the past several years, I have heard many learned people repeat the same phrase. That the phrase came from a fellow physician, however, struck me as particularly interesting. I wondered how my colleague could take such a naïve view of rights, given how they are articulated in the founding documents of the United States. The phrase “right to health care,” which is now bordering on a cliché, is not benign, particularly coming from a fellow physician. Because of this prevalence and particularly for the sake of younger physicians entering the profession of medicine, we might well consider what this phrase means for physicians.

I believe that adherents to this idea are using the Merriam-Webster website’s second definition of *right*, which is as follows¹:

[S]omething to which one has a just claim: as

a: the power or privilege to which one is justly entitled <voting rights> <his *right* to decide>

b (1): the interest that one has in a piece of property—often used in plural <mineral *rights*>

Part “a” might be construed to bolster the idea that “health care is a right”—in

other words, that society has agreed that individuals are entitled to health care. In fact it sounds very enlightened and beneficent to say such things, compassionate even. It certainly sounds worthy of repeating by educated people who care for others.

Unfortunately, part “b” provides a foil to part “a” by inserting the concept of property. We might also substitute “delivering services” for “a piece of property” because a physician never delivers real property as part of the health care transaction. Authors and musicians feel entitled to compensation for their “services” (sometimes referred to as “intellectual property”) and our society even provides legal protection of those entitlements through copyright laws. So too do physicians reasonably deem that they “own” their services and may trade them in lawful transaction.

This tradition has its roots in the philosopher John Locke, who defined “property” as an individual’s “life, liberty, and estate.”² Locke elaborated by stating that because human beings form societies, they sacrifice some freedoms enjoyed in the state of nature for greater security in the protection of individual property. Furthermore, he said that governments of such societies that fail to protect those properties essentially break the contract with the people of the society and place themselves in a state of war with their own citizens.²

Whereas readers may not be familiar with Locke, they will undoubtedly be familiar with Thomas Jefferson, who penned the following in the US Declaration of Independence³:

We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness. --That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed.

This passage is distinctly Lockean in its verbiage, tone, and intent. Locke was quite clear in his treatise that mankind forms governments at the expense of some forms of pure liberties, for the sake of securing others. Jefferson reiterated this contract in the founding document of the United States of America.

So herein lies the rub: we find ourselves in potential conflict with our national philosophy by suggesting that people have a “right” to health care but then not examining how that right is to be secured. Notice the critical distinction between having a right to health care and having a right to care for oneself. The former implies an external provision separate from the individual while the latter imposes a responsibility on the individual—the responsibility to care for him- or herself.

In Open Salon, a user-generated blog from Salon.com, a website not normally associated with Constitutional conservatism, Kent Pitman⁴ wrote an interesting post called “What Is a Right?” In it, Pitman suggests that true rights are “cost free.” That is, freedom of speech costs nothing to guarantee the individual. Pitman goes on to suggest that we ought to replace the word “right” with “goal” in situations where we would say things like “health care is a right.” We might say that having universal health care is a “goal”

akin to the goal of having adequate food. Such ideas appear to be morally compelling, a good thing to pursue, but may in fact be modulated by available resources. Pitman suggests that this is a better use of words because it allows for the pursuit of noble ends in a world of limited resources, whereas the consideration of such concepts as “rights” becomes highly problematic in times of scarcity.

Unfortunately, while an interesting examination, Pitman’s concept of measuring rights against costs fails to directly address the second necessary component of the health care economy: the physician.

If physicians were merely a fiscal commodity, traded in markets, then we might be able to measure Pitman’s test in a more refined manner. But physicians are not commodities, much as health maintenance organizations and large managed care executives might want that to be the case. Physicians are individual citizens. As such, they have the same “unalienable rights” as articulated by Locke and incorporated into our national culture by Jefferson. And it is this individuality—the personhood and citizenship of physicians—that ought to be at the crux of the fight against the notion of health care as a “right.” Monetary concerns should play no role in the discussion. In an age of continuous infringement on and erosion of physician autonomy, this sense of individual rights is a critical concept.

How can we define a “right” in any true sense of the term when that right is dependent on the skills of one person to guarantee to another? The very notion suggests servitude of one citizen toward another and clearly, unless the physician’s notion of “life, liberty and the pursuit of

happiness” is defined as effective dependence on the portion of society that chooses to demand their “right,” then we have a serious conflict.

I find it helpful to look at rights in a different manner, one that I call—yes, it is my creation, I admit—the *Deserted Island Test*. That is to say, rights are considered legitimate if one can exercise those rights as the sole occupant of a deserted island. For instance, the often controversial Second Amendment guarantees that “the right of the people to keep and bear arms shall not be infringed.”⁵ Does this stand up to the Deserted Island Test? If the sole inhabitant decides to fashion a weapon or find one washed up on the shore, then that individual could bear that weapon without infringement. The right is not contingent on any other citizen’s labor or input to exercise. The weapon borne by the sole occupant of the island may not be the precise kind he or she wants. The ultimate form of the weapon is limited by the burden of finding materials, producing the weapon, or having the weapon delivered to the island—all factors that, in a situation where one is not the sole occupant, might compel another citizen to deprive them of their own unalienable rights. All that is certain is that should the individual come to be in legal possession of a weapon that they have the right to retain it and use it without interference.

Thus, the Deserted Island Test is helpful in examining the notion of health care as a “right.” What happens when physicians decide that they do not want to provide this “right” because they find it an infringement on their own liberty? What happens when a government tries to compel them under threat of legal action

to provide care under the notion of this “right”?

This argument arose last summer when the Catholic Church was compelled by the Patient Protection and Affordable Care Act to provide contraceptive services as part of health insurance coverage for employees. Edward Morrissey⁶ of *The Fiscal Times* summarized the risks involved: Catholic leadership may have decided to simply shut down operations to avoid the profound ethical dilemma raised by a “right” that was in direct conflict with Catholic doctrine. The Catholic Church operates about 12.6% of US hospitals. Morrissey described the economic and social impact of shutting that system down over a policy that—while couched in the notion of “rights”—failed to meet that standard under any reasonable test of the same using a US notion of the concept of religious liberty.

Based on these long-held notions of liberty, the idea of health care as a “right” is not peripheral to the modern US physician’s practice; it is central to the core of what has distinguished the practice of medicine in the United States since its inception: physician autonomy. The impact of the loss of physician autonomy cannot be underestimated, whether by nonmedical administrative decisions on the corporate level or by a national policy conceived out of law that fails to respect the fundamental rights of physicians to exercise their own liberty.

This is not a discussion about the standard of care. The US medical system has a very healthy notion of that concept and, in my perspective, views those who violate that standard with suspicion at best and contempt at worst. A recent article

in *Wired* magazine⁷ details the use of induced coma for the treatment of rabies. Untreated rabies is nearly a uniformly fatal disease with few known survivors. Rodney Willoughby Jr, MD, however, has become a national celebrity in the realm of rabies treatment because, as one study reported,⁸ survival rates have spiked using his protocols. Dr Willoughby is an infectious disease specialist at Children's Hospital of Wisconsin. He is not on the periphery of the US medical community or otherwise engaged in quackery. Yet, even with such high stakes for a disease with such dismal outcomes, controversy is present.

When a health care system does not allow for free thought or the exercise of individual decision making with patients, physicians might opt out on moral, ethical, and even religious grounds. How much will this constricting climate discourage the many high-quality students who might otherwise thrive in the field of medicine? Surely, a portion of the traditional pool of medical students—highly motivated, highly intelligent, and resourceful—will decide that the price of losing personal freedom is just too high, and they will choose to find other work.

The implication of such restrictive policy to the osteopathic medical profession is even more profound. Had Andrew Taylor Still, MD, DO, lived under such a policy, I am convinced that the profession would not exist. The entire profession of osteopathic medicine exists because one man was determined to exercise his freedom of intellect, liberty, and sound judgment in the face of a rigid, conventional medical establishment that was unwilling to accept his ideas. One cannot easily

imagine the development of osteopathic medicine in an environment dominated by central bureaucracy, one that diminishes physician autonomy and wields corporate- or government-directed standards of medical necessity. It just would not happen.

When health care is determined to be a “right” for individuals, it necessarily deprives some physicians of their own rights to liberty, such as the right not to manage some conditions and even treat some patients. Also, physicians have the right to “dismiss” patients who are unruly, who are difficult, or who do not benefit from the physician's care. These patients might want services that the physician is not willing to provide. These rights strike a balance in the medical system by meeting the needs of the greatest number of patients because it allows choice.

As the system stands now, employees of the Catholic hospital system are able to obtain contraception—they just have to use secular private insurance to do it. Surely it is far better to be employed and have to use other means to acquire their contraceptives than to be jobless, as these employees would have been had the Catholic Church shut its system down rather than acquiesce to something that the institution finds morally repugnant.

There may come a time when a substantial portion of US physicians, be they Catholic or some other moral conviction, are forced out of medicine by the specious “right” to health care. To avoid violating their own conscience, these physicians will have to walk away so that they can exercise their right to “life, liberty and the pursuit of happiness.” If this comes to pass, individuals in the United States

will not only lose flexibility and breadth in their health care system, but they will also lose an intrinsic aspect of what makes them Americans. This should concern all US physicians deeply.

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