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Publication Best practice in radiofrequency denervation of the lumbar facet joints; a consensus technique

Abstract

Background: Radiofrequency denervation is used to treat selected people with low back pain. Recent trials, have been criticised for using a sub-optimal intervention technique.

Objectives: To achieve consensus on a best practice technique for administering radiofrequency denervation of the lumbar facet joints to selected people with low back pain.

Study design: A consensus of expert professionals in the area of radiofrequency denervation of the lumbar facet joints.

Methods: We invited a clinical member from the 30 most active UK departments in radiofrequency pain procedures and two overseas clinicians with specific expertise to a one day consensus meeting. Drawing on the known anatomy of the medial branch, the theoretical basis of radiofrequency procedures, a survey of current practice, and collective expertise, delegates were facilitated to reach consensus on the best practice technique.

Results: The day was attended by 24 UK and international clinical experts. Attendees agreed a best practice technique for the conduct of radiofrequency denervation of the lumbar facet joints.

Limitations: This consensus was based on a one day meeting of 24 clinical experts who attended and took part in the discussions. The agreed technique has not been subject to input form a wider community of experts.

Conclusions: Current best practice for radiofrequency denervation has been agreed for use in a UK trial . Group members intend immediate implementation in their respective Trusts. We propose

using this in a planned Randomised Controlled Trial RCT of radiofrequency denervation for selected people with low back pain.

Keywords

Low back pain, lumbar facet joints, radiofrequency denervation, medial branch of the dorsal ramus, medial branch block, facet rhizolysis, lumbar zygapophyseal joints.

Introduction

Low back pain (LBP) is a leading cause of years lived with disability (1) . Facet joints have been identified as a possible source of LBP. Studies report variable pain relief in response to diagnostic blocks of the medial branch nerves (MBN) which innervate facet joints indicating that these can be a source of LBP. A variable number of low back pain sufferers report clinically significant pain relief in response to medial branch blocks (2-4) . Radiofrequency denervation (RFD) of the MBN is a minimally invasive percutaneous procedure. Radiofrequency (RF) energy is delivered along an insulated needle in contact with the target nerve. This focused energy heats and denatures the nerve. It is unclear how effective RFD is at relieving LBP. NICE 2016 (NG59) guidance (5) on LBP recommends RFD as a treatment option for people with suspected facetogenic LBP who fail to respond to conservative treatment and respond positively to medial branch blocks. A subsequent (2017) Dutch study (MINT), found no benefit from the addition of RFD to an exercise programme for people with LBP who had responded positively to a medial branch block (MBB) (3).

The MINT study was heavily criticised for multiple reasons, including the utilisation of a sub-optimal RFD technique, which was inconsistently delivered (6, 7) . In 2018 the National Institute for Health Research Health Technology Assessment Program (HTA 18/49) called for a study aiming to determine the effectiveness and cost effectiveness of RFD in people with LBP. It is imperative that any such study delivers an optimal and consistent RFD technique.

The described technique of RFD varies between published studies (2, 4, 8, 9). The British Pain Society (BPS) and Faculty of Pain Medicine (FPM) Standards of good practice for medial branch block injections and radiofrequency published in March 2014 (10) provides the broad framework for delivery of RFD and patient selection but does not specify the technical detail of needle placement, lesion temperature, duration or choice of joint level. The Spine Injection Society guidelines (11) are widely adopted by most but not all practitioners. Furthermore, the technique is published in the society's book and only available on payment of a fee. There is a need for a peer reviewed,

accessible, consensus on an optimum RFD technique applicable to UK practice and endorsed by UK physicians to be utilised in any future study.

Methods

We surveyed 30 clinical experts representing the English NHS Trusts with the largest number of RFD procedures recorded in the Hospital Episode Statistics database (12). The centres were contacted eight weeks before the consensus meeting; with one reminder. The 17 questions relating to each operative step of RFD and MBB procedures as well as a description of the technique. (**Appendix 1**) were circulated. Fifteen expert (50% response rate) clinicians sent their responses prior to the consensus meeting, results were analysed and distilled in a slide presentation with areas that required further consensus highlighted. A consensus meeting was attended by a number of stakeholders including 24 clinical experts.

The cost of the meeting was met though unrestricted educational grants paid to the BPS by Abbott and Boston Scientific. Five industry representatives from three companies producing RF devices were present for the meeting. They did not take part in proceedings other than to answer specific technical queries relating to the devices. They had no input into the agreed consensus nor the writing of this paper.

The meeting opened with presentations on the anatomy of the medial branch and an update on the technique of RF and sham presented by two international invited experts (SN and FH) with opportunity for questions. A facilitator (MU) with no interventional pain experience then presented the 18 questions in sequence to the group and facilitated discussion and consensus building among the group for each step of the technique to be used for RFD.

Where a full group consensus was not possible, **Table 1** below, adapted from Deer et al (13) was used to portray the strength of the consensus. The majority of the consensus was agreed by >80% of the clinicians, which is a strong consensus.

Results

The results from the survey were presented to the group, via quantitative summary slides. The data consisted of the summary reply to the pre-meeting survey and led to discussion during the consensus meeting (**Table 2**). As there were notable differences in practice amongst clinicians, the rationale behind individual practices was discussed for each survey question.

Apart from a single unanimous response to question 12 on whether the clinicians do motor threshold testing (yes, n=15, no, n=0), the remainder of the questions elicited different responses to all other steps for the conduct of MBB and RFD. **Table 2** lists the survey questions and responses illustrating the extent of divergence of the UK clinical practice.

The document 'Lumbar RF (radiofrequency) in 10 easy steps' by Dr Nath **Appendix 2**, was distributed to the clinicians and presented at the consensus meeting.

The discussion led to the consensus on the method to employ for lumbar RFD at the respective sites for those that were present.

Where there was agreement, the strength of each consensus was recorded in **Table 3** for each survey question.

Survey questions 1-6 resulted in a short discussion, consensus was strong and largely in agreement with the majority response to the survey questions. For example, survey question 2, the majority of the responder (9/15) routinely use sedation for RFD. The consensus reached was that the use of sedation was reasonable where it was judged to be clinically appropriate and beneficial. Survey question 4 had most respondents using chlorhexidine (n=13) for skin preparation. There was a

strong consensus for use of chlorhexidine in a future study with the specific concentration used in accordance with local Trust guidance.

Survey question 6 produced a strong consensus on the use of lidocaine as the local anaesthetic used for skin and subcutaneous infiltration based on its rapid onset of action, however following on from that, question 7 on the local anaesthetic preferred in MBB produced no clear consensus among survey responders, following discussion a moderate consensus was reached around levo-bupivacaine 5mg/ml being the local anaesthetic of choice for MBB due its safety profile as well as longer duration of action compared to lidocaine.

Survey questions 8 and 9 produced strong consensus on the use of a 22G needle for MBB and an 18G cannula for RF, in agreement with the survey results. Only two of the clinicians present at the meeting used a 25G needle for diagnostic MBB. For the RF cannula gauge, users of the 16G and 20G cannulae were readily willing to adopt the 18G cannula. There was thus strong consensus for the use of an 18G curved RF cannula with 10mm active tip. It was agreed that in clinical practice a curved tip may facilitate placement.

Following the discussions around survey question 10 relating to use of sensory threshold the assembled agreed that sensory thresholds did not add value in ensuring appropriate target nerve lesioning and may be incompatible with the use of deep sedation. This rendered survey question 11 as not applicable.

Survey Questions 14 and 15 on time and temperature of the lesion were discussed simultaneously. Although the survey results predominantly favoured 90 seconds (n=9) over 60 seconds (n=4). It was agreed, based on additional material tabled to the meeting that the lesion size would be 94% formed after 60 seconds and be likely to increase in size minimally beyond 60 seconds (11, 14). The consensus agreement was that two lesions of 60 seconds each at 80 degrees Celsius, rotating the needle 90 degrees medially between lesioning, would maximise chances of producing effective denervation without significant risk of iatrogenic harm. However, more recent studies examining the

interaction between the composition of preinjected fluids and duration of RF on lesion size (15, 16) concluded that the standard recommendation for lesioning time of 90 seconds should be reconsidered. When fluid is preinjected, including 1% lidocaine in 0.7% NaCl, extending lesion time to 180 seconds allows for lesion size to be maximized while limiting lesion size variability (16) However, we recognise that this conclusion needs to be balanced against the potential for larger lesions to affect non-target tissue as well as our consensus of utilising two lesions per medial branch. The group therefore adopted a 120 second duration for RF lesions as a clinically safe and effective lesion time.

The group considered that different manufacturers machines and consumables might perform differently. It was agreed, therefore, for the purposes of the proposed trial, that all sites should use identical RF lesion generator and consumables from a single manufacturer. No manufacturer was specified.

The discussion on the number of levels was based on the survey question 16. Currently clinicians are either doing two, four, or six levels. The consensus was that RFD should be done on maximum of four spinal levels; unilaterally or bilaterally, with a maximum of eight medial branches lesioned according to the clinical picture. For people with unilateral pain it would not be appropriate to perform invasive diagnostic or therapeutic interventions on a pain free locality. For the purposes of a study people with either unilateral or bilateral pain may be included. A clinical assessment conducted on the day of the procedure would inform the decision regarding the appropriateness of the procedure for that individual as well as the levels and laterality for MBBs and RFD.

The sham procedure would be exactly the same except that the machine will not be activated. A trained machine operator will be shielded from the patient and clinician placing the needles by a screen. The machine should be set to emit the same sounds in sham mode as in verum mode.

Survey question 17 had almost unanimous agreement (yes, n=14, no, n=1), on the injection of a local anaesthetic before lesion. The discussion highlighted the risk of pain reports associated with verum

RFD unblinding the clinicians performing the technique. There was a strong consensus for the use of lidocaine 20mg/ml as that local anaesthetic of choice. Clinicians pointed out that a prespecified volume may prove insufficient for some patients and that in practice the volume of 2% lidocaine necessary to prevent pain from RFD varies considerably between patients. The consensus therefore was to start with 0.5 ml of 2% of lidocaine per level and to increase this in 0.5 ml increments to ensure no pain is reported with RFD.

Positioning the RF cannula:

The assembled agreed unanimously to adopt the Nath technique (2) which is summarised by Dr Nath in the 10 steps below:

1. Identify the L5-S1 disc interspace.
2. Identify the L5 vertebral body.
3. Rotate the image intensifier laterally to visualise the bony curvature between the transverse and the articular process. Occasionally the curvature is visible in the AP view and no lateral rotation is necessary.
4. Once the curvature is identified tilt the image intensifier inferiorly keeping the curvature clearly in view.
5. Tilt the image intensifier so as to view curvature as medially and inferiorly as possible.
6. Once the above view is achieved local anaesthetic is infiltrated at the skin entry point. This is in a line directly below curvature at lower border of transverse process of the same level.
7. Aim to contact bone below curvature.

8. Advance your RF cannula in a posterolateral view needle at 4 o'clock or 8 o'clock depending on right or left side. The target is the middle 2 fourth of the lateral aspect of the articular process aiming to contact the medial branch before it courses under the mammillo-accessory ligament in a trajectory parallel to the nerve.

9. Once the RF cannula is in position use the tunnel view to confirm needle in curvature on bone.

10. Use the superior (cranial tilt) view with needle at 6 o'clock to assess depth of the cannula.

The same technique is applicable to the L5/S1 level with consideration to the restricted space by the iliac crest and posterior superior iliac spine.

Summary of the consensus technique:

1. Number and laterality of medial branches to be lesioned is to be decided after a clinical examination by the pain physician.
2. A maximum of eight medial branches at a maximum of four vertebral levels may be lesioned in a single sitting, subjects with unilateral pain to receive unilateral treatment.
3. Subject to be positioned in the prone position with or without abdominal support according to body habitus, intravenous access is to be routinely established.
4. Conscious Sedation is administered based on need, circumstance and clinical judgment.
5. Chlorhexidine is to be applied for skin preparation, the concentration utilised will depend upon local Trust guidance.
6. A full aseptic technique including hand scrub, use of mask, gown and gloves is recommended.
7. Lidocaine is the local anaesthetic preferred for skin infiltration.

8. A curved 18 G RF cannula with a 10mm active tip is used for targeting the medial branch. Position of the RF cannula will be confirmed with cranial, caudal and lateral views.
9. Once the cannula(e) position is confirmed, routine motor testing is to be carried out with a threshold for lower limb muscle contraction of 2 volts. Lower limb muscle contractions occurring below the threshold will prompt a repositioning of the RF cannula at the level.
10. Local anaesthetic is to is to be infiltrated before the lesion in order to minimise discomfort. Lidocaine 20mg/ml in 0.5ml boluses is recommended.
11. Each lesion is to be carried out at 80C for 120 seconds with two lesions per medial branch. For the second lesion the RF cannula tip will be rotated medially by 90 degrees, with the curve to face the articular process before lesion delivery.
12. Within the context of a research study all lesions should be delivered using similar consumables and lesion generator to ensure uniformity of the size of the lesions generated.
13. All clinicians delivering the RF lesions should undergo training to ensure uniformity of the technique used to generate the lesion.

Medial Branch Blocks (MBB):

1. Patient preparation will follow the same steps as described above.
2. 22 G needles are preferred for delivery of the local anaesthetic.
3. Needle tip to be positioned on the curvature between the articular process and transverse process.
4. 0.5 ml of levo-bupivacaine 5mg/ml is the consensus preferred solution.
5. Pain measurements to be done on a Visual Analogue Scale (VAS) before and after the MBB.

Discussion

The technique of medial branch RFD is key to the success of the therapy. A substandard technique, particularly within the context of a UK national study, risks compromising the validity of a future study and possibly restricting access to a potentially useful therapy. The MINT study (3) has been

criticised for utilising an inconsistent and suboptimal technique. Critics have cited the poor technique as the main driver of the negative outcomes of the study (6). While many studies have compared the effectiveness of RFD in LBP (2, 3, 8, 9, 17) most have used different RFD techniques and none have attempted to demonstrated that the technique utilised resulted in an anatomical lesion of the medial branch nerve. A small number of studies have attempted to capture the physiologic consequences of a lesion of the medial branch nerve through electromyography of the multifidus muscle (18), or changes in its MRI appearance (19) again these studies use different RFD techniques and approaches.

Development of a consensus on technique is therefore the first step required to investigate the effectiveness and cost effectiveness of RFD of the MBN.

The strength of this work is the conduct of a two-step process, thus guaranteeing opportunities for clinicians to make their views heard and then see them implemented in a future study. Expert clinicians from large volume practice centres were invited to join the meeting and to contribute towards the development of a consensus on RFD technique that would be appropriate for a national study. A mixture of views was presented and a non-pain physician facilitated the meeting. The final manuscript was reviewed and agreed by all authors. A review of the evidence base and existing guidelines was provided to the expert clinicians before the consensus meeting was conducted, to ensure all the participants had up-to-date information on published studies in this area.

Weaknesses of this consensus include the limited number of participants at the face to face meeting and the relatively low response to the survey questionnaire despite two rounds of emails as well as the lack of endorsement by national UK pain bodies.

Device manufacturers have much to gain from a positive outcome of a future trial demonstrating effectiveness of this approach, particularly if it their RF generator and consumables are used in the main trial. Nevertheless, they have little, if anything, to gain from any changes in the details of the process of carrying out RFD. By having three manufacturers in the room we ensured no single

manufacturer gained a commercial advantage and we were able to have technical points clarified for the participants. The clinical participants' professional identities are, at least in part, defined by delivery of RFD and many of them are in private practice delivering RF procedures. They have clear professional and financial interests in demonstrating that RF is effective. They too have little, if anything, to gain from the details of the process of delivering RFD. We are satisfied that these interests will not have materially affected the conclusions of this consensus meeting.

We have developed a consensus on the details of best practice for RFD of MBN. Participants have agreed to modify their current practice to be consistent with these recommendations. We recommend that a future RCT of RFD of lumbar MBN should explicitly use this approach.

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Disclaimer

The views presented in this paper are solely those of the authors and do not represent the views of any company, society or agency.

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