THE BRITISH PAIN SOCIETY

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An alliance of professionals advancing the understanding and management of pain for the benefit of patients

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Dear Dr Small,

Thank you for inviting the British Pain Society to provide input into a review of BUPA's back pain policy.

You will be aware of the NICE guideline on the early management of chronic low back pain (CG88) published earlier this year. Both the British Pain Society and the Faculty of Pain Medicine of the Royal College of Anaesthetists disagreed with many of the recommendations and findings. The British Pain Society has since established contact with NICE and is now in discussion with them with a view to amending the guidelines for eventual republishing.

With this in mind it is timely and appropriate that BUPA have asked for an independent review of the published clinical evidence on the management of low back pain and we thank BUPA for inviting the British Pain Society to comment as a stakeholder organisation.

We wish to submit comments on the subjects of facet joint injection and facet joint radiofrequency denervation and ask you to consider these comments when reviewing and updating your back pain policy. We have specifically excluded epidural and nerve root injections as these are used for leg and arm pain ensuing from nerve compression within the spinal column (radiculopathy). This type of pain was also exluded in the NICE Low Back Pain Guidance and we would be happy to provide a review of epidural and nerve root injections if required.

Facet Joint Injection

Lumbar facet joint and lumbar facet nerve injections have diagnostic utility but can also be therapeutic as evidenced by published studies and have become common practice in many western countries. In accordance with the criteria established by the International Society for the Study of Pain, the facet joints have been shown to be the source of chronic pain in 15% to 45% of patients with chronic low back pain (1, 2).

Recently there have been two systematic reviews – one on the diagnostic utility of facet joint injections in chronic spinal pain (Sehgal N, et al 2007) (3) and the other (Boswell et al, 2007) on therapeutic utility of facet joint interventions in chronic spinal pain (4).

There has only been one randomised controlled trial of facet joint injections with normal saline with steroid verses normal saline (placebo) – Carette et al (5).

No subsequent randomised controlled trials concerning facet joint injections versus placebo have been published since BUPA conducted their review of evidence in 2002.

In the RCT by Carette et al the selection to be eligible for inclusion in the study as stated by the authors was "had a first or recurrent episode of low back pain, buttock pain, or both, that had lasted for at least six months. The pain could be intermittent or constant, unilateral or bilateral, radiating or not, but it had to be present, at rest of during movement, on the day of entry into the study".

As mentioned in the paper the Median duration of current episode of pain was 18 months in the methylprednisolone group and 24 months in the placebo (saline) group. This study should be cited with caution when considering evidence for the management of back pain of lesser duration.

It is important to note the following comment about the RCT from the systematic review by Boswell MV, et al (4):

"Carette et al (5) failed to exclude placebo responders, which may account for the relatively high incidence of patients in their study with presumed facet joint pain. They showed a prevalence of lumbar facet joint pain of 58% in patients with spinal pain, based on inclusion criteria in Phase 1 of the study. Failure to exclude placebo responders may have diluted the findings of true responders, making detection of differences between the study and control groups difficult. Further even though the results were judged to be positive at 6 months in the methylprednisolone group, they performed various types of analyses and finally concluded that there were no significant differences between groups".

The study by Carette et al, demonstrated that 46% of patients in the methylprednosolone group and 15% of patients in the placebo group had marked or very marked improvement at 6 months after the injection and this was statistically significant ($P = 0.002$). They also state that patients in the methylprednisolone group had more interventions than in the saline group. The additional 'interventions' cited in the study were, in general, further injections of steroid into

the lumbar facet joints and not rehabilitation strategies. To negate the positive outcome of this trial on the basis of the steroid group receiving more additional interventions than the saline group is misleading.

Furthermore, we would question the validity of saline joint injection as a placebo. The effectiveness of saline injection into small joints (metacarpophalangeal and temperomandibular) has been demonstrated and reasons for such a significant 'placebo' response in the Carette study include synovial cyst rupture secondary to joint distension, the 'washout' of inflammatory mediators and facet capsule puncture.

What is clear from the Carette study is that facet joint injections have the potential, at least in the short to medium term, to provide excellent pain relief in nearly half of our patients. Within the context of multidisciplinary pain management this option for patients should remain available.

To abandon a potentially useful, inexpensive and low risk procedure on the strength of a single RCT published nearly 20 years ago and whose findings remain controversial needs to be carefully considered. The reliance on a single RCT is unsafe.

Facet joint injections are primarily diagnostic injections. However, if the patients experience significant pain relief they can be repeated to provide pain relief and improve function and decrease intake of oral medication. If the duration of significant pain relief is not long enough it can be repeated once more to eliminate placebo responders before proceeding to radiofrequency denervation of the fact joints which is an established and proven technique to prolong pain relief as shown by RCTs.

We should not be under any illusion that facet joint injections are a cure for pain originating from facet joints. It should be viewed as a treatment modality to provide us with a diagnosis and in some cases help to relieve pain and allow improved function and promote physical therapy. Having said this, a recently published review of the efficacy of facet joint steroids (with analysed data up until 2007) concluded that there is "Moderate evidence for short & long-term improvement in LBP. " (4)

The following studies should also be considered:

Manchikanti L, et al. Lumbar Facet Joint Nerve Block in Managing chronic facet joint pain: one-year follow-up of a randomised, double-blind controlled trial. Pain Physician 2008; 11: 121-132. (6)

In this study the authors enrolled patients who had chronic function-limiting low back pain for at least 6 months, who were competent to understand the study protocol and had responded with at least 80% pain relief following diagnostic comparative local anaesthetic block. 120 patients were randomised into two groups. In group 1 medial branch block was performed with bupivacaine (15 patients) or bupivacaine and Sarapin (15 patients). In group 2 medial branch block was performed with bupivacaine and steroid (15 patients) or with bupivacaine with steroid and serapin. Blocks were repeated if necessary during the follow-up period of one year.

The authors found that lumbar facet nerve block was effective in over 82% of patients with improvement in functional status.

The authors conclude "lumbar facet joint pain diagnosed by controlled comparative local anaesthetic blocks with the criteria of 80% pain relief, which is sustained after prior painful movements for appropriate duration of action of local anaesthetic, may be treated with lumbar median branch block with or without steroid providing approximately 15 weeks of pain relief and requiring 3 to 4 episodes of treatment per year".

However, although the authors recruited patients with back pain of at least 6 months, the mean duration of pain in this study was 108 ±102 months (Mean ± SD).

Manchikanthi L, et al. Effectiveness of Lumbar Facet Joint Nerve Blocks in Chronic Low Back Pain: A Randomised Clinical Trial. Pain Physician 2001; 4: 101-117 (7)

In this study 200 patients were evaluated with controlled diagnostic block for the presence of facet joint mediated pain. Eighty four patients (42%) were determined to have lumbar facet joint mediated pain. These patients were randomly allocated to two groups. Group 1 received therapeutic injection with local anaesthetic and Sarapin and Group 2 received injections with local anaesthetic, Sarapin and methylprednisolone. A total of 73 patients were treated with medial branch block under fluoroscopy. Patients underwent multiple procedures over a period of 2 years and 6 months.

25% patients had pain of less than one year duration and the rest had pain for more than one year.

There was a significant improvement noted in the overall health status with improvement not only in pain relief, but also with physical function and psychological status, as well as return to work.

The duration of >50% pain relief was 10.7 + 0.58 weeks (mean + SEM) with each injection. The cost for 1 week improvement of quality of life was estimated to be $67.

The authors concluded that medial branch blocks are an effective modality of treatment in managing lumbar facet joint mediated pain confirmed by controlled diagnostic blocks. Medial branch block with local anaesthetic and Sarapin, with or without steroids, are a cost-effective modality of treatment, providing significant pain relief, improvement in functional status, improvement in overall psychological status, and return to work. Medial branch block also exerts some effect on patients' state of depression, anxiety, and symptom magnification. Medial branch block significantly decreased somatisation.

The other prospective studies to be considered are

A prospective observational study by Shih et al (8) reported the results of lumbar intraarticular facet joint injections in a prospective study of 277 patients with low back pain. Following injections of lidocaine, betamethesone and contrast, positive responses were noted in 72.1%

(147/204) of patients after 3 weeks, 40.7% (83.204) after 6 weeks and 31.4% (64/204) after 12 weeks. The injections were done for diagnostic purpose and the authors noted modest pain relief as described above. This study was designed primarily to test the disgnostic value but does indicate that in some patients the pain relief can be prolonged for reasons not yet known.

Other prospective observational studies by Murtagh FR et al (9) and Destouet JM, et al (10) have also shown that 54% and 38% of patients respectively had pain relief in for more than 3 months.

Injections for Diagnosis of non-specific low back pain

Diagnosis is an important aspect of managing pain and precision diagnostic techniques are the only means of diagnosing non-specific low back pain. The following support this statement:

Lumbar facet joints are innervated by the articular branches which arise from the meidal branches of the dorsal primary rami. Lumbar medial branch blocks are a diagnostic procedure designed to test if a patient's pain is mediated by one or more of the medial branches of the lumbar dorsal rami. It has been shown that the medial branches can be effectively blocked with a tiny volume of local anaesthetic injected onto to the medial branch in an effort to relieve the patient's pain (11, 12).

By convention, lumbar medial branch blocks are used to test if a patient's pain stems from a given lumbar fact joint. For that purpose, the nerves that innervate the joint are anaesthetised. This convention is based on the argument that, of all the structures innervated by the medial branches of the lumbar dorsal rami, the facet joints are the only ones that might harbor a discrete, focal source of chronic pain. No pathology capable of producing chronic pain is known to affect the segmentally specific muscles innervated by the dorsal rami (13).

If pain is relieved, following lumbar facet nerve block the response constitutes evidence that the targeted nerves are mediating the patient's pain; but steps need to be taken to ensure that the observed response is not false-positive (13).

Comparative local anesthetic blocks constitute a more practical form of control that can be readily incorporated into routine and conventional practice. A true-positive response to comparative local anesthetic blocks is one in which the patient reports complete relief of pain for a shorter duration when a short-acting agent is used, and for a longer duration when a long-acting agent is used. Such a response is referred to as “concordant” in that it is concordant with the expected action of the agents used (14).

Lumbar medial branch blocks have diagnostic utility, in that if and once positive, they identify the source of pain. Establishing a positive diagnosis protects the patient from the futile pursuit of other and competing diagnosis, and from undergoing presumptive treatment or treatment that is not appropriate for pain mediated by the lumbar medial branches.

Lumbar medial branch blocks have therapeutic utility, in that a positive response predicts a good chance of obtaining complete relief of pain from percutaneous radiofrequency neurotomy

Dreyfuss et al (11) showed that lumbar medial branch blocks were target specific, provided that precise target points were accurately used, and that needles were introduced in a particular direction. Structures other than the target nerves were not anaesthetized by lumbar medial branch blocks. Kaplan et al (12) showed that normal volunteers were protected from experimentally induced lumbar facet joint pain if the appropriate medial branches were anaesthetized. Together, these studies showed that lumbar medial branch blocks were target-specific and were a valid test of facet joint pain.

Dreyfuss et al (16) showed that dramatic and lasting relief from back pain could be achieved with lumbar medial branch neurotomy in patients carefully diagnosed with controlled diagnostic blocks of their lumbar medial branches. Accordingly, lumbar medial branch blocks were shown to have both diagnostic utility and therapeutic utility.

Summary

The study by Carette et al, demonstrated that 46% of patients in the methylprednosolone group and 15% of patiens in the placebo group had marked or very marked improvement at 6 months after the injection and this was statistically significant (P = 0.002).

Facet joint injections are primarily diagnostic injections. However, if the patients experience significant pain relief they can be repeated to provide pain relief and improve function and decrease oral medication intake. If the duration of significant pain relief is not long enough it can be repeated once more to eliminate placebo responders before proceeding to radiofrequency denervation of the fact joints which is an established and proven technique to prolong pain relief as shown by RCTs.

We should not be under any illusion that facet joint injections are a cure for pain originating from facet joints. It should be viewed as a treatment modality to provide us with a diagnosis and in some cases help to relieve pain and allow improved function and promote physical therapy.

Contrary to common belief that facet nerve blocks are mainly diagnostic, Manchakanti et al (6, 7) have shown in randomised controlled trials that facet nerve injections can in addition have significant therapeutic utility.

As stated in the Practice guidelines (13) set out by a well recognised international body (International Spinal Intervention Society) and as proven by studies from Dreyfuss (11) and Kaplan (12) facet joint nerve blocks have a diagnostic role. Establishing a positive diagnosis protects the patient from the futile pursuit of other and competing diagnosis, and from undergoing presumptive treatment or treatment that is not appropriate for pain mediated by the lumbar medial branches.

Lumbar medial branch blocks have therapeutic utility, in that a positive response predicts a good chance of obtaining complete relief of pain from percutaneous radiofrequency neurotomy.

We feel that facet joint injections and facet nerve block with local anaesthetic and steroids have therapeutic value in carefully selected patients and should be recommended by BUPA with the provision that it is performed within the context of a multidisciplinary pain clinic.

Diagnostic facet nerve block (Medial Branch Block) should be recommended for establishing a positive diagnosis of chronic low back pain thus protecting patients form the futile pursuit of other and competing diagnosis, and from undergoing presumptive treatment or treatment that is not appropriate for pain mediated by the lumbar medial branches.

Diagnostic facet nerve block (Medial Branch Block) should be recommended before radiofrequency denervation of the facet joints for chronic low back pain with the provision that it is performed within the context of a multidisciplinary pain clinic.

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Facet Joint Radiofrequency Denervation

We accept that the evidence to support facet joint injections with steroid as a therapeutic modality is not strong though we also acknowledge that the total evidence base for the procedure amounts to a single (and controversial) randomised controlled trial performed almost 20 years ago and it is clear that further research is needed.

The evidence to support the use of medial branch blocks as a diagnostic intervention is strong – in a recent best evidence review by Rubinstein and Van Tulder, the authors conclude that:

'***There is strong evidence for the diagnostic accuracy of facet joint blocks in evaluating spinal pain, and moderate evidence for transforaminal epidural injections, as well as sacroiliac joint injections for diagnostic purposes.'(1)***

> Rubinstein SM, van Tulder M. A best-evidence review of diagnostic procedures for neck and low-back pain. Best Pract Res Clin Rheumatol. 2008 Jun;22(3):471-82

Given that we can accurately diagnose facetogenic low back pain it is important that BUPA consider some of the more recent evidence available to support the widely accepted definitive therapeutic procedure for facetogenic low back pain – radiofrequency denervation (medial branch radiofrequency neurotomy).

There is much confusion regards the evidence base for radiofrequency denervation. The following article, published in Pain Medicine recently, is reproduced with permission from the author. The review considers all the evidence to date and accurately reflects the British Pain Society position with respect to radiofrequency denervation.

A Narrative Review of Lumbar Medial Branch Neurotomy for the Treatment of Back Pain

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Introduction

Confusion has arisen about a family of procedures variously known as lumbar facet denervation, lumbar medial branch neurotomy, lumbar radiofrequency neurotomy, or lumbar RF neurotomy, amongst other names. As a result of this confusion, these procedures have frequently been misrepresented, with the attributes of one being mistakenly applied to another, particularly in systematic reviews. Despite the efforts of some commentators [1,2,3], the confusion and misrepresentation continue.

Systematic reviews were devised in order to provide a synthesis of the best available evidence about treatments. However, the methodology of systematic reviews was based on methods used for drug trials. Drugs have a consistent effect; their use is not operator-dependent. Consequently, in the case of drug trials, systematic reviews could focus on outcomes and important variables such as blinding, randomisation, statistical power, validity of outcome measures, and effect sizes, without regard to the intervention itself. Furthermore, in the fields of musculoskeletal medicine and pain medicine, systematic reviews have been performed typically of interventions for conditions defined by a single symptom, such as back pain or shoulder pain. Interventions such as physical therapy, manual therapy, drugs, exercises, or acupuncture, have not been applied to patients who must satisfy criteria for a particular, patho-anatomic diagnosis.

In contrast to drug trials, the outcomes of minimally invasive interventions, irrespective of randomisation, can be confounded by errors in diagnosis, errors in treatment, and operator competency. Contemporary systematic reviews do not accommodate these confounding variables. They are performed without regard to such errors, as if these errors are not germane to conclusions about efficacy. With respect to lumbar medial branch neurotomy, these errors are not just relevant, they are crucial.

Any review of the literature on this topic needs to question domains not considered by conventional systematic reviews. Unless this is done, the conclusions drawn by systematic reviews may be erroneous. More egregiously, a danger arises when authorities responsible for recognition and reimbursement of procedures take the conclusions of systematic reviews literally and at face value, without realising their omissions and limitations.

Accordingly, this narrative review has been composed to highlight the shortcomings of systematic reviews to date. It has been composed by authors who, to various extents, have been involved in the development and evaluation of the procedure. The review serves to clarify the procedure itself, and to provide evidence of its efficacy.

On the one hand, a narrative review composed by authors with content-expertise might seem to affront the contemporary fashion for arm's length appraisal by disinterested parties with expertise in the methodology of reviews. However, content-expertise is what has conspicuously been lacking in previous reviews, which results in misconceptions and misrepresentations. Readers concerned about bias, can judge for themselves by consulting the primary evidence and determining if it has been represented and interpreted fairly.

Methods

The literature pertaining to the index procedures was harvested from the personal libraries of the authors, who had been involved in the field since its inception, and who had published several of the seminal studies. That literature was cross-referenced against the bibliographies of all systematic reviews published to date on the topic [5-10].

Historical Perspective

A historical perspective is pertinent because it illustrates several flaws in past practice that have been repeated, and which affect the assessment of contemporary practices. Neither these flaws, nor their repetition, have been recognised or acknowledged by systematic reviews.

Although the proposition that the lumbar zygapophysial joints might be a source of back pain had been articulated several decades previously [11], it was not until 1971 that a method was described by which to treat this particular source of pain. Skyrme Rees [12,13] claimed that back pain stemming from the lumbar zygapophysial joint could be treated by severing the articular nerves that innervated these joints, using a special scalpel to make longitudinal incisions through the back muscles. The procedure was called "rhizolysis" [12,13]. Conspicuously, no diagnostic criteria were applied or required. Patients were treated presumptively. Astoundingly high success rates were claimed [12,13]. Others adopted the procedure, and although their success rates were more modest, they were nonetheless substantial [14-17].

An anatomical study subsequently showed that this intervention was without foundation [18]. The articular nerves that Rees claimed could be severed did not run where he depicted them. They were too deep to be reached by the blade that he used, and they ran longitudinally, rather than transversely, and could not be transacted by longitudinal incisions. Consequently, the results claimed for rhizolysis could not be attributed to the denervation of lumbar zygapophysial joints. Although this was pointed out in the literature [19,20], no explanation for the effect has been forthcoming other than a placebo effect.

Inspired by the publications of Rees [12,13], Shealy modified the intervention by using radiofrequency electrodes purportedly to coagulate the articular nerves and thereby to denervate painful lumbar zygapophysial joints [21-24]. His procedure became known as facet denervation. He claimed impressive success with this operation, and others echoed this success [25-27].

In due course, however, it was demonstrated that no nerves were located where Shealy described placing his electrodes [38,39]. Therefore, the outcomes of his procedure could not be attributed to

denervation of painful lumbar zygapophysial joints. This revelation was not heeded, and publications worldwide continued to report the success of lumbar facet denervation [40-44] . As a result of this endorsement facet denervation became an "accepted" practice in the United States, despite having had its anatomical basis refuted.

In order to distinguish it from "facet denervation" as described by Shealy [21-24], the procedure corrected for surgical anatomy was named lumbar medial branch neurotomy [38,39]. The targets for denervating lumbar zygapophysial joints were not articular nerves, but the medial branches of the lumbar dorsal rami (or the dorsal ramus itself, at L5) which furnished articular branches to these joints. The pivotal revision was that if operators sought to denervate the joints they should place their electrodes accurately on the target nerves.

A later revision pertained to the orientation of electrodes. It had been common practice to place electrodes perpendicular to the target nerve, in the same manner in which hypodermic needles might be placed in order to anesthetise the nerve. The assumption was that radiofrequency electrodes coagulated distal to their tip. This assumption proved wrong.

Disappointed at the short duration of relief obtained in their patients following lumbar medial branch neurotomy, investigators examined the nature of the lesions produced by their electrodes [45]. In experimental media, they found that radiofrequency electrodes produced substantial lesions circumferentially in a transverse direction around the active tip of the electrode, but very little lesion distally [45]. Placing the electrode perpendicular to the nerve risked having the lesion miss the nerve altogether, or at best incorporating it with no more than a "spot" lesion. Consequently, it was recommended that electrodes should be placed parallel to the target nerve, in order to achieve coagulation along a substantial length of the nerve [45].

The concept validity of this recommendation seemed obvious, and its face validity was implicit. However, not all operators adopted the recommendation. This prompted a reaffirmation of the recommendation, some 20 years later, together with a demonstration of its face validity in a radiographic cadaver study [46]. As well, it was shown that accuracy of coagulation depended critically on the size of the electrode used. Large gauge electrodes could be relied upon to capture the target nerve, because the lesion produced was large. Smaller gauge electrodes, however, need to be placed exactly on the nerve for them to have any prospect of capturing the nerve. A displacement as little as 1 mm could result in the lesion produced failing to encompass the target nerve [46].

Despite these recommendations, operators – particularly in the Netherlands and

Europe – preferred to continue with perpendicular placement of their electrodes [47]. If placed in this manner, exactly on the target nerve, electrodes could possibly succeed in coagulating the nerve. However, the length of the lesion produced would be short, which theoretically would result in limited duration of relief. The shorter the length of nerve coagulated, the sooner it would repair, and the shorter the duration of relief obtained. Otherwise, if the electrode placed perpendicular to the nerve was not placed exactly on the nerve, the lesion made could fail to incorporate the nerve. This would limit the yield of the produce and its success rate.

Standards

In the light of this history, the International Spine Intervention Society prescribed certain standards of practice for lumbar medial branch radiofrequency neurotomy [48]. It recommended that, for lumbar medial branch neurotomy to be anatomically accurate, electrodes should be placed parallel to the target nerve. Furthermore, operators should understand that small electrodes might fail to capture the nerve. They could not rely on single placements of the electrode. Multiple placements might be required in order to cover all possible, albeit small, variations in the exact location of the nerve. Also, lesions should be placed along the maximal available length of the nerve, in order to optimise duration of effect.

Diagnostic Criteria

The paradigm of lumbar medial branch neurotomy is that a patient's pain can be relieved by coagulating the nerves that mediate (transmit) their pain. An essential prerequisite, therefore, is that it must be shown that the target nerves are responsible for the patient's pain. This is achieved by controlled diagnostic blocks of the medial branches of the lumbar dorsal rami that mediate the pain [49].

Medial branch blocks involve anaesthetising the nerve with a tiny volume of local anaesthetic, as a test to see if doing so relieves the patient's pain. Single diagnostic blocks are not valid, because they carry an unacceptably high false-positive rate [50,51,52]. In order to reduce the likelihood of responses being false-positive, controlled blocks are mandatory [49].

For various reasons, medial branch blocks are the only acceptable and validated diagnostic test as an indication for medial branch neurotomy. Firstly, there is the logic that before a nerve is coagulated, in the name of treatment, it should be shown that blocking the nerve temporarily relieves the patient's pain. There is neither logic nor merit in "treating" a nerve that has not been shown to be relevant to the patient's complaint. Secondly, medial branch blocks have been validated for face validity [53], target-specificity [54], and construct validity [50]. Thirdly, they are predictive of outcome from medial branch neurotomy [55].

Patients with positive responses to controlled blocks can expect to have substantial and lasting responses to medial branch neurotomy [55].

No other diagnostic test pertinent to medial branch neurotomy has been evaluated, let alone vindicated, for construct validity or predictive validity. In particular, intra-articular blocks of the lumbar zygapophysial joints have not been validated. Intra-articular blocks have not been subjected to controls, and have not been shown to be predictive of response to any form of treatment.

The singular diagnostic criterion for lumbar medial branch neurotomy, therefore, is complete relief of pain – or sufficiently close to complete relief – following controlled medial branch blocks [48,49]. Blocks that are not controlled, or intra-articular blocks, are not a substitute, for they lack validity. If controlled blocks are not performed the risk obtains that patients will undergo treatment for a condition that they do not have and, therefore, are destined to failure or to no more than a placebo response.

Efficacy

Earlier publications no more than described the theoretical basis of lumbar medial branch neurotomy [38,39]. The first clinical study that used appropriate selection criteria and that used correct surgical technique was a descriptive study [55]. Some 60% of patients obtained at least 80% relief of their pain, lasting at least 12 months, and 80% of patients sustained at least 60% relief [55]. This relief of pain was accompanied by improvements in disability that were both clinically and statistically significant.

Similar outcomes were corroborated by another descriptive study [56]. During a 10-year period, 209 patients were treated by lumbar medial branch neurotomy, and 174 were reviewed. Of these, 68% (or 56% of the original sample) maintained at least 50% relief of their pain for between 6 and 24 months. Pain relief was associated with improved activities and decreased consumption of analgesics.

A third study, of 44 patients, showed that medial branch neurotomy achieved significant reductions in pain, improvements in disability, and reduced analgesic requirements [57]. These effects peaked at 3 and 6 months, but attenuated thereafter. The study recorded high patient satisfaction with the procedure.

Descriptive studies such as these are not admitted as evidence by systematic reviews, which restrict their purview to randomised, controlled trials. However, the virtue of descriptive studies is that they establish a benchmark: of what outcomes can be achieved if correct selection criteria and correct technique are used.

Many of the studies accepted by systematic reviews are not valid studies of lumbar medial branch neurotomy. They fail either in selection or surgical technique or both.

The study of Gallagher et al [43] was not a test of lumbar medial branch neurotomy. In the first instance, it selected patients on the basis of single, uncontrolled, intra-articular, diagnostic blocks. Therefore, the patients enrolled were not necessarily ones who would be expected to respond to medial branch neurotomy. Secondly, the study explicitly used the technique of Shealy [21-24] which has been discredited [38,39]. In essence, it was a study that used a flawed surgical technique to coagulate nerves that were not shown to mediate the patients' pain.

The study of Leclaire et al [58] was not a test of lumbar medial branch neurotomy. Controlled blocks were not used. Medial branch blocks were not used. The investigators relied on delayed responses to intra-articular injections of steroids, which have been shown to be no more effective than placebo [59]. Therefore, the patient sample did not necessarily have pain that was amenable to treatment by medial branch neurotomy, and was unlikely to be so. Furthermore, the operative technique was not described. The outcome data strongly suggest that it was an inaccurate technique. The active treatment group did not achieve outcomes anywhere near the benchmark standard for lumbar medial branch neurotomy [55]. Indeed, the success rate was minimal to zero, and less than that of the placebo group. This suggests that one sham treatment was compared with another sham treatment. In order for a controlled trial to be an adequate test of an intervention, that trial should achieve outcomes at least comparable to those evident in the descriptive literature. Zero outcomes from active treatment strongly suggest a surgical flaw.

The study of van Wijk et al [60] was not a test of lumbar medial branch neurotomy. However, it was expressly and explicitly a test of how radiofrequency neurotomy is practised in the Netherlands [60]. The results were negative: active treatment was not detectably more effective than sham treatment. Explicitly, therefore, the conclusion is that the manner in which neurotomy is practised in the Netherlands is no more effective than placebo.

The fatal flaws in the study were that patients were not selected using controlled medial branch blocks, and that a highly inaccurate surgical technique was used. This was evident in the illustrations of the publication, as demonstrated in a letter to the editor following publication of the study [61]. Electrodes were placed in locations remote from the target nerves, with little to no prospect of coagulating the nerves. Consequently, the study amounted to comparing one sham treatment with another.

The study by van Kleef et al [62] was suboptimal in certain respects but more informative and relevant than others. It did not select patients on the basis of controlled diagnostic blocks, but nevertheless did require relief of pain following a single diagnostic blocks. An effect of this limitation is that whereas some of the patients recruited possibly did have pain amenable to treatment by lumbar medial branch neurotomy, it is also possible that others did not. Therefore, a low success rate should be expected. This expectation was reflected in the data. As well, the surgical technique used involved perpendicular placement of electrodes, but the illustrations of the procedure are compatible with accurate placement on the target nerve. The effect of this limitation would be that although relief might occur its duration would be less than that achieved in benchmark studies. This, too, was reflected in the data.

Only a minority of all patients treated achieved complete relief of pain or at least 50% relief, and few had enduring relief. Nevertheless, active treatment was superior to placebo treatment. Of the 15 patients treated with active neurotomy, 7 (47%; 22% - 72%) achieved relief, compared with 3 out of 16 patients (19%; 0% - 38%) treated with placebo [62]. Although these proportions are palpably different, they are not significantly different statistically, for their 95% confidence intervals overlap. However, survival analysis over the ensuing 12 months showed a significant difference ($p = 0.002$) in favour of active treatment [62], with a number needed to treat of 4.This relief of pain was accompanied by significant improvements in disability, and reduction in the consumption of analgesics [62].

The study of van Kleef et al [62] was not an example of correct selection of patients or of optimal technique. Quantitatively, therefore, its outcomes are less favourable than those reported in descriptive studies. However, the use of randomisation made the study a valid test of medial branch neurotomy against placebo. It serves to show that the outcomes reported by descriptive studies cannot be summarily dismissed and attributed to untested placebo effects.

A similar contribution was provided by Nath et al [63]. These investigators studied a particularly difficult sample of patients, who had multiple sources of pain. Pain mediated by the lumbar medial branches was only one of several types of pain suffered. Nevertheless, the patients were confident in being able to distinguish that pain relieved by medial branch blocks, and subsequently by medial branch neurotomy. The particular virtues of this study were that controlled diagnostic blocks were used to select patients and that optimal technique [48] was used. Complete and enduring relief of pain was not demonstrated, because the patients still had other sources of persisting pain. However, for the pain for which patients were treated, the study showed significantly greater improvements following active medial branch neurotomy

compared with sham treatment. Therefore, the effects of radiofrequency neurotomy cannot be wholly attributed to placebo effects. Relief of pain was accompanied by reduction in the use of analgesics [63].

In another study [64], the primary objective was to evaluate a new procedure – pulsed radiofrequency – whose efficacy is not known [65], by comparing it with conventional, i.e. thermal, radio-frequency neurotomy. That study, however, provided outcome data and controlled data concerning conventional lumbar medial branch neurotomy, irrespective of the comparison with pulsed RF. The study enrolled patients who obtained at least 50% relief of pain following single, uncontrolled, diagnostic blocks [64]. The authors explained that, in their health system, controlled blocks were not supported and so, could not be used. Patients were then randomised for treatment by either thermal or pulsed RF, but for thermal RF a correct technique was used. The electrode was placed parallel to the target nerves. As well, the study included a group who underwent sham treatment, in which the electrode was placed as for thermal RF but no lesion was generated. For the relief of pain, thermal RF was significantly more effective than sham treatment immediately after treatment, at 6 months, and at 1 year; and thermal RF was significantly more effective than pulsed RF at 6 months and at 1 year [64]. For improvement in disability, thermal RF was more effective than sham treatment immediately after treatment, at 6 months, and at 1 year; and thermal RF was more effective than pulsed RF at 1 year [64]. After treatment, 95% (85% - 100%) of patients who underwent sham treatment still required analgesics, compared with only 40% (18% - 61%) of those treated with thermal RF. Of those who underwent sham treatment, 20% (2% - 38%)) reported an excellent outcome, compared with 65% (44% - 86%) of those treated with thermal RF.

Notwithstanding what the authors sought to conclude about pulsed RF, their data clearly show that conventional lumbar medial branch neurotomy was significantly more effective than sham treatment, for relief of pain, improvement in disability, use of other health care, and global satisfaction. Pulsed RF appeared to be effective immediately after treatment, but had no enduring effects. Therefore, pulsed RF is not a substitute for conventional, thermal, lumbar radiofrequency medial branch neurotomy.

By definition, medial branch neurotomy is not a permanent cure for pain. It is natural, and to be expected, that the coagulated nerve will regenerate. In that event, however, the procedure can be repeated [66], and relief reinstated. Repeat treatment can be justified if previously the patient has reported satisfying relief from pain, corroborated by restoration of function, and return to work – if socioeconomically possible.

When performed correctly, lumbar medial branch neurotomy is a remarkably safe

procedure. Side-effects are uncommon [67], of limited duration, and minor in nature, as might be expected of a minor neurosurgical procedure. They include soreness from the electrode track and temporary pain from the sites where lesions are placed. Major complications have been encountered only when operators have failed to follow guidelines for the safe and accurate conduct of the procedure [68].

Discussion

The acme of evidence-synthesis is meta-analysis, by which results from multiple studies can be pooled in order to consolidate trends in the literature. But meta-analysis requires that studies be totally homogenous in terms of samples and methods. Rarely has this been the case in pain medicine.

Instead, systematic reviews typically undertake a "head count", balancing the number of positive studies against the number of negative studies. By this process, the evidence can be said to favour an intervention if positive studies outnumber negative ones; or be "conflicting" or "inconclusive" when the numbers are equal. Errors arise, however, if positive studies are overlooked, ignored, or discredited, while negative studies are accorded undue prominence. This process becomes particularly egregious when negative studies that are fundamentally inadmissible are nevertheless accepted as evidence simply because of their negative result. This suggests either a bias against the procedure or a lack of insight into it.

In the Law, two standards of evidence apply. For criminal proceedings the standard is "beyond all reasonable doubt". For lesser proceedings the standard is "on the balance of probabilities". The former standard is sometimes the level of evidence called for by systematic reviews and critics, but is very costly to achieve in studies of Pain Medicine. The latter standard is far more reasonable and practical. Moreover, it translates into a form of Bayesian logic when applied to pain medicine. It asks what the likelihood is that a procedure works, before it is tested; and whether the evidence subsequently moves one to affirm or reject that view.

In the case of lumbar medial branch RF neurotomy, the procedure is conceptually sound; it has a plausible, biological rationale. Diagnostic blocks show that the patient's pain can be interrupted, albeit temporarily. RF coagulation has the ability to prevent conduction along nerves for periods longer than does a local anaesthetic agent. RF neurotomy, therefore, should provide prolonged relief. The *a priori* expectation, therefore, is that this treatment should work. The subsequent question is whether the evidence contradicts this expectation or is compatible with it.

Pivotal to evaluating the evidence is the realisation that medial branch neurotomy is

not a treatment for any form of back pain. It is a treatment for a particular form of back pain. Under those conditions it is not a valid criticism of a study that patients were "highly selected". The paradigm of medial branch neurotomy demands that patients be highly selected. A complement to this requirement is that the intervention cannot be tested in patients who have not been properly selected. Nor can it be tested if surgically inaccurate techniques are used.

In this regard, the evidence shows that RF "treatment" fails when patients are wrongly selected or when inaccurate technique is used. Others have identified these reservations [69], but they are no longer a matter of theory, opinion or choice. The evidence explicitly shows that when patients are selected by intra-articular injections [58], or when unvalidated [58,60] techniques are used, RF "treatment" does not work. But this does not constitute evidence against procedures that are performed properly. Yet reviews in the past admitted procedurally flawed studies [4,5,6], and continue to do so [7-10] , giving them equal status, as evidence, to procedurally valid studies. Some reviews [7,8] cite only the flawed studies [43,58,60], to the exclusion of valid studies [61,64], in order to emphasise their negative or neutral results, seemingly to justify drawing negative conclusions about the procedure. Even when all studies have been considered [6,9], the inclusion of procedurally flawed studies speciously dilutes the evidence to inconclusive or conflicting.

Whenever patients have been correctly selected, and when anatomically accurate surgical techniques have been used, the pre-test expectations of success have consistently been vindicated (Table 1). Lumbar medial branch neurotomy achieves relief of pain, improvements in disability, and reductions in the need for analgesics. No evidence stemming from valid studies refutes the pre-test expectations. In Bayesian terms, therefore, the evidence fails to refute the pre-test expectations that the treatment should work and, indeed, consistently corroborates that expectation.

Not all studies have tested how well medial branch neurotomy works, in terms of optimal success rates and lasting effect. Only the studies of Dreyfuss et al [55], Gofeld et al [56], Burnham et al [57] Tekin et al [65], used correct technique; achieved lasting outcomes; and provided long-term data (Table 1). However, three randomised studies have shown that active treatment is more effective than sham treatment [62,63,65]. This is a crucial step in the assessment of the procedure. This evidence vaccinates the results of descriptive studies [55,56,57] against being dismissed as due to placebo effects. In contrast, no valid study has shown that medial branch neurotomy is a placebo.

What might be of concern to insurers and others who pay for these procedures are standards of practice. Since the literature describes erroneous practices in selection and technique, insurers and others can expect similar aberrations in the communities that they service. It is for this reason that the International Spine Intervention Society sought to prescribe

appropriate, evidence-based guidelines for how medial branch blocks and medial branch neurotomy should be conducted. It is not an indictment of the procedure if practitioners do not perform it as recommended. That is a matter of discipline. If insurers and others are concerned about abuses and lack of discipline, the problem is not one of science and evidence; it becomes a matter of quality assurance. Seeking to discredit a procedure by incomplete or erroneous reviews of the purported evidence is neither honourable nor helpful. It disadvantages worthy patients and responsible practitioners. An alternative solution is available.

Procedures performed according to guidelines should be supported. Those that deviate from guidelines should not. The guidelines published by the International Spine Intervention Society [48,49] provide the means by which that distinction can be made.

The evidence requires that the singular indication for lumbar medial branch neurotomy is a positive response to controlled diagnostic blocks [49]. If controlled blocks are not allowed by administrations, single blocks are possibly tolerable, but the consequence is that samples of patients selected for treatment will be contaminated by patients who would not qualify under more rigorous conditions. Therefore, lesser success rates should be expected. Nevertheless, worthy patients would not be denied care. Subsequently, the surgical technique should be consistent with the known anatomy and rationale for the procedure [48]. What makes a procedure a correct lumbar medial branch neurotomy is not what it is called but how it is executed.

Nor should insurers fear being overwhelmed by an unaffordable avalanche of neurotomies. Amongst injured workers with back pain, pain amenable to medial branch neurotomy is uncommon to rare [3,70], when stringent diagnostic criteria are applied. It is common only amongst elderly patients [3,71]. Excesses in medial branch neurotomy occur only if responsible diagnostic criteria are not applied or if correct practice is not enforced.

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STUDY	PATIENT SELECTION		SURGICAL TECHNIQUE	OUTCOMES				
	Medial Branch Blocks	Controlled Blocks		> sham	Success Rate	Pain Relief	Improved Disability	Reduced Analgesics
VALID STUDIES								
Van Kleef [62]	yes	no	partially valid	yes	47%	yes	yes	yes
Tekin [65]	yes	no	valid	yes	65%	yes	yes	yes
Nath [63]	yes	yes	valid	yes		yes		yes
Dreyfuss [55]	yes	yes	valid		80%	yes	yes	
Gofeld [56]	yes	yes	valid		56%	yes	yes	yes
Burnham [57]	yes	partial*	valid		43%	yes	yes	yes
INVALID STUDIES								
Gallagher [43]	no	no	discredited	Immaterial				
Leclaire [58]	no	no	unknown					
Wijk [60]	yes	no	inaccurate					

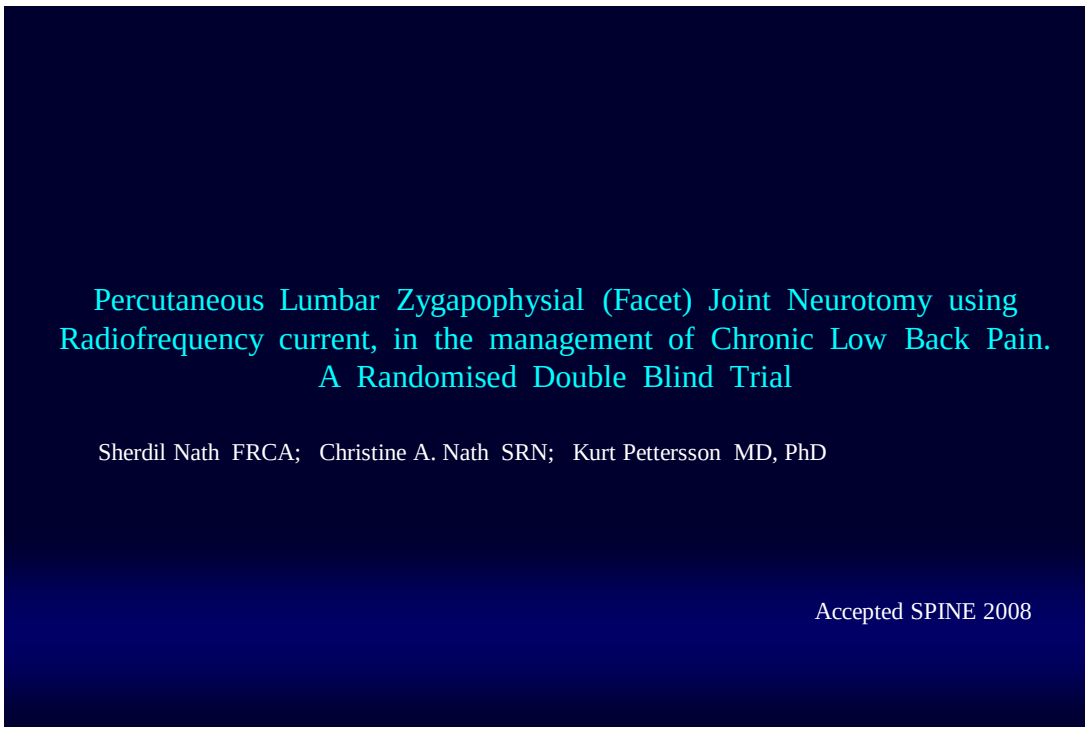
Table 1. A summary of the validity of studies of lumbar medial branch neurotomy, and the outcomes of the valid studies.

*: The study of Burnham et al [57] required a positive response to both a medial branch block and an intra-articular block.

Summary and other considerations

It is clear that there is now moderate to strong evidence to support radiofrequency denervation preceded by diagnostic medial branch blocks in the treatment of low back pain. The evidence to support the indiscriminate use of intra-articular facet joint injections is much less compelling.

The most recent radiofrequency denervation RCT by Nath et al, and referred to above in the paper by Bogduk deserves further consideration. The following presentation was sent to us by the authors and details some important points. Please click the slide to start the presentation.



We ask BUPA to note that:

1. The study had small numbers of participants although power was adequate. The author points out that nearly half of the patients (111) who underwent diagnostic medial branch block enjoyed persistent relief from the blocks and did not require further treatment. In other words, for a very large group of patients, medial branch blocks provided adequate relief and there was no requirement to progress to radiofrequency denervation.

2. The long term outcomes of this study are unpublished yet merit comment. At 5 years, 13 out of 19 patients in the active treatment group were pain free.

We would also ask BUPA to note the findings of Van Zundert in :

Low Back Pain: From Algorithm to Cost-Effectiveness? Jan van Zundert, MD; Maarten van Kleef, MD, PhD Pain Practice, Volume 5, Issue 3, 2005 179–189*

Van Zundert describes the results of a cost evaluation for the management of low back pain in Belgium compared with that in the Netherlands, two neighbouring countries with different social security systems.

In brief, a comparison was made between two countries who have adopted differing treatment strategies for low back pain.

In Belgium, TENS and radiofrequency denervation are not routinely reimbursed. These techniques are adequately reimbursed in the Netherlands.

The following table illustrates the differences in treatment usage arising as a result of these reimbursement anomalies:

Table 3. Comparison of the Frequency of Use of Different Pain Management Options in Belgium (Be) and the Netherlands (NL)

	Total Number Be	Total Number NL	*N* per 1000 Inhabitants Belgium	*N* per 1000 Inhabitants NL	ratioBe/NL
Medication	1,883,000	1,784,527	188.30	118.97	1.6/1
TENS	1,100	5,000	0.11	0.33	1/3
Epidural steroids	35,000	17,640	3.50	1.16	3.3/1
Radiofrequency	1,428	6,011	0.14	0.40	1/2.8
Epidural neurostimulation	233	89	0.02	0.001	4/1
Intrathecal drug	82	32	0.008	0.002	4/1
Surgery without arthrodesis	12,899	3,528	1.29	0.24	5.5/1
Surgery with arthrodesis	3,198	1,851	0.32	0.12	2.6/

If radiofrequency and TENS is not reimbursed and therefore not utilised, it is clear that there are consequences for the health economy.

In this study, rates of surgery for low back pain are 3-5 times higher in Belgium where conservative treatments are not used as frequently as they are in the Netherlands.

Almost certainly as a consequence of this, the rates of epidural stimulation and intrathecal drug administration are 4 times higher in Belgium. This reflects the natural increase in rates of ‘failed back surgery syndrome’ as a consequence of the higher rates of surgery.

Van Zundert also analysed the total costs for these various treatments in Belgium showing:

	COST PER PATIENT (EUROS)	% COST
TENS	468	1.36
EPIDURAL STEROID	316	12.20
RADIOFREQUENCY	276	1.04
NEUROSTIMULATION	9160	5.65
INTRATHECAL DRUGS	6992	1.52
SURGERY NO ARTHRODESIS	655	22.37
SURGERY ARTHRODESIS	6595	55.85

Clearly, radiofrequency denervation is a cost effective option and it could be argued that where it is reimbursed, fewer patients go on to be offered expensive surgical treatment.

In summary, we would support radiofrequency denervation as a treatment for low back pain. It is in our view exceptionally safe, efficacious and cost effective. When reviewing the evidence, we hope that BUPA will acknowledge the comments made by Bogduk in his narrative review.

Radiofrequency denervation should be preceded by diagnostic medial branch blocks and it is clear that a significant proportion of patients experience short to medium term pain relief from these blocks alone.

Intraarticular facet joint injections with steroid is a useful procedure in selected patients yet the evidence to support its indiscriminate use is lacking.

Dr Stephen Ward
On behalf of The British Pain Society
16/11/09