



Guidelines for composing and assessing a paper on the treatment of pain: A practical application of evidence-based medicine principles to a cost-effectiveness analysis of the MINT randomized clinical trials

ARTICLE INFO

Keywords

Cost Effectiveness
Chronic Low Back Pain
Evidence-Based Medicine
Facet Joint
Radiofrequency Neurotomy
Sacroiliac Joint
Zygapophysial Joint

ABSTRACT

Objective: Apply established principles of evidence-based medicine to the interpretation of the cost-effectiveness analysis related to the MINT Randomized Clinical Trials (RCTs).

Design: Editorial

Methods: Spine Intervention Society's guidelines for assessing studies on the treatment of pain were applied to a published cost-effectiveness analysis of radiofrequency denervation data from the MINT RCTs.

Results: Application of evidence-based medicine principles reveals the MINT RCTs' major deficiencies in patient selection, diagnostic paradigm, radiofrequency neurotomy technique, co-interventions, outcome measurement, power analysis study sample characteristics, data analysis, and loss to follow-up; which marginalizes the generalizability and conclusions of the cost-effectiveness analysis.

Conclusions: The cost analysis performed in "Cost-Effectiveness of Radiofrequency Denervation for Patients With Chronic Low Back Pain: The MINT Randomized Clinical Trials" is based on the MINT RCTs results. The MINT RCTs significant methodological design flaws, lead to issues in validity for the subsequent cost-effectiveness analysis. Application of the cost-effective analysis to patient care paradigms should be limited given the concerns with validity.

1. Background

Guidelines for assessing a scientific publication studying the treatment of pain have been previously published by Bogduk et al. [1] and are part of the curriculum of Spine Intervention Society's (SIS) [2]. The guidelines review the core principles and practical application of evidence-based medicine (EBM). Members of the SIS Standards Division previously published an application of the SIS EBM guidelines to the methodology, outcomes data reporting, and primary conclusions of the MINT randomized clinical trials (RCTs) [3].

In the present article, we applied these guidelines to the article by Maas et al. [4] which aims "to evaluate the cost-effectiveness of radiofrequency denervation when added to a standardized exercise program for patients with chronic low back pain" [4]. We aimed to assess if the fundamental criteria of the EBM guidelines are satisfied in this cost-effectiveness analysis. The present article expands on the concepts previously presented in a letter to the editor [5] in order to provide the medical community with a more thorough analysis of the article by Maas et al. [4]. Given the potential impact on practice of such a study, a thorough analysis of the paper using the EBM guidelines is warranted.

The validity and applicability of the MINT RCTs [6], upon which the cost-effectiveness analysis (CEA) is based, have been questioned by numerous researchers in the field of interventional spine [3,7–9].

Although this current article focuses on the cost-effectiveness study by Maas et al. [4], the methodological concerns with the MINT trials, previously addressed in-depth by McCormick et al. [3], must be briefly reviewed in order to address the fundamental validity of the CEA.

The MINT RCTs were designed to investigate if radiofrequency neurotomy (RFN) performed based on "standard practice" [6,10] in addition to a standardized exercise program was more effective than a standardized exercise program alone. Patients were selected for RFN based on a single diagnostic block, of which 50% or greater reduction in pain, evaluated after 30 minutes, constituted a positive block [10]. This definition and utilization of a single diagnostic block, deviates from prior studies that established proper patient selection for RFN [11–13]. Deviating from established guidelines for patient selection increases the risk of misdiagnosis of the facet joint, sacroiliac joint, or a combination of the two as the pain generator for the symptom of chronic low back pain [14,15]. Furthermore, the RFN technique described did not adhere to the SIS Guidelines in the recommended cannula gauge size or needle positioning [14]. These technical variations increase the risk of a failed neurotomy [8]. RFN was performed during a wide follow-up period, ranging from 3 to 12 months in both groups. Moreover, there was no clear reporting on the exact number of RFNs performed during this period. Ultimately, these methodological issues with the MINT study call into question the conclusions drawn by Maas et al. [4] and their generalizability to RFN cost effectiveness.

<https://doi.org/10.1016/j.inpm.2022.100010>

Received 3 November 2021; Received in revised form 10 January 2022; Accepted 10 January 2022

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2. Assessment of introduction

The fundamental questions that must be applied during the assessment of the introduction of any paper on the treatment of pain must include 1) Does the introduction justify why the study was undertaken? 2) Is the study question defined appropriately?

The study introduction by Maas et al. reviews the global burden of low back pain and presents data on health expenditures related to low back pain in the Netherlands [16–21]. Furthermore, it explains why the study was undertaken and appropriately defines the study question.

A major issue with the introduction that must be addressed is the reference to the MINT study [6] as a study of clinical ineffectiveness of radiofrequency denervation as an add-on to a standardized exercise program. The authors failed to discuss the significant limitations and criticisms of the study [3,7–9]. They did, however, acknowledge that the conclusions may be related to selection criteria and technique differences by recommending “future studies with a focus on patient selection, treatment techniques, and outcome parameters”. However, in failing to acknowledge the flaws of the MINT study, the authors did not explain why the cost-effectiveness analysis was performed on a fundamentally flawed study.

3. Assessment of study aim

The study objective was appropriately defined “to evaluate the cost-effectiveness of adding radiofrequency denervation to a standardized exercise program compared with maintaining a standardized exercise program alone for patients with chronic mechanical low back pain from a societal perspective”. Maas et al. [4] specifically aimed to evaluate the cost-effectiveness of RFN for patients unresponsive to initial conservative therapy and suffering from chronic low back pain attributed to facet joints, sacroiliac joints, or a combination of facet joint, sacroiliac joint, and intervertebral disc pathology.

4. Assessment of methods

The fundamental questions that must be applied during the assessment of the methods of any paper on the treatment of pain must include 1) Is the study design defined? 2) Are the study inclusion criteria defined? Are they valid? 3) Are study treatments defined with adequate detail? Are they valid? 4) Were co-interventions allowed? 5) Are validated outcome measures used? Are multiple categories of measurement used in addition to pain, including physical and psychological functioning? 6) Was the method of obtaining outcome data appropriate, performed at relevant time intervals relative to the intervention studied, and performed by an independent assessor? 7) Is the power analysis based on appropriate literature or reasonable assumptions? 8) Was categorical analysis applied? Was worst-case analysis applied? 9) Was intention-to-treat analysis applied? 10) Were outcomes stratified for confounders? 11) Were statistical testing methods appropriate?

Significant methodological flaws present in the MINT study invalidated the fundamental validity of the subsequent cost-effectiveness analysis. As previously noted, McCormick et al. published a detailed critique of the MINT study, which discusses issues with study design, study funding, inclusion criteria in terms of demographics, inclusion criteria in terms of diagnostic categorization, study interventions (RFN vs. both groups), co-interventions, outcome measurement, power analysis and data analysis, as well as an analysis of the statistical issues [3].

The selection criteria used by the MINT study make the study unrepresentative of patients who have axial pain. Rather than using validated diagnostic interventional algorithms to define the source of pain, the study used physical examination findings to select the sacroiliac joint pain group and clinical impressions alone to select the lumbar facet joint pain group, a lumbar disc pain group, and a combination pain group (facet, sacroiliac joint, and disc pain). Contrary to the recently published systematic review [22] that advocate for dual diagnostic lumbar facet

joint blocks in the research setting, a single diagnostic local anesthetic block was the criterion used to confirm the clinical diagnosis. It is noteworthy that a recent multispecialty consensus guideline [23] recommended a single block (grade C recommendation, low-to-moderate level of certainty), however the same document stated that “In the only guidelines espoused by pain organizations, SIS and the ASIPP both advocate two blocks before RFA, with the latter concluding that the evidence for diagnostic accuracy is poor (<75% relief) to limited (≥75% relief) when single blocks are used ...”; in addition the multispecialty consensus guideline was not for research but for clinical practice in the context of “personalized medicine”.

In the facet pain and sacroiliac pain treatment arms, participants that tested negative were excluded from the study and those that tested positive were randomized to the respective RFN procedure combined with an exercise program or to an exercise program only. The disc pain group arm was discontinued for unclear reasons. The “combination” group was the most concerning as the name was a complete misnomer. The combination trial treatment group consisted of 202 participants with pain “suspected to arise from multiple entities”. Unlike the other study arms, this group was randomized prior to any diagnostic blocks. Of the 103 participants randomized for intervention, 35 participants had “negative results for diagnostic blocks and did not receive radiofrequency denervation”. The authors reported positive diagnostic blocks in 68 “combination trial” participants, of whom “25 received facet joint radiofrequency denervation, 21 sacroiliac joint radiofrequency denervation, 21 received a combination of radiofrequency denervation treatments (facet and sacroiliac joint radiofrequency denervation), and 1 participant did not receive radiofrequency denervation despite a positive result for the diagnostic block”. Diagnostic blocks detected combined facet joint and sacroiliac joint pain in less than 1/3 of the “combination” group, providing further evidence that the clinical history and physical examinations used to identify appropriate procedural candidates were often inaccurate.

It is, thus, not surprising that the incremental cost-effectiveness ratios (ICER) for the combination group “indicated that RFN combined with a standard exercise program dominated a standard exercise program alone”. Based on the flawed selection criteria and diagnostic techniques utilized in the facet joint trial and the sacroiliac joint trial, it is likely that many participants were given the wrong diagnoses and received the wrong treatment. Interventions directed at the wrong anatomic structures inevitably result in treatment failure, as reflected in the ICER for the facet joint and sacroiliac joint groups. Hence, although the ICER was an appropriate statistical parameter, the fundamental analysis was flawed.

In the facet joint treatment group, the higher costs in the intervention arm correlated directly to the cost of the RFN procedure. Contrary to typical practice, each participant in the MINT study facet treatment group received RFN to three bilateral lumbar segments, as no attempt was made to discern which facet joint(s) accounted for the positive diagnostic block. Such indiscriminate use of RFN increased both direct and indirect costs. While the MINT study authors defend this multilevel, bilateral facet joint treatment as standard practice, it is inconsistent with standard pain medicine guidelines and evidence-based clinic practice, thereby undermining the generalizability of the study’s economic conclusions.

Furthermore, the authors indicated that RFN combined with standardized exercises program was more costly and less effective than standardized exercise program alone; the flawed indiscriminate application of the RFN render this conclusion unlikely. Beyond the cost of radiofrequency, the between-group differences in quality-adjusted life-years (QALY) disaggregate costs were statistically insignificant.

Another issue with the cost analysis, irrespective of the issues with validity and applicability of the MINT study, stemmed from the seemingly unrelated regression analyses and bias corrected and accelerated bootstrapping nested in multiple imputation. Although this method was certainly not ideal, it was not wrong or inappropriate. It would have been better to have complete data on all patients, but likely unrealistic to

expect this to be the case. What was concerning was the lack of information about missing data and the limited data available to conduct the bootstrapping. Of note, costs were estimated only from 2/16 centers in the RCT.

5. Assessment of results

The fundamental questions that must be applied during the assessment of the results of any paper on the treatment of pain must include 1) Were participant screening, enrollment, and dropout/exclusion described? 2) Were the baseline features of the study sample described? Was the study sample uniform? 3) Is loss to follow-up minimal? 4) Are the raw outcome data published? 5) Are the results presented accurately?

McCormick et al. [3] reviewed in detail the issues with screening, enrollment, dropout/exclusion, study sample characteristics (i.e. median duration of pain at time of study), loss to follow-up, and presentation of outcome data associated with the MINT RCTs. The same issues apply to the cost-effectiveness analysis.

Maas et al. struggled with explaining the ICER calculations, particularly the discrepancy found in the combination (facet joint, sacroiliac joint, disc) group compared to the other two groups. The results showed that radiofrequency denervation in the combination group alongside a standardized exercise program was in fact superior to a standardized exercise program alone. Though the procedural costs were higher, the total societal costs were lower. *Prima facie*, utilizing diagnostic blocks in an algorithmic fashion to select the appropriate anatomic targets for RFN is more cost-effective than using unvalidated clinical impressions to direct treatment. The authors were unable to provide an explanation for the variation in the combination group ICER compared to the facet and sacroiliac joint groups.

6. Discussion

The fundamental questions that must be applied during the assessment of the discussion of any paper on the treatment of pain must include 1) Do the authors examine and discuss the flaws, limitations, or biases that affect the validity of the study? 2) Do the authors compare the outcomes with other similar literature? 3) Do the authors draw appropriate conclusions from the study data?

Maas et al. reported on the cost-effectiveness of radiofrequency denervation added to a standardized exercise program as compared to a standardized exercise program alone [4]. They concluded that “radiofrequency denervation combined with a standardized exercise program cannot be considered cost-effective from a societal perspective for patients with chronic low back pain originating from either facet or sacroiliac joints” but qualified the statement as relevant to “a Dutch healthcare setting.”

It is important for policy makers, interventionalists, and most importantly patients considering RFN to be aware of the methodological flaws of the MINT study [6], and that substantially higher success rates with favorable cost-effectiveness have been reported by other investigators [22,24]. We propose that clinical effectiveness and cost-effectiveness may have been demonstrated in the Dutch healthcare setting if appropriate methods were employed. The study was conducted in the Netherlands and analyzed a study that *performed assessment and interventions based on “standard practice in the Netherlands”* [10]. They found that there was no difference in cost between the groups for the facet joint or a combination of facet and sacroiliac joints. However, the cost was higher for the radiofrequency denervation sacroiliac group as compared to standardized exercise.

The authors also reported that the probability that radiofrequency denervation would be cost effective across a range of willingness to pay values was approximately 0.65. In many situations, including this one, cost-effectiveness analysis requires the decision maker to determine if the additional benefit is worth the additional cost. This is referred to as the willingness to pay for an additional whole unit of outcome [25]. In this

model, the outcome of interest was a QALY. The probability of being cost-effective is typically plotted on a cost-effectiveness acceptability curve (CEAC) – with probability of being cost-effective on the y-axis, and a range of willingness to pay values on the x-axis. Because cost-effectiveness models incorporate both stochastic and deterministic data for costs, utility values, and probability of achieving certain outcomes, it is not possible to determine statistical significance. Rather, CEA studies report findings using the CEAC to give the reader (e.g., payer or decision maker) information to assist in making a decision about coverage policies for a specific intervention. In this study, treatment of both facet and sacroiliac joints had a probability of being cost-effective of 0.65 across a wide range of willingness to pay values.

Irrespective of the methods used to determine cost-effectiveness, we contend that Maas et al. drew inappropriate conclusions that radiofrequency denervation would not be cost-effective. The conclusions made by Maas et al. revealed the lack of comparisons and review of cost-analysis of other similar published studies. This is most evident when considering the data presented in the review by Schneider et al. [22]. The MINT CEA study made no attempt to compare the results with outcomes of similar literature regarding the clinical efficacy and cost-effectiveness of RFN. The authors went so far as to state that “the effectiveness of radiofrequency denervation has not been demonstrated unequivocally, and its cost-effectiveness is unknown.” But contrary to these statements, Burnham et al. [24] noted significant improvements in pain, analgesic requirement, satisfaction, disability, and direct costs after lumbar RFN. Prospective studies by Dreyfuss et al. [13] and MacVicar et al. [26] robustly demonstrated the clinical efficacy of lumbar facet RFN when selection criteria and procedural protocols adhered to SIS guidelines.

Maas et al. did examine and discuss the flaws, limitations, or biases that may have affected the validity of the study. Although the conclusions reached by Maas et al. from their examination of the strengths and weaknesses of the study differed from ours, we commend them for stating that “researchers and clinicians in other countries or settings should evaluate whether these procedures reflect their daily practice” [4].

7. Summary

The fundamental issue with their cost-effectiveness analysis is the flawed methodological design of the MINT RCTs. These erroneous diagnostic and treatment methods can be illustrated by a hypothetical study designed to evaluate the cost-effectiveness of an antibiotic for cough. Let us consider a study investigating the cost-effectiveness of an antibiotic treatment with supportive therapy versus supportive therapy alone. If the means of diagnosing the underlying etiology of infection (viral vs. bacterial) is invalid and not based on evidence-based guidelines, it will most likely show that antibiotics are ineffective for the treatment of cough. While participants with cough due to bacterial infection are likely to respond favorably, those participants with cough due to viral infection (misdiagnosed as bacterial infection) will not, leading to the spurious conclusion that antibiotics are clinically ineffective and, of course, also cost ineffective for the treatment of cough. This example is analogous to inappropriately using RFN of lumbar medial branch nerves to treat lower back pain secondary to disc herniation or of discogenic origin that had been misdiagnosed as lumbar facet joint pain. This hypothetical exercise can be extended to include participants with a correct diagnosis (bacterial infection), but for whom an incorrect treatment is administered. If a patient with cough due to methicillin resistant staphylococcus aureus (MRSA) pneumonia is treated with antibiotics that do not cover MRSA, the study risks an invalid conclusion that antibiotics are not a cost-effective strategy to treat cough secondary to bacterial infection. The lack of cost-effectiveness here only reflects the improper utilization of the intervention in a patient population that has been appropriately selected. This is analogous to performing RFN with an electrode gauge, placement, duration, and temperature inconsistent with established evidence-based guidelines, as was the case with the Juch et al. MINT study [3,6].

Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Disclosures

- Reza Ehsanian: None.
- Daniel C. Malone: None.
- Johan Hambaereus: None.
- Pedro Monteiro: None.
- Michael Hodde: None.
- David W. Lee: Abbott Neuromodulation Speakers Bureau, Mainstay Medical Speakers Bureau.
- Michael McKenna: None.
- Sayed E. Wahezi: Consultant Boston Scientific.
- Zachary L. McCormick: service on the board of directors of the Spine Intervention Society, research funding from Avanos Medical (paid directly to the University of Utah)
- Belinda Duszynski: None.
- David S. Cheng: None.

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