Multisociety Statement on *Effect of Radiofrequency Denervation on Pain Intensity Among Patients with Chronic Low Back Pain: The Mint Randomized Clinical Trials* by Juch *et al.*

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Representatives of the undersigned twelve medical specialty societies, comprising physicians who prescribe and/or perform interventional spine procedures to accurately diagnose and treat patients suffering from spine pathologies, have convened to issue a statement on the recently published Mint Randomized Clinical Trials[1] from the Netherlands. These medical specialty societies share a common goal with patients and payers: identifying procedures that provide value to the patient and society through measurable improvements in pain and physical function with no or minimal adverse events. To this end, the undersigned societies think it is critical to repudiate the conclusions of the Mint Trials and support continued access to these invaluable procedures.

The MINT Trials are irredeemably flawed by study design, patient selection, procedural technique, and data analysis. Our critique below is specific to the facetogenic pain trial, but the criticisms also apply to the sacroiliac joint (SIJ) pain and the combination facetogenic/SIJ pain arms.

Study Design

A pragmatic comparative effectiveness trial should reflect usual practice. Radiofrequency (RF) neurotomy is only provided upon failure of conservative care, including exercise. The MINT Trial studies a choice no patient would face: an exercise program in conjunction with RF or an exercise program alone. Furthermore, in a stunning omission, there is no measurement of baseline pain or function prior to RF, following medial branch block (MBB). Hence the confounded trial is really: MBB, RF, and exercise versus MBB and exercise. Afterward, there are no useful data beyond three months, as any co-interventions (medications, RF, surgery) were allowed after that point. The value of RF neurotomy is its durability, unstudied here.

Patient Selection

It is paramount in a study assessing the effectiveness of an intervention in patients with a specific diagnosis that the patients selected *actually have* the diagnosis in question, and criteria for an accurate diagnosis of facetogenic pain exist. Contrary to this, the MINT Trial employed selection criteria lacking sufficient rigor. Consider that 931 study participants underwent single bilateral MBBs at L3-4, L4-5, and L5-S1; and an extraordinary 72% of them were reported to have a positive block response. This is *more than twice* the disease prevalence of facetogenic low back pain in any studied population. In addition, recall that nobody was treated for unilateral or for more localized back pain. Rather, all blocks and RF were *bilateral and multilevel* in this population with > 10 years of low back pain. Thus, the study participants were more likely chronic non-specific back pain patients than patients suffering from true facetogenic pain.

RF Technique

The study employed small-gauge electrodes, generating small lesions. Standard practice for RF neurotomy is to employ large-gauge electrodes to generate larger lesions, which are more likely to capture and ablate a larger portion of the target nerve. Just as important, the RF electrode placement technique is ambiguously described in the supplementary content and unreferenced,

and not described in the study. The authors' published protocol describes their plans to "submit images to an expert panel to assess correct needle placement." The results of any expert panel review have not been published, nor any images provided in the publication. The authors have possibly used an invalidated needle trajectory known to fail to adequately capture the target nerve[2]. There is serious doubt as to whether RF neurotomy was accomplished in this study population.

Data Analysis

Diverging from guidelines on reporting results of studies on spine pain treatments, the investigators' interpretation of the results relies solely on the between-group mean differences in outcomes data, rather than interpreting the outcomes based on the recommended assessment of each treatment's success or failure to achieve statistically significant and clinically meaningful change in response to treatment, and analysis of categorical outcomes comparing treatment success rates in each group. Without the results of these more appropriate analyses, the authors' conclusions remain unsupported. Of additional concern, patients lost to follow-up were omitted from analysis rather than accounted for as treatment failures. An intention-to-treat analysis was applied, but many participants did not receive their assigned treatment. Without an as-treated analysis, it is unclear how patients fared with the treatments they actually received. Unfortunately, the authors did not publish the study's primary data to allow further analyses and accounting for these glaring omissions in the published results.

A pragmatic RCT assessing the effectiveness of a therapeutic intervention is meaningful only when the intervention is performed on appropriately selected patients using documented anatomically accurate technique. RCT methodology has no value if the patients did not have the condition under investigation, the therapeutic procedure as performed lacks validity, the study design does not reflect real-life clinical choices, and the data analysis is flawed. As a result, we conclude that the MINT Trials provide no useful commentary on the well-established clinical effectiveness of RF neurotomy.

Current Best Available Evidence

Fortunately, several studies have been published that establish the effectiveness of RF neurotomy when performed according to standard practice -- using large-gauge electrodes with anatomically correct needle placement in patients with confirmed facetogenic pain. While, in practice, some physicians rely on 50% relief from a single medial branch block, studies establishing the effectiveness of RF neurotomy in treating facet pain should use more rigorous patient selection (i.e. dual comparative local anesthetics blocks) to limit the study population to those with facetogenic pain. In brief, sufficient pain relief following appropriately performed diagnostic medial branch nerve blocks determines patient selection for RF neurotomy. Low amounts of pain relief following a block, or a patient's response to a single diagnostic block, are unacceptable selection methods for study inclusion due to high false-positive rates. Specifically, the single block false-positive rate is between 25-45%, and this is significantly reduced by performance of a second comparative block.[3-10]

Two benchmark studies of RF neurotomy used appropriate patient selection and treatment technique; [11,12] selection was based on comparative local anesthetic blocks. Both studies achieved the best results heretofore reported in the literature. The first study reported 60% of patients maintaining at least 80% relief for 12 months.[11] The second study reported complete relief of pain for at least 6 months in 55% of patients, accompanied by restoration of function, return to work, and no need for other health care, for a median duration of 15 months per treatment.[12]

The results of these two studies illustrate what can be achieved by RF neurotomy if performed correctly and in appropriately selected patients. An impressive 55-60% of patients experience at least 80% pain relief. **No other intervention of any kind, for any form of back pain, provides this size of effect at this level of success.**

American Academy of Pain Medicine (AAPM)
American Academy of Physical Medicine and Rehabilitation (AAPMR)
American College of Radiology (ACR)
American Pain Society (APS)
American Society of Anesthesiologists (ASA)
American Society of Neuroradiology (ASNR)
American Society of Regional Anesthesia and Pain Medicine (ASRA)
American Society of Spine Radiology (ASSR)
North American Neuromodulation Society (NANS)
North American Spine Society (NASS)
Society of Interventional Radiology (SIR)
Spine Intervention Society (SIS)

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