Revista Mexicana de Anestesiología

ORIGINAL RESEARCH
Vol. 32. No. 1 January-March 2009
pp 19-25

Assessment of epidural steroids in the treatment of low back pain

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Received for publication: 06-02-08
Accepted for publication: 14-03-08

SUMMARY

Introduction: In Mexico it has been identified that dorsopathies are among the principal causes of family medical consultation in the IMSS (Medical Institute for the Social Security). Several therapeutic approaches have been proposed; however, 10% of the cases do not respond to the conventional treatment. Therefore, the interventionist approaches may be useful in the treatment of this kind of pain. **Objective:** To evaluate the analgesic effect of steroids through epidural route to treat patients suffering from low back pain. **Material and methods:** An ambispective and descriptive study on patients suffering from lumbalgia. In a retrospective way, it was identified the patients that received steroids through epidural route. In a prospective way, it was selected the patients that had been diagnosed lumbalgia, establishing two randomized groups (A Group: 80 mg of epidural methylprednisolone and B Group: 6 mg of epidural betamethasone). It was recorded: (i) pain intensity through the Visual Analogue Scale (VAS); (ii) Oswestry function scale; and (iii) satisfaction grade at three different moments (before, one week after, and two weeks after of operation). **Results:** In a retrospective way, 50 patients were analyzed. Two sub-groups of 25 patients each were identified (A sub-group: 80 mg of epidural methylprednisolone and B sub-group: 6 mg of epidural betamethasone). In a prospective way, two groups of 8 patients each were analyzed. In the comparative analysis, the studied steroids did not present any differences in the three studied variables. **Conclusions:** Seemingly, both steroids present a similar analgesic effect. However, further studies are required in order to confirm this tendency.

Key words: Lumbalgia, chronic pain, methylprednisolone, betamethasone, epidural.

RESUMEN

Introducción: *En México se ha identificado que las dorsopatías se encuentran entre los principales motivos de consulta médica familiar en el IMSS. Se han propuesto múltiples abordajes terapéuticos; sin embargo, un 10% de los casos, no responde al tratamiento convencional. Por ello, los abordajes intervencionistas pueden ser útiles en el manejo de este tipo de dolor.* ***Objetivo:*** *Evaluar el efecto analgésico de los esteroides por vía epidural en enfermos con dolor de espalda baja.* ***Material y métodos:*** *Estudio ambispectivo y descriptivo en pacientes con lumbalgia. En forma retrospectiva, se identificó a pacientes que recibieron esteroides por vía epidural. En forma prospectiva, se seleccionó a pacientes con diagnóstico de lumbalgia, aleatorizando dos grupos (Grupo A: 80 mg de metilprednisolona epidural y Grupo B: 6 mg de betametasona epidural). Se documentó en tres momentos (antes, una semana y dos semanas después de la intervención): (i) la intensidad del dolor mediante la escala visual análoga (EVA), (ii) escala de funcionalidad de Oswestry, y (iii) grado de satisfacción.* ***Resultados:*** *Retrospectivamente, se analizó a 50 pa-*

cientes. Se identificaron dos subgrupos de 25 pacientes cada uno (subgrupo A: 80 mg de metilprednisolona epidural y subgrupo B: 6 mg de betametasona epidural). Prospectivamente, se analizaron dos grupos de 8 pacientes cada uno. En el análisis comparativo, los esteroides estudiados no presentaron diferencias significativas; sin embargo, individualmente se presentaron diferencias en las tres variables estudiadas. ***Conclusiones:*** *Al parecer ambos esteroides presentan una analgesia similar. Sin embargo, se requieren nuevos estudios de este tipo para confirmar esta tendencia.*

Palabras clave: *Lumbalgia, dolor crónico, metilprednisolona, betametasona, epidural.*

INTRODUCTION

Low back pain is a global health problem. It has been estimated that it affects more than 70% of the population of developed countries. Similarly, it has been found that people aged 35 to 55 are most affected[1,2].

In our country we have no epidemiological documentation about the frequency of this condition in the general population. However, according to figures from the National Health Information System (SINAIS, by its Spanish acronym), nearly 2.3% of the causes of hospitalization were a source of low back pain during 2005. These include: (i) ill-defined and musculoskeletal diseases; (ii) spondylopathies and dorsopathies; (iii) degenerative joint disease; and (iv) rheumatoid arthritis[3].

Moreover, during that year the Mexican Social Security Institute reported that dorsopathies were positioned among the top ten reasons for consultation in family medicine units, with about 1.4 million consultations[4]. Thus, these indirect data reflect the importance of this health problem in the Mexican population.

Methodology in epidemiological reports has several problems about low back pain, one main problem is the fact that regardless of treatment, about 90% of cases are resolved spontaneously over a period of six weeks. However, despite this symptomatic recovery, it has been documented that the remaining cases will develop chronic pain[1,2].

This situation deeply affects health systems worldwide, due to the high cost of treatment and its impact on the functionality of the individual. It has been estimated that the United Kingdom incurred annually from 11 to 20.6 billion USD by this cause[5] and that this condition contributes to 13% of work absenteeism in that country[6].

The diversity of diseases that cause backache and the multiple functional and anatomical structures involved in its genesis are the main reason why this disorder has a wide variety of treatments.

Among the various therapeutic approaches for pain relief in this anatomic region are: (i) pharmacological therapy (non-steroidal antiinflammatory drugs (NSAIDs), acetaminophen, muscle relaxants, opioids, corticosteroids, antidepressants); (ii) non-pharmacological therapy (physical measures, activity modification, exercise, heat therapy, multidisciplinary rehabilitation, other physical modalities); (iii) psychological therapy (psychosocial treatments, behavioral therapies, educational interventions); and (iv) interventional therapy (neurostimulation techniques, elective invasive treatments, epidural administration of steroids, etc.)[2,6,7].

Because a proportion of patients do not respond satisfactorily to conventional management, different treatment approaches have been evaluated including, but not limited to, the epidural steroid administration. This technique has shown controversial results, but recently it has been documented that its use provides favorable results in the short, medium and long term[8].

In this sense, it has been proposed that its efficacy is possibly due to its inhibitory action on phospholipase A2, interfering locally on irritative or inflammatory response of the nerve roots (radicular nerves) [9]. Therefore, it has been documented that epidural administration is indicated for patients with: (i) sciatic pain; (ii) lower back pain; (iii); radicular pain; (iv) radiculopathy secondary to nerve root compression; (v) pain due to lumbar disc herniation; (vi) pain due to post laminectomy syndrome; and (vii) pain in narrow lumbar canal[9,10].

Based on this set of considerations, we decided to evaluate the analgesic effect of deposit steroids (methylprednisone and betamethasone) epidurally in patients with low back pain.

MATERIAL AND METHODS

Overview

Following the Mexican regulations for health research[12], the ethical standards for human experimentation[13,14] and with previous approval from Local Ethics Committee, ambispective study was conducted in patients with low back pain to evaluate the analgesic effect of deposit steroids administrated by epidural route.

Retrospective Stage

We identified those patients receiving steroids by epidural route (80 mg methylprednisolone, or 6 mg betamethasone) during the period from 01st November 2005 to 30th November 2006 for management of low back pain (LBP). Subsequently, we selected those patients with complete records, regardless of gender and age, diagnosed with low back pain, without psychiatric disorders, without oncological disease, and without criteria of terminal illness.

The following information was recollected: (i) age, (ii) gender, (iii) intensity of pain using a 10 cm visual analogue scale (VAS) (0 cm represents no pain and 10 cm the worst imaginable pain), and (iv) used steroid. Regarding intensity of pain, VAS was documented before and after conducting the procedure.

Prospective Stage

A group of patients with complete records, regardless of gender and age, diagnosed with low back pain, without psychiatric disorders, without oncological disease, and without criteria of terminal illness was selected. Those patients who reported pain intensity as mild or VAS < 4, and/or a history of known allergy to the study drugs were eliminated. All study individuals were informed about the procedure to be performed, their doubts and questions were resolved, their voluntary participation were requested, and they provided freely their informed consent.

After performing the above mentioned, the following treatments were discontinued: (i) analgesic drugs (opioids and non-opioid), (ii) adjuvants for the treatment of pain (anticonvulsants, antidepressants, steroids, etc.), and (iii) alternative and/or complementary medicine. The withdrawal of these drugs was conducted one week before the epidural steroid administration, and continued for two weeks after it. During this period, "rescues" were allowed in case of severe pain in intensity, with 500 mg paracetamol, which should not exceed 2 grams per day.

We removed from study those patients who: (i) failed to comply with the washout period; (ii) did not wish to participate or have been removed from the study; (iii) manifested severe and unbearable pain; (iv) required opioid analgesia; (v) died; (vi) underwent to some type of surgical procedure; (vii) reported pregnancy or lactation; (viii) have had advertent dural puncture during the procedure; and/or (ix) have had criteria for post-dural puncture headache. Patients eligible for analysis were distributed randomly into two groups. Group A, which received 80 mg methylprednisolone by epidural route, and group B, which received 6 mg betamethasone by epidural route.

Type I monitoring was carried out for performing the procedure, the patient was placed in lateral decubitus position with genuflection. Asepsis and antisepsis were performed in the lumbosacral region using povidone by placing sterile fields. Equipment for epidural anesthesia with 16-gauge Tuohy needle and polyamide catheter was used (Perifix®, Braun LTD, Mexico).

The needle insertion site was anesthetized with 1 mL of 2% simple lidocaine administered at dermoepidermis. The Tuohy needle was introduced by technique described by Pages[15,16], and epidural compartment was identified by the Dogliotti's technique. Subsequently, the polyamide catheter was inserted through the needle by introducing 1 centimeter of catheter inside the epidural space. Depending on the group, Methylprednisolone (Depo-Medrol®, Pfizer, Mexico) or betamethasone (Celestone®, Schering-Plough, Mexico) diluted to volume with 0.9% saline solution to give 10 mL were administrated through catheter. Once the above was completed, the catheter and needle were removed, hemostasis with manual compression was performed, the patient was placed in the dorsal recumbent position, and the procedure was completed.

Gender and age were documented in both groups. Additionally, the following was registered: (i) *pain intensity by VAS*; (ii) the function by the *Oswestry Disability Index* or ODI (where 0% represents no dysfunction, and 100% represents total disability; and classifying in minimal, moderate, and severe dysfunction, and disability)[17,18]; and (iii) the *percentage of satisfaction* (0 represents the absence of satisfaction and 100 represents the greatest possible satisfaction). This information was collected on three occasions: (i) 30 minutes before performing the procedure, (ii) one week after performing the procedure, and (iii) two weeks after surgery.

Statistical Analysis

Descriptive statistics was performed on the studied variables, identifying the measures of central tendency and dispersion. A Student's t test was carried out for parametric variables, and a chi-squared (χ^2) test was conducted for non-parametric variables. p values ≤ 0.05 were considered significant. The results were analyzed using a statistical program for personal computers compatible with Windows™ (SPSS v. 10.0 for Windows®, SPSS, Inc.; Chicago, Illinois, EUA).

RESULTS

Retrospective Assessment

We analyzed 25 patients receiving 80 mg methylprednisolone by epidural route (Group A) and 25 patients receiving

6 mg betamethasone by epidural route (Group B). It was found that women had a higher frequency (Group A, 20 women vs. 5 men; Group B, 21 women vs. 4 men) in both groups. These differences were statistically significant (Group A, p = 0.000; Group B , p = 0.000). Similarly, it was observed that the overall average age was 65 years (SD: 12).

As shown in Table I, compared with group B, patients who received methylprednisolone (Group A) showed: (i) significantly higher age; (ii) a significantly lower pain intensity before the procedure; (iii) absence of significant differences concerning the pain intensity after the procedure; and (iv) decrease in the significantly lower pain intensity. However, by individually assessing each drug, a significant decrease in pain intensity in both groups was observed (Table II).

Prospective Assessment

We analyzed 8 patients receiving 80 mg methylprednisolone by epidural route (Group A) and 8 patients receiving 6 mg betamethasone by epidural route (Group B). It was noted that the overall average age was 58 years (SD 9). There were 4 men and 4 women in both groups, no significant differences by gender were observed. As shown in Table III, when performing a comparison between the two groups, they did not differ significantly in relation to: (i) age, (ii) pain intensity of the three measurements, and (iii) the overall decrease in the pain intensity. However, by individually assessing each drug, a significant decrease in pain intensity in both groups was observed (Table IV).

With regard to functionality, a comparative assessment showed no significant differences (Table V). However, by individually assessing each drug, a significant decrease from ODI was observed (Table VI). In comparative assessment, the proportion of satisfaction also showed no significant differences (Table V); in individual assessment of these drugs, the proportion of satisfaction showed statistically significant differences (Table VI).

DISCUSSION

Epidural steroid use as an treatment option is an alternative for various conditions such as sciatic pain, low back pain, radicular pain and radiculopathy or compression of lumbar nerves, herniated lumbar discs, lumbosciatic syndrome, post-laminectomy syndrome, and narrow lumbar canal. The irritation or inflammation of nerve roots (radicular nerves) may be the common mechanism of these disorders on which the epidural injection of corticosteroids exerts its effect[19,20].

Table I. Comparative analysis of retrospective assessment on administration of steroids into the epidural space.

	Group A (n = 25)		Group B (n = 25)		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
Age (years)	68	12	61	11	7	0.01
Initial intensity (VAS)	6	1	7	1	(-) 0.8	0.01
Final intensity (VAS)	3	1	3	1	0.08	0.8
Difference between Initial and final intensity	3	1	4	1	(-) 0.9	0.002

Abbreviations: Group A, 80 mg of metylprednisolone by epidural route. Group B, 6 mg of betamethasone by epidural route. SD, standar deviation. VAS, visual analog scale.

Table II. Pain intensity in retrospective assessment on administration of steroids into the epidural space.

	Pain intensity (VAS)					
	Before the procedure		After the procedure		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
Group A (n = 25)	6	1	3	1	2.6	0.000
Group B (n = 25)	7	1	3	1	3.6	0.000

Abbreviations: Group A, 80 mg of metylprednisolone by epidural route. Group B, 6 mg of betamethasone by epidural route. SD, standar deviation. VAS, visual analog scale.

Table III. Comparative analysis of prospective assessment on administration of steroids into the epidural space.

	Group A (n = 8)		Group B (n = 8)		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
Age (years)	61	5	56	12	4.12	0.39
Initial intensity (VAS)	7.5	1.2	7	1.5	0.5	0.27
1st week intensity (VAS)	4.7	1.5	4.6	2	0.1	0.87
2nd week intensity (VAS)	3.6	0.9	2.7	1.4	0.9	0.13
Difference between initial and the 2nd week intensity	3.8	0.6	4.2	1.5	(-) 0.3	0.44

Abbreviations: Group A, 80 mg of metylprednisolone by epidural route. Group B, 6 mg of betamethasone by epidural route. SD, standar deviation. VAS, visual analog scale.

Table IV. Pain intensity in prospective assessment on administration of steroids into the epidural space.

	Pain intensity (VAS)					
	Before the procedure		Two weeks later		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
Group A (n = 8)	7.5	1.2	3.6	0.9	3.8	0.000
Group B (n = 8)	7	1.5	2.7	1.4	4.2	0.000

Abbreviations: Group A, 80 mg of metylprednisolone by epidural route. Group B, 6 mg of betamethasone by epidural route. SD, standar deviation. VAS, visual analog scale.

Table V. Comparative analysis of prospective assessment with respect to functionality and satisfaction.

	Group A (n = 8)		Group B (n = 8)		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
ODI Before the procedure	56.2	5.8	47.5	19.1	8.7	0.17
ODI 1st week	37	9.9	42.5	18.2	(-) 5.2	0.42
ODI 2nd week	29.5	6.2	27.2	10.4	2.2	0.3
Difference of ODI before precedure and the 2nd week	20.7	6.2	20.2	11.2	6.5	0.16
Satisfaction after procedure (%)	65	11.9	62.5	27.6	2.5	0.76
Satisfaction 1st week(%)	77.5	11.6	63.6	21.3	13.5	0.06
Satisfaction 2nd week(%)	82.5	8.8	69.3	23.3	13.1	0.12
Difference in satisfaction after procedure and the 2nd week (%)	17.5	8.8	6.8	21.8	10.6	0.1

Abbreviations: Group A, 80 mg of metylprednisolone by epidural route. Group B, 6 mg of betamethasone by epidural route. SD, standar deviation. ODI, Oswestry disability index.

In this study, retrospective analysis shows that both drugs reduce significantly pain. However, compared with the betamethasone group, the methylprednisolone group has lower analgesia, thus demonstrating that both drugs are effective. These results are similar to those reported in several studies evaluating independently these drugs[8,10,11,19,20].

Neuraxially-administered steroids produce pain relief, their mechanisms seem to be related to the decreased inflammatory edema of the harmed root nerve, thus improv-

Table VI. Functionality and satisfaction in prospective assessment on administration of steroids into the epidural space.

	ODI					
	Before the procedure		Two weeks later		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
Group A (n = 8)	56.2	5.8	29.5	6.2	26.7	0.000
Group B (n = 8)	47.5	19.1	27.2	10.4	20.25	0.001
	Satisfaction (%)					
	Before the procedure		Two weeks later		Mean	P value
	Mean	SD	Mean	SD	difference	(Paired sudent's t)
Group A (n = 8)	65	11.9	82.5	8.8	26.7	0.000
Group B (n = 8)	62.5	27.6	69.3	23.3	20.2	0.001

Abbreviations: Group A, 80 mg of metylprednisolone by epidural route. Group B, 6 mg of betamethasone by epidural route. SD, standar deviation. ODI, Oswestry disability index.

ing the microcirculation. This results in the recovery of ischemia. On the other hand, steroids inhibit phospholipase A2 and thereby directly inhibit neuronal excitation[21,22]. Johansson et al (1990) proposed that steroids suppress the transmission of normal nociceptive C-fibers by direct action on the membrane in an experimental model[21].

On the other hand, in the prospective analysis it was observed that both drugs reduce significantly pain; notwithstanding the above, comparative assessment does not show statistically significant differences with respect to analgesia. Similarly, the ODI decreased significantly by assessing individually each of the drugs, but no significant differences were observed in comparative assessment, thus demonstrating the effectiveness of steroids in the management of low back pain. Likewise, the proportion of satisfaction was increased in meeting increased significantly in the individual assessment of these drugs; however, no significant differences were found in the comparative assessment.

This makes us suppose that both drugs provide analgesia, improve functionality and increase patients' satisfaction. However, no differences are observed between the two drugs, it is therefore proposed that they are equally effective in relieving lower back pain. These results seem consistent with those reported by other authors regarding both drugs independently [8,10,11,19,20].

Low back pain is a common problem in our environment, its treatment is costly and currently there are no guidelines that govern our therapeutic behavior. It is therefore necessary to generate lines of research with respect to the attention of such pain and generate practical parameters that enable streamlined and optimal management of these patients.

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