Interventional Pain Medicine 2 (2023) 100279

Contents lists available at ScienceDirect

Interventional Pain Medicine

journal homepage: www.journals.elsevier.com/interventional-pain-medicine

Comparing the effectiveness of lumbar medial branch radiofrequency coagulation using 18-gauge and 16-gauge cannulae

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1. Introduction

Lumbar medial branch radiofrequency coagulation (RFC) is an established treatment for back pain mediated by the medial branches of the lumbar dorsal rami [1]. Ostensibly the pain arises in one or more of the zygapophysial joints that are innervated by these nerves [1–3]. This form of back pain is diagnosed by diagnostic blocks of the nerves that innervate the joint or joints suspected of being the source of pain [2,3].

A recent review [1] showed that the number of diagnostic blocks used, or the degree of relief required for the block to be called positive, does not particularly affect the success rate, *per se*, of lumbar medial branch RFC; but it does affect the grade of success. Complete relief of pain, accompanied by restoration of function, has been reported only in studies that required 80% [4,5] or complete [6] relief of pain following controlled diagnostic blocks. However, all these studies also used large-gauge electrodes to treat the pain. This has prompted some proponents of lumbar medial branch RFC to recommend using only large-gauge electrodes [1,7].

Larger gauge cannulae and electrodes significantly increase the diameter of a radiofrequency lesion both in theory and as shown in laboratory studies [8]. An anatomical study [9] illustrated how large-gauge electrodes increased the likelihood of capturing larger segments of the target nerve, thereby ensuring greater and more thorough coagulation of it. However, the recommendation to use large-gauge electrodes has not been validated empirically. No head-to-head studies have compared the effectiveness of large-gauge and smaller-gauge electrodes.

The present study was undertaken in order to determine the effect of cannula size on success rates. The null hypothesis tested was that success rates would not differ when using a large-gauge electrode or a smaller-gauge electrode.

2. Methods

Data were retrieved retrospectively from practice records of the senior author (MHL). Institutional Review Board approval for the study was obtained from the University of Kansas School of Medicine. Data collection was performed by senior anesthesia residents.

In order to ensure that all eligible patients were included, daily patient logs of the senior author were reviewed, and compared with office and surgery center schedules. The names of all patients who had undergone lumbar medial branch RFC were matched with their medical records. Those records included progress notes, procedure narratives, baseline data and follow-up data, from which data pertinent for the present study could be harvested.

The audits of the medical records identified 336 consecutive patients who had undergone lumbar medical branch RFC between 2005 and 2019. All of the identified patients presented with an index chief complaint of chronic low back pain of greater than three months duration, with a pain intensity of 4 or more on a 0–10 numerical pain rating scale, and restrictions in their activities of daily living. Previously, most patients had tried pharmacological and non-pharmacological treatments over a period ranging from months to decades without significant relief.

The senior author completed a medical history and physical examination on each patient at the first office consultation. A recent magnetic resonance imaging (MRI) or computerised tomography (CT) scan was required, and was personally interpreted prior to the physical examination. All consultations, evaluations, and procedures were performed by the senior author, at either a private practice setting or an outpatient surgery center.

Eligible for inclusion in the study were: (1) patients who had never undergone lumbar medial branch RFC in the past, or (2) patients who had undergone lumbar medial branch RFC by the treating physician in

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https://doi.org/10.1016/j.inpm.2023.100279
Received 24 July 2023; Received in revised form 5 September 2023; Accepted 6 September 2023
Available online 14 September 2023
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the past, with significant relief for at least a six-month period, but whose original pain had recurred, and (3) patients who had undergone lumbar medial branch RFC by other physicians but without relief of pain or with recurrence of previous pain.

Selection of the segmental level to be treated was guided by studies of the prevalence and segmental location of zygapophysial joint pain [10,11], pain diagrams drawn by the patient, and where the patient pointed when asked to point to the "center of your pain". Medical imaging was not used to decide the levels to be tested.

The diagnostic protocol used followed the algorithm for the investigation of low back pain recommended by the International Spine Intervention Society [12]. If a patient's MRI did not show Modic changes or a high-intensity zone in a disc, they summarily underwent medial branch blocks. If the MRI did show Modic changes or a high-intensity zone, those patients first underwent discography, because each of these MRI features is strongly predictive of discogenic pain [13]. If provocation discography was positive, those patients were excluded from the present study. If discography proved negative, those patients became eligible for the present study, and underwent lumbar medial branch blocks.

The diagnosis of pain mediated by lumbar medial branches was tested by performing dual lumbar medial branch blocks, according to current, internationally recognized guidelines [14], using lidocaine 4% or bupivacaine 0.75%. Intravenous access was not used during medial branch blocks, and sedation was never provided because it is not routinely warranted, and none of the patients had co-morbid conditions requiring sedation.

Before and after each block, the attending physician assessed pain provocation by testing active lumbar range of motion, and recorded the pain intensity on a numerical pain rating scale. From these values percentage pain reduction following the procedure was calculated and recorded. Post procedure evaluations were performed in recovery 30–60 min following the procedure.

If the first diagnostic block did not produce at least 80% relief of the index pain, the patient was not evaluated further for zygapophysial joint pain. For patients who experienced 80% or greater relief, a second confirmatory block was scheduled at a later date. Only patients who again experienced at least 80% relief proceeded to treatment with medial branch RFC.

For low back pain at or near the level of the lumbo-sacral junction, the majority of initial diagnostic medial branch blocks targeted the L4,5, L3,4, or L3,4,5 medial branches. If the patient stated that they were no longer experiencing any of their "lower pain", but still had some "higher pain", the subsequent confirmatory block included the next, more rostral medial branch, in order to capture this remaining, higher pain. For index pain at upper lumbar levels, the initial medial branch blocks were performed at levels which correlated with the centroid of the pain as indicated by the patient.

The initial diagnostic procedure was performed unilaterally in approximately 95% of patients. If the patient suffered bilateral pain, the side of greater pain intensity was evaluated first. If the pain on both sides was relieved by the initial block, unilateral, second diagnostic blocks were scheduled. If, the first diagnostic block relieved pain on the side that was blocked but pain persisted on the contralateral side, one of two alternatives was chosen. The preferred option was to complete second blocks on the initial side, and then to investigate the opposite side as separate a separate, concurrent source of pain, at later dates. The second option was to perform a first block on the opposite side, and if this produced at least 80% relief, a third block was performed bilaterally.

When dual positive medial branch blocks indicated probable zygapophysial joint pain, lumbar medial branch RFC was discussed at length with the patient, and any questions were answered. After providing consent, the patient was scheduled for the procedure.

The time required to complete lumbar medial branch RFC is often greater than 1 h. In that many patients were anxious as to their ability to remain comfortable for this length of time, sedation was discussed on an individual basis. It was emphasized that sedation is not intrinsically required for the procedure to be completed [7]. If sedation was desired, a separate informed consent was obtained with the understanding that the level of sedation would be such that the patient would be alert, conversant, and remain responsive to voice and pain so as to enable reaction to any unexpected pain resulting from unintentional misplacement of the cannula prior to or during lesioning.

When sedation was requested for the procedure, intravenous access was obtained, and physiologic monitoring initiated. Approximately 90% of patients requested sedation which consisted of a total dose of midazolam (1–2 mg) and fentanyl (25-50mcg) titrated to effect. At any time during the procedure if the patient failed to respond to the frequent enquiry as to their wellbeing, the procedure was immediately paused, until communication with the patient was restored.

Lumbar medial branch RFC was performed using 18-gauge (18G) or 16-gauge (16G) radiofrequency cannulae with bent 10 mm active tips (Bayliss-Kimberly Clark- Halyard) that were either 100 mm or 150 mm in length to match body habitus,. The choice of 16G versus 18G was based on availability. The 16G cannulae were first manufactured and made available by Bayliss Medical in September 2009. Prior to this date all procedures were performed using the 18G cannula. Very occasionally an 18G cannula was used until December 2010, after which 16G cannulae were exclusively used.

In preparation for insertion of the cannulae, the skin was prepped and draped. Using fluoroscopic guidance, the insertion point on the skin and the intended track of the cannula were anesthetized to a depth of 1.5 inches using 5–6 cc of lidocaine 1%. To facilitate insertion of the cannula through the skin, the puncture point was pierced with a 15G needle. No difference in discomfort was noticeably evident between the 18G and the 16G cannulae during insertion.

During the medial branch RFC procedure, the cannulae were placed under fluoroscopy in multiple planes of view so as to lie parallel, and in close proximity, to the target medial branches, according to the Guidelines of the International Spine Intervention Society [7], and the pertinent surgical anatomy studies [9]. Neither motor (5 Hz) nor sensory (50 Hz) stimulation was used for needle placement in that it is superfluous, there being no pertinent literature to show either increased success rates or greater safety; and the practice is not advocated by the standard of care guidelines [7].

After injection of 1 cc of lidocaine (4% or 1%) through the cannula, multiple contiguous RF lesions at 90 °C, each for a duration of 90 s, were produced along each medial branch treated. Between each lesion the cannula was repositioned to ensure that the total area of the possible course of the target nerve was adequately captured [7]; and images of cannula position were archived. The number of lesions created across each target zone differed according to the size of the superior articular zone with respect to the size of the cannula used. Typically a higher and a lower trajectory across the neck of the superior articular process were used. Along each trajectory a first lesion was produced. If required to cover the target zone fully, a second lesion was produced on one or both trajectories after withdrawing the cannula slightly.

Following the lumbar medial branch RFC, patients were taken to the recovery room and then discharged from the post-anesthesia care unit with an analgesic prescription adequate for 3–4 days to be filled and taken as needed for post procedure pain. On discharge, patients were instructed that some exacerbation of their index low back pain might be expected but if any significant symptoms differing from their "usual pain" were experienced, a call to the physician's office was warranted.

All patients were contacted by a nurse 24–72 h post-procedure and questioned as to their condition. An appointment with the treating physician was scheduled 4–6 weeks post-procedure to assess effectiveness of the treatment. For the rare patient who experienced burning dysesthesia post-discharge which required treatment, a prescription for gabapentin was offered.

At the 4–6-week follow-up appointment, patients were asked if they had experienced any side effects or problems other than mild increase of

the index back pain. The present pain score was recorded, along with any change in level of activities of daily living, and changes in analgesic use. Percentage relief of pain was calculated and recorded.

Duration of relief was not addressed by the present study. For lack of resources for a long-term follow-up, the study looked only at the response rate at the 4–6 weeks follow-up.

Demographic and clinical features of the patients treated were tallied and tabulated. Categorical variables were compared using 95% confidence intervals of proportions. Continuous variables were compared used a two-sample *t*-test.

In order to compare the effectiveness of the two gauges of cannulae, the number and proportions were tallied of patients who obtained less than 50% relief, 50–74% relief, 75–89% relief, and 90% relief or greater. Cumulative numbers and proportions were also tallied in order to show how many patients achieved at least a particular grade of relief. For that purpose, patients who obtained higher grades of relief were considered to have also achieved lower grades of relief. For each grade of relief, statistical significance of differences between groups was tested by calculating the 95% confidence intervals of the difference between the success rates achieved. Success rates were considered to be significantly different, with 95% confidence, if the 95% confidence intervals of the difference between groups did not overlap zero.

3. Results

Of the 336 patients who were treated, 49 (14.6%) could not be included in the final analysis because they were lost to follow-up. One other patient was excluded because they were less than 18 years of age, leaving a total of 286 (85%) for final analysis. These were 121 males with a mean age of 61 and 165 females with a mean age of 53. The patients treated with different gauge cannulae did not differ, to any statistically significant extent with respect to gender, age, or segments treated.

When the outcomes for the patients treated with 16G cannulae were compared with those of patients treated with 18G cannulae, statistically significant differences arose (Table 1, Table 2). Significantly fewer patients treated with 16G cannulae reported less than 50% relief and reciprocally, significantly more patients obtained ≥50% and ≥75% relief. A greater proportion of patients treated with 16G cannulae obtained ≥90% relief, but the difference fell short of significance at the 95% level.

No significant complications were reported by any of the 336 patients. Post-procedure low back pain lasting longer than 5 days was seen in the rare patient. When post-procedure pain treatment was required, all patients reported significant relief over 1–2 weeks with the transient use of gabapentin alone or combined with non-steroidal anti-inflammatory medications or low dose opioids, with resolution of adverse symptoms at 1 month post procedure.

4. Discussion

As a rule, prospective studies are the preferred method for establishing that there is a difference in effectiveness between two interventions. However, embarking on a prospective study is inefficient if there are no prior data upon which to base power calculations, or no data suggesting that there might actually be a difference. Under those conditions, retrospective studies are a pragmatic way of determining, in the first instance, if there is a difference and what its magnitude might be. In that event, however, measures need to be taken to eliminate or reduce the risks of compromising the internal and external validity of retrospective studies.

With respect to internal validity, the foremost risk is that the sample studied might not be representative, because not all eligible patients were recruited. In the present study that risk was eliminated. In the first instance, the database of the practice in which the present study was conducted was small compared with the large databases of hospitals, with fewer records to be trawled, and fewer locations that might be overlooked and in which records might be lost. In the second instance, steps were taken to cross-reference the physician's personal daily log with facility appointments and procedure lists. This ensured that all eligible patients were captured. So, the risk is low of having missed the records of a sufficient number of patients that would prejudice the data reported.

A second risk pertains to the fidelity of medical records: that records did not contain all the data necessary for the study, or that different users completed the records differently. This did not apply in the present study, because the one physician completed all the records in the same manner, consistently over time; and no record lacked any of the data required.

A third risk is that different physicians may have performed the interventions in a different manner. This did not apply to the present study. The one physician performed all the procedures, and every procedure was consistently performed according to published guidelines [7,12,14]. The only difference was the gauge of the electrode used.

A fourth risk applies as much to prospective studies as it does to retrospective studies. The results obtained may be compromised if too many patients are lost to follow-up. In that regard, the standards adopted by systematic reviews for rating the quality of studies prefer

Table 2
A summary of the statistically significant differences between success rates for achieving various grades of relief after treatment using 16G or 18G cannulae. The success rates are significantly different if and when the 95% confidence intervals (CI_{95}) of the difference between proportions do not cross zero.

Grade of Relief	Treatment Group 16G Proportion (CI_{95})	Treatment Group 18G Proportion (CI_{95})	Difference Between Proportions (CI_{95})	Significance
<50%	25% (19–31)	42% (33–51)	17 (6–28)	Less with 16G
50%	10% (6–14)	10% (4–16)	0 (0–0)	
75%	24% (18–30)	13% (7–19)	11 (2–20)	Greater with 16G
90%	41% (34–48)	35% (25–44)	6 (-6 – 18)	
≥50%	75% (68–81)	58% (48–67)	17 (6–28)	Greater with 16G
≥75%	64% (57–71)	47% (38–57)	15 (3–27)	Greater with 16G

Table 1
The numbers (N), proportions, cumulative proportions, and the 95% confidence intervals (CI_{95}) of those proportions, of patients who achieved different grades of relief of pain after treatment by lumbar medial branch radiofrequency coagulation using either a 16G or an 18G cannula.

Category of Relief	Treatment Group 16G Per Category N	16G Per Category Proportion (CI_{95})	16G Cumulative N	16G Cumulative Proportion (CI_{95})	18G Per Category N	18G Per Category Proportion (CI_{95})	18G Cumulative N	18G Cumulative Proportion (CI_{95})
<50%	46	25% (19–31)			44	42% (33–51)		
50%	19	10% (6–14)	136	75% (69–81)	11	10% (4–16)	60	58% (49–67)
75%	43	24% (18–30)	117	64% (57–71)	13	13% (7–19)	49	47% (37–57)
90%	74	41% (34–48)	74	41% (34–48)	36	35% (26–44)	36	35% (26–44)

that loss to follow-up be less than 10%, but a loss of less than 20% can be tolerable [15–18].

In the present study loss to follow-up was 15%, which might qualify as tolerable; but mathematically, it happens to be of a magnitude that, in theory, could extinguish the statistically significant differences found in the results. However, for that to be the case, the patients lost to follow-up would have to be ones virtually all of whom either had poor outcomes after treatment with the 16G cannula or had better than average outcomes after treatment with the 18G cannula. Because such extreme distributions are unlikely, the loss to follow-up is unlikely to threaten the results of the present study, and loss to follow-up can be rated as tolerably small.

A fifth risk is difficult to quantify and evaluate. Smaller electrodes were used early in the study, before the larger electrodes became commercially available. On the one hand, the possibility arises that the treating physician had more experience when he started to use the larger electrodes and, therefore, that proficiency rather than electrode gauge explains the differences in outcome. On the other hand, for a physician who consistently follows the same technical guidelines, the data may show the benefits that arise when they change to using a larger gauge electrode.

External validity pertains to how well the results of the present study match the experience of others, and are, therefore, applicable to practice at large. In that regard, the outcomes encountered in the present study notionally fall short of those of the benchmark study of MacVicar et al. [6], who reported 56% of their patients achieving complete (100%) relief of their pain. However, the success rate in the present study for achieving 90% relief (41%; 34–48%) was not significantly different statistically from that of MacVicar et al. (56%; 47–75%) for achieving 100% relief. For achieving grades of relief of 50%, 75%, and 90%, the success rates of the present study are indistinguishable statistically from those of Speldewinde [5]. So, the present study can be considered representative of outcomes achieved by others who used the same surgical technique.

For lack of resources, the present study did not conduct a longer term follow-up of patients to determine if the gauge of the cannula used might have affected the duration of relief obtained by the patients. Others who have the resources to do so might choose to investigate this variable, if they think it is important to do so. In the meantime the results of the present study provide proof of principle that, in the short term, using a 16G electrode less often achieves poor outcomes and, reciprocally, more often achieves better outcomes than using an 18G cannula.

The differences in outcomes observed in the present study are not startling, but this could be expected. The difference in size of lesions made by 16G and 18G cannulae or electrodes is not great: 9.4 mm vs 7.6 mm [19]. Nevertheless, the differences observed in the present study are statistically sound, and refute the null hypothesis addressed by the present study. Greater differences might arise if the use of 21G cannulae and 16G cannulae was to be compared.

This result provides the first empirical data to corroborate the inferences drawn from in-vitro studies [9] and the implications of a systematic review [1] that better outcomes are achieved with larger gauge electrodes. However, because this was the first study to do so, and because it was retrospective, the present study does not provide proof beyond reasonable doubt. That proof would need to come from studies by others that replicated the present results. In that regard, the present study provides a foundation for replication studies, by offering sentinel evidence that empirical differences, in favour or larger electrodes, can occur and can be detected.

Funding

No outside funding was used for this study.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests.

Acknowledgements

Dr Landers planned this study with Dr Newton and Dr Alvarado. As Senior Anesthesia Residents, Dr Alvarado, along with Dr Vinh Pham, and Dr Hai Nguyen harvested the data. Dr Newton collated those data, and helped Dr Landers draft a manuscript. Dr Landers then consulted Professor Bogduk for advice on how best to present and analyze the data, and how to improve the manuscript. In response to his suggestions and amendments, Dr Landers produced an almost final version of the manuscript; but he fell ill to cancer of the pancreas. Sadly he passed away before completing a final version [20]. Consequently, Professor Bogduk undertook the final revisions and submitted the manuscript in memory of Dr Landers.

In the drafts of the manuscript Dr Landers wished to thank Baylis Medical for developing and supplying the 16-gauge RF cannulae from September 2009 until its later commercial release.

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