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Original Article

Caudal Epidural Injections with Sarapin or Steroids in Chronic Low Back Pain

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Epidural steroid injections are the most commonly used procedures to manage chronic low back pain in interventional pain management settings. Approaches available to access the epidural space in the lumbosacral spine include the interlaminar, transforaminal, and caudal. The overall effectiveness of epidural steroid injections has been highly variable.

This study included 65 patients who underwent diagnostic facet joint nerve blocks utilizing comparative local anesthetic blocks and were shown to be negative for facet joint pain and other problems such as sacroiliac joint pain before enrollment into the study. They were randomly selected from 105 patients negative for facet joint pain allocated into three groups, with Group I consisting of 15 patients comprising a convenience control sample treated conservatively; Group II, consisting of 22 patients treated with caudal epidural with local anesthetic and Sarapin®; and Group III, consisting of 33 patients treated with caudal epidural with a mixture of local anesthetic, and betamethasone. The study period lasted for 3 years.

Results showed that there was significant improvement in patients receiving caudal epidural injections, with a decrease in pain associated with improved physical, functional and mental status; and decreased narcotic intake combined with return to work. The study showed that at 1 month 96% of the patients evaluated showed significant improvement, which declined to 56% at 3 months and 16% at 6 months, with administration of 1 to 3 injections. Cumulative relief with 1 to 12 injections was noted in 96% of the patients at 1 month, 95% at 3 months, 85% at 6 months, and 67% at 1 year. The study also showed cost effectiveness of this treatment, with a cost of $ 2550 for 1-year improvement of quality of life .

In conclusion, caudal epidural injections with steroids or Sarapin are an effective modality of treatment in managing chronic, persistent low back pain that fails to respond to conservative modalities of treatments and is also negative for facet joint pain. The treatment is not only effective clinically but also is cost effective.

Keywords: Chronic low back pain, caudal epidural injections, epidural steroids, betamethasone, Sarapin

Epidural steroid injections are not only the most commonly used procedures in interventional pain management, but also the most contentious and misunderstood modality of treatment (1-19). Among the chronic pain problems, chronic low back pain is the most frequent and persistent pain, with a source of frequent or persistent pain being estimated at around 15% of the US population, and a lifetime prevalence of 65% to 80% (20, 21). It also has been reported that 13% of the population suffers with persistent low back pain of high intensity, with either moderate or severe disability (22). Back pain is prevalent in 12% of children and adolescents, 15% of adults, and 27% of the elderly (20). The prevalence of chronic, persistent low back pain at 12 months is shown to be 28% to 75%, in contrast to the earlier reports of 10% (1, 20).

Approaches available to access the epidural space in the lumbosacral spine include the interlaminar, transforaminal, and caudal. The first reports of management of low back and lower-extremity pain were of Sicard (23), and Pasquier and Leri (24) in 1901. Interlaminar epidural injections utilizing a paramedian approach were proposed by Pages in 1921 (25).

Since the introduction of epidural injections in the early 1900s, numerous publications have appeared in support and some in opposition of epidural injections in managing low back pain or lower extremity pain. Along with

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these reports numerous systematic reviews of the effectiveness of epidural steroid injections have also appeared, with conflicting opinions (1, 9-12, 14-17, 19). The overall effectiveness of epidural steroid injections has been highly variable. Perceived advantages and disadvantages of each of the three approaches, (ie, interlaminar, caudal, and transforaminal injections) also have been described (1). Even though interlaminar lumbar epidural steroid injections have been studied more extensively than either caudal or transforaminal routes, more opinions have been expressed in favor of caudal epidural steroid injections, as well as transforaminal epidural injections (1, 9, 11, 26). Target specificity has been an important aspect of epidural steroid injections (26). In addition, in almost all studies, epidural steroid injections were administered without fluoroscopy except in transforaminal and a few caudal epidural steroid injection studies; and the patients selected were heterogeneous.

Tissues in the low back capable of transmitting pain include muscles, ligaments, fascia, discs, nerve root dura, and facet joints (27). It is difficult to identify the causative factor for low back pain which may be either a facet joint or disc or another structure, which, generally, is differentiated based on clinical features of somatic/referred pain or radicular pain (1). Chronic low back pain is a diagnostic dilemma in 85% of patients, even in experienced hands with all of the available technology (1). Considering the above factors, it is logical to assume that, in some cases, epidural steroids were not indicated or delivery of steroids was not target specific. In addition, it is believed that the benefits of epidural steroid injections may be twofold. The explanations are based in part on the pharmacological and physical actions of local anesthetics, corticosteroids, and other agents, as well as physical effects, including clearing of the adhesions or inflammation from the vicinity of the nerve root sleeve (1). Thus, it is not quite certain at this point whether steroid administration is essential to achieve a therapeutic effect, even though the results have shown better therapeutic results when steroid was administered rather than the local anesthetic alone. In addition to local anesthetic and steroids, Sarapin® (High Chemical, Levittown, PA) is another agent used in neural blockade. Sarapin has been shown to provide significantly longer relief than local anesthetic and relief almost equal to methylprednisolone acetate (DepoMedrol®) in both diagnostic as well as therapeutic facet joint nerve blocks (28, 29). However, there are no studies or reports in the literature evaluating the effectiveness of Sarapin in caudal epidural injections.

Hence, this study was designed and undertaken to evaluate the role of a mixture of a local anesthetic and Sarapin or local anesthetic and steroids in managing chronic low back pain. The issues explored included duration of relief with caudal epidural injections with local anesthetic and Sarapin or local anesthetic and steroids, in a prospective study evaluating significant pain relief, overall health status, drug intake, and cost-effectiveness.

METHODS

This study included 65 patients divided into three groups derived from a sample of 200 consecutive patients seen in one private pain management practice in a nonuniversity setting. Patients younger than 18 years or older than 90 years, those who exhibited neurological deficits, those who had had pain for less than 6 months, those who had responded to conservative management, and those who had undergone neural blockade in the past were excluded.

All patients consented to participate. Initially, all the patients (200) underwent diagnostic facet joint nerve blocks on one or two separate occasions using lidocaine 1% and bupivacaine 0.25% (30). Following the diagnostic blocks, 42% of the patients, or 84, were diagnosed with facet joint pain based on controlled, comparative local anesthetic blocks. Eleven patients had other problems such as sacroiliac joint pain. Of the remaining 105 patients, 65 were randomly allocated to this study group; further allocation into three groups was by patient choice. Group I consisted of 15 patients comprising a convenience sample that was considered as a control group treated conservatively, due either to nonapproval of the treatment or the patient's desire to undergo conservative treatment. Group II consisted of 22 patients treated with caudal epidural with local anesthetic and Sarapin, whereas Group III consisted of 33 patients treated with caudal epidural with a mixture of local anesthetic and betamethasone. The study period lasted from January 1998 to December 2000, providing 3 years of management and follow-up.

The evaluation included data collection as to the variables of age, gender, duration of pain in months, nature of onset, height, weight, and history of previous surgical interventions; the number of injections received by each patient in each group; the quality and duration of pain relief; overall health status in pre- and post-treatment phases; psychological status in pre- and post-treatment phases; narcotic intake in pre- and post-treatment periods; and employment and work status in pre- and post-treatment periods. The quality of pain relief was characterized as less

than 50% relief, or greater than 50% relief. Pain relief greater than 50% was considered significant, and these patients were characterized as successful, with "significant pain relief."

All procedures were performed by one physician in an ambulatory surgery setting, either in a sterile operating room or a treatment room. All caudal epidural injections were performed under fluoroscopy, with patients in the prone position, under appropriate monitoring with intravenous (IV) access and sedation with midazolam and fentanyl. With sterile preparation, access to the epidural space was obtained and then confirmed by injection of nonionic contrast. Following this, based on each patient's contrast flow and distribution, 10 mL to 20 mL mixture was injected. Group II received a mixture of local anesthetic with lidocaine hydrochloride (Xylocaine®) and Sarapin, whereas Group III received local anesthetic and 6 mg of betamethasone.

Following the blocks, the patients were discharged home. Upon a return visit, each patient was evaluated for amount of relief of pain on the basis of a numeric and verbal pain-rating scale, perceived physical health by the patient and physician, perceived mental health by the physician and patient, and perceived functional status by the patient and physician. Patients were also evaluated at each visit as to narcotic intake. All features were evaluated at each visit by a treating physician and at the end of treatment by a physician not involved in treatment, and the data were tabulated. Any potential complications were also evaluated at each visit.

Demographic features of age, mode of onset of pain, work status, history of surgery, and other historical features were obtained from the patient history and recorded. The patient's age was calculated from his/her birth date, whereas duration of pain was calculated based on the patient's memory of the onset of pain to the closest month, when available. Pain characteristics were obtained from the history, comprehensive pain questionnaire, and pain diagram. Pain rating was obtained from a 10-point numeric and verbal pain-rating scale. Average pain, physical health, mental health, and functional status were determined from multiple sources, including patient description of the pain; and patient perception of physical health, mental health and functional status; as well as objective evaluations performed with psychological evaluation and range-of-motion evaluation and ability to function and carry on important activities the patient was unable to perform prior to the intervention. Psychological status was determined by a psychological questionnaire, as well as psychological evaluation utilizing Millon Clinical Multiaxial Inventory (MCMI-II) and Beck's Depression Inventory. Major depression, generalized anxiety disorder, and somatization disorder were determined from these tests. Symptom magnification was determined utilizing a set of signs and symptoms that included multiple items: strategy to control symptoms, control over environment, overt pain behavior, pain rating, pain diagram, nonphysiologic symptoms and signs, presence or absence of objective signs, laboratory evidence, coefficient of variation with functional testing, cooperation with evaluation and presence or absence of somatization as determined by MCMI-II. Narcotic intake was determined as none, mild, moderate, and heavy based on the dosage, frequency and class of drug. Intake of class IV narcotics, ie, propoxyphene napsylate (Darvocet®), pentazocine hydrochloride (Talwin®), on tramadol hydrochloride (Ultram®), up to a maximum of four times, or hydrocodone twice or less per day, was considered as mild; intake of class III narcotics, ie hydrocodone, up to four times, as moderate; and intake of class II narcotics, (ie, oxycodone, morphine, meperidine, transdermal fentanyl, and methadone) in any dosage was considered as heavy. Employment and work status classified as employed, unemployed, housewife, disabled, and retired were also determined from the pretreatment and post-treatment work status. Only employed and unemployed patients were considered to be eligible for employment, whereas disabled patients and patients over 65 were considered not employable; however, data were tabulated if any of these patients returned to work. The data were evaluated and confirmed by one of the two physicians who were not performing the blocks and treating the patients.

Data were recorded on a database using Microsoft® Access®; the SPSS Version 9.0 statistical package was used to generate frequency tables, and the chi-squared statistic was used to test the significant difference between groups. Fisher's Exact Test was used wherever expected value was less than five. Student's t-test was used to test mean difference between groups. Results were considered statistically significant if the *P*-value was less than 0.05.

RESULTS

Patient Characteristics

Demographic data are shown in Table 1, with no significant differences noted between groups in terms of age, weight, height, mode of onset of pain, duration of pain, and history of previous surgical intervention. However,

Table 1. *Patient Characteristics*

		Group I	Group II	Group III
Number of patients		**N= 16**	**N=22**	**N=33**
Gender	Men	69% (11)	45% (10)	27% (9)
	Women	31% (5)	55% (12)	73%* (24)
Age (yrs.)	Range	32 - 77	31 - 83	27 - 87
	Mean + SEM	48.8 + 3.63	49.1 + 3.38	48.3 + 2.85
Weight (lbs.)	Range	127 - 280	121 - 276	106 - 300
	Mean + SEM	181 + 11.1	188 + 9.7	169 + 8.0
Height (inches)	Range	61 - 74	51 - 72	59 - 73
	Mean + SEM	68.4 + 0.84	66.2 + 0.97	65.6 + 0.64
Body Mass Index		27.1 + 1.44	30.3 + 1.59	27.7 + 1.3
Mode of onset of pain	Following an incident	43% (7)	54% (12)	48% (16)
	Gradual onset	57% (9)	46% (10)	52% (17)
Duration of pain (years)	Range	0.5 - 25	0.5 - 25	0.5 - 20
	Mean + SEM	8.8 + 1.81	7.8 + 1.67	5.9 + 0.85
Postsurgical		19% (3)	36% (8)	30% (11)

Group I = Control Group II = Caudal with Sarapin Group III - Caudal with steroids SEM = Standard error of mean * Indicates significant difference between groups

Table 2. *Details of multiple procedures*

	Group II		Group III		Total (Groups II and III)	
Multiple procedures	Number	%	Number	%	Number	%
One	22	100%	33	100%	55	100%
Two	22	100%	33	100%	55	100%
Three	20	91%	30	91%	50	91%
Four	19	86%	28	85%	47	85%
Five	17	77%	25	76%	42	76%
Six	17	77%	21	64%	38	69%
Seven	15	68%	18	55%	33	60%
Eight	12	55%	16	48%	28	51%
Nine	9	41%	12	36%	21	38%
Ten	7	32%	9	27%	16	29%
Eleven	6	27%	1	3%	7	13%
Twelve	4	18%	1	3%	5	9%

Table 3. *Comparison of number of interventions at various levels of study period*

	Group II	Group III	Total (Groups II and III)
3 months	3.1 + 0.18 (21)	3.1 + 0.14 (31)	3.1 + 0.11 (52)
6 months	4.5 + 0.26 (19)	4.5 + 0.18 (29)	4.5 + 0.15 (48)
1 year	6.4 + 0.36 (18)	6.3 + 0.30 (23)	6.4 + 0.23 (41)
2 years	8.7 + 0.78 (15)	9.5 + 0.42 (13)	9.1 + 0.46 (28)

the ratio of women in Group III was higher than in Group I and Group II.

Injection Characteristics

Table 2 illustrates the details of patients undergoing multiple procedures over a period of 3 years. Sixty percent of the patients underwent seven procedures, which was reduced to 51% for eight procedures, 29% for ten procedures, and 9% for 12 procedures.

As shown in Table 3, the mean number of interventions was from 3.1 + 0.11 at 3 months, whereas it was 4.5 + 0.15 at 6 months, 6.4 + 0.23 at 12 months, and 9.1 + 0.46 at 2 years. There were no significant differences noted between the groups with multiple procedures, or mean episodes of medial branch blocks.

Table 4 shows the proportion of patients who continued in the study, at various intervals during a 3-year period. Patients who failed to respond at various levels were provided with other treatments, with or without interventional procedures.

Pain Relief

Table 5 shows significant relief with each injection. There was no significant difference noted among groups with any injection throughout the course of treatment with 1 to 12 injections. Relief ranged from 0 to 104 weeks, with mean relief ranging from 3.1 + 0.33 weeks to 14.6 + 1.71 weeks. Average relief for all patients and all injections was 9.7 + 0.48 weeks.

Fig. 1 illustrates cumulative relief (>50%) with one to three injections; 96% of the patients experienced relief lasting 1 month, which declined to 56% at 3 months, and to 16% at 6 months. Fig. 2 illustrates cumulative relief with 1 to 12 injections, which also declined with time.

Overall Health Status

Table 6 shows significant overall improvement in health status, with improvement in both treatment groups; whereas the control group failed to show any difference.

Psychological Status

Psychological status evaluation (Table 7) showed no significant differences between treatment periods, pre- and post-treatment in Group I. However, significant improvement was seen in treatment groups, specifically with somatization, and symptom magnification aspects.

Table 4. *Illustration of proportion of patients in the study at various times during the study period*

Study period	Group I (16)	Group II (22)	Group III (33)
Initial	100% (16)	100% (22)	100% (33)
3 months	100% (16)	96% (21)	94% (31)
6 months	88% (14)	86% (19)	88% (29)
1 year	81% (13)	82% (18)	70% (23)
2 years	37% (6)	68% (15)	42% (14)

Table 5. *Comparison significant relief (>50%) with each injection by group in weeks*

Injection Number	Group II		Group III		Total (Groups II and III)	
	Mean + SEM	Range	Mean + SEM	Range	Mean + SEM	Range
One	3.1 + 0.51 (22)	0 - 9	3.1 +0.44 (33)	0 - 9	3.1 + 0.33 (55)	0-9
Two	9.7 + 4.52 (22)	0 - 104	5.8 + 0.82 (33)	0 - 26	7.4 + 1.87 (55)	0-104
Three	7.9 + 0.85 (20)	4 - 21	7.7 + 0.78 (30)	3 - 26	7.7 + 0.57 (50)	3 - 26
Four	12.2 + 3.57 (19)	4 - 76	9.0 + 0.82 (28)	2 - 26	10.3 + 1.52 (47)	2-76
Five	10.4 + 0.71 (17)	4 - 17	16.4* + 4.07 (25)	0 - 102	14.0 + 2.46 (42)	0-102
Six	9.9 + 1.00 (17)	1 - 17	10.9 + 0.95 (21)	4 - 26	10.5 + 0.69 (38)	1 - 2
Seven	12.5 + 0.77 (15)	9 - 17	13.3 + 2.45 (18)	0 - 52	12.9 + 1.36 (33)	0-52
Eight	13.7 + 0.96 (12)	9 - 21	11.3 + 0.89 (16)	3 - 17	12.3 + 0.68 (28)	3-21
Nine	11.8 + 1.22 (9)	2 - 13	13.0 + 0.70 (12)	9 - 17	12.5 + 0.65 (21)	2-17
Ten	16.1 + 3.85 (7)	9 - 39	13.4 + 0.80 (9)	9 - 17	14.6 + 1.71 (16)	9-39
Eleven	13.0 + 1.03 (6)	9 - 17	6.0 + 0.0 (1)	6 - 6	12.0 + 1.33 (7)	6-17
Twelve	14.0 + 1.00 (4)	13 - 17	9.0 + 0.0 (1)	9 - 9	13.0 + 1.26 (5)	9-17
Average	10.1 + 0.78	0 - 104	9.4 + 0.59	0 - 102	9.7 + 0.48	0 - 104

SEM = Standard error of mean * Indicates significant different between groups

Narcotic Intake

Table 8 illustrates narcotic intake and changes in three groups. Treatment groups showed reduction in narcotic intake, with heavy intake. Fig. 3 illustrates changes in narcotic intake in 3 groups, showing no narcotic intake and heavy intake.

Employment Status

Employment or work status is shown in Table 9. Patients who were employed and unemployed were considered as candidates for future employment or continued employment. Housewives, disabled patients, and patients over 65 who were retired were considered not eligible for future employment. A total of 13 patients, 5 from group II and 8 from group III, became employed during the treatment period and continued to be employed at the end of the treatment period. The increase in employment and reduction in unemployment were significant in the treatment groups. Fig. 4 illustrates comparison of employment status prior to and following the treatment.

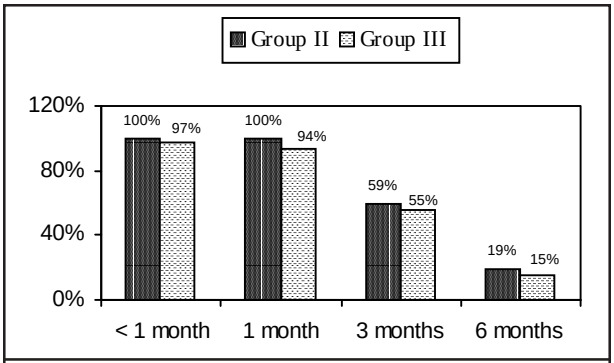

Fig. 1. Illustration of cumulative relief (50%) with one to three injections

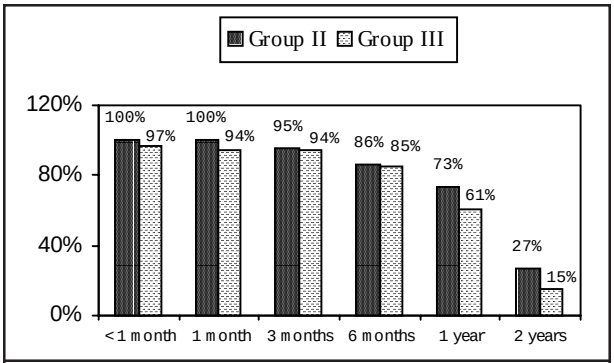

Fig. 2. Illustration of cumulative relief (50%) with 1 to 12 injections

Table 6. *Comparison of overall health status pre- and post-treatment*

	Group I		Group II		Group III	
	Pre	Post	Pre	Post	Pre	Post
Average pain	7.0 + 0.22	6.2 + 0.50	7.6 + 0.23	3.3* + 0.16	7.9 + 0.21	3.9* + 0.25
Physical health	5.7 + 0.35	5.8 + 0.31	4.9 + 0.24	7.0* + 0.18	4.9 + 0.20	6.4* + 0.21
Mental health	5.6 + 0.16	5.2 + 0.28	4.6 + 0.21	7.0* + 0.20	4.9 + 0.24	6.3* + 0.24
Functional status	4.4 + 0.26	4.6 + 0.34	3.5 + 0.13	5.6* + 0.16	5.0 + 0.15	5.2* + 0.17

* Indicates significant difference between pre- and post-treatment values

Cost Effectiveness

Cost effectiveness was analyzed, as shown in Table 10, for both treatment groups. The total cost was calculated for all procedures, including complications, in all patients. The number of weeks with significant relief was calculated as 1719, with a mean relief of 10.1 + 0.78 weeks per procedure for Group II, 2127 weeks, with a mean relief of 9.4 + 0.59 weeks per procedure for Group III; and 3846 weeks, with a mean relief of 9.7 + 0.48 weeks per procedure for both groups combined. Total expenditures were calculated from net collections, or the patient's expenses for the outpatient surgical center and physician fees as incurred by the insurer and/or the patient. The total cost per procedure was $487, $341, and $475 for Groups II and III and a combination of Groups II and III, respectively. Further calculations showed that significant pain relief was provided with a cost-per-1-week improvement of quality of life in Group II of $48, in Group III of $50, and of $49 for both groups combined. Calculation of these cost figures with conversion to a 1-year improvement of quality of life showed a cost of $2505 for Group II, $2586 for Group III, and $2550 when combined for all patients, with no significant difference noted between groups. However, this cost-effectiveness analysis did not take into consideration the patients' return to work and various other benefits; nor did the cost-benefit ratio consider the money spent outside therapy for drugs or other types of treatments. In addition, the cost of the diagnostic blocks was also not included in this analysis.

Complications

None of the various types of complications, including infection, rash, reaction to drugs, epidural or subarachnoid blockade, postlumbar puncture headache, and/or weight gain, were observed in any patients.

DISCUSSION

The effects of caudal epidural steroid injections were first reported by Goebert and colleagues (31). They administered three injections of procaine and hydrocortisone into the epidural space to 239 patients with sciatica and reported greater than 60% relief of symptoms in 58% of the patients. Since that time, the technique and indications of epidural steroid injections have been changing constantly. Numerous reviews have appeared in the literature evalu-

Table 7. *Psychological status of the patients pre- and post-treatment in three groups*

	Group I		Group II		Group III	
	Pre	Post	Pre	Post	Pre	Post
Depression	50% (8)	56% (9)	82% (18)	73% (16)	85% (28)	70% (23)
Generalized anxiety disorder	63% (10)	56% (7)	82% (18)	73% (16)	82% (27)	73% (24)
Somatization disorder	50% (8)	50% (8)	41% (9)	9%* (2)	73% (24)	33%* (11)
Symptom magnification	50% (8)	50% (8)	41% (9)	9%* (2)	51% (17)	27%* (9)

* Indicates significant difference between pre- and post-treatment values

Table 8. *Comparison of narcotic intake in pre- and post-treatment periods*

	Group I		Group II		Group III	
	Pre	Post	Pre	Post	Pre	Post
None	6% (1)	0%	0%	14% (3)	12% (4)	15% (2)
Mild	19% (3)	19% (3)	9% (2)	27% (6)	6% (2)	30% (10)
Moderate	56% (9)	44% (7)	41% (9)	55% (12)	21% (7)	39% (13)
Heavy	19% (3)	37% (6)	50% (11)	4%* (1)	61% (20)	15%* (5)

* Indicates significant difference between pre- and post-treatment values

ating the effectiveness of epidural steroid injections. The first systematic review of the effectiveness of epidural steroid injections was by Kepes and Duncalf in 1985 (14). They concluded that the rationale for epidural systemic steroids was not proven. However, in 1986 Benzon (15), utilizing the same studies, concluded that mechanical causes of low back pain, especially those accompanied by signs of nerve root irritation, may respond to epidural steroid injections. Bogduk et al (11) in an extensive review concluded that the balance of the published evidence supports the therapeutic use of caudal epidurals. Koes et al (9) in 1995 reviewed 12 trials of lumbar and caudal epidural steroid injections, with 5 studies involving caudal epidural steroid injections, of which 4 were positive. Watts and Silagy (12) in 1995, after a meta-analysis of the available data on epidural steroid injections, concluded that caudal and interlaminar epidural steroids were equally effective. Manchikanti et al (1), concluded that caudal epidural steroids met the criteria for moderate-to-strong evidence. Similar conclusions were drawn by McQuay and Moore (19). Extensive literature available on caudal epidural injections includes seven randomized trials (32-38), four prospective trials (39-42) and numerous uncontrolled reports (1, 7, 11, 31, 43-45). However, none of the controlled studies and only a small number of uncontrolled or observational reports were performed under fluoroscopy by interventional pain specialists. Of seven randomized trials, six were positive. In addition, multiple prospective and retrospective evaluations also provided favorable results consistent with randomized trials. Thus, it appears that caudal epidural steroid injections are an effective modality of treatment in managing chronic low back pain.

In this study, both groups of patients, with Sarapin or steroids, showed significant improvement in all parameters. Significant differences were noted between the control group and the treatment groups. Further, this study also showed that caudal epidural injections are cost-effective compared to numerous other modalities of treatments in managing low back pain.

Corticosteroids have been used since 1952 in the management of chronic low back pain by injecting them into the epidural space (1, 11). The rationale for steroid usage in neural blockade is primarily based on the benefits of neural blockade, including the pain relief which outlasts by

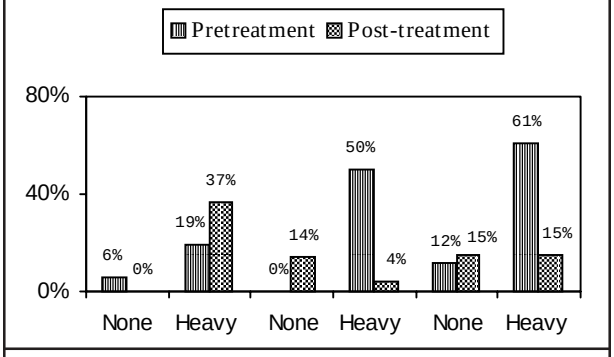

Fig. 3. Comparison of narcotic intake pre- and post-treatment

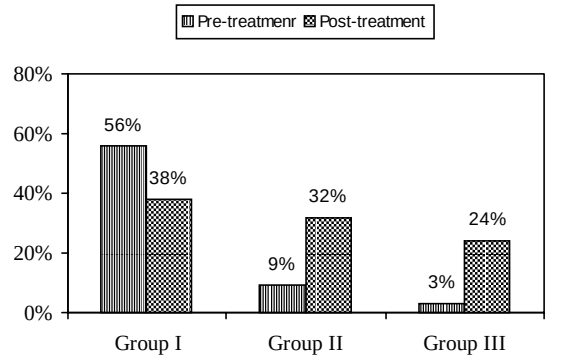

Fig. 4. Change in employment status

Table 9. *Employment status of the patients pre- and post-treatment in three groups*

	Group I		Group II		Group III	
	Pre	Post	Pre	Post	Pre	Post
Employed	56% (9)	38% (6)	9% (2)	32% (7)	3% (1)	24%* (8)
Unemployed	19% (3)	31% (5)	18% (4)	0%	10% (3)	6% (2)
Housewife	6% (1)	6% (1)	5% (1)	5% (1)	0% (0)	0%
Disabled	6% (1)	13% (2)	41% (9)	36% (8)	46% (15)	49% (16)
Over > 65(retired)	13% (2)	13% (2)	27% (6)	27% (6)	21% (7)	21% (7)

* Indicates significant difference between pre- and post-treatment values

hours, days, and sometimes weeks, the transient pharmacologic action of other adjuvant agents such as local anesthetics and others. While there are no clear-cut explanations for these benefits available currently, it is believed that neural blockade alters or interrupts nociceptive input, reflex mechanism of the afferent limb, self-sustaining activity of the neuron pools and neuraxis, and the pattern of central neuronal activities (46). Corticosteroids reduce inflammation either by inhibiting the synthesis or release of a number of pro-inflammatory substances (1). Various modes of action of corticosteroids include membrane stabilization; inhibition of neural peptide synthesis or action;

Table 10. *Analysis of cost-effectiveness of epidural injections*

	Group II	Group III	Total
Number of patients	22	33	55
Total number of procedures	170	227	397
Number of treatments per patient (mean + SEM)	7.7 + 0.70	6.9 + 0.5	7.2 + 0.41
Visits with significant relief (>50%)	98%	98%	98%
Number of weeks with significant relief for all patients in the study in weeks	1719	2127	3846
Significant relief in weeks per procedure (mean + SEM)	10.1 + 0.78	9.4 + 0.59	9.7 + 0.48
Total Cost ($)			
Physician	23,128	28,318	51,446
Facility	59,684	77,441	137,125
Total	82,812	105,759	188,571
Cost per procedure ($)			
Physician	136	125	130
Facility	351	341	345
Total	487	466	475
Cost for 1-week improvement of quality of life ($)	48	50	49
Cost for 1-year improvement of quality of life ($)	2,505	2,586	2550

SEM = Standard error of mean

blockade of phospholipase A_2 activity; prolonged suppression of ongoing neuronal discharge; suppression of sensitization of dorsal horn neurons; and reversible local anesthetic affect (1). The scientific basis of some of these concepts, at least in part, is proven for spinal pain management with epidural injections of betamethasone, and IV methylprednisolone (47-52).

Sarapin is a suspension of powdered S*arracenia purpurin* (pitcher plant) in alkaline solution. The value of Sarapin in relieving pain of neurologic origin was reported by Bates and Judovich in 1931 (53, 54). However, clinical investigations of this unique product for epidural administration are lacking. Sarapin has been reported to cause no motor weakness following injection of the peripheral nerve; it also does not cause or affect loss of touch, pressure, pinprick, or temperature sensibility and has an excellent risk/benefit ratio. Controlled studies with procaine, saline, and water show prolonged duration of effect in favor of the pitcher-plant preparation (54). The basis of the pitcher plant derivative, or Sarapin, was explained by experiments performed on the action potentials of the saphenous nerve of the cat, which showed that the C-fiber potential was completely obliterated by pitcher-plant extract after immersion in the solution for about 5 minutes. Researchers theorize that the distillate contained an unidentified biological substance that potentiates the action of the ammonium ion. Modest but significant benefits were demonstrated with diagnostic blocks utilizing Sarapin, which provided not only diagnostic validity, but also therapeutic value (28). Significant therapeutic effect was seen with Sarapin when utilized in medial branch blocks, which was similar to the relief seen with a mixture of Sarapin and methylprednisolone (29). However, the lack of local anesthetic efficacy of Sarapin was demonstrated in the horse (55). Harkins et al (55) demonstrated that Sarapin has no significant classic or local anesthetic actions in the horse, and probably not in other species either. However, this finding is not surprising as Sarapin has been demonstrated to relieve pain of neurologic origin, but not by local anesthetic action.

This study was prospective, even though it was not blinded. Issues of ethics, feasibility, cost, and reliability pose challenges to a double-blind trial in interventional pain medicine. Concato et al (56) found that well-designed observational studies do not systematically overestimate the magnitude of effects of treatments as compared with those in randomized, controlled trials on the same topic. In addition, Schulz et al (57) also postulated that lack of randomization overestimates the treatment effects by 41%, whereas lack of blinding overestimates the treatment effect only by 17%.

The cost effectiveness analysis may be criticized for various reasons. However, the outcome measures used in cost-effectiveness analysis studies in chronic pain research mainly include outcomes, such as disability days saved; pain free days; or improved quality of life, etc. (58). Evaluation of the quality of life, which is also known as functional status, includes health status, or health related quality of life; well-being of the patient; satisfaction with care and health service utilization/economic analysis, and medical findings (59). The quality of life assessment is designed to evaluate the patient's ability to function in his/her own world. Physical function measures the ability to perform physical activities such as walking, climbing stairs or carrying things. The costs of an inpatient chronic pain program range from $17,000 to $25,000. The costs of outpatient treatment programs range from $7,000 to $10,000 in 1989 dollars, without consideration of inflation; and chronic pain patients may incur health-care bills in excess of $20,000 annually for repetitive and, in some cases, redundant diagnostic workups, physical therapy, psychological interventions, and drugs (60). Guo et al (61) estimated that back pain accounted for 150 million lost workdays in the United States every year, which worked out to be about $14 billion in wage costs alone. They also postulated that the magnitude of the back pain problem is so large that even a 1% reduction in overall prevalence could considerably reduce morbidity and save billions of dollars.

The cost effectiveness of lumbar discectomy for the treatment of herniated intervertebral discs has been based on the conclusion that surgery increases the average quality-adjusted life expectancy by 0.43 years during the decade following treatment; compared to conservative treatment, a result comparable to extending a healthy life by 5 months (62). Malter et al (62) also concluded that, for carefully selected patients with herniated discs, surgical discectomy is a cost-effective treatment at a discounted cost of $12,000 per discectomy, or $29,000 per life year adjusted for quality. Kuntz et al (63) studied the cost effectiveness of fusion with and without instrumentation for patients with degenerative spondylolisthesis and spinal stenosis. They showed that laminectomy with a noninstrumented fusion costs $56,500 per quality-adjusted year of life versus laminectomy without fusion. The cost-effectiveness ratio of instrumented fusion compared with noninstrumented fusion was $3,112,800 per quality-adjusted year of life. However, they also stated that, if the proportion of patients experiencing symptom relief after instrumented fu-

sion was 90%, as compared with 80% for patients with noninstrumented fusion, then the cost-effectiveness ratio of instrumented fusion compared with noninstrumented fusion would be $82,400 per quality-adjusted year of life. Mueller-Schwefe et al (64), in evaluating the cost-effectiveness of intrathecal therapy for pain secondary to failed back surgery syndrome, compared alternative therapies for achieving a defined outcome, reporting the cost of medical management to be $17,037 per year or $1,420 per month. They also showed that intrathecal morphine delivery resulted in lower cumulative 60-month costs of $16,579 per year, and $1,382 per month.

The cost-effectiveness evaluation for blind interlaminar, fluoroscopically directed caudal or transforaminal epidural injections for the management of low back pain showed the cost effectiveness of caudal epidural steroids to be $3,635 and that of transforaminal steroids to be $2,927 per year, with a stark contrast with blind interlaminar lumbar epidural steroid injections at $6,024 per year (45). Similarly, the cost effectiveness of percutaneous nonendoscopic adhesiolysis and hypertonic saline neurolysis was demonstrated to be variable, from $2028 to $5564 for improvement of 1 year of quality of life for patients with chronic low back pain nonresponsive to numerous other modalities of treatment (65-67). The cost effectiveness of therapeutic medial branch blocks was shown as $3,461 for 1 year of quality of life improvement for patients with chronic low back pain nonresponsive to conservative modalities of treatments, and the diagnosis of lumbar facet joint pain was confirmed by controlled comparative local anesthetic blocks (29). Thus, cost effectiveness analysis of this evaluation with caudal epidural injections with $2550 for 1 year of improvement in the quality of life is similar to various investigations in the past with neural blockade but also significantly better than improvement with intrathecal morphine delivery, lumbar laminectomy, on lumbar laminectomy with or without instrumented fusion. In addition, interpretation of the current results should be placed in the context of not only other interventional procedures, but also surgery and other modalities of treatments. Therefore, caudal epidural injections with Sarapin or steroids for patients suffering with chronic low back pain with or without lower extremity pain have a cost-effectiveness ratio not only in the same approximate range as that of other well-accepted modalities of treatment in managing chronic low back pain, but, also well within reasonable limits for present-day cost-effective management of other medical conditions (29, 58-71).

CONCLUSION

Caudal epidural injections are an effective modality of treatment in managing chronic low back pain after exclusion of facet joint pain. Caudal epidural injections with or without steroid but with local anesthetic and Sarapin are effective in providing significant pain relief, improvement in functional status, improvement in overall psychological status, and return to work. Caudal epidural injections also have exerted modest but statistically insignificant effect on the patient's state of depression, anxiety, symptom magnification and somatization. It is concluded that caudal epidural injections with Sarapin or with steroid are an effective modality of treatment in managing chronic low back pain without facet joint involvement.

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