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Intrathecal Drug Delivery System in Chronic Low Back Pain: Case Series

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Background: Modern science says that persistent low back pain is the main cause of years lived in disability. Among pain management approaches, we highlight the intrathecal drug delivery system (IDDS). The aim of this observational study was to assess pain intensity in a series of cases of patients with chronic low back pain using IDDS.

Case Series: This is a series of cases with 14 patients affected by chronic degenerative spinal disease using IDDS. Regarding age, an average of 81.57 (SD ± 7.44) was obtained, in addition, everybody reported being retired, having at least completed high school, with failure of conservative treatment, and none were smokers.

Conclusion: Patients with chronic degenerative spine disease responded successfully to the IDDS treatment, obtaining pain relief in 100% of patients through the Numeric Rating Scale, which enabled a moderate quality of life on average and mild/moderate disability in most of the sample.

Key words: Drug delivery systems, indicators of quality of life, low back pain

BACKGROUND

Chronic pain is a condition that causes suffering, anguish, and disability, requiring special treatment and care (1,2). Modern science says that prolonged nonspecific low back pain is considered the main contributor to years lived with disability (2,3). In Brazil, it is suggested that approximately 76% of the population lives with recurrent chronic or long duration low back pain, the most affected are people who are over 65 years old, and the prevalence is higher in women (4).

Among pain management approaches, the intrathecal drug delivery system (IDDS) stands out, which consists of the use of an implantable infusion pump and a specific catheter. The technique has been used since 1980 in the treatment of chronic pain (5). This modality administers a small amount of analgesic medication into the intrathecal space in order to provide pain relief by direct infusion of the drug into the cerebrospinal fluid. It is indicated as a viable treatment option when conservative, noninvasive and minimally invasive measures do not achieve the expected result (5,6).

This fact justifies the need for studies on the use of IDDS in patients with chronic nonmalignant pain, who have failed other treatment modalities. The aim of this observational study was to evaluate changes in pain level in a series of cases of patients with chronic noncancer low back pain using the IDDS. Furthermore, to verifying the quality of life and the level of disability of the studied sample.

METHODS

This study comprises a series of cases with 14 patients who have chronic pain of nononcological origin, with chronic degenerative spinal disease using IDDS. This is a descriptive, retrospective and prospective observational study, approved by the Ethics and Research Committee of Universidade Tiradentes (ERC/UNIT) with opinion

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number 46249021.8.0000.5371. Those who agreed to participate in the study signed the informed consent form and the methodological procedures are in accordance with Resolution CNS nº 466/12. Retrospective data were collected from the responsible institution's electronic medical record and comprised information about pain intensity, clinical evaluation, current and past treatment. Prospective data were obtained through the application of 4 instruments: a form developed by the authors to collect current clinical information, current pain level by the Numeric Rating Scale (NRS), WHOQOL-bref quality of life questionnaire, and The Pain Disability Questionnaire (PDQ).

In all patients, a test was performed with a temporary intrathecal epidural catheter between 3 and 7 days and the procedure was performed by an interprofessional team composed of a pain interventional anesthesiologist, an orthopedic surgeon specializing in spine, and a neurosurgeon. To perform the IDDS procedure, the patient submitted to general anesthesia and a percutaneous puncture was performed with an epidural needle from the device kit, subsequently implanted with a programmable Medtronic Synchromed II pump (Medtronic Corp, Minneapolis, MN, USA). The intrathecal catheter was implanted under fluoroscopic guidance and anchored in the L3–L5 interspace. The filling of the medications that were placed inside the pump were morphine + heavy neocaine.

The pump was placed in a subcutaneous pocket in the lower abdominal region, with closure in layers: using 2.0 vicryl for muscle layers, 3.0 nylon for pump anchorage, and 3.0 monocryl for skin. Twelve hours after the placement of the IDDS, the oral opioid was suspended, as this is the period for the medication to reach the intrathecal space. To measure the amount of the dosage, the conversion of the oral dosage to the intrathecal one was performaed, in which the ratio 100 to 1 was used. The bolus was not programmed, for this reason the rescue dosage was orally oriented.

The patients were discharged after 24 hours and in the first post-procedure visit to the doctor (7 days), all patients were referred for multidisciplinary follow-up with a nutritionist, physiotherapist, and psychologist. In addition to the 7-day visit, all patients were seen by the physician 15 and 30 days after the operation to assess healing, dosage modulation, as necessary, and clarifying any questions.

Pain was assessed using the NRS, measured using scores ranging from 0 to 10 points, which was used before and after the procedure to assess the patients' pain intensity. Pain scores were interpreted as: 0 = no pain; 1–3 = mild pain; 4–6 = moderate pain and 7–10 = severe pain (7).

To verify the quality of life, the WHOQOL-bref test was used. The version composed of 4 domains: physical, psychological, social relations, and environment, containing 26 questions (8). The PDQ was applied with the aim of measuring the disability generated by pain. It consists of 15 items that assess the interference of pain in certain activities. Total scores are classified as follows: 0: no disability; 1-70: mild/moderate disability; 71-100: severe disability and 101-150: extreme disability (9).

The application of the instruments presented was carried out between September and October 2021. Patients were invited to respond to the sessions and form at the time they attended the review appointment with the physician in charge. As a way of maintaining a standard and guaranteeing the same application conditions for all patients, the reading of the instruments was always conducted by the same researcher, at a single moment.

Statistical Analysis

The collected data were tabulated, numerically and/or textually, in the Excel program. After being analyzed, with the aim of knowing and describing the behavior of the variables, the quantitative and qualitative data were expressed on tables, presented through the absolute and relative frequencies (Fi, Fr, and Fr%), of the measures of central tendency (mean, median, and mode), and measures of dispersion (variance, standard deviation, and coefficient of variance) whenever appropriate.

RESULT

There were 14 patients with chronic nonmalignant pain who had failed multiple lines of conservative and invasive treatment. Case data are presented individually in Table 1. Regarding age, an average of 81.57 (SD ±7.44) was obtained, in addition, everybody reported being retired, having at least completed high school, with failure of conservative treatment and none were smokers. Half of the sample (50%) reported sleep disorders, and in relation to the practice of physical exercise, 5 patients (35.7%) did not exercise, 7 (50%) practiced less than 150 min/week or 30 min 5x/week, and 2 (14.2%) practiced 150 min/week or 30 min 5x/week. One patient used the device for less than 6 months, 2 for more than 6 months and less than a year, and 11 were using the IDDS for more than 2 years.

Table 1. Summary of clinical information of the 14 patients.

Cases	Gender	Age	Family income	Practice of Exercise	Mental Heath	Obesity	Use of analgesic
1	M	89	R$ 2.090,01 a 4.180,00	Practice	No	Regular weight	No use
2	F	91	10.450,01 a 20.900,00	Practice	Anxiety	Overweight	No use
3	F	72	R$ 2.090,01 a 4.180,00	No practice	Anxiety	Overweight	No use
4	F	64	10.450,01 a 20.900,00	Practice	Depression	Overweight	Rarely
5	F	85	R$ 4.180,01 a 10.450,00	Practice	Anxiety	Overweight	No use
6	F	74	R$ 2.090,01 a 4.180,00	No practice	Anxiety	Regular weight	Rarely
7	F	81	10.450,01 a 20.900,00	No practice	Depression	Regular weight	Rarely
8	F	82	R$ 4.180,01 a 10.450,00	Practice	No	Regular weight	Rarely
9	F	80	R$ 4.180,01 a 10.450,00	No practice	Anxiety	Regular weight	Daily
10	F	87	R$ 4.180,01 a 10.450,00	Practice	No	Overweight	Monthly
11	F	83	R$ 4.180,01 a 10.450,00	Practice	No	Overweight	Daily
12	F	81	10.450,01 a 20.900,00	Practice	Depression	Obesity level 1	Weekly
13	F	90	R$ 2.090,01 a 4.180,00	Practice	Depression	Overweight	Daily
14	F	83	Até R$ 2.090,00	No practice	Depression	Overweight	Daily

Male (M); female (F).

Regarding the side effects found in the sample, in the first 15 days after implantation, it was reported that 6 patients (42.8%) had nausea, one (7.1%) urinary retention, one (7.1%) vomiting, one (7.1%) 1%) confusion, 3 (21.4%) constipation, 3 (21.4%) pruritus, and 3 (42.8%) had no side effects. The same patient could have one or more side effects.

Table 2. Pain before and after the implantation of the intrathecal pump

	μ	Md	V	DP±	CV%
NRS before	9,57	10	0,262	0,509	5,32%
NRS after	2,71	4	6,212	2,492	91,95%

NRS,Numeric rating scale; μ, arithmetic mean; Md, mode; V= variance; SD, standard deviation; CV%, coefficient of variance.

NRS

Before IDDS implantation, 14 patients (100%) had severe pain, being 6 with pain 7 (42.8%) and 8 with pain 10 (57.14%). After insertion of the device, 7 patients (50%) started to have moderate pain, one (7.1%) reported mild pain, and 6 (42.8%) said they did not feel pain (Table 2). Information on pain reduction in each patient and time of device use can be seen in Table 3.

The minimum clinically important difference was considered with a 50% improvement in pain. Out of the 14 patients (100%), 11 (78.54%) had a pain reduction equal to or greater than 50% (Table 3).

WHOQOL-bref

The WHOQOL-bref quality of life assessment was performed after the procedure and on the dates of device usage referenced in Table 3. For this adopted instrument, the closer the final result is to 100, it is considered a better quality of life. Thus, in general, the quality of life was considered moderate among the patients. The mean value of the total score was 63.26 (SD ± 7.56). The physical and social domains were the ones with the lowest mean values – 46.17 (SD ± 8.89) and 47.62 (SD ± 8.58), respectively. The highest mean values were found in the psychological and environmental domains – 73.21 (SD ± 12.66) and 76.34 (SD ± 12.43), respectively.

PDQ

The evaluation of the disability caused by pain was performed after the procedure and on the dates of use of the device referenced in Table 3. Regarding the functional capacity, an average of 39.28 (SD ± 13.9) was verified, whereas the average of psychosocial condition was 19.64 (SD ± 8.87), and the total mean of counseling was 50.64 (SD ± 19.31). Following the classification, 10 patients (71.45%) had mild/moderate disability and 4 (28.5%) had severe disability.

DISCUSSION

The method of application and administration of the IDDS in this study sought to be based on the recommendations of the Polyanalgesic Consensus Conference (10). We verified a decrease in pain through NRS with the implantation of the IDDS in 100% of the patients

Table 3. Pain before and after implantation of the intrathecal pump seen individually and time of device use.

	NRS pre-implant	NRS post-implant	Pain reduction	Device usage time
Participant 1	9	5	44%	7 years and 8 months
Participant 2	10	3	70%	4 years and 6 months
Participant 3	10	5	50%	2 years and 9 months
Participant 4	10	0	100%	3 months
Participant 5	9	5	44 %	3 years and 5 months
Participant 6	9	0	100%	2 years old
Participant 7	10	5	50%	10 months
Participant 8	10	0	100%	2 years and 6 months
Participant 9	9	0	100%	2 years and 6 months
Participant 10	9	5	44%	4 years old
Participant 11	9	0	100%	3 years 5 months
Participant 12	10	5	50%	2 years 4 months
Participant 13	10	0	100%	3 years old
Participant 14	10	5	50%	9 months

with noncancer low back pain, and of these, clinically important improvement was reported in 78.54% of the cases.

Corroborating the findings, Grider et al (11) verified in a prospective observational cohort study with 58 patients who had noncancer pain related to the spine, the application of the IDDS and evaluated pain by the visual analog scale (VAS) before and after the implant, pain was significantly different at 6, 12, 24, and 36 months (11). Similarly, Hayek, Veizi, and Hanes (12) found a significant improvement in pain, through peripheral nerve stimulation (PNS), in patients with low back pain and who used IDDS at 6, 12, and 24 months when compared with preimplantation. However, there were no significant differences in NRS scores between follow-up dates at 6, 12, or 24 months post-implantation (12).

Grider et al (13) evaluated 22 patients by VAS. Before opioid tapering, pain scores were reported as an average of 7.3 ± 1.9. At follow-up, one week after implantation, the VAS was reported as 3.1 ± 2.4. At 12 months, VAS increased, but not significantly, to 3.9 ± 2.6. After the 12-month period, there was no significant change, the average VAS was 3.76 ± 1.9, with a follow-up interval of 12-44 months. The dose was titrated every 12 hours until pain relief was achieved, or therapy-limiting side effects were identified, with the lowest dosage at which efficacy was found to be 50 µg/d of intrathecal morphine with an average dosage of approximately 140 µg/d (13). The patients in this series of cases underwent a measurement of the dosage amount, converting the oral dosage by 100x less to the intrathecal dose.

Regarding quality of life, Health Quality Ontario (14) in a systematic review, found no significant difference in quality of life and well-being in patients with IDDS compared to patients who received only oral opioids or a rehabilitation program. In the case reports presented in this study, quality of life was considered moderate after IDDS implementation, but without comparing scores before implementation.

CONCLUSION

Patients with chronic degenerative spinal disease responded successfully to the IDDS treatment by obtaining pain relief through PNS, which enabled, on average, a moderate quality of life in most of the sample. In terms of disability, most of the sample was classified as mild/moderate. Further investigations should be carried out regarding IDDS as a treatment option for similar cases that do not respond to conservative treatment.

REFERENCES

1. Mills SEE, Nicolson KP, Smith BH. Chronic pain: A review of its epidemiology and associated factors in population-based studies. *Br J Anaesth* 2019; 123:e273-e283.
2. Treede RD, Rief W, Barke A, et al. Chronic pain as a symptom or a disease: The IASP Classification of Chronic Pain for the International Classification of Diseases (ICD-11). *Pain* 2019; 160:19-27.
3. Oliveira CB, Maher CG, Pinto RZ, et al. Clinical practice guidelines for the management of non-specific low back pain in primary care: An updated overview. *Eur Spine J* 2018; 27:2791-2803.
4. de Carvalho RC, Maglioni CB, Machado GB, de Araújo JE, da Silva JRT, da Silva ML. Prevalence and characteristics of chronic pain in Brazil: A national internet-based survey study. *Br J Pain* 2018; 1:331-338.
5. Fitzgibbon DR, Stephens LS, Posner KL, et al. Injury and liability associated with implantable devices for chronic pain. *Anesthesiology* 2016; 124:1384-1393.

6. Duarte RV, Lambe T, Raphael JH, Eldabe S, Andronis L. Intrathecal drug delivery systems for the management of chronic noncancer pain: A systematic review of economic evaluations. *Pain Pract* 2018; 18:666-686.
7. Williamson A, Hoggart B. Pain: A review of three commonly used pain rating scales. *J Clin Nurs* 2005; 14:798-804.
8. THE WHOQOL GROUP. Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychol Med* 1998; 28:551-558.
9. Denteneer L, van Daele U, Truijen S, et al. The modified low back pain disability questionnaire. *Spine (Phila Pa 1976)* 2018; 43:E292-E298.
10. Deer TR, Pope JE, Hayek SM, et al. The Polyanalgesic Consensus Conference (PACC): Recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation* 2017; 20:96-132.
11. Grider JS, Etscheidt MA, Harned ME, et al. Trialing and maintenance dosing using a low-dose intrathecal opioid method for chronic nonmalignant pain: A prospective 36-month study. *Neuromodulation: Technology at the Neural Interface* 2016; 19:206-219.
12. Hayek SM, Veizi E, Hanes M. Intrathecal hydromorphone and bupivacaine combination therapy for post-laminectomy syndrome optimized with patient-activated bolus device. *Pain Med* 2016; 17:561-571.
13. Grider JS, Harned ME, Etscheidt MA. Patient selection and outcomes using a low-dose intrathecal opioid trialing method for chronic nonmalignant pain. *Pain Physician* 2011; 14:343-351.
14. Health Quality Ontario. Intrathecal drug delivery systems for noncancer pain: A health technology assessment. *Ont Health Technol Assess Ser* 2016; 16:1-77.