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Role of Adhesiolysis and Hypertonic Saline Neurolysis in Management of Low Back Pain: Evaluation of Modification of the Racz Protocol

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Epidural adhesiolysis utilizing the Racz protocol is becoming increasingly common as the treatment of choice in the management of chronic resistant low back and lower extremity pain [1–6]. As described by Racz and colleagues [1–4], the technique involves epidurography; adhesiolysis; and injection of hyaluronidase, bupivacaine, triamcinolone diacetate, and 10% sodium chloride solution on Day 1 and injection of bupivacaine and hypertonic sodium chloride solution on Days 2 and 3. In a retrospective analysis, Racz and Holubec [2] reported favorable results with good-to-excellent relief from pain for up to 1 mo in 65% of the patients, for 1 to 3 mos in 43% of the patients, and for 3 to 6 mos in 13% of the patients. Similarly, Arthur and coworkers [7] studied 100 patients and found that, when hyaluronidase was added to the injectate, 82% reported initial pain relief compared to 68% in those without the hyaluronidase. However, there was no significant difference in long-term improvement (14% vs. 12%). Devulder and colleagues [8] noted that filling defects were confirmed in 88% of the patients with epidurography; but lysis of adhesions failed to correspond with improvement in pain, which was seen in only 33% of the patients at 1 mo, 13% at 3 mos, and 0% at 12 mos. Their conclusion was that epidurography might confirm epidural filling defects but that a better contrast spread during scar lysis does not guarantee sustained relief. Contentious arguments for and against adhesiolysis and hypertonic saline neurolysis, along with observations of complications linked to the technique and injected solutions, have been published [9–12].

Treatment of chronic back pain, specifically for post-surgical patients, continues to be a challenge. Even though reasonably positive results were reported with the Racz technique, the use of three injections for one procedure is cumbersome. Other disadvantages include injection of a long-acting local anesthetic with its potential for prolonged subarachnoid blockade in case of a misadventure, administration of hyaluronidase with an associated increase in cost and volume of injectate, and the high cost of a 3-day procedure. Due to the difficulty of consecutive scheduling for 3 days in an outpatient setting and the prohibitive cost of the procedure in an inpatient setting, modifications of the Racz technique of adhesiolysis and hypertonic saline neurolysis were sought. These modifications included reduction of the 3-day procedure to a 2-day and a 1-day procedure; change of local anesthetic from bupivacaine to lidocaine; substitution of triamcinolone diacetate (Aristocort®) with either methylprednisolone acetate (Depo-Medrol®) or betamethasone acetate and phosphate mixture (Celestone Soluspan®), and reduction of the volume of injectate. We did not notice any substantial differences in outcomes with these modifications. Hence, we undertook a detailed and systematic retrospective evaluation to measure their effectiveness more accurately. The primary purpose of this evaluation is to compare results of the procedure performed on a 1-day, 2-day, and 3-day protocol, and identify advantages and disadvantages of each method. Secondary purposes of the study are to evaluate cost effectiveness of adhesiolysis and hypertonic saline neurolysis in managing chronic low back pain, and to evaluate the differences between various injectate solutions.

Methods

This retrospective evaluation included all patients who underwent adhesiolysis and hypertonic saline neurolysis from January 1, 1994, through December 31, 1996. From the total of 536 patients, computerized random selection was used to choose 150 patients who underwent a 2-day procedure for Group I, and 150 patients who underwent a 1-day procedure for Group II. All charts were reviewed, and the patients were contacted by a physician who was not involved in the treatment of these patients. This survey provided a minimum time interval of 1 yr between treatment and evaluation and a maximum interval of 4 yrs. The evaluation included patient characteristics of age, gender, duration of pain in months, nature of the onset of pain, distribution of pain, and history of previous surgical interventions. The number of injections received by each patient in each group was also noted. The quality of pain relief was categorized as 1% to 25%, 26% to 50%, 51% to 75%, and 76% to 100%. Relief greater than 50% was considered significant, and these patients were categorized as "successful." Duration of pain relief was categorized as 2 wks, 1 mo, 2 mos, 3 mos, 6 mos, and 12 mos

or longer. Data of total volume of injectate of local anesthetic, deposteroid, and hypertonic saline, and type of deposteroid were also collected.

All procedures were performed under fluoroscopy in an ambulatory surgery setting in sterile operating rooms by two physicians. The initial procedure on Day 1 was the same in both groups. Access to the epidural space was obtained with an RK® needle (Epimed International, Inc., Gloverville, New York). An epidurogram was obtained, identifying filling defects and/or epidural fibrosis. Adhesiolysis was carried out in all cases utilizing a Racz® catheter, with final positioning of the catheter on the side of the defect and the source of pain and an additional injection of contrast to identify successful adhesiolysis. An injection of 10 cc of xylocaine® 1% preservative free and 40 mg of Depo-Medrol, followed by injection of 10 cc 10% sodium chloride solution in three divided doses of 3 cc, 3 cc, and 4 cc over a period of 10 to 15 minutes, was carried out on Day 1.

Patients in Group I were sent home to return the second day, at which time injection of 10 cc of 1% xylocaine® was followed by injection of 10 cc of 10% sodium chloride solution in divided doses at appropriate intervals. The volume of injectate was changed in approximately 50% of the patients surveyed to 5 cc of 1% xylocaine® with 6 cc of 10% hypertonic saline.

Overall quality and duration of pain relief were noted along with functional status at the first repeat visit on the second day, as well as at follow-up visits. In addition, psychological status, medication intake, and complications were monitored.

Statistical analyses were performed by utilizing two-by-two chi squared tests used as a simple-effects follow-up test. A *t*-test was used to compare the means. Results were considered statistically significant if p values were less than 0.05.

Results

Patient Characteristics

A study population of 150 patients was randomly selected for each group from a total of 532 names (218 in Group I and 314 in Group II). A total of 47 patients from Group I and 21 patients from Group II was excluded applying the following exclusion criteria: patients who had undergone both types of procedures, patients for whom sufficient follow-up information was not available, patients who were not given a hypertonic saline injection due to subarachnoid blockade, and patients who experienced catheter dislocation. After the exclusions, 103 patients in Group I and 129 patients in Group II were studied. As shown in Table 1, gender distribution was 47% male and 53% female in Group I, and 46% and 54%, respectively, in Group II, with no significant difference (p = 0.8955). Ages ranged from 23 through 81 yrs in Group I and 21 through 84 yrs in Group II, with a mean age of 45.4 yrs ± 11.73 in Group I and 50.1 yrs ± 14.52 in Group II, with a statistically significant difference (p = 0.0085). Mean duration of pain was 52.7 ± 48.02 mos in Group I and 71.9 ± 57.76 mos in Group II, with a longer duration of pain in Group II than Group I that was statistically significant (p = 0.0414). Pain was related to a work-related injury in 50% of patients in Group I in contrast to 30% in Group II, with a statistically significant difference (p = 0.0028). The postsurgical population was 65% in Group I and 37% in Group II, with a statistically significant difference among the groups (p = 0.0028).

Table 1. Patient characteristics

	Group I	Group II
Number of patients	103	129
Gender		
Male	47%	46%
Female	53%	54%
Age (years)		
Mean ± S.D.	45.4 ± 11.73	50.1* ± 14.52
Range	23–81	21–84
Duration of pain (months)		
Mean ± S.D.	52.7 ± 48.02	71.9* ± 57.76
Range	3–144	3–144
Mode of onset of pain		
Work-related	50%	30%
All other causes	50%	70%*
Pain pattern		
Unilateral	42%	48%
Bilateral	58%	52%
Post surgery	65%	37%*

* Indicates significant difference

Injection Characteristics

The details of the number of procedures in each group are listed in Table 2. The number of patients who underwent more than two injections was significantly higher in Group II than in Group I. The maximum number of procedures in Group I was 5 (3 patients), in contrast to Group II with 41 patients. None of the patients underwent more than 10 procedures.

Pain Relief

Quality and duration of pain relief associated with each injection by members of the two groups are illustrated in Table 3. No statistically significant differences were demonstrated among the groups experiencing either greater than 50% relief or those experiencing 50% or less pain relief.

Duration of pain relief was compared with the quality of the relief for each of the four procedures at 2 wks, 1 mo, 2 mos, 3 mos, 6 mos, and 12+ mos (Table 3). Statistically significant differences in continued pain relief between the two groups were seen at 2 and 3 mos after the first injection. A total of 52% of Group I patients experienced continued relief at 2 mos and 22% at 3 mos, compared with 35% of Group II patients at 2 mos and 11% at 3 months (p = 0.0111; p = 0.0228). No differences in the duration of pain relief were observed with subsequent procedures.

Effectiveness of multiple injections on duration of significant relief was evaluated in both groups for four consecutive procedures (Fig. 1). For Group I, improvement occurred from procedure 1 to 2 and 3, while in Group II it was from 1 to 2, 3, and 4.

Figs. 2 and 3 show the effectiveness of adhesiolysis and hypertonic saline neurolysis of Groups I and II in comparison to the study of Racz and Holubec [2]. Racz and

Table 2. Details of patients undergoing multiple procedures

No. of procedures	No. of patients in Group I	No. of patients in Group II
1	103	129
2	56	86
3	26	69
4	14	52
5	3	41
6	0	31
7	0	25
8	0	18
9	0	13
10	0	10

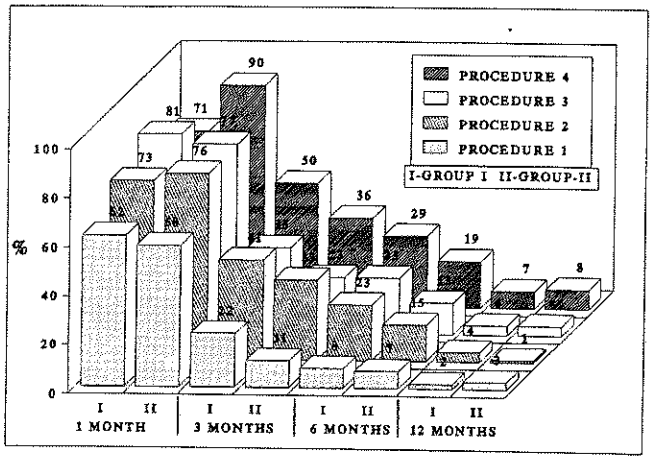

Fig. 1. Comparison of effectiveness of multiple procedures on duration of significant relief (>50%) in both groups.

Table 3. Percent of patients with pain relief for four procedures

Duration of relief	Quality	First		Second		Third		Fourth		Average	
		I	II	I	II	I	II	I	II	I	II
2 wks	≤50%	32	33	25	22	19	22	29	8	26	21
	>50%	68	67	75	78	81	78	71	92	74	79
1 mo	≤50%	24	16	20	17	19	21	21	6	21	15
	>50%	62	58	73	76	81	77	79	90	74	75
2 mos	≤50%	19	8	16	6	15	9	21	4	18	7
	>50%	52*	35	62	63	73	65	71	80	65	61
3 mos	≤50%	2	0	11	1	8	3	7	0	7	1
	>50%	22*	11	41	33	35	23	50	36	37	26
6 mos	≤50%	0	0	2	0	8	1	0	0	2	0
	>50%	8	7	23	15	23	13	29	19	21	14
≥12 mos	≤50%	0	0	0	0	4	0	0	0	1	0
	>50%	2	3	4	1	4	4	7	8	4	4

I—Group I; II—Group II

* Indicates significant difference

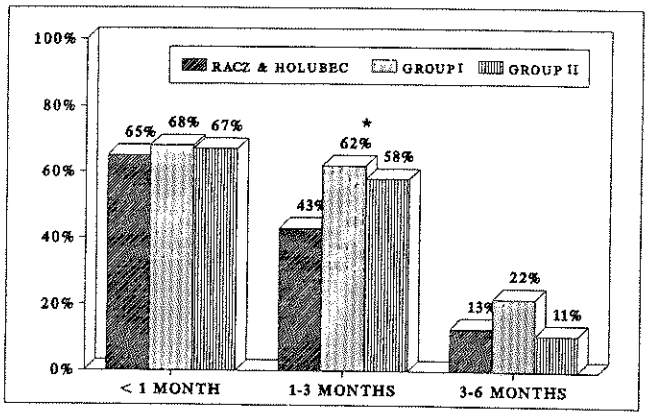

Fig. 2. Comparison of effectiveness of duration of significant relief (>50%) of Groups I and II (first procedure) with the study of Racz and Holubec [2].
* Indicates significant difference.

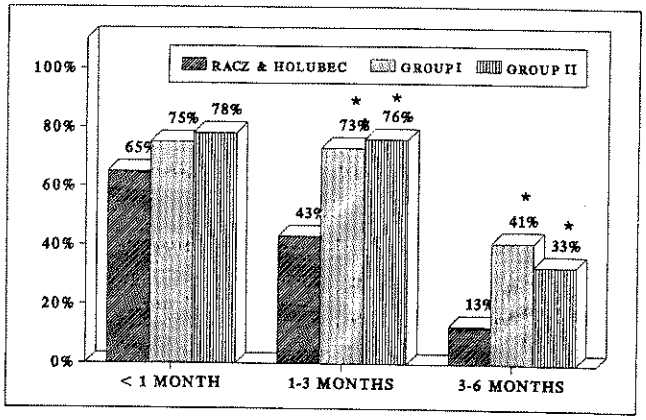

Fig. 3. Comparison of effectiveness of duration of significant relief (>50%) of Groups I and II (second procedure) with the study of Racz and Holubec [2].
* Indicates significant difference.

Holubec [2] described the quality of relief in terms of 0% to 20%, 20% to 40%, 40% to 70%, and 70% to 100% in contrast to this study where it is described as 1% to 25%, 26% to 50%, 51% to 75%, and 76% to 100%. Significant relief was considered from the study of Racz and Holubec [2] as good and excellent relief (>40% relief), whereas in the present study it was defined as greater than 50% relief. This comparative evaluation for first injection with significant relief at less than 1 mo, 1 to 3 mos, and 3 to 6 mos showed no significant advantage with a 3-day procedure performed by Racz and Holubec [2]. In fact Group I showed significantly better results at 1 to 3 mos than did patients studied by Racz and Holubec ($p = 0.0190$). Similarly, comparative evaluation with the second injection, while showing no significant difference at less than 1 mo's relief, demonstrated significantly better improvement with relief at 1 to 3 mos with Group I ($p = 0.0030$) as well as Group II ($p = 0.0000$) and at 3 to 6 mos with Group I ($p = 0.0010$) as well as Group II ($p = 0.0060$).

This study compared the influence of age, gender, mode of onset of pain, duration of pain, pain distribution, prior surgery, type of steroid, and volume of injectate on the dura-

tion of significant relief as shown in Table 4. There were no significant differences noted among the groups with any of the variables.

Cost Effectiveness

Cost effectiveness was analyzed first by calculating the total cost of all procedures, including complications, in all patients, divided by a total significant relief factor (Table 5). The number of weeks with significant relief was calculated as 1,970 for Group I and 3,759 for Group II. This showed a mean significant relief per procedure of 9.7 ± 21.63 wks per procedure for Group I and 7.9 ± 11.02 wks for Group II. Mean significant relief in weeks when calculated only for successful patients and visits was 13.5 ± 24.55 wks for Group I and 9.9 ± 11.52 wks for Group II. Total expenditures were calculated from net collections or the patient expenses for outpatient surgical center and physician services as incurred to the insurer and the patient. The total costs for Group I with 103 patients for 202 procedures was $276,956 (facility, $182,021; physician, $94,935) and $402,646 (facility, $253,667; physician, $148,979) for Group II with 129 patients and 474 procedures. The average cost for treatment was $1,371 for Group I patients and $849 for Group II patients. Significant relief was provided for Group I patients at a cost of $141 per wk and $107 for patients in Group II. Conversion of these cost figures resulted in a determination of a yearly quality-of-life improvement in Group I patients of $7,332 and for Group II of $5,564, representing a substantial difference in cost effectiveness. However, this cost-effectiveness analysis does not take into consideration the patient's return to work and the various other benefits nor does the cost-benefit ratio consider the monies spent outside this organization for drugs or other types of treatments.

Complications

Patients were also evaluated for various types of complications including infection, rash, reaction, and subarachnoid blockade. Complications included subarachnoid blockade in 2% of the patients (5) in both groups. Serious infection was noted in one patient with development of an abscess, however, without involvement of the spinal canal, which had to be drained. Suspicion of infection occurred in 2% of the cases (4 patients). No arachnoiditis, paralysis, weakness, bladder disturbances, or other serious complications were seen. Minor complications such as rash and itching occurred in 6% of patients.

Table 4. Influence of various factors on duration of significant relief (>50%)

	1 Mo (%)	2 Mos (%)	3 Mos (%)	6 Mos (%)	12 Mos (%)
Age (yrs)					
<65	73	59	27	14	3
≥65	60	49	23	9	4
Gender					
Male	74	62	31	18	5
Female	70	56	24	11	2
Mode of onset of pain					
Work-related	73	58	28	17	3
All other causes	70	58	26	12	3
Duration of pain					
<1 year	78	58	30	16	5
≥1 year	69	58	26	13	2
Pain distribution					
Unilateral	75	64	31	16	3
Bilateral	73	61	28	15	3
Prior surgery					
History	72	61	28	16	4
No history	70	56	26	13	3
Steroids					
Kenalog®	71	58	29	15	3
Depo-Medrol®	85	69	15	8	—
Celestone®	72	59	20	10	5
Volume of injection					
21 ml	67	60	29	15	2
12 ml	78%	67%	31%	17%	5%

Table 5. Analysis of cost effectiveness

	Group I	Group II
No. of patients	103	129
Procedures per patient		
Average	2	4*
Range	1–5	1–10
Visits with significant relief (>50%)	72% (146)	80%* (378)
No. of weeks with significant relief (>50%)	1,970	3,759
Significant relief (>50%) per procedure in weeks		
Mean ± SD	9.7 ± 21.63	7.9 ± 11.02
Range	2–156	2–104
Total cost		
Facility	$182,021	$253,667
Physician	$94,935	$148,979
Total	$276,956	$402,646
Cost per procedure		
Facility	$901	$534
Physician	$470	$314
Total	$1,371	$849
Cost per 1-wk improvement of quality of life	$141	$107
Cost per 1-yr improvement of quality of life	$7,332	$5,564

* Indicates significant difference

Discussion

The first use of intrathecal saline to relieve pain in cancer patients was reported by Ventrafridda and Spreafico [13]. Significant research and advances were made by Racz and colleagues [5], which stimulated resurgence of hypertonic saline use in epidural injections for neurolytic purposes. Even though the importance of epidural fibrosis has been questioned in the past, Ross and coworkers [14] in their study of the association between peridural scarring and recurrent radicular pain after lumbar discectomy utilizing magnetic resonance imaging showed that the probability of recurrent pain increased as scar scores increased. Subjects with extensive peridural scarring were 3.2 times more likely to experience recurrent radicular pain, quantifying the extensivity of the scar with recurrent pain. Filling defects were documented by epidurography in patients who did not undergo surgical intervention, even though Devulder et al. [8] reported no correlation between adhesiolysis and pain relief.

The majority of opinion rests with the philosophy that adhesiolysis is helpful. This procedure laid the foundation for adhesiolysis and decompression with spinal endoscopy [15].

While the protocol as described by Racz and colleagues [5,6] is performed by many clinicians, major criticisms persist, including procedure, rigid protocol, and lack of evaluations with modifications. The current study shows that modifications have been made successfully without compromising the quality or duration of pain relief since we were unable to demonstrate any substantial difference between a 1-day and a 2-day hypertonic saline neurolysis or between results published by Racz and Holubec [2] and our findings. In addition, there was no evidence to show any correlation between pain relief and gender, age, a history of previous surgery, the dosage of local anesthetic and hypertonic saline, the mode of onset of pain, distribution of pain, and the type of steroid used. This study is the first to evaluate the cost effectiveness of neural blockade, specifically adhesiolysis and hypertonic saline neurolysis. Results showed that an average 1-yr quality-of-life improvement or 1-yr-of-life gain can be achieved at a total cost of $7,332 per yr with a 2-day procedure or $5,564 per yr with a 1-day hypertonic saline neurolysis procedure. The costs of inpatient pain treatment programs range from $17,000 to $25,000, and the costs of outpatient treatment programs range from $7,000 to $10,000 [16]. It is common knowledge that chronic pain patients may incur health care bills in excess of $20,000 annually for repetitive and redundant diagnostic tests, physical therapy, psychological intervention, and drugs.

In a surprising study, Malter and coworkers [17] evaluated the cost effectiveness of lumbar discectomy for the treatment of herniated intervertebral discs and concluded that surgery increased average life expectancy, adjusted for quality of life, by 0.43 yrs during the decade following treatment, a benefit equivalent to extending a healthy life by 5 mos. In addition, they concluded that, for carefully selected patients with herniated discs, surgical discectomy is a cost-effective treatment at a discounted cost of $12,000 for discectomy or $29,000 per yr adjusted for quality of life. They stated that cost effectiveness of the procedure is well within the $20,000 to $100,000 range that most authorities define as acceptable cost effectiveness, and even within the more conservative range of $20,000 to $40,000 as proposed by others, and compares favorably with coronary bypass surgery for angina ($73,000) or medical treatment for mild hypertension ($38,000). Considering these reports, it appears that hypertonic saline neurolysis performed on a 1-day basis with a cost of $5,564 per yr of improvement is especially reasonable in terms of cost effectiveness (Fig. 4).

This study may be criticized for its retrospective nature; significant differences in study population in terms of age, duration, and onset of pain; lack of third-party review; and lack of outcome parameters to include return to work. While retrospective analysis is not considered as valid as results from randomized, controlled, prospective trials, it should be pointed out that prospective patient studies also have serious limitations such as small numbers of patients and significant expenses. Conduct of such a study is extremely difficult and impractical. Advantages of our retrospective survey include computerized randomization and ability to select from a large database.

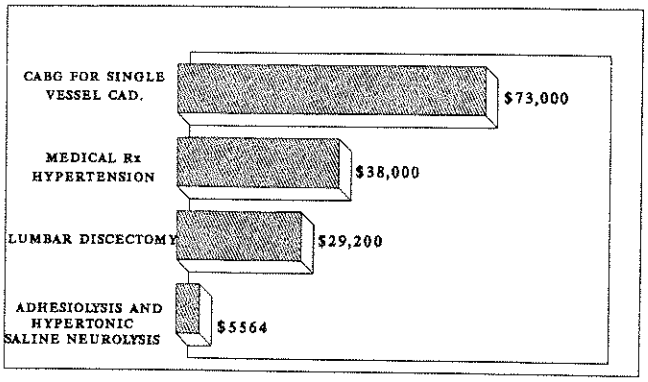

Fig. 4. Cost effectiveness of selective therapies per quality-adjusted year of life gained. Adapted and modified from Malter et al [17].

Patient population characteristics showed significant differences: Group II, with a higher mean age than Group I; duration of pain, with longer duration in Group II than Group I; and mode of onset of pain, with a higher number of work-related injury patients in Group I than Group II. However, no significant differences were shown when variables were analyzed (Table 5).

Return-to-work outcome criteria were not utilized in this evaluation because a substantial number of patients were disabled or retired. Instead, improvement in functional status with the ability to perform activities of daily living and improvement in activities a patient likes to perform were used. These were utilized as an equivalent measure to return to work in Racz and Holubec's study [2]. Disinterested third-party evaluation of the results is considered standard by North and coworkers [18]. We also cite the fact that it is standard practice in spine care to utilize a physician not involved in the care of the patients being studied to provide an independent evaluation [19]. Hence, we consider our retrospective evaluation on a par with other disinterested third-party evaluations.

Finally, methodology utilized in evaluation of cost effectiveness of adhesiolysis and hypertonic saline neurolysis may be criticized by some. It should be noted that the criteria utilized for this study are similar to those utilized by Malter and colleagues [17] in evaluating the cost effectiveness of lumbar discectomy for the treatment of herniated intervertebral disc. Their analysis was based on previously published efficacy data and newly gathered cost data with effectiveness estimated from the 1-yr, 4-yr, and 10-yr outcomes data from Weber's study of 126 subjects randomly assigned to medical or surgical treatment for radicular pain unresponsive to conservative therapy [20]. Costs in the Malter and coworkers' study [17] were determined from insurance claims, and cost effectiveness was estimated from the payers' perspective [21–25]. Effectiveness was defined as the number of quality-adjusted life-years gained with a treatment. In contrast to Malter and colleagues [17], our study included actual cost figures on all patients. Thus, based on current literature, our evaluation of cost effectiveness appears to be optimal. Additionally, this analysis is based on patients seen in an outpatient surgical facility, with physician and facility charges that are reasonable and customary with no "creative" billing.

Conclusions

Modified adhesiolysis with hypertonic saline neurolysis is a valuable, safe, and cost-effective technique for relieving chronic intractable pain when performed in an outpatient setting with reasonable and customary charges for the facility and physician services. This study also demonstrated that repeat or multiple procedures were performed with significant relief with increasing duration, with each procedure in a staircase fashion, with no deleterious effects.

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