

Surgical Decompression for Diabetic Sensorimotor Polyneuropathy

Diabetic neuropathy remains an unmet medical need. While scientific advances (1,2) have been made in understanding pathophysiology, the impact on the clinical care of patients has been minimal, aside from symptomatic treatments for the pain that may accompany diabetic sensorimotor polyneuropathy (DPN) (3). Improved glucose control is still the main recommendation for the prevention and treatment of DPN, based on studies conducted over 10 years ago. Recently, two evidence-based reviews (4,5) for the treatment of diabetic neuropathy have been published, which form the basis of the subsequent American Diabetes Association position statement (6) on the topic.

Into the apparent void of therapy for DPN, surgical decompression of multiple lower or upper limb nerves is being advocated as the treatment (7). The procedure is being utilized to treat symptomatic and generalized DPN. This approach is based on a series of hypotheses. First, the signs and symptoms of DPN are due to multiple nerve entrapments. In the lower limb, foot numbness is ascribed to “entrapment” of the peroneal nerve at both the fibular head and the anterior tarsal tunnel, the tibial nerve in the tarsal tunnel, and the sural nerve in the distal posterior calf. In the upper limb, hand numbness is ascribed to entrapment of the ulnar nerve at both wrist and elbow, the radial nerve in the radial tunnel, and the median nerve at the wrist. Second, these entrapments can be diagnosed by a trained examiner whose sole tool is the Tinel sign. Third, surgical “release” of these nerves will correct DPN by decompressing the “compressed” nerves. Fourth, special surgical training is needed to be able to identify these patients and operate on them. This series of hypotheses has spawned an entire industry.

There is much that is wrong with this thinking. First, the distal neuropathy that characterizes DPN is due to progressive distal axonal loss (8–10). The proposed pathophysiological mechanism of entrapment cannot explain sensory or motor symptoms or signs above the anatomic levels of the “entrapped” nerves. Despite

this, patients have undergone these operations with neuropathy above the level of the foot and hand. Additionally, the actual frequency of peripheral nerve entrapment in diabetic individuals is small.

While some patients with DPN have superimposed nerve entrapment syndromes, these are the well-known sites of classic entrapments: the median nerve at the wrist causing classic carpal tunnel syndrome, the ulnar nerve at the elbow causing ulnar neuropathy at the elbow, and the peroneal nerve at the fibular head causing foot drop. Before this recent “epidemic” of nerve entrapments, entrapments at the other postulated sites have been considered rare or even nonexistent (11–13).

Second, the Tinel sign (14), which was originally described in the setting of nerve regeneration and not entrapment, is poorly standardized and lacks sensitivity and specificity. The proponents of the subjective Tinel sign ignore the proven value of electrodiagnostic studies, an objective test of nerve function.

Third, the American Academy of Neurology (15) used an evidence-based criteria review for decompression surgery for generalized DPN. Using standard procedures to assess evidence, there was only one prospective trial. The utility of surgical decompression for symptomatic diabetic neuropathy received a grade IV rating; i.e., based on evidence from uncontrolled studies, case reports, or expert opinion. It was assigned a U grading, which is defined as “data inadequate or conflicting given current knowledge, treatment is unproven.” Given that conclusion, we believe that the treatment cannot be recommended at this point in time. A report on this topic by the Cochrane Collaboration will shortly follow.

In the unblinded series of these procedures, pain relief as assessed by the operating surgeon occurred in 80–92% of patients, some even occurring on the operating table while recovering from the anesthetic. Even more impressive are patients reporting bilateral improvement from unilateral procedures or patients with numbness or pain beyond the anatomic distribution of the released nerves who improve after these procedures. If only symptoms are being reported, the re-

sults may be no better than a number of other noninvasive and less expensive interventions (15–18), all of which have been claimed to achieve symptomatic short-term improvement.

Fourth, numerous centers have sprung up around the U.S. and the world promoting their specially trained surgeons and touting the benefits of these procedures (7). One can only guess the medical costs of these unproven procedures.

Unfortunately, medicine has been here before. For >50 years, surgical procedures have been advocated for all sorts of diseases. In the 1950s, there were a number of procedures for angina with many others to follow (19). While there are many explanations for the results from these types of surgeries, most important are the placebo effect and the natural history of the disorder. Only well-controlled, randomized, double-masked, sham-procedure, controlled clinical trials will allow us to know whether these surgeries are safe and effective for this indication—the same standard that any drug for DPN would have to meet.

What are we to do now? First, we believe the findings of the American Academy of Neurology’s evidence-based review (15) should be strong evidence that the procedures should not be considered care but, rather, subjected to further research until proven beneficial. Second, we strongly support trials to determine whether these surgical procedures are beneficial. At this point, pilot trials should be conducted to see whether there is reason to mount large phase 3 studies. The Centers for Medicare and Medicaid Services (CMS), which supported the recent Lung Volume Reduction Surgery trial (20), is in the best position to support such trials and should have a great interest in doing so, given the widespread application of these unproven surgical procedures among Medicare patients. Third, we support further research into the causes and treatment of DPN, an unmet medical need. In conclusion, until such time as definitive randomized trials are conducted and the supporting evidence is stronger, surgical decompression should not be recommended for patients with diabetic sensorimotor polyneuropathy.

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