

Efficacy of Epidural Injections of Kenalog and Celestone in the Treatment of Lower Back Pain

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OBJECTIVE. Epidural corticosteroid injections have been used extensively to treat lower back pain, but the relative effectiveness of one corticosteroid versus another has never been reported in a large patient series. We retrospectively reviewed 597 patients who had epidural corticosteroid injections to determine any difference in Kenalog or Celestone efficacy.

MATERIALS AND METHODS. We reviewed charts and self-reported pain score evaluations of 597 patients who received either Kenalog or Celestone Soluspan as an epidural injection for the treatment of lower back pain from 1997 to 2002 at our university hospital and affiliated Veterans Affairs hospital. Kenalog was used for the initial 2 years and Celestone was used for the next 3 years. Fluoroscopic guidance was used to confirm epidural location, and each patient was injected with a mixture of 5 mL of 0.5% preservative-free lidocaine and 2 mL of either Kenalog 40 mg/mL (triamcinolone acetonide injectable suspension) or Celestone Soluspan 6 mg/mL (betamethasone sodium phosphate and betamethasone acetate injectable suspension). Each patient was given a standardized pain evaluation sheet that used an 11-point scale for initial pain severity. Scoring of pain compared with baseline during the following 14 days was based on a 5-point scale of pain improvement or worsening.

RESULTS. On days 0–3 after the procedure, no statistical significance in improvement of lower back and buttock pain was seen between groups. On day 7, 59% of Celestone recipients and 73% of Kenalog recipients showed improvement in lower back pain ($p = 0.002$, Pearson's chi-square test), and 58% of Celestone recipients and 75% of Kenalog recipients had improvement in leg or buttock pain ($p < 0.001$). On day 14, 54% of Celestone recipients and 71% of Kenalog recipients showed improvement in lower back pain ($p < 0.001$), and 54% of Celestone recipients and 71% of Kenalog recipients had improvement in leg or buttock pain ($p < 0.001$).

CONCLUSION. The epidural injection of Celestone Soluspan and Kenalog reduced lower back and radicular pain in more than half the patients, although Kenalog reduced pain in a significantly larger number of patients than Celestone Soluspan at 1 and 2 weeks after injection.

According to the American College of Radiology appropriateness criteria, lower back pain is one of the most common health problems in the United States and is the leading cause of disability for persons younger than 45 years [1]. The estimated cost of evaluation and treatment, not including time lost from work, runs into the billions of dollars annually. Epidural injections have long been used in an effort to treat lower back pain. Evans [2] was the first to describe treatment of sciatica by epidural injection in 1930. Treatment via epidural injection of corticosteroids was first described in 1952 [3] and first reported in the United States in 1961 [4]. Currently, epidural steroid injections are used by multiple disciplines for the treatment of

both acute and chronic lower back pain. Because of concerns of possible neurotoxicity from polyethylene glycol found in some preparations, Silbergleit et al. [5] use either triamcinolone acetonide or a combination betamethasone sodium phosphate and betamethasone acetate preparation. For the most part, the medications are used interchangeably by most practitioners. However, to our knowledge, no published study has compared the efficacy of these two agents.

Materials and Methods

We reviewed charts and self-reported pain score evaluations of 597 patients who received either Kenalog-40 (40 mg/mL of triamcinolone acetonide injectable suspension, Bristol-Myers Squibb, Princeton,

Received April 3, 2003; accepted after revision May 16, 2003.

Presented at the annual meeting of the American Roentgen Ray Society, San Diego, May 2003.

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AJR 2003;181:1255–1258

0361–803X/03/1815–1255

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NJ) or Celestone Soluspan (3 mg of betamethasone sodium phosphate and 3 mg of betamethasone acetate/mL injectable suspension, Schering, Kenilworth, NJ) as an epidural injection for the treatment of lower back pain from 1997 to 2002 at our university hospital and affiliated Veterans Affairs hospital. Kenalog-40 was used for the initial 2 years, and Celestone Soluspan was used for the next 3 years. At the time the study was undertaken, approval by an institutional review board was not required. No relationship, financial or otherwise, exists between the manufacturers of these two medications and any of the authors of this article or the University of Wisconsin Health Care System.

Under sterile technique, either a 25-gauge 3.5-inch (9-cm) or a 22-gauge 6-inch (15.25-cm) spinal needle was advanced into the lumbar posterior epidural space under fluoroscopic observation using an interlaminar approach. The location was achieved using an air-release technique and confirmed using a small amount of nonionic iodinated contrast material. In 15 patients, a translumbar (interlaminar) approach was not possible, so a caudal approach was used; these two techniques have been reported to have equal efficacy [6, 7]. Each patient was injected with a mixture of 5 mL of 0.5% preservative-free lidocaine and 2 mL of either Kenalog-40 or Celestone Soluspan.

Each patient was given a standardized pain evaluation sheet. Patients kept their own personal pain records for 14 days after the procedure and then either mailed or personally returned the standardized pain sheet to the spine clinic. Patients were asked to rank their initial pain using an 11-point scale (0 = no pain, 10 = maximum pain). Patients were then instructed to rank their pain compared with baseline at designated times during the next 14 days on the basis of pain improvement or worsening. With this system, patients were allowed to select postprocedural pain levels from a list of worse pain, same pain, little better pain, much better pain, and no pain, at each of the designated times: the evening of the procedure, 1 day after the procedure, 3 days after the procedure, 7 days after the procedure, and 14 days after the procedure. After 14 days, patients were also asked to

categorize the amount of pain medication needed as increased, decreased, or unchanged.

Results

During the study period, 597 epidural steroid injections were performed on 446 patients. Three hundred twenty patients received single injections and 126 patients received multiple injections. Of the 126 who received multiple injections, 22 patients received both Kenalog-40 and Celestone Soluspan on different occasions. Each injection was considered a single occurrence. The time between injections varied, ranging from 0.5 to 36 months (mean, 4.9 months; median, 3 months).

There were 278 injections of Celestone Soluspan and 319 injections of Kenalog-40. Two hundred forty-eight of the 278 patients who received Celestone Soluspan and 289 of the 319 patients who received Kenalog-40 ranked their average baseline lower back pain and buttock pain (Table 1). The differences in mean lower back pain were statistically significant ($p = 0.002$) using the Student's *t* test, whereas those for buttock pain were not. In an attempt to adjust for potential confounding factors, we present analyses of pain change, which are both adjusted and unadjusted for baseline lower back pain.

On the days after the procedure, the average scores for lower back pain and buttock pain were tabulated for each group. The percentages of patients who relayed improvement in their lower back pain are summarized in Table 2, and the results for buttock pain are summarized in Table 3. The unadjusted *p* value is based on Pearson's chi-square test for differences in the percentage of patients showing improvement on the two medications. The covariate adjusted analysis is based on the linear regression of the raw pain change scores with treatment and baseline lower back pain.

On day 3 after the procedure, 64% of patients who received Celestone Soluspan and 72% of patients who received Kenalog-40 showed improvement in their lower back pain. This is statistically significant only after adjusting for baseline lower back pain (unadjusted $p = 0.15$, adjusted $p = 0.01$).

On day 7 after the procedure, 59% of patients who received Celestone Soluspan and 73% of patients who received Kenalog-40 showed improvement in their lower back pain, which is statistically significant (unadjusted $p = 0.002$, adjusted $p < 0.001$). At that same time, 58% of patients who received Celestone Soluspan and 75% of patients who received Kenalog-40 had improvement of their buttock pain. This also is statistically significant (unadjusted $p < 0.001$, adjusted $p < 0.001$).

On day 14 after the procedure, 54% of patients who received Celestone Soluspan and 71% of patients who received Kenalog-40 showed improvement of their lower back pain. This is statistically significant (unadjusted $p < 0.001$, adjusted $p < 0.001$). At that time, 54% of patients who received Celestone Soluspan and 71% of patients who received Kenalog-40 showed improvement in their buttock pain (unadjusted $p < 0.001$, adjusted $p < 0.001$).

To illustrate the changes from the evening of the procedure until day 14, we tabulated the differences in self-reported symptom relief. Forty percent of patients who received Kenalog-40 showed improvement in back pain from the evening of the procedure through day 14, whereas only 29% of the patients who received Celestone Soluspan reported similar relief ($p = 0.005$). Similarly, 39% of patients who received Kenalog-40 and 25% of patients who received Celestone Soluspan showed improvement of self-reported buttock pain ($p < 0.001$).

TABLE 1 Baseline Scores for Back Pain of 289 Patients Who Received Kenalog-40 and 248 Patients Who Received Celestone Soluspan

Medication	Initial Lower Back Pain	Initial Buttock Pain
Kenalog-40 ^a	5.67 (0.17)	6.44 (0.16)
Celestone Soluspan ^b	6.59 (0.25)	6.57 (0.17)
<i>p</i>	0.002	0.58

Note.—Numbers in parentheses are SDs.

^aTriamcinolone acetonide injectable suspension, Bristol-Myers Squibb, Princeton, NJ.

^bBetamethasone sodium phosphate and betamethasone acetate injectable suspension, Schering, Kenilworth, NJ.

TABLE 2 Percentage of Patients Who Reported Improvement in Lower Back Pain at Specified Intervals

Medication	Evening After Procedure	Day 1	Day 3	Day 7	Day 14
Kenalog-40 ^a	54	71	72	73	71
Celestone Soluspan ^b	59	73	64	59	54
Unadjusted <i>p</i>	0.78	0.66	0.15	0.002	< 0.001
Adjusted <i>p</i>	0.54	0.97	0.01	< 0.001	< 0.001

Note.—*p* values are result of Fisher's exact test and covariate analysis.

^aTriamcinolone acetonide injectable suspension, Bristol-Myers Squibb, Princeton, NJ.

^bBetamethasone sodium phosphate and betamethasone acetate injectable suspension, Schering, Kenilworth, NJ.

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TABLE 3 Percentage of Patients Who Reported Improvement in Buttock Pain at Specified Intervals					
Medication	Evening After Procedure	Day 1	Day 3	Day 7	Day 14
Kenalog-40 ^a	55	71	71	75	71
Celestone Soluspan ^b	58	62	65	58	54
Unadjusted <i>p</i>	0.81	0.4	0.62	< 0.001	< 0.001
Adjusted <i>p</i>	0.19	0.51	0.27	< 0.001	< 0.001

Note.— *p* values are result of Fisher's exact test and covariate analysis.

^aTriamcinolone acetonide injectable suspension, Bristol-Myers Squibb, Princeton, NJ.

^bBetamethasone sodium phosphate and betamethasone acetate injectable suspension, Schering, Kenilworth, NJ.

In a further attempt to illustrate pain reduction, patients were asked on day 14 after the procedure if they were using more, less, or the same amount of analgesic medication when compared with before the procedure. Nineteen percent of patients who received Celestone Soluspan and 27% of patients who received Kenalog-40 relayed that less pain medication was needed. This comparison is suggestive ($p = 0.055$, Pearson's chi-square test) but not significant at the cutoff value for p of 0.05.

Discussion

Epidural corticosteroid injections have long been used by multiple disciplines in the treatment of lower back pain. Although many corticosteroids are used, concern exists that polyethylene glycol, a component of some depot preparations, may cause neurotoxicity [8]. For this reason, recommendations have been made to use either Kenalog-40 or Celestone Soluspan for epidural injections [5]. Although both drugs are widely used, little research has been performed comparing them. In fact, the epidural injection of these two medications has not formally been approved by the Food and Drug Administration; however, injection is widely accepted as an "off-label" route of administration. The question of efficacy has recently become an even greater concern because of the recent national shortage of Celestone preparations that has forced many institutions to either stop performing procedures or seek alternative medications.

Perhaps little is reported because no established basis exists for a comparison. Over the years, most radiology groups have agreed that 80 mg of Kenalog-40 is equivalent to 12 mg of Celestone Soluspan when administered in an epidural location. For this reason, these doses were administered during our study. However, to our knowledge no formal study or research proves that therapeutic levels achieved with

each reagent are equivalent when the medication is placed in the epidural space.

The goal of epidural steroid injection is not to cure anatomic abnormalities but rather to reduce pain [9], which allows patients to engage in rehabilitation and to return to a more normal lifestyle [10]. Because pain improvement is the goal, our results clearly indicate that Kenalog-40 is superior to Celestone Soluspan when placed epidurally. A greater percentage of Kenalog-40 patients (72%) than Celestone Soluspan recipients (64%) showed improvement in lower back pain on day 3 after the procedure when adjusting for baseline lower back pain. This difference is not significant in the unadjusted analysis. The improved efficacy is clearly apparent 7 and 14 days after the procedure, when a much higher percentage of patients who received Kenalog-40 had improvement in both their lower back pain and radicular symptoms. The results of both the unadjusted and adjusted analyses were statistically significant ($p < 0.001$). The patients who received Kenalog-40 also had a higher incidence of pain medication reduction ($p = 0.055$).

The difference in efficacy may be related to chemical structure. Although both reagents are categorized as salts, in our anecdotal experience Kenalog-40 is more difficult to dissolve in solution than Celestone Soluspan. The latter contains both betamethasone sodium phosphate and betamethasone acetate; betamethasone sodium phosphate is reported to be more water-soluble and is thought to have a more rapid onset, whereas betamethasone acetate is less water-soluble and thought to have more of a depot effect [11]. In our clinical experience, Kenalog-40 is much less water-soluble than Celestone Soluspan. At times, this factor has made Kenalog more difficult to work with because we have had needles become clogged with Kenalog-40 crystals during administration. Furthermore, several spine surgeons at

our institution have relayed finding crystals in the epidural space during surgery after patients received epidural injections of Kenalog-40. However, these crystalline deposits may act as a better reservoir than Celestone Soluspan, thus, explaining the prolonged efficacy of Kenalog-40.

Additional factors we considered when interpreting our data include the following: First, when baseline lower back pain was evaluated, a statistical difference existed between the two groups. Kenalog-40 recipients had an average baseline score of 5.67, whereas Celestone Soluspan recipients had an average baseline of 6.59. It could be argued that because the Kenalog-40 recipients had a statistically significant lower baseline of disease, the observed pain improvement simply reflected selection bias. However, probably no real biophysical difference exists between a reported score of 6 or one of 7 with regard to morbidity rates. Even after adjusting for this factor, the treatment differences were still significant.

Second, our study included patients who received multiple injections and even a few patients who received both of the corticosteroid preparations at one time or another. Although we know of no published data, anecdotal reports indicate that patients have better improvement with repeated injections. However, only a few patients were in this category, and the number of patients in each of the crossover groups was similar. Because of the small numbers, the multiple injections should not have a major impact on the basic conclusion of our analysis.

Third, our study did not take into account multilevel disease or duration of pain before the procedure. This information was not available in our retrospective study. We believe that a prospective analysis is the next logical step to further analyze these findings. We are performing a prospective analysis in an attempt to stratify for multiple factors; these include (but are not limited to) level of disease, duration of symptoms, and MRI correlation for suspected cause of symptoms.

In conclusion, epidural injections of Kenalog-40 and Celestone Soluspan clearly improve patients' symptoms of back pain. Epidural injections of Kenalog-40 appear to provide longer relief of symptoms and may even lower patient needs for analgesic medications when compared with Celestone Soluspan. Our study shows a definite advantage to epidural injections of corticosteroids in the appropriate patient population. At present, many

institutions do not have a choice as to which agents are used because of the national shortage of some corticosteroids. However, when a choice is available, Kenalog-40 appears to be more efficacious than Celestone Soluspan when administered epidurally.

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