

Diagnostic Evaluation

Indications for Repeat Diagnostic Medial Branch Nerve Blocks Following a Failed First Medial Branch Nerve Block

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No studies have directly measured the false negative rate of medial branch block (MBB) with correlation to medial branch neurotomy (MBN) outcome. We investigated the potential false negative MBB rate and the subsequent MBN outcome on a consecutive audit of all patients undergoing a double MBB protocol.

We prospectively collected audit data and retrospectively collected data by phone on 229 consecutive patients undergoing diagnostic MBB. One-hundred-twenty-two patients reporting greater than 50% of subjective pain relief subsequently underwent either MBN or a confirmatory block followed by MBN. A total of 55 patients underwent a second confirmatory MBB and within that group 27.3% (15/55) reported less than 50% relief post initial MBB and 30.9% (17/55) between 50% and 69% relief. We performed an in-depth analysis of these 2 subgroups focusing on the reason a second MBB was performed despite a "negative" or "indeterminant" first MBB.

We divided the "negative" responders to the first MBB into those reporting < 50% relief (Group 1) and those reporting between 50% and 69% relief (Group 2). We calculated a potential 46.7% false negative rate in Group 1 and 47.1% false negative in Group 2; however, the false negative results in Group 1 were predominately in those patients reporting delayed relief of pain and those re-blocked greater than 2 years after the first MBB. The success rate in all patients undergoing MBN was 87% compared to the 75% relief in the false negative groups with no statistically significant difference.

In summary, the false negative rate for patients reporting less than 50% relief post MBB is probably less than 20% although there is a high "apparent negative" response in patients reporting delayed relief or in those who had a second block 2 or more years post initial MBB. Patients reporting between 50 and 69% pain relief have a false negative response rate of 47.1% and should be considered for a confirmatory block.

Key words: Facet rhizotomy, zygapophyseal joint, low back pain, chronic pain, facet joint, radiofrequency neurotomy, medial branch block, medial branch neurotomy

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The definition of a false positive or negative response to a diagnostic medial branch block (MBB) depends on one's definition of the criterion standard. Prior studies define false positive as a situation where the first MBB provides less than a particular cut-off value that typically ranges between 50% and 100% and the second confirmatory injection does not provide the cut-off relief or the duration is

less than anticipated. In the case of a false negative the opposite would apply. Similar to the argument for discography, if the goal is a "criterion standard" for diagnosis, the above concept has merit. However, another equal and perhaps more common goal of MBB (or discography) is the prognostic value. When used as a prognostic tool, the false negative and positive rate of diagnostic MBB depends on the eventual outcome

of medial branch neurotomy (MBN). One might label the former as the potential rates and the latter as the confirmed rates.

Numerous studies document a significant false positive rate of MBB used to establish a diagnosis of posterior element pain (1-13). Few have studied the false negative potential (4,14-17). From a patient perspective, a potential false negative MBB study is likely a greater disservice than a potential false positive response because the negative test will often result in denial of appropriate care or continued ineffectual treatment of structures not responsible for their chronic pain (18). In a cadaver study, Dreyfuss et al (14) showed the injection of local anesthetic in the vicinity of the medial branch only missed the target nerve in 8% and intravascular injection may occur in only 3.7% (16) to 6.1% (17) in *in-vivo* cases. However, Kaplan et al (15) found a potential false negative rate of 11%, but possibly in as high as 31% based on 95% CI when he tested pain provocation during capsular distension before and after MBB in asymptomatic volunteers. Schwarzer et al (4) estimated 5% from unreported series of patients who failed to relieve genuine pain after the injected local anesthetic failed to anaesthetize the target joint adequately.

If the MBB is incomplete the patient could potentially report less pain relief than one's cut-off value, which may range from 50% to 100%. These patients would be excluded from potential treatment for posterior element pain and may undergo further diagnostics or treatment directed at the middle or anterior columns.

Studies report the frequent failure of a confirmatory MBB to confirm a "successful" first MBB (1-13). Lord et al (6) found a 46% false negative rate of comparative local anesthetic MBB when compared to a placebo standard. Although recognized as a likely occurrence (18,19), no studies report results of a second MBB following a "failed" first block where one still suspects significant posterior element pain despite a less than 50% response on the primary diagnostic MBB. Even more vexing is a first diagnostic MBB resulting in a patient report of pain relief of 50% or greater but below one's cut-off value that is typically between 70% and 100%. In both the ASSIP (75%) (11,20,21) and ISIS guidelines (22) such a response is classified as a failure to confirm the z-joints as a source of pain and thus the patient would be eliminated from further consideration for a repeat MBB and possible subsequent MBN (21,23-30).

Integral to our audit of MBN outcome based on stratified cut-off values of MBB results (31), we plotted

a 2 by 2 table of reported subjective relief following the first versus second MBB in a consecutive series of patients undergoing a 2 MBB protocol. Although most (107/229) of the patients that reported less than 50% relief following MBB were excluded from further evaluation, 15 patients underwent a second block despite failing the first block. In addition a second group (44/229) who reported between 50% and 69% relief, 17 patients underwent a confirmatory injection. We report why we chose to perform a second block despite a failed first block in the first group of less than 50% relief, and the potential false negative results in both groups. We classified patients reporting 70% or greater pain relief on the second MBB as apparent false negative blocks. Following subsequent MBN success rates allowed comparison between the negative-positive MBB responders to our previously gathered results of positive-positive MBB responders. Comparison allowed a reasonable assumption that the MBN results were similar between our calculated and estimated false negative rate.

Our primary purpose is to provide a set of circumstances that justifies repeat MBB despite negative or indeterminate results of the initial diagnostic MBB.

METHODS

Study Design

We analyzed audit data from a consecutive patient series undergoing MBB and outcome data on those patients that underwent subsequent MBN. A research assistant entered data into a separate audit database. We routinely obtained follow-up MBN data at 6 week post procedure, at subsequent follow-up visits when the symptoms returned, and with retrospective phone interviews. Patient data was reviewed from August 2007 to September 2010 in all patients who underwent diagnostic lumbar MBB. The early cases in the series contained patients included in prior studies (31,32).

A research assistant stratified the patients without looking at outcomes and was told to include all patients who had undergone MBB within a specific audit period. Patients had chronic debilitating low back pain with or without proximal non-radicular extremity pain of greater than 6 month duration, a clinical diagnosis of a lumbar facet syndrome, and pain unresponsive to conservative treatment including medical management, physical therapy, and previous interventions. All patients had undergone one or more diagnostic MBBs performed on a separate session from MBN. Posterior

element pain was typically considered and evaluated by the senior author when the following symptoms were present: local tenderness over one or more facet joints, morning stiffness or pain worse in the morning and improving with movement, and no other obvious cause for chronic back pain. The author did, however, recognize that none of these symptoms are proven to be associated with positive response to MBB (1,2,9,10,18,33).

Medial Branch Blocks/Dorsal Ramus Blocks

The senior author performed diagnostic MBBs in the surgical suite of an ambulatory surgical center. Prior to the procedure, all patients were tested by an independent observer in a variety of stationary and dynamic loading positions. We recorded a visual analog scale (VAS) during patient movements including flexion, extension, and side bending, and during activities including sitting, standing, and walking. We performed MBBs using anterior-posterior and oblique fluoroscopic views to guide a 25 gauge 3.5 inch spinal needle to the junction of the transverse process and SAP at each lumbar level above L5, and to the junction of the SAP and sacrum to anesthetize the L5 dorsal ramus. At each level incremental volumes of either .5% or .75% bupivacaine was injected at 3 separate locations along the course of the targeted medial branch or dorsal ramus of L5. The total volume was adjusted from ~ .5 to 1 mL depending on the size of the patient and the technical difficulty that was typically caused by enlarged degenerated joints. The senior author routinely uses the multiple injection site technique to potentially reduce false negative responses. In support, Verrilles et al's (16) data shows that injection at more than one location lowers the intravascular occurrence from 3.5% to less than one percent. Furthermore, our MBN outcome data following a double MBB protocol had robust outcomes inconsistent with high false positive rates compared to studies using the standard single .5 mL at a single injection site (31).

An independent observer again tested patients 45 to 60 minutes following the block and in more recent cases the observer retested one to 2 hours after self-testing outside of the surgical suite. We then instructed patients to record their pain levels in a pain diary over the rest of the day and for several days following the block. Patients were seen in follow-up in 2 to 3 weeks to discuss results of the MBB. When allowed by insurance and the patient we offered repeat MBBs on patients reporting between 50% and 69% pain relief. For patients reporting less than 50% pain relief, we offered confirmatory MBB on those patients who reported more convincing relief of

pain after they left the recovery area and those noting a significant reduction of pain for several weeks. We also offered confirmatory MBB to patients failing to respond to treatment of other structures over the course of time where we still suspected the posterior elements to be a significant source of symptoms.

Medial Branch Neurotomy

We offered MBN if patients reported 50% or greater subjective relief on the second MBB, however, the majority of patients had greater or equal to 70% relief. Ten of 33 patients (30.3%) had yet to undergo MBN or declined to undergo MBN despite a positive response to the confirmatory block.

The senior author performed MBN in the surgical suite of an ambulatory surgical center under fluoroscopic guidance. In most cases 2 Teflon-coated 18-gauge RF needles were placed parallel to each other separated by one to 3 mm lying at the junction of the superior articular process and either the transverse process or the sacrum (Fig. 1) (31,32). Both needles were heated simultaneously. In a few early MBN procedures we performed radiofrequency (RF) using a single lesion at each level, and in later cases we supplemented the primary lesion with either another bipolar or a unipolar lesion. Prior to lesioning, we stimulated each needle at 2 hertz/3 volts to test for multifidus muscle contractions and to confirm the absence of lower extremity motor fasciculation. RF current was applied for 90 seconds at 85 degrees Celsius.

Outcome Measures

We evaluated MBB results in those patients who underwent a second MBB despite reporting less than 70% relief following the first MBB. We divided patients reporting less than 70% pain relief into 2 groups, based on the percent of initial relief: 0 – 49% in Group 1, and 50 – 69% in Group 2. The reasons we selected patients for a second MBB are documented in Table 4.

We assessed outcome results of a therapeutic MBN procedure at a scheduled 6-week follow-visit, and subsequent follow-up was done by phone interview. "Successful outcome" of MBN was defined as a $\geq 50\%$ subjective pain relief for ≥ 6 months.

To compare results of MBN between groups, the Kruskal-Wallis test, the nonparametric equivalent of one-way variance analysis was used. All statistical analyses were performed with the Statistical Package for the Social Sciences/PC+ software version 20 (SPSS Inc., Chicago, IL, USA). Statistical testing was performed at a pre-set alpha of 0.05.

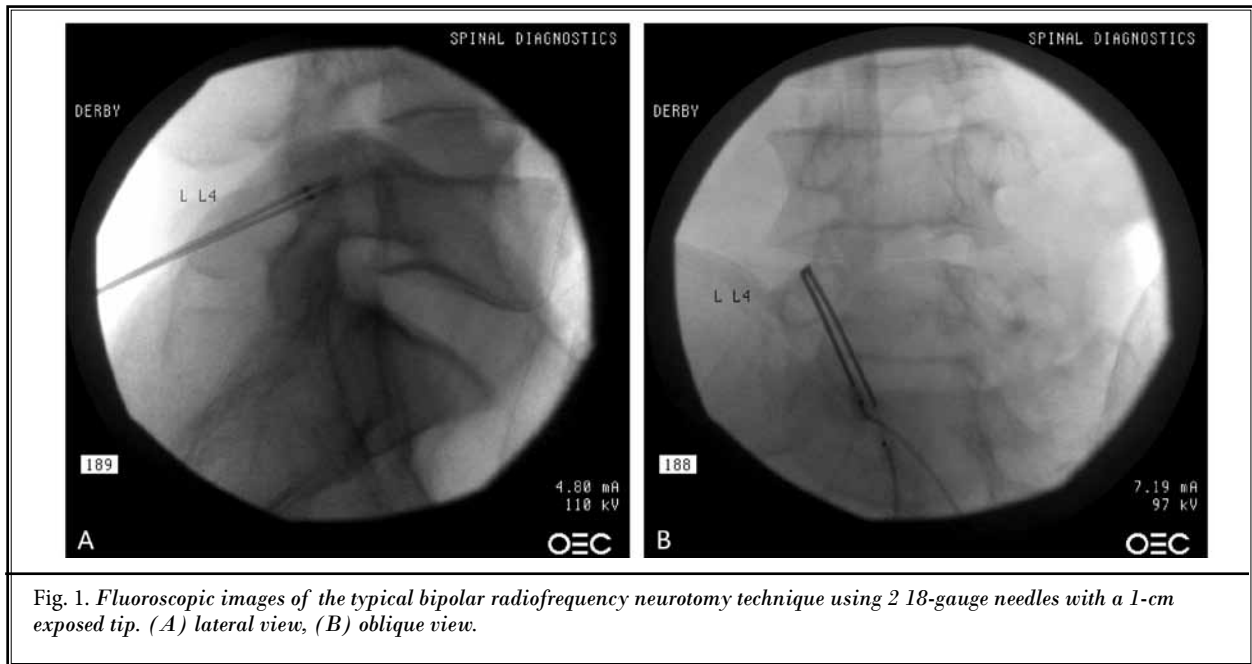


Fig. 1. Fluoroscopic images of the typical bipolar radiofrequency neurotomy technique using 2 18-gauge needles with a 1-cm exposed tip. (A) lateral view, (B) oblique view.

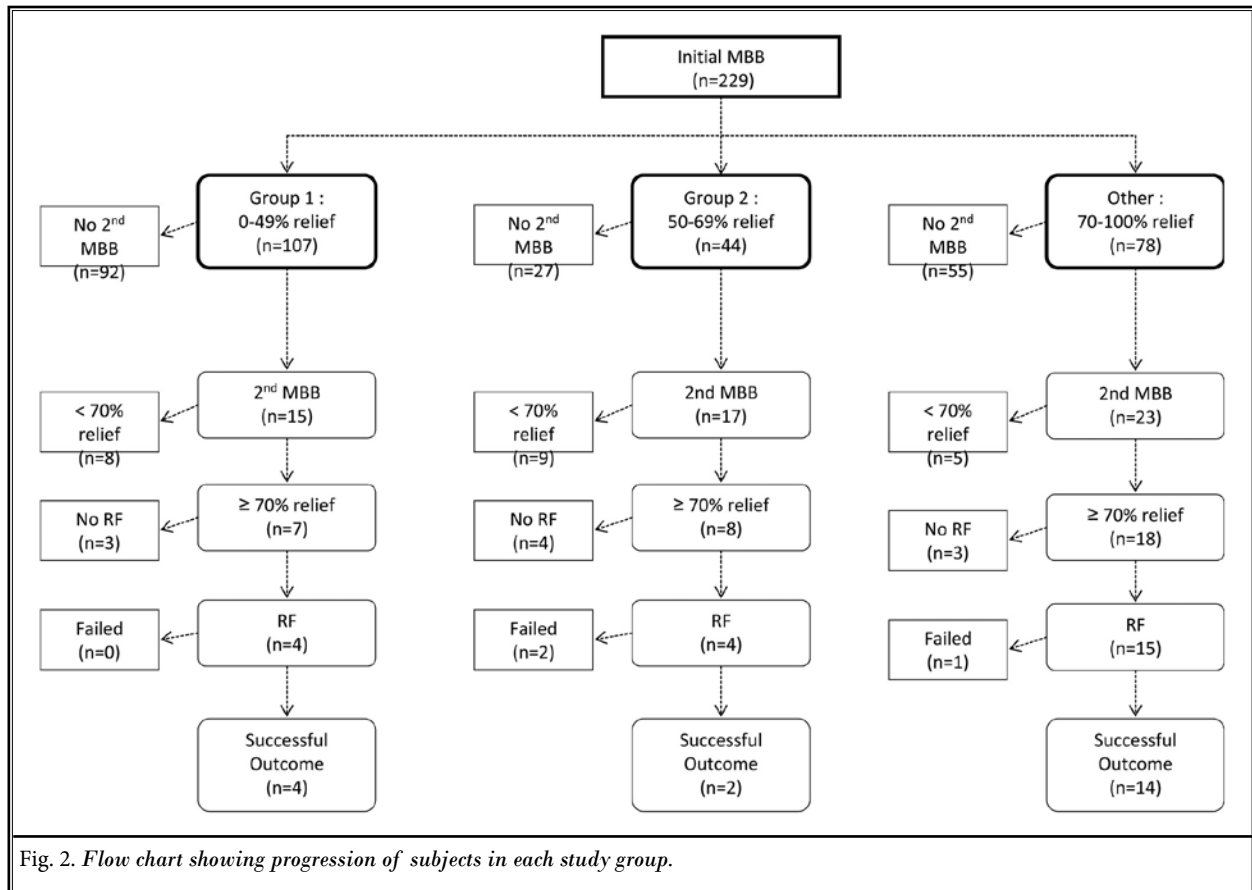


Fig. 2. Flow chart showing progression of subjects in each study group.

RESULTS

Demographics

Two hundred twenty-nine consecutive patients had undergone one or 2 diagnostic MBBs. Fifty-five of those had double diagnostic MBBs. A flowchart showing the progression of patients in each group is provided in Fig. 2 and demographic and clinical characteristics of the patients are presented in Table 1. The average age was 56.0 ± 13.5 years (range, 15 – 86) with equal distribution of men and women. The mean height of the patients was 66.6 ± 3.9 inches (range, 58 – 75) and mean weight was 175.6 ± 49.9 pounds (range, 102 – 355). The average duration of symptoms was 10.1 ± 10.0 years (range, 0.3 – 39). Less than one third of patients had previous surgery. The distress and risk assessment method (DRAM) score showed that 71% of the patients had a “normal” psychological score (1/4 DRAM score) and 25% of patients were in the “at risk” category (2/4 DRAM score). Thirty-six percent of patients were covered by workman’s compensation. Less than 20% of patients were involved in motor vehicle accidents and litigation. The average number of MBB levels and MBN levels was 3 and mostly performed at L3, L4, and L5. Sixty-five percent of the patients had unilateral procedures and 35% had bilateral procedures.

Outcomes

We plotted a 2 by 2 table of reported subjective relief following the initial and second MBBs in 10% increments (Table 2).

One hundred fifty-one of 229 patients reported less than 70% pain relief (50 – 69%: 44 patients, < 50%: 107 patients) on the initial MBB (Fig. 2). Thirty-two of 151 patients underwent a secondary MBB despite of their negative result on the initial test. We divided those 32 cases into 2 groups for detail analysis. Group 1 includes 15 patients who underwent confirmatory MBB from 107 patients who showed less than 50% relief after the initial MBB. Group 2 includes 17 patients who underwent confirmatory MBB from the 44 patients who reported 50 – 69% pain relief following the first MBB. The false negative rate of each group is summarized in Table 3. We use a 70% cutoff of pain relief on MBB for positive/negative result.

The reasons for performing the confirmatory MBB are summarized in Table 4. In Group 1, 4 patients reported less than 50% pain relief at the 45 to 60 minute evaluation, but they were convinced that they experienced pain relief after they left the recovery area or the

Table 1. Demographic and clinical characteristics of study patients.

Age (years)	56.0 ± 13.5
Gender	
Male (%)	43.6%
Female (%)	56.4%
Height (inches)	66.6 ± 3.9
Weight (pounds)	175.6 ± 49.9
Duration of symptoms (yrs)	10.1 ± 10.0
Previous Surgery (%)	25.5%
Psychological score (DRAM)	
Normal	70.8%
At Risk	25.0%
Distressed Depressive	4.2%
Distressed Somatic	0%
WC	
Yes (%)	36.4%
No (%)	63.6%
Motor vehicle accident	
Yes (%)	12.7%
No (%)	87.3%
Litigation	
Yes (%)	18.2%
No (%)	81.8%
Number of levels treated (Unilaterally)	3.2 ± 0.6
Level	
T12	0.6%
L1	1.7%
L2	9.3%
L3	28.5%
L4	29.7%
L5	27.9%
S1	2.3%
Laterality	
Unilateral	65.5%
Bilateral	34.5%

next day after the MBB. These patients are categorized as the “delayed pain relief” group. Eleven patients in the group reported no improvement from alternative treatment modalities after initial negative MBB and despite an initial negative MBB were still thought to have posterior element pain. This group is labeled “failure of alternative treatment” and underwent a second

Table 2. Correlation of incremental percent of pain relief following initial MBB and percent of pain relief following a second MBB.

		2nd MBB relief (%)											
		0	10	20	30	40	50	60	70	80	90	100	
Initial MBB relief (%)	Group 1	0	O						● _s		● _s		
		10			O			● _f	● _s				
		20		O O		O				O		O	● _s
		30						O		O			
		40	O										
		50			O O			O O	O	● _f		O ● _s	O ● _s ● _f
	60				O		O O		O	● _f	O		
	Other	70	O					● _f	● _f ● _s ● _s ● _s	● _s	● _s		
		80	O					● _s		O ● _s ● _s ● _s	● _s	● _s ● _s	
		90		O						● _s	● _s	O	
		100									O	● _s	

●: patients who underwent MBN after 2 MBBs, s: successful MBN; f: failed MBN
 O: patients who did not undergo MBN after 2 MBBs

Table 3. False negative rate of the initial MBB in relation to the successful second MBB in groups reporting less than 70% of pain relief.

Group	Reported % of pain relief following initial MBB	Number of patients	Patients undergoing 2nd MBB	Patients reporting ≥70% relief after 2nd MBB	False negative rate (%)
Group 1	0-49%	107	15	7	46.7
Group 2	50-69%	44	17	8	47.1
Total		151	32	15	46.9

MBB. All 17 patients in Group 2 underwent a second MBB to confirm the initial block. The interval between MBBs and the false negative rate for each group are summarized in Table 4 and show a tendency of a direct correlation between the interval between MBB session and the number of false negative responses. In Group 1, 3 patients underwent a second MBB within 6 months because of delayed relief and 2 patients (66.7%) had a positive result with the second MBB. Four patients in Group 1 underwent a second MBB within 12 months because they failed to respond to alternative treatments with one patient (25%) testing positive after

the second MBB. In Group 2, 10 patients underwent a second confirmatory MBB within 12 months with 3 patients (30%) testing positively after the second MBB.

Table 5 presents the results of MBN in each group. Four patients in Group 1 underwent a MBN and 100% (4/4) reported ≥ 50% pain relief for 8 months. In Group 2, 4 patients underwent a MBN, 50% (2/4) reported 50% or greater pain relief for 7 months. These results are less but statistically equivalent (Kruskal-Wallis test, P = .058) to the 93% MBN success rate in other patients who reported 70% or greater pain relief following both MBBs.

False Negative Potential of Medial Branch Block

Table 4. Summary of patients with false negative response who underwent a second MBB.

Group	Reasons for 2nd MBB	Interval between 1st and 2nd MBB (months)	Number of patients	Patients reporting $\geq 70\%$ pain relief after 2nd MBB	False negative rate (%)
Group 1 (0-49% relief after initial MBB)	Delayed pain relief following MBB	<6	3	2/3	66.7
		12-24	1	1/1	100
	Total		4	3/4	75
	Failure to respond to ongoing treatment	< 6	2	1/2	50
		6-12	2	0/2	0
		12-24	2	0/2	0
		≥ 24	5	3/5	60
	Total		11	4/11	36.4
Sub Total		15	7/15	46.7	
Sub Total *			6	1/6	16.7
Group 2 (50-69% relief after initial MBB)	To confirm the initial MBB	<6	8	3/8	37.5
		6-12	2	0/2	0
		12-24	6	4/6	66.7
		≥ 24	1	1/1	100
	Sub Total		17	8/17	47.1
Sub Total *			16	7/16	43.8
Total			32	15/32	46.9

* excluding patients with “delayed relief” following first MBB and those with ≥ 24 months interval between MBBs

Table 5. Summary of MBN outcomes.

Group	Reported % of pain relief following initial MBB	Number of patients who underwent MBN	Successful rate of MBN	Average % improvement	Average duration of relief (months)
Group 1	0-49%	4	100% (4/4)	83.1%	8.3
Group 2	50-69%	4	50% (2/4)	72.5%	6.8
Other	70-100%	15	93% (14/15)	70.4%	11.0
Total		23	87% (20/23)	73.8%	10.1

No statistically significant difference in success rate of MBN between groups (Kruskal-Wallis test $P = .06$)

DISCUSSION

In our practice a 70% cut-off value based on the confirmatory second MBB best predicted positive MBN results in patients undergoing a 2-MBB protocol (31). In this audit we continued the consecutive patient series audit of MBB and MBN results. We compare results of the first MBB to the second MBB regardless of initial first MBB results. Our focus were patients reporting less than 70% relief following the first MBB, but still undergoing a confirmatory MBB at a later date. Illustrating consistency with prior MBN outcome studies (25,26,34-

40), our outcome audit found that 93% patients within the MBB group having 70% or greater relief at 2 consecutive sessions reported 50% or greater pain relief (average 70% improvement) for greater than 6 months (average 11 months).

The 2010 study of Manchikanti et al (41) is perhaps the most directed and thorough study of the consistency of MBBs over time. The study found that 93% of patients reporting 80% or greater relief after a closely spaced 2 MBB protocol had a like response over a 2 year

period compared to 75% of patients reporting 50% or greater relief. Because patients reporting less than 50% relief were deemed failures, a second MBB was not performed in those patients.

Although no published MBN outcome study is designed to determine the prognostic false negative MBB rate, Cohen et al's (19) randomized comparative study comparing MBN outcomes on patients undergoing 0, 1, or 2 MBB protocols using a 50% cut-off value for the first MBB is an indirect study of the confirmed false negative rate of MBB as a predictor of MBN success. Consistent with a significant potential false negative MBB rate, the study found a greater than anticipated 33% success rate defined as a 50% decrease in pain for minimum of 3 months in the patient undergoing MBN based on clinical suspicion alone compared to the 39% for one MBB and 64% for the 2 block group. Cohen et al's (19) study was not, however, designed to re-block the negative responders and thus the potential negative MBB rate can only be inferred as significant.

We stratified patients into 2 groups for the purpose of determining the potential false negative rate of the first MBB compared to the second MBB. Group 1 consisted of patients reporting less than a cut-off value of 50% and Group 2 consisted of patients reporting between 50% and 69% pain relief after the first MBB. We defined a false negative response to the first MBB when the patient reported 70% or greater relief on the second MBB. We chose the cut-off value of less than 50% reported pain relief of Group 1 because less than 50% reported relief is typically used to "rule out facets" as a significant source of pain. We chose a cut-off value between 50% and 69% for Group 2 because the 50% to 69% range is often considered either a negative or an indeterminate response (21,23-30). It is important to note that both groups were subgroups within the larger group of patients undergoing the first diagnostic MBB who were "dropped" from a second MBB because they did not meet either the 50% or 70% cut-off relief value. The rationale for re-blocking the patients despite less than 50% relief in Group 1 could be reduced to the following 2 reasons: the patients reported delayed relief of pain greater than the cut-off value and the patients failed to respond to treatment for anterior and middle column pain sources where there was a continued strong clinical suspicion that their pain source was the posterior elements despite the negative MBB. In Group 2, the confirmatory MBB was performed because we considered reported pain relief between 50% and 69% as an indeterminate response.

In Group 1, we found a 75% false negative rate (3 out of 4 patients) in the first subgroup (Table 4). This subgroup within Group 1 were patients that reported less than 50% initial pain relief but on subsequent follow-up 2 to 3 weeks later reported that they experienced more convincing relief after they left the recovery area or the next day with ongoing partial relief for several days. In fact, we noted these responses during our audit and subsequently changed our evaluation protocol to include an initial 45 minute to one hour evaluation followed by a self evaluation for another one to 2 hours of self testing outside the surgical center with a second formal testing after returning to the recovery area.

Eleven patients in Group 1 reported less than 50% relief after the first MBB, but failed to respond to subsequent ongoing treatment of other structures. We re-blocked these patients because we felt that the posterior elements were a cause of pain despite the negative first MBB. However, of the 6 patients re-blocked within 2 years of the first MBB, only 17% (one of 6 patients) reported 70% or greater pain relief. On the other hand, 3/5 (60%) patients re-blocked 2 years or longer after the initial MBB reported 70% or greater pain relief.

One could, however, argue that patients reporting delayed relief were not true false negative responders, but were the result of an inadequate initial evaluation and patients undergoing repeat MBB several years after the initial MBB may have developed posterior element pain in the interim period. The potential false negative rate in this group excluding those patients may therefore be only 16.7% (1/6) (Table 4).

In Group 2 of patients reporting between 50% and 69% relief following the initial MBB, 47% (8/17) patients reported 70% or greater pain relief after the second MBB. This group may therefore be considered an indeterminate response and justify repeat MBBs.

Ideally, all the apparent false negative MBB cases would be confirmed or refuted by MBN outcomes. However, for a variety of physician, patient, and insurance related reasons a significant number of the patients in both groups did not undergo a MBN. Therefore we use the MBN outcome of the treated cases as an estimated MBN success rate in the group of patients that had less than 50% (Group 1) and 70% (Group 2) relief on the first MBB session and 70% or greater relief on the second MBB session. The MBN outcome potential of Group 1 that included patients with delayed pain relief and patients re-blocked ≥ 2 years after a negative first MBB was similar to the 93% (14/15) success rate of the group reporting $\geq 70%$ relief on both MBB sessions.

On the other hand the final outcome of the indeterminate Group 2 patients reporting 50% to 69% relief was unclear. Half (4/8) of patients did not undergo MBN and only 2 of the 4 patients undergoing MBN reported satisfactory relief (Table 5). The 50% success rate is, however, compatible with Cohen et al's (42) recent study showing a 54% MBN success rate at 3 months for patients reporting between 50% and 66% pain relief after a single session diagnostic MBB.

CONCLUSION

In summary, our audit indicates that repeat MBBs may be considered in selected patients reporting less than 70% relief following the first lumbar MBB session. Patients that report between 50% and 69% pain relief on the initial MBB may be considered for a second MBB as the false negative likelihood approaches ~ 50% as evidenced by the repeat MBB providing 70% or greater pain relief. Since only half (4/8) of patients underwent

MBN in this group, the predictive outcome of MBN success for the patients reporting 70% or greater relief may or may not be equivalent to the 93% in the 70 – 70 group (patients who reported 70% or greater pain relief following both MBBs). Patients that report delayed relief of pain within 24 hours of the procedure day or the following day should be considered for a repeat MBB as 75% reported 70% or greater relief on a confirmatory injection. Patients with continuing unresolved pain several years after the initial MBB and continued signs and symptoms consistent with posterior element pain should also be considered for a repeat MBB. The MBN outcomes in these later 2 subgroups are comparable to the outcomes of the 70 – 70 MBB group. Patients reporting less than 50% of initial MBB response not confounded with a multi-year gap between blocks nor significantly delayed pain response may be counseled that their chances of having significant relief on a repeat MBB is less than 20%.

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