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REVISITING SOME CONTROVERSIAL TOPICS

TAKING OUR PULSE

Practicing medicine, or making decisions about the appropriateness of treatment, and the presence and extent of disability, is not always a straightforward issue. How many times have you heard the "experts" change their minds about whether a certain vitamin is useful, or whether eggs and coffee are good or bad for you?

In our world, we also must confront controversial issues and ensure that we are adopting "best practices" based on the most current evidence-based medical research.

So today we will revisit a few ongoing issues, see what the prevailing wisdom is, and review our current approaches.

JUST WHAT THE DOCTOR ORDERED

A) Fibromyalgia

Fibromyalgia is not quite a disease, but rather a syndrome of various complaints involving fatigue, pains in muscles and other soft-tissues, and sleep disturbances. It doesn't qualify as a disease because, to this point, there is really no firm evidence of any objective physical findings (that can be seen in lab tests, x-rays, tissue biopsies, etc.). It remains a largely subjective phenomenon.

There is debate about its cause, with proponents disputing whether it is a "brain" condition or a musculoskeletal one. Some scientists claim to have noted abnormalities on central nervous testing, such as MRIs. Others feel that is a psychological state akin to depression, which is why anti-depressants are often successfully used to treat it.

In 2013, one laboratory claimed to have discovered a blood test that can diagnose fibromyalgia, which would be a breakthrough. However, even though some insurance carriers now reimburse the test, many others consider it to be of unproven value, as do many researchers.

From our perspective the most important fact is that, regardless of what stance one takes on the above, there is certainly no evidence of an occupational causation. Consequently, our policy remains as follows, per our medical advisory on the subject:

[FIBROMYALGIA MEDICAL ADVISORY](#)

Medical Advisory:

Based on the above considerations, fibromyalgia, chronic fatigue syndrome (FM/CFS) and other related conditions, and treatments for such conditions, cannot be considered work-related. There is no evidence at all to substantiate any occupational factors or injuries as causative. The current best hypothesis is that FM/CFS, to the extent that it has "legitimacy as a discrete entity" represents a genetic pain sensitization phenomenon due to dysregulation of pain pathways related to atypical neurotransmitter levels.

With respect to disability (functional impairment), this needs to be carefully evaluated based on objective evidence of physical and cognitive deficits.

B) Viscosupplementation (hyaluronic acid, HA) injections to the knee

These injections have been used for a long time to reduce the pain and stiffness of arthritic knees. They can be thought of as a "lubricant" that cushions the knee as the joint is in motion. However, there have always been skeptics questioning the effectiveness of this therapy.

Several recent studies, one of which is excerpted below, now validate this skepticism, demonstrating that there is no, or minimal, benefit from HA injections.

However, the Official Disability Guidelines (ODG) continue to recommend this therapy, although a very long list of utilization criteria must be met prior to approval. As further evidence is published, ODG may reconsider its stance on viscosupplementation.

Of course causality is also an important consideration. Knee osteoarthritis is a degenerative condition which, unfortunately, many of us will get, and not necessarily related to occupational activities. It typically affects multiple joints in the body and is thought to have a genetic predisposition as well. A careful analysis to determine whether the condition is genuinely causally related to an individual's occupation is recommended.

ODG:

Recommended as an option for severe knee osteoarthritis (OA) for patients who have not responded adequately to conservative treatment (exercise, NSAIDs, corticosteroid injections), in order to potentially delay total joint replacement. Higher quality studies have shown the magnitude of improvement to be modest at best. While medial and/or lateral compartment OA is a recommended indication, there is insufficient evidence for other conditions including patella-femoral arthritis, chondromalacia patella, patella-femoral syndrome (kneecap pain), or osteochondritis dissecans.

C) Platelet Rich Plasma (PRP)

PRP is one of several blood products that can be extracted from a patient's own blood, and then injected into a painful body part. In the case of PRP, the blood is concentrated to achieve a high number of platelets, which contain growth factors that, theoretically, when injected into damaged tissue, can help to heal and strengthen the involved area. It is commonly used for soft tissue injuries, although you may have noticed local newspaper ads in which medical entrepreneurs advertise its use for myriad conditions. Similar claims are being made for stem cell therapy.

Despite all the fuss, there remains no consensus that PRP or related therapies have meaningful benefit. Broadspire's medical advisory, as well as the ODG, reinforce this view. The prevailing recommendation is that this therapy should be confined to rigorous clinical studies, and not used in the general population.

Medical advisory:

Blood product injection therapies are not recommended for certification/ authorization due to an absence of high-grade medical evidence permitting an evaluation or confirmation of the efficacy of this modality. There is currently insufficient evidence to support the use of these injection therapies. Rigorous studies of sufficient sample size, using validated clinical, radiological and biomechanical measures and tissue injury healing response biomarkers are needed to determine long-term effectiveness and safety.

[BLOOD PRODUCT INJECTIONS MEDICAL ADVISORY](#)

ODG: Platelet-rich plasma (PRP)

Not recommended for chronic pain except in a research setting. PRP therapies are more complicated than previously acknowledged, and an understanding of the fundamental processes and pivotal molecules involved will need to be elucidated. PRP therapies in clinical trials await assessment. Platelet-rich plasma (PRP) therapy is a recently developed technique that uses a concentrated portion of autologous blood to try to improve and accelerate the healing of various tissues. There is considerable interest in using PRP for the treatment of musculoskeletal disorders, particularly athletic injuries. Because PRP products are safe and easy to prepare and administer, there has been increased attention toward using PRP in numerous clinical settings. Platelet-rich plasma has been used to treat conditions such as lateral epicondylitis, ligament and muscle strains, and tears of the rotator cuff, anterior cruciate ligament, Achilles tendon, plastic surgery and other conditions. Platelet-rich plasma can be applied at the site of injury either during surgery or through an injection performed in the physician's office. However, there is little published clinical evidence that proves its efficacy in treating the multitude of injuries/disorders that are thought to benefit from PRP.

CIRCULATING IN THE PRESS

More Insurance Companies Now Paying for Fibromyalgia Blood Test¹

“In 2013, Los Angeles-based biomedical company EpicGenetics made international headlines when it introduced FM/a, the first ever fibromyalgia blood test.

While FM/a hasn't caught on in most doctors' offices, more insurance companies are now paying for the test.

Dr. Bruce Gillis, EpicGenetics' CEO, says the No. 1 reason patients get the test is to prove to family members and others that they are really sick.

He believes physician bias is the main reason why the test is not more widely used.

The legitimacy of fibromyalgia has been complicated for decades because of the lack of a diagnostic test to prove its existence. It's typically a diagnosis of exclusion – meaning illnesses with similar symptoms have been ruled out through extensive (i.e. often expensive) medical testing.

We believe [the term] fibromyalgia is a misnomer, he says. These people aren't suffering with anything that's affecting the muscles, per say. What they are suffering with is their immune system cannot produce normal quantities of protective proteins. There are cells in the immune system called peripheral blood mononuclear cells. They are not producing normal quantities of the protective proteins called chemokines and cytokines.

EpicGenetics' research and the FM/a test aren't without critics. Fibromyalgia expert Dr. Daniel Clauw has said EpicGenetics' studies contradict other research, which has shown normal or elevated cytokine levels in fibromyalgia sufferers.

Researcher and rheumatologist Dr. Fred Wolfe called one of EpicGenetics' studies "junk science", saying it didn't meet minimal scientific standards."

Viscosupplementation for Osteoarthritis of the Knee²

"Knee osteoarthritis is responsible for a large burden of care and cost within health care. Osteoarthritis results from an imbalance between the breakdown and repair of articular cartilage in any joint and occurs as a result of multiple risk factors including mechanical overload (obesity, heavy lifting), trauma, overuse (repetitive knee bending), and genetic predisposition. The CDC (U.S. Centers for Disease control and Prevention) reports that one in two individuals may develop symptoms of osteoarthritis in at least one knee by eighty five years of age.

In conclusion, this best-evidence systematic review assessing the clinical significance of outcomes involving pain relief and functional improvement does not support the routine use of intra-articular HA. In contrast to previous reviews, we found no significant evidence of publication bias in the studies that we selected for analysis. The patient benefit of intra-articular HA was not clinically important when compared with intra-articular saline solution injections used as a placebo. Subdividing HA preparations by molecular weight did not change the results of the analyses. Selecting the best evidence resulted in significantly reduced heterogeneity but did not change the outcome; no clinically important improvement in pain and other outcomes from a patient's perspective was found."

How effective are platelet rich plasma injections in treating musculoskeletal soft tissue injuries?³

“Platelet-rich plasma (PRP) has become increasingly popular in sports medicine and orthopaedic practice as treatment for muscle, tendon, and ligament injuries, and has received media attention because of its promise as a regenerative therapy.

We argue that patients should only be offered PRP for musculoskeletal soft tissue injuries within the context of well-designed clinical trials, with informed consent, high quality verbal explanations, and supporting written information. Advise patients that there is currently insufficient evidence to show that it is effective treatment for musculoskeletal soft tissue injuries. Clinicians offering PRP should ask manufacturers for the evidence of the platelet and growth factor concentrations, the constitution, and the viability of their PRP product (platelet activation levels).”

Efficacy of Autologous Platelet-Rich Plasma Use for Orthopaedic Indications: A Meta-Analysis⁴

“The recent emergence of autologous blood concentrates, such as platelet-rich plasma, as a treatment option for patients with orthopaedic injuries has led to an extensive debate about their clinical benefit. We conducted a systematic review and meta-analysis to determine the efficacy of autologous blood concentrates in decreasing pain and improving healing and function in patients with orthopaedic bone and soft-tissue injuries.

The current literature is complicated by a lack of standardization of study protocols, platelet-separation techniques, and outcome measures. As a result, there is uncertainty about the evidence to support the increasing clinical use of platelet-rich plasma and autologous blood concentrates as a treatment modality for orthopaedic bone and soft-tissue injuries.”

REFERENCES:

- 1) “More Insurance Companies Now Paying for Fibromyalgia Blood Test”, Donna Gregory Burch, <http://nationalpainreport.com>.
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