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Randomized controlled trial comparing technical features and clinical efficacy of a multi-tined cannula versus a conventional cannula for cervical medial branch radiofrequency neurotomy in chronic neck pain

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ABSTRACT

Objectives: Compare procedural characteristics and clinical efficacy of cervical medial branch radiofrequency neurotomy (CMBRFN) using a multi-tined cannula (MTC) versus a conventional cannula (CC) to treat chronic neck pain.
Design: Prospective, double-blinded randomized controlled trial.
Methods: Patients who responded to dual medial branch blocks with ≥75% pain relief were randomized to receive RFN with either the MTC or the CC. Primary outcomes: procedural pain, procedure duration, fluoroscopy time and radiation dose. Secondary outcomes: proportion of patients reporting ≥50% numerical rating scale reduction and ≥30% neck disability index reduction at 3, 6 and 12 months.
Results: Forty-two patients underwent treatment. There was no difference in procedural pain between the MTC and CC groups (NRS 4.7 ± 2.0 vs. 4.2 ± 1.8, $p = 0.465$), but three patients, all in the CC group, could not complete the procedure due to pain. CMBRFN in the MTC group was significantly faster than in the CC group (35.5 ± 7.3 min vs. 58.2 ± 14.8 min, $p < 0.001$), with less fluoroscopy time (167.6 ± 76.4 s vs. 260.8 ± 123.5 s, $p = 0.004$). Radiation dose was 8.95 ± 7.9 mGy in the MTC group and 11.53 ± 10.3 mGy in the CC group ($p = 0.36$). Rates of ≥50% NRS reduction were not significantly different between the two groups at 3 months, but at 6 and 12 months, they were significantly higher in the CC group. At 3, 6 and 12 months, rates of ≥30% NDI reduction were significantly higher in the CC group.
Conclusions: The MTC offers technical advantages compared to the CC for both the operator and the patient. However, CMBRFN with the multi-tined cannula seems less effective to treat neck pain than with the conventional cannula.

1. Introduction

Although multiple anatomical structures of the cervical spine were identified as potential neck pain generator, the zygapophyseal joint, or facet joint, accounts for up to 54–60% of cases [1–3]. A study of referred pain patterns has shown that zygapophyseal joint pain can also manifest as headaches [4,5]. When headache accompanies neck pain and is dominant, prevalence of zygapophyseal joint pain ranges between 50 and 53% [2,6].

In the late 1990s, cervical medial branch radiofrequency neurotomy (CMBRFN) was established as an effective treatment for cervical zygapophyseal joint pain [7]. Currently, the conventional CMBRFN technique described in the Spine Intervention Society (SIS) Practice Guidelines remains the standard of care [8]. A systematic review reported that CMBRFN provided complete pain relief in 63% of patients at 6 months and 38% of patients at 12 months [9]. In a study of over a hundred patients, 66% of patients achieved a successful outcome at 6 months, defined as complete pain relief, or at least 80% relief,

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restoration of all activities of daily living and work duties, as well as not requiring any health care for their pain [10]. In another study focusing solely on cervicogenic headaches, complete relief was obtained in 65% of patients at 6 months and 20% of patients at 12 months after CMBRFN of the third occipital nerve (TON) [11]. Furthermore, if pain recurs, similar results, sometimes of longer duration, can be achieved when the CMBRFN is repeated, even on multiple occasions [10–14].

It is well known that the success of CMBRFN relies on careful patient selection. Early studies used 100% pain relief after each of two comparative medial branch blocks as inclusion criteria [7,10,11,14,15]. More recently, a study of 100 patients reported no significant difference in pain relief and global improvement between patients selected by an 80–99% MBB criteria versus a 100% MBB criteria [16]. However, clinical efficacy with both selection criteria was lower than in the aforementioned studies, perhaps due in part to the high proportion of patients treated with cooled, perpendicular CMBRFN (79%). In a systematic review studying the effectiveness of CMBRFN based on different selection criteria, 59% of patients selected by ≥ 75% MBB response reported ≥50% pain relief at 6 months, while 31% of them reported complete relief [17]. In comparison, in this same study, selection with 100% dual comparative blocks rendered a 61% rate of complete relief at 6 months. Although it appears to lead to a reduced efficacy, the use of less strict criteria allows more patients to benefit from a treatment for which they would not otherwise have been a candidate.

In 1987, Bogduk and al. showed that radiofrequency lesions produced with a conventional cannula did not extend distal to the tip of the electrode, but rather spread radially around it in an oval fashion [18]. Consequently, a lesion generated by a perpendicular approach may not completely ablate the nerve, potentially accounting for inadequate pain relief in some patients. To achieve better targeting of the medial branch, a parallel approach was proposed and has become the standard of care in accordance with the SIS Practice Guidelines [8]. However, new multi-tined cannulas (MTC) seem to provide a solution to overcome this technical limitation previously identified. As shown in an ex vivo study, the distally deployable tines generate a sufficiently large lesion around the distal tip regardless of the approach angle used, allowing for perpendicular placement of the cannula when targeting the medial branch [19].

At the time of writing this article, the literature regarding the use of this type of cannula for radiofrequency neurotomy (RFN) in the spine is limited and focuses more on the lumbar spine. A prospective observational study comparing the MTC and CC for lumbosacral RFN in 51 patients showed similar clinical efficacy, but the MTC offered technical advantages [20]. In the cervical spine, the available data comes from research abstracts and indicates that pain relief following CMBRFN using the MTC is comparable to that obtained with the CC [21]. From our own experience, 50% of 28 patients had at least 50% pain relief 6 months after receiving CMBRFN with the MTC [22].

This technique has not been the subject of any randomized controlled clinical trial. The purpose of this study was to compare the technical features and clinical efficacy of CMBRFN using the MTC versus the CC.

2. Methods

2.1. Trial design

This was a randomized, double-blinded, controlled trial conducted at a single academic tertiary care hospital in Montréal, Canada, with approval from the local institutional research ethics committee (agreement number: CE 19–101). The study was registered at ClinicalTrials.gov (registration number: NCT04152954), and all participants provided written informed consent. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors. The funding for this study came from the annual budget allocated to the PM&R department by the hospital.

2.2. Participants

Patients were eligible if they met all the following inclusion criteria: age ≥18 years old; axial neck pain with a pain score ≥4 on the numerical rating scale (NRS); pain duration of ≥6 months despite adequate conservative care; ≥75% pain relief with dual medial branch blocks. Patients were excluded from participation if they had neurological motor deficits of one or both upper limbs; radicular more than axial pain; radiological evidence of a neoplastic or inflammatory etiology of neck pain; received a cervical facet joint corticosteroid injection in the past 3 months; were pregnant or breastfeeding; or had a contraindication to the procedure itself, such as active, local or systemic infection, having a pacemaker or neurostimulator, or an unstable medical or psychiatric condition. Previous radiofrequency neurotomy or cervical spine surgery did not disqualify patients from participation in the trial, as it reflects current clinical practice.

2.3. Recruitment

Patients who presented to the Physical Medicine and Rehabilitation department with neck pain suspected to be originating from cervical zygapophyseal joints were scheduled for dual comparative medial branch blocks to confirm the diagnosis. The clinician selected the anatomical levels to be treated based on the pain topography. For one diagnostic block, 0.3–0.5 cc of 0.5% bupivacaine was injected and for the other one, 0.3-0. 5 cc of 2% lidocaine was injected, in no particular order. The threshold of pain relief considered positive was set at ≥75% for each MBB, to facilitate patient recruitment, but still produce clinically significant results.

2.4. Randomization and blinding

After enrollment, patients were randomized in a 1:1 ratio in one of two treatment groups. The control group underwent radiofrequency neurotomy using the CC and the interventional group underwent radiofrequency neurotomy using the MTC. Randomization was carried out using a randomization block design with five envelopes, each containing five “conventional” and five “multi-tined” etiquettes, from which the research assistant randomly drew to determine each patient’s assignation. Participants as well as the single outcome assessor were unaware of the intervention received. Particular care was taken to provide patients with minimal information regarding the technique to prevent them from identifying their treatment group. Blinding of the physiatrists performing the procedure was not possible given the procedural differences between the two techniques of CMBRFN. However, they were not involved in data collection nor their analysis.

2.5. Interventional procedures

All procedures were performed under fluoroscopic guidance by one of four experienced physiatrists. For conventional CMBRFN, patients were placed prone. An 18G cannula with a 10 mm active curved tip was used. All lesions of the same medial branch were made from a single entry point, midway between the usual parasagittal and oblique trajectories, since the 10 mm curved tip allowed as much coverage of the articular pillar as both paths using a 5 mm tip cannula. The cannula was inserted and advanced under fluoroscopic control with lateral and antero-posterior views until it was parallel to the path of the targeted medial branch. Motor stimulation (2 Hz) was performed as an additional safety measure. The nerve was then anesthetized with 1–2 cc of 1% or 2% lidocaine. According to the practice guidelines issued by the SIS for cervical radiofrequency neurotomy, it was planned that 4 lesions per medial branch be made (6 for the TON) by heating the electrode to 80° Celsius for 90 s, after a 15 s ramp up time. However, inadvertently, only 2 lesions per level (3 for the TON) were made in half of the conventional techniques (9/18 patients), due to initial misinterpretation of the

protocol.

For patients in the interventional group, CMBRFN was carried out with an 18G multi-tined cannula with a 5 mm active tip (Diros Technology Inc, Markham, Ontario, Canada). Patients were positioned in lateral decubitus on the table, and the cannula was inserted in the lateral neck to allow perpendicular placement in relation to the nerve, the same way as one would perform a medial branch block. The progression of the cannula was monitored on the lateral and AP projections, with the final position shown in Fig. 1. Upon reaching the target, the tines were deployed. The remainder of the procedure followed identical steps as the conventional method, apart from the number of lesions produced. To increase the likelihood that the nerve be fully encompassed by the lesion, the operator performed 2 lesions per nerve (3 for the TON).

2.6. Outcomes and data collection

After the intervention, patients were asked to rate their procedural pain on a visual analogue scale (VAS) ranging from 0 to 10 cm, 0 indicating no pain and 10, the worst possible pain. Technical aspects evaluated were fluoroscopic time and radiation dose, displayed by the fluoroscopic unit, as well as the duration of the procedure, defined as the time elapsed between the insertion of the first needle and the removal of the last needle. Neck pain and function were evaluated at baseline, using a numerical rating scale (NRS) from 0 to 10, and the validated French version of the Neck Disability Index (NDI) [23]. The NRS and NDI were reassessed at 3, 6 and 12 months by a single physiatrist during telephone follow-ups. Patients were also asked about opioid use, and any adverse events that occurred during the follow-up period.

The primary outcomes of this study were the procedural pain and technical characteristics, which included fluoroscopic time, radiation dose and procedure duration. Secondary outcomes included [1]: the proportion of patients reporting ≥50% decrease in the NRS score [2], the proportion of patients reporting ≥30% decrease in the NDI score [3], the proportion of patients achieving satisfactory outcome, defined as both ≥50% NRS score decrease and ≥30% NDI score decrease [4], the mean change in NRS and [5] the mean change in NDI.

2.7. Statistical analysis

To ensure the validity of the 95% confidence intervals (CI) for each of the means and mean differences studied, the sample size of 50 participants (25 per group) was determined based on the central limit theorem in statistics, in order to detect differences in technical characteristics. Descriptive statistics were used to analyze patient demographics and clinical features, procedural characteristics, and measures of pain and function. Continuous variables were presented as mean and standard deviation, while categorical variables were presented as frequency and percentage.

Data analysis was conducted using the Statistical Package for Social Sciences (SPSS) version 23.0 (IBM Corp., Armonk, NY). The level of statistical significance was set at $p < 0.05$. Demographics, clinical features, procedural pain and technical characteristics were compared between groups using independent *t*-test for quantitative variables and chi-squared test for categorical variables. The rates of ≥50% NRS reduction, ≥30% NDI reduction and satisfactory outcomes were compared using chi-square test. The changes in NRS and NDI scores in each group were evaluated using repeated measure one-factor analysis. Repeated-measure two-factor analysis was used to compare changes between groups over time. Multiple comparisons were obtained following a contrast under Bonferroni correction. Within the CC group, a sub-analysis was performed to compare responder rates of the optimal CMBRFN with that of the suboptimal CMBRFN, using chi-square test.

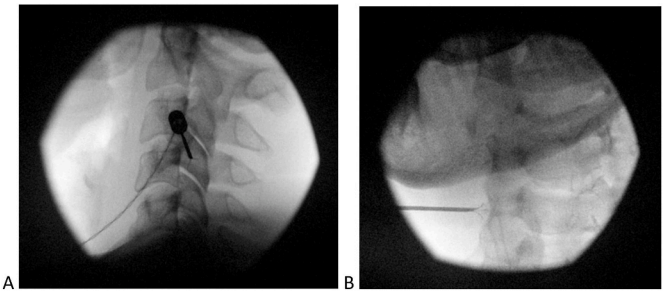

Fig. 1. Fluoroscopic images in the lateral (A) and anteroposterior (B) views of radiofrequency neurotomy of the left C4 medial branch showing multi-tined cannula placement and tine deployment.

3. Results

3.1. Study population

Fifty-three patients were assessed for eligibility between November 2019 and December 2021, of which 3 patients refused to participate (CONSORT diagram, Fig. 2). The remaining 50 patients were randomly assigned to either the multi-tined cannula (MTC) or conventional cannula (CC) group, with 25 patients in each group. For practical reasons, enrollment and randomization occurred immediately after the second positive MBB, and the CMBRFN was scheduled shortly after. In the MTC group, one patient had a pacemaker installed between the time of randomization and his appointment, so the procedure was not performed. In the CC group, 3 patients ended up not receiving the CMBRFN because they had prolonged relief after MBB that no longer made them eligible for RFN, even after subsequent follow-ups. Still within the CC group, 4 patients failed to complete the procedure, 3 because of severe procedural pain and one because of transient paresthesias of all limbs. The remaining forty-two patients (24 in the MTC group and 18 in the CC group) were included in the analysis.

Participants' demographics and clinical features are summarized in Tables 1 and 2. The patients in the MTC group were significantly older than those in the CC group ($p = 0.031$). Other than age, no significant intergroup difference was observed. In the MTC group, one patient had previously received contralateral CMBRFN, while another had a history of cervical spine surgery at the C7-T1 level. None of the other patients had prior surgery or CMBRFN.

3.2. Procedural pain and technical features

Procedural pain and technical variables for each group are summarized in Table 3. There was no significant difference in the mean NRS of the procedure for either cannula ($p = 0.465$), nor was there any significant association between the type of cannula and intensity of procedural pain ($p = 0.764$). The 3 participants in the CC group who requested that the procedure be discontinued because of severe pain were withdrawn from the study and not included in the analysis. Total duration and fluoroscopy time were significantly shorter in the MTC group (each $p < 0.001$). Although the mean radiation dose was smaller in the MTC group, the difference was not statistically significant ($p = 0.363$).

3.3. Categorical outcomes of pain and function

At 3, 6 and 12 months, the rates of ≥50% NRS reduction were 45.8% (95% CI = 26–66%), 25.0% (95% CI = 8–42%) and 17.4% (95% CI = 2–33%) in the MTC group, versus 64.7% (95% CI = 42–87%), 61.1% (95% CI = 39–84%) and 70.6% (95% CI = 49–92%) in the CC group, respectively (Fig. 3). At 3 months, no significant difference was observed between the two groups ($p = 0.233$), but at 6 and 12 months, the rates of ≥50% NRS reduction in the CC group were significantly higher than those in the MTC group (6 months, $p = 0.018$; 12 months, $p = 0.001$).

At 3, 6 and 12 months, 41.7% (95% CI = 22–61%), 41.7% (95% CI =

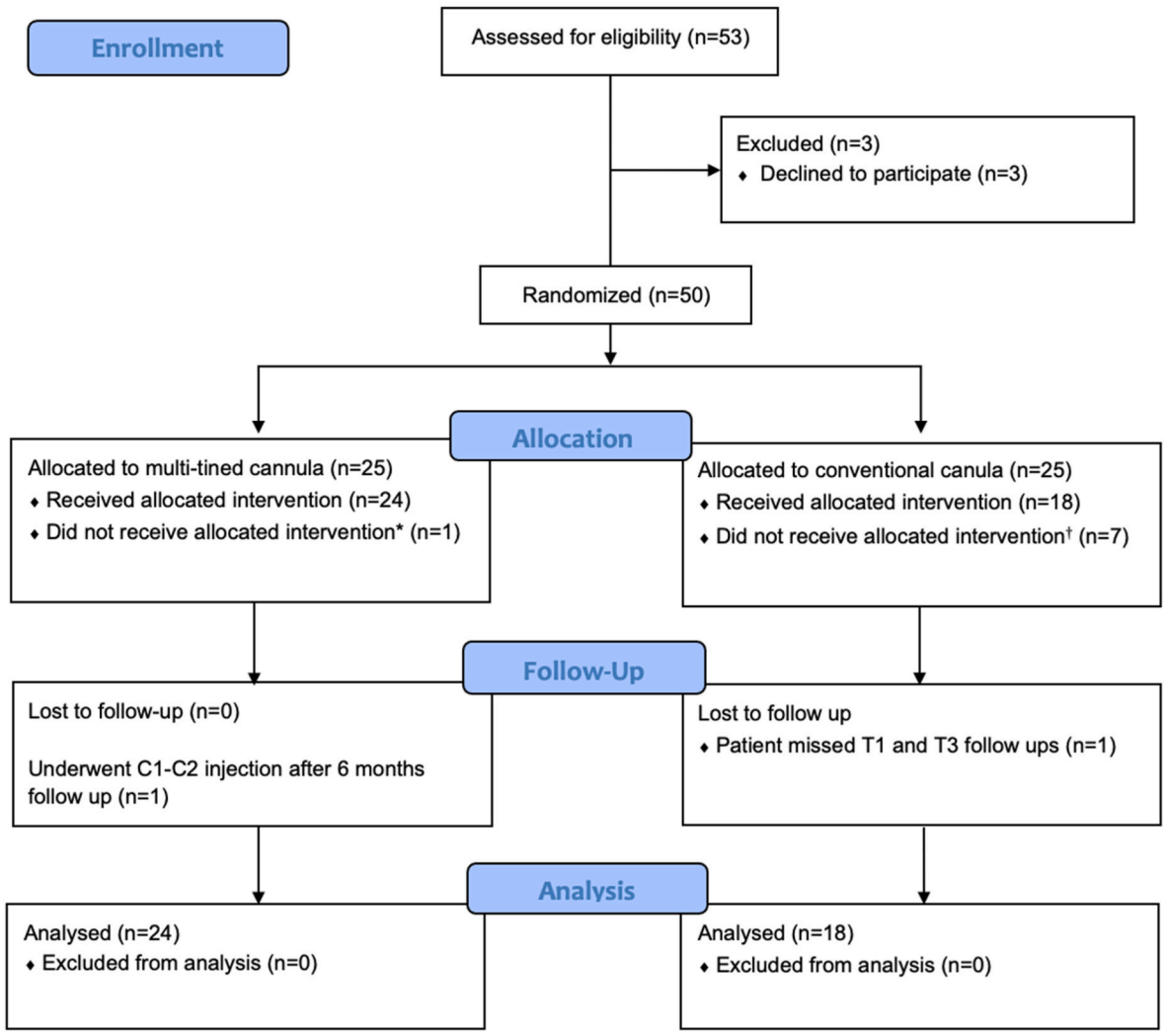

Fig. 2. CONSORT diagram of the progress of patients through enrollment, allocation, follow up and analysis.
* Had pacemaker installed between the time of randomization and his appointment
† 4 discontinued interventions (3 because of severe pain and 1 because of paresthesias of 4 limbs) and 3 patients who did not meet the inclusion criteria anymore on the day of the procedure.

22–61%) and 30.4% (95% CI = 12–49%) of patients in the MTC group versus 76.5% (95% CI = 56–97%), 72.2% (95% CI = 52–93%) and 70.6% (95% CI = 49–92%) of patients in the CC group reported ≥30% NDI reduction, respectively. The rates of ≥30% NDI reduction were significantly higher in the CC group at all time points compared with those of MTC group (3 months, p = 0.027; 6 months, p = 0.049; 12 months, p = 0.012).

The rates of satisfactory therapeutic outcome, defined as reduction of both ≥50% NRS and ≥30% NDI, were not significantly different between the MTC and CC groups at 3 months (MTC group = 29.2% [95% CI = 11–47%], CC group = 58.8% [95% CI = 35–82%], p = 0.058). However, those at 6 and 12 months were significantly higher in the CC group than those in the MTC group (6 months: MTC group = 16.7% [95% CI = 2–32%], CC group = 61.1% [95% CI = 39–84%], p = 0.003; 12 months: MTC group = 17.4% [95% CI = 2–33%], CC group = 64.7% [95% CI = 42–87%], p = 0.002).

3.4. Changes in NRS scores

Both groups showed a decrease in mean NRS scores after treatment, as depicted in Fig. 4. In the intragroup comparison, scores on the NRS for each group were significantly different over time (repeated measure one-factor analysis, p < 0.001). In the MTC group, scores at 3 and 6 months were significantly lower than the pretreatment score (3 months,

Table 1
Demographic characteristics of patients, by treatment group.

	Multitined Group N (%) or Mean ± Standard Deviation	Conventional Group N (%) or Mean ± Standard Deviation	*p*-value[a]
Age	51.0 ± 11.6	42.8 ± 12.0	0.031
Female	16 (66.7)	12 (66.7)	1.000
BMI (kg/m^2)	25.9 ± 5.5	24.0 ± 2.8	0.165
Level of Education			0.520[b]
Elementary	2 (8.3)	0 (0.0)	
High School	11 (45.8)	7 (38.9)	
College	6 (25.0)	5 (27.8)	
University	5 (20.8)	6 (33.3)	

[a] Independent *t*-test unless specified otherwise.
[b] Chi-square test for proportions.

Table 2
Clinical features of patients, by treatment group.

Clinical Features	Multitined Group N (%) or Mean ± Standard Deviation	Conventional Group N (%) or Mean ± Standard Deviation	*p*-value[a]
NRS	6.1 ± 1.3	6.2 ± 1.0	0.777
Neck Disability Index (NDI)	49.6 ± 11.3	45.8 ± 20.7	0.488
MBB #1 response, (%)	89.9 ± 10.2	93.9 ± 8.5	0.178
MBB #2 response (%)	87.5 ± 10.1	86.7 ± 9.4	0.785
# of medial branches targeted	3.5 ± 0.6	3.6 ± 0.9	0.665
TON included	6 (25.0)	9 (50.0)	0.094[b]
Pain duration (months)	76.9 ± 81.9	73.2 ± 70.4	0.734
Taking opioids	6 (25.0)	5 (27.8)	0.839[b]
Cointerventions	7 (29.2)	9 (50.0)	0.169[b]
Compensation (car/work accident)	2 (8.3)	2 (11.1)	0.762[b]

[a] Independent *t*-test unless specified otherwise.
[b] Chi-square test for proportions.

Table 3
Comparison of procedural pain and technical variables between both groups.

Procedural Characteristics	Multitined Group N (%) or Mean ± Standard Deviation	Conventional Group N (%) or Mean ± Standard Deviation	*p*-value[a]
NRS of the procedure	4.7 ± 2.0	4.2 ± 1.8	0.465
Categorical NRS of the procedure			0.764[b]
Mild (<4)	7 (29.2%)	7 (38.9%)	
Moderate [4–7]	16 (66.7%)	10 (55.6%)	
Severe (>7)	1 (4.2%)	1 (5.6%)	
Total duration (minutes)	35.5 ± 7.3	58.2 ± 14.8	<0.001
Fluoroscopy time (seconds)	167.6 ± 76.4	260.8 ± 123.5	<0.001
Radiation dose (mGy)	8.95 ± 7.9	11.5 ± 10.3	0.363

[a] Independent *t*-test unless specified otherwise.
[b] Chi-square test for proportions.

$p < 0.001$; 6 months, $p = 0.001$), while the NRS scores at 12 months did not show a significant decrease compared to the pretreatment score ($p = 0.060$). In the CC group, NRS scores were significantly decreased at all time points when compared to pretreatment scores (3 months, $p < 0.001$; 6 months, $p = 0.001$; 12 months, $p < 0.001$). In the intergroup comparison, the reductions in NRS scores over time were significantly larger in the CC group than those in the MTC group (repeated measure two-factor analysis, $p = 0.041$). The NRS scores at 3 and 6 months were not significantly different between 2 groups (3 months, $p = 0.536$; 6 months, $p = 0.469$), but the NRS scores at 12 months were significantly more reduced in CC group than in the MTC group ($p = 0.015$).

3.5. Changes in NDI scores

In both groups, the mean NDI decreased after treatment (Fig. 5). In the intragroup comparison, scores on the NDI for each group were significantly different over time (repeated measure one-factor analysis, $p < 0.001$). In the MTC group, the NDI scores were significantly decreased at all time points when compared to pretreatment score (3 months, $p = 0.005$; 6 months, $p < 0.001$; 12 months, $p = 0.004$). Likewise, in the CC group, NDI scores at 3, 6 and 12 months were significantly decreased when compared to pretreatment scores (all $p < 0.001$). In the intergroup comparison, changes in the NDI scores over time were not significantly different between the MTC and CC groups ($p = 0.311$).

3.6. Responders rates in optimal versus suboptimal conventional subgroups

The rates of ≥50% NRS reduction and ≥30% NDI reduction at all time points in each CC subgroup (optimal conventional subgroup and suboptimal conventional subgroup) are summarized in Table 4. The rates of ≥50% NRS reduction at 3, 6 and 12 months were 66.7% (95% CI = 36–98%), 77.8% (95% CI = 51–100%) and 88.9% (95% CI = 68–100%) in the optimal conventional subgroup compared with 62.5% (95% CI = 29–96%), 44.4% (95% CI = 12–77%) and 50% (95% CI = 15–85%) in the suboptimal conventional subgroup, respectively. The rates of ≥30% NDI reduction at 3, 6 and 12 months were 88.9% (95% CI = 68–100%), 77.8% (95% CI = 51–100%) and 88.9% (95% CI = 68–100%) in the optimal conventional subgroup compared with 62.5% (95% CI = 29–96%), 66.7% (95% CI = 36–98%) and 50% (95% CI = 15–85%) in the suboptimal conventional subgroup. No significant difference was observed between the 2 groups for any outcome measure at any time point.

3.7. Opioid use

The rates of patients taking opioids were not significantly different between the MTC and CC groups at all time points. At 3 months, 37.5% (95% CI = 12–77%) in the MTC group and 29.4% (95% CI = 8–52%) in the CC group were taking opioids ($p = 0.591$). At 6 months, 20.8% (95% CI = 5–37%) in the MTC group and 33.3% (95% CI = 12–55%) in the CC group were taking opioids ($p = 0.362$). At 12 months, 26.1% (95% CI = 8–44%) in the MTC group and 35.2% (95% CI = 25–84%) in the CC group were taking opioids ($p = 0.530$).

3.8. Adverse events

No significant adverse events were reported at follow-up visits. One patient in the CC group experienced paresthesias in all limbs following local anesthetic injection of the second medial branch. The symptoms fully resolved shortly after, and the patient was kept for observation for an hour. The most common adverse events were sensory disturbances such as local cutaneous hypoesthesia, paresthesia or allodynia. Some patients reported local neuropathic pain at the site of injection or in a typical referred pattern, which lasted for no longer than 6 weeks. The occurrence rates were not significantly different between the two groups (37.5% (95% CI = 18–57%) in the multi-tined group and 29.4% (95% CI = 8–51%) in the conventional group, $p = 0.591$).

4. Discussion

This is the first randomized controlled study comparing the

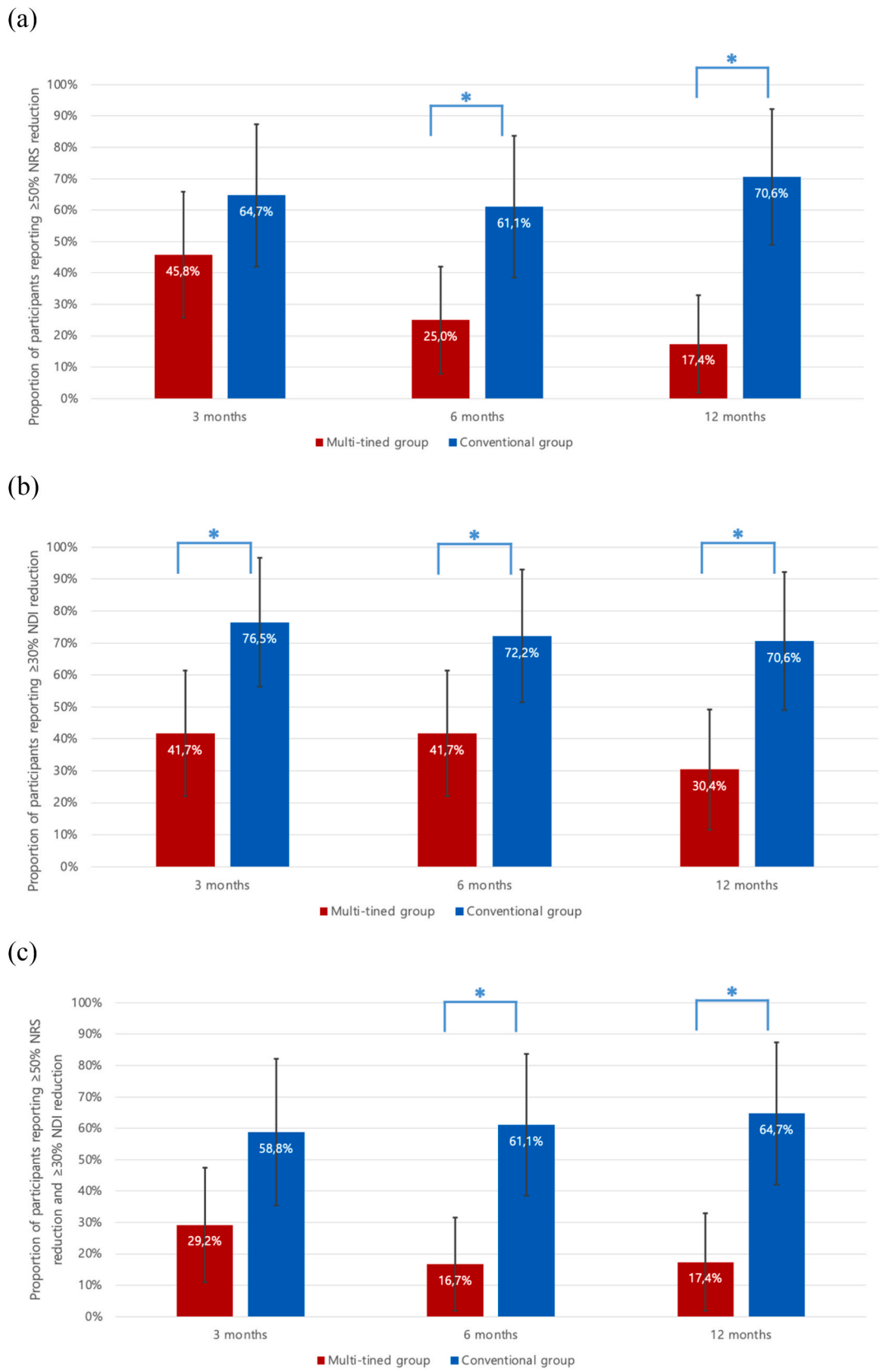

Fig. 3. A) Rates of ≥50% NRS reduction, by treatment group (with 95% CI). B) Rates of ≥30% NDI reduction, by treatment group (with 95% CI). C) Rates of satisfactory outcomes, defined as both ≥50% NRS and ≥30% NDI reductions, by treatment group (with 95% CI).
NRS = Numerical Rating Scale; NDI = Neck Disability Index
* Significant difference between 2 groups (chi-square test, $p < 0.05$).

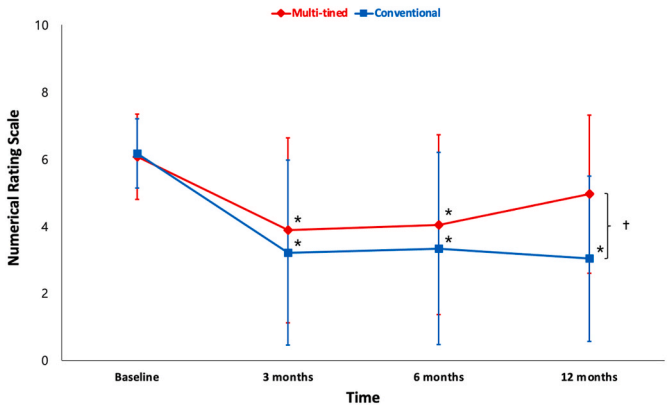

Fig. 4. Changes in numerical rating scale overtime in both groups (mean and SD). *p < 0.05: intragroup comparison between each time point and baseline. †p < 0.05: intergroup comparison for each time point.

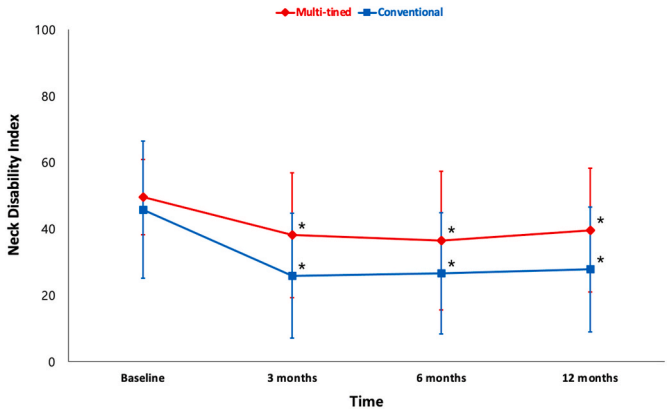

Fig. 5. Changes in neck disability index overtime in both groups (mean and SD). *p < 0.05: intragroup comparison between each time point and baseline.

Table 4
Comparison of rates of responders between both conventional subgroups.

	Optimal Conventional Subgroup N = 9		Suboptimal Conventional Subgroup N = 9		*p*-value[a]
≥50% NRS reduction					
3 months	66.7	36–98	62.5	29–96	0.858
6 months	77.8	51–100	44.4	12–77	0.147
12 months	88.9	68–100	50	15–85	0.079
≥30% NDI reduction					
3 months	88.9	86–100	62.5	29–96	0.200
6 months	77.8	51–100	66.7	36–98	0.599
12 months	88.9	68–100	50	15–85	0.079

[a] Chi-square test for proportions.

procedural characteristics and clinical efficacy of CMBRFN using either the MTC or the CC. This study showed that the MTC allows significantly shorter procedure and fluoroscopy times. CMBRFN with the MTC also trended towards lower radiation dose, but the difference was not significant. As for procedural pain, no significant difference was found between the two groups. When evaluating clinical effectiveness, although mean pain and function improved overtime with both cannulas, magnitude of improvement and rates of responders were significantly higher with conventional CMBRFN, especially at 6 and 12 months.

Our sample population had moderate-to-severe pain and disability at baseline, which is consistent with other study samples that underwent CMBRFN [7,10,11]. Although patients in the CC group were significantly older, the mean age in each group fell within the range reported across other studies [7,10,11,14,16], thus it is unlikely that this substantially influenced the observed results.

Our results, demonstrating the technical advantages of the MTC over the CC, align with previous data published in the form of research abstract [21]. This was to some extent anticipated, given the shorter distance from skin to target, the similarity to the well-known MBB approach, and the reduced number of lesions that were necessary at each level compared to the conventional technique. We acknowledge the prevalence of TON RFN was twice as high in the CC group as in the MTC group, and although the difference was not significant, the higher number of lesions required for this specific nerve could have partially contributed to the observed difference in procedural characteristics. On the other hand, the use of a slightly modified SIS technique with a single entry point and the fewer lesions generated in 50% of our cases, both of which have become pragmatically adopted practice in North America, most likely led to an underestimation of the difference in procedure duration, fluoroscopy time and radiation dose between the two cannulas. While it has been described that the duration of true conventional CMBRFN as suggested in SIS Practice Guidelines is between 2 and 4 h [7,10], in our study, conventional CMBRFN duration was a slightly less than an hour on average. This represents a considerable saving of time that allows for more patients to receive interventional care.

Regarding procedural pain, although no significant difference was found, our analysis did not include patients who were unable to complete the full procedure. Considering the prone position that patients must assume, the longer duration of the procedure, and the fact that the cannula must pass through the posterior neck muscles, it was reasonable to believe that the conventional technique might be more difficult to tolerate for patients. This seems to have been demonstrated in this study by the fact that in the CC group, 3 out of 22 patients (13.6%) requested that the CMBRFN be discontinued because they could not withstand the pain. One could even argue that with the true conventional technique involving 2 entry points, a difference in procedural pain could potentially have been observed between the groups or more procedure discontinuation would have occurred. In comparison, all 24 patients in the MTC group were able to complete the procedure.

Upon examination of therapeutic outcomes, the responder rates we obtained in the conventional group compare to that observed in the literature under the same conditions. In a systematic review studying the effectiveness of CMBRFN based on different selection criteria, 59% of patients (versus 61% in our study) selected by ≥ 75% MBB response reported ≥50% pain relief at 6 months [17]. At 12 months, our 70.6% conventional responder rate was more than the 55% obtained in a study of 28 patients [24]. Still, only a small majority of the patients in our study achieved complete relief. In the CC group, 3/18 patients (16.7%) were pain-free at 6 months and 1/18 (5.6%) were pain-free at 12 months, which is far less than the 63% and 38%, respectively, obtained by Engel and al. in their systematic review [9].

While the less stringent MBB selection criteria probably had a large role to play, it is likely that technical factors contributed to the observed reduced efficiency. The use of a 18G cannula and the proportion of suboptimal techniques resulted in fewer, smaller lesions, with less chance of encompassing the nerve. For instance, MacVicar and al. used a 16G cannula with 5 mm active tip, but the difference in gauge was potentially mitigated by the longer active tip of our cannula (10 mm). Also, interestingly, the first 5 patients in the conventional group were non-responders, accounting for almost all the treatment failures. Given that our interventional physiatrists had mainly traded the conventional approach for the multi-tined approach over the past years, they may have had some technical adaptations in performing their first procedures before becoming fully reacquainted with the technique. Of the remaining 13 patients, 11 (84,6%) were responders in terms of pain and function at 6 and 12 months. This reinforces the importance of mastering the technique. Another factor that appears to have an impact on the success of the intervention is adherence to established guidelines,

as responder rates were observed to be higher in the optimal conventional subgroup than in the suboptimal conventional subgroup. However, due to the small sample size, these results did not reach statistical significance. It must be acknowledged that the technique employed in the suboptimal CC group is what is considered the new pragmatic approach taught during the SIS radiofrequency course, accepted as standard practice although not validated.

For the multi-tined approach, the only data available for comparison are from research abstracts. In the short-term, our results are similar to the 43.3% of patients with at least 50% pain relief at 2 months which we previously obtained in a prospective follow-up [22], and slightly below the ones reported by another practice [21]. However, unlike the patients in the latter studies and those in our CC group, who had prolonged relief, pain relief in our MTC group was not sustained over time. At 6 months, the responders rates decreased by almost half. Because of its design, our study was less prone to bias and confounding factors, and thus the results obtained probably give a closer estimate of the cannula's true effectiveness. Furthermore, we expected the MTC to perform as well as the CC, which makes these findings even more significant as they contradict our initial hypothesis, despite any potential bias we may have had towards it. One possible explanation for this lower efficacy could be the position of the cannula in relation to the articular pillar. Because of the convex aspect of the latter in the axial plane, the multi-tined cannula abuts in the groove at the apex of the articular pillar's curvature. A lesion at this site does not extend far enough anteriorly to reach the more proximal part of the medial branch, as the oblique path would allow in the conventional approach. As a result, it may potentially cover a shorter and more distal portion of the nerve, possibly allowing for faster regrowth or missing some articular branches which could have originated from a more proximal segment of the medial branch. Another explanation would be that if the tip is slightly off-center with respect to the groove, deployment of the tines could result in the cannula hanging over the nerve rather than immediately adjacent. However, images were reviewed to assess tine deployment in the pillar groove and it did not seem to be an issue in a majority of cases.

Nevertheless, some patients reported complete pain relief with the MTC. With 4/24 patients (16.7%) at 6 months and 2/24 (8.3%) at 12 months, the rates are surprisingly similar to those of the CC group (16.7% and 5.6%, respectively). There were no significant adverse events observed, and no notable difference in the frequency of minor adverse events between the two groups. These results indicate that both MTC and CC have a similar safety profile for CMBRFN. Considering all this and the technical advantages, the MTC might be a reasonable option for a certain subset of patients, such as those who cannot tolerate the conventional method or those who had prolonged complete relief with the MTC in the past. We acknowledge that there are currently no clearly established parameters for CMBRFN with the MTC. Our own protocol was extrapolated from conventional RFN and ex-vivo results [19]. More studies are needed to determine the optimal parameters that will yield the most success. For now, and until more data emerges to support the multi-tined approach, the conventional technique should remain the standard of care and preferred option.

This study has some limitations. Firstly, a significant number of patients in the conventional group did not undergo the procedure. This was due in part to the timing of enrollment, randomization and treatment, as some patients were no longer candidates for RFN after experiencing unexpectedly prolonged pain relief following the second MBB. Additionally, patients who could not tolerate the conventional technique were not offered to cross over to the MTC group. As a result, we were possibly deprived of valuable data. This could have been avoided by better planning. Secondly, due to procedural differences between the two techniques, patient blinding may have been compromised, introducing a bias. However, given the limited information the patients received and the fact that only one patient had prior experience with CMBRFN, it is unlikely that a significant number of them would have been able to accurately identify the cannula used. Lastly, there were deviations from the pre-established protocol of conventional CMBRFN, which affected the interpretation of the results. However, the separation into two subgroups provided insight into the relationship between adherence to the established guidelines and the success of conventional CMBRFN.

5. Conclusions

This randomized controlled study demonstrates that CMBRFN performed using the multi-tined cannula is quicker and requires less fluoroscopy time. In addition, although procedural pain is similar, the discontinuation of some conventional CMBRFNs testifies to the difficulty for some patients to tolerate this procedure. Nevertheless, the technical advantage observed with the multi-tined cannula comes at the expense of therapeutic efficacy, which falls short of that achieved with the conventional catheter.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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