

LUMBOSAKRAL SİYATALJİ İÇİN TEK VE ÇOKLU DOZ KAUDAL EPİDURAL STEROİD ENJEKSİYONLARININ KARŞILAŞTIRILMASI

COMPARISON OF THE SINGLE AND THE MULTIPLE DOSE CAUDAL EPIDURAL STEROID INJECTIONS FOR LUMBOSACRAL SCIATICA

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ÖZ

Giriş: Kaudal epidural steroid enjeksiyonları (KESE), tek veya çoklu seviye lomber diskopatilerin ve lomber spinal stenozun neden olduğu radikülopati tedavisinde yaygın olarak kullanılır. Çalışmamızda lumbosakral siyataljisi olan olgularda tek ve çoklu KESE'nin etkinliğini karşılaştırmayı amaçladık.

Gereç ve Yöntem: L4-5 ve/veya L5-S1 diskopatisi ve lomber radiküler ağrısı nedeniyle kliniğimizce KESE uygulanan 50 hasta retrospektif olarak incelendi. Tek enjeksiyon ve 10 günlük aralıklar ile 3 enjeksiyondan oluşan müdahalelerin sonuçları karşılaştırıldı. Ağrı yoğunluğunu belirlemek için bağımsız bir gözlemci tarafından hastaların işlem öncesi, işlem sonrası 1. ay, 3.ay, 6/ay ve 12/ayda not edilen Oswestry Ağrı Skalası (OAS) ve Visual Analog Skalası (VAS) sonuçları toplanarak analiz edildi.

Bulgular: Hastaların yaş ortalaması tek doz uygulanan grupta $57,9 \pm 12,8$ (34-79), çoklu doz uygulanan grupta ise $53,7 \pm 11,6$ (35-78) idi. 1,3,6,12. ay VAS ve OAS değerlendirmesi sonuçları 1,3 ve 12. ay değerleri arasında anlamlı farklılık bulunmadı. Ancak 6. Ay VAS değerlerinin tekli doz grubunda $3,8 \pm 2,1$, çoklu doz uygulanan grupta ise $4,9 \pm 2,3$ oranında azaldığı saptandı ve istatistiksel olarak anlamlı bulundu ($p = 0,034$).

Sonuç: Lumbar siyataljinin tedavisi halen zor ve sorunludur. Cerrahi tedavi güvenli ve etkilidir ancak fitik nüksü, enfeksiyon veya kök yaralanmaları gibi ciddi riskleri de beraberinde barındırır. KESE, lomber disk hastalığı nedeniyle lomber radikülopatisi olan hastalar için alternatif bir tedavi seçeneği olabilir. Tam olarak netlik kazanmamış olan tedavi protokoller, daha geniş hasta popülasyonları ile yapılacak olan ileri çalışmalarla belirlenebilir.

SUMMARY

Introduction: Caudal epidural steroid injections (CESI) are commonly used in the treatment of radiculopathies caused by single or multiple level discopathies and lumbar spinal stenosis. We aim to determine the efficacy and necessity of single and multiple CESI in patients with lumbosacral sciatica.

Material and Method: 50 patients with L4-5 and/or L5-S1 discopathy and lumbar radicular pain underwent CESI were retrospectively examined. The results of the intervention, consisting of one and three injections performed at 10 day-intervals are compared. Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) were utilized to compare the pain intensity at 4 time periods: 1 month, 3 months, 6 months, and 12 months after injection by an independent observer.

Results: Mean age was 57.9 ± 12.8 (34-79) for single, 53.7 ± 11.6 (35-78) for multiple CESI group. Results of 1, 3, 6, 12. month VAS and ODI evaluation showed that no differences at the 1., 3., and 12. months. Of note, 6th month VAS values were decreased by 3.8 ± 2.1 in the single dose group, 4.9 ± 2.3 in the multiple dose group. These results were found statistically significant ($p = 0.034$).

Conclusion: Treatment of the lumbar sciatica is problematic. Surgery in the interest area is safe and effective but it has higher risks and some complications such as infection, hernia recurrence or rootlet injury. Caudal epidural steroid injection may be an alternate option for the patients that have lumbar radiculopathy due to lumbar disc disease. Further studies with larger patient populations are required to define treatment modalities.

INTRODUCTION

Epidural steroid injections are common for lumbosacral sciatica treatment due to discopathies (1, 2). Conservative treatment is preferred in patients that with unspecified operative indications (1, 2). Several types of epidural steroid injections have been defined : including interlaminar, transforaminal and caudal (2, 3). Similar to the aforesaid procedures, CESI is a minimally invasive procedure which has the potential to provide relief for pain of the sciatica (3, 4).

These drugs include: corticosteroid and local anesthetic agents, and can help alleviate pain by reducing inflammation (1, 5). Results are generally satisfying to the patient if the injection is performed at the appropriate spinal level (1). Due to anatomical structures such as the meningovertebral ligaments special care must be taken to ensure that the injection does not diffuse to one side of the epidural space. As improper delivery of the agent reduces the effect of the treatment (1, 2). Paisley et al. reported 360° circumferential flow of injectate (6) with a 90% success rate with epidurogram analysis performed after interlaminar epidural injections of 10 patients. However Botwin et al. reported a 36% success with the same approach (7).

While CESI procedures are beneficial minimally invasive methods, some minor complications have been reported in literature (3, 4). These include: local bleeding, infection at the injection site, back pain, headache, increased blood glucose level. In addition, dural puncture, nerve

damage, osteoporosis, paraparesis, dizziness and fatigue are rare and serious complications (3, 4, 7).

MATERIAL AND METHOD

This single-center retrospective study was approved by the local ethics committee of University of Health Science, Tepecik Research and Training Hospital. We retrospectively evaluated patients who presented to the neurosurgery outpatient clinic of our tertiary university medical center between January 2013 and June 2018.

Study Characteristics

50 patients with persistent unilateral or bilateral lumbar radiculopathy who are not candidates for conservative modalities were identified.

Exclusion criteria included: disc herniation above L4/5, presence of extruded or sequestered lumbar disc herniation with motor deficits, cauda equina syndrome, history of allergy to any of the drugs injected or any associated chronic diseases (diabetes mellitus, ischaemic heart disease, hypertension, ankylosing spondylitis, rheumatoid arthritis etc.) as well as any reported history of prior pathology, infection or surgery involving the area of interest. Selected patients did not have occupations that required heavy lifting or other strenuous activity. Also, patients who treated with CESI for the persistent lumbar radiculopathy were included. All patients' discopathies and characteristics of the lumbar vertebra were confirmed with magnetic resonance imaging (MRI).

Injection Process

The procedures were performed by the same physician under the hemodynamic monitorization. The patients were positioned using a silicon pillow under their stomach to curve their back on the operation table. The skin of the injection related area was cleaned with povidone-iodine. Sacral horns were palpated and sacral hiatus was found in the midline, then, numbed with a local anesthetic (1% lidocaine). A 22-gauge needle was advanced through the caudal canal. After the confirmation, 40 mg of depomedrol, 1 mL bupivacaine 0.25%, 1 mL of 2% lidocaine and 7 mL of distilled water (total, 10 mL) were slowly injected from the sacral notch. Each patient was observed post-operatively for 3 hours prior to discharge.

Outcome measures

Visual analogue scale (VAS) scores and Oswestry Disability Index (ODI) values noted before the CESI procedure and at the 1., 3., 6., and 12. Months were collected. This study compared the clinical effectiveness of the CESI in two groups of which single and multiple injections were performed.

Statistical analysis

Mean, range, and SD were calculated for each of the patient data. In the statistical comparison, chi square tests were used for categorical data. The variable was investigated using Kolmogorov-Smirnov test to determine whether the statistics were normally distributed. Student T and Mann Whitney U tests were used for statistical comparison of data between independent groups as necessary. For statistical significance, p value <0.05 was considered to be significant in the 95% confidence interval. Statistical analyses were performed by using SPSS v21.0.

RESULTS

50 eligible patients were selected and evaluated for CESI with lumbosacral sciatica according to the VAS and ODI. Mean age was $57,9 \pm 12,8$ (34-79) in single, $53,7 \pm 11,6$ (35-78) in multiple CESI group. Female/Male ratio was 72%/28% in single

and 44%/56% in multiple CESI group. There was no statistically significant difference between the two groups in terms of gender ($p = 0,085$), age ($p = 0,234$) and preoperative VAS ($p = 0,734$) and ODI ($p = 0,943$) values.

Firstly, mean VAS was $3,6 \pm 2,4$ of single-dose CESI group at 1. month-after the procedure, $3,7 \pm 2,4$ at 3. month, $4,6 \pm 2,2$ at 6. month, $5,3 \pm 1,7$ at 12. month. The same scale that VAS was $3,5 \pm 2,1$ at 1. month, $3,5 \pm 2,1$ at 3. month, $3,6 \pm 1,9$ at 6. month and $5,3 \pm 1,7$ at 12. month for multiple dose CESI group. The VAS values were decreased in the single and multipl-dose CESI groups by a mean of $3,8 \pm 2,1$ and $4,9 \pm 2,3$ at 6. month. These results showed a statistically significant change ($p = 0,034$). On the other hand, the 6. month ODI values were found to be more significant for multiple- dose CESI group than single-dose CESI group, but these values did not show statistically significant ($p=0,268$). There were similar values between the two groups according to the VAS and ODI at 12. month ($p = 0,747$ $p = 0,733$).

Secondly, VAS and ODI statistics were examined according to the discopathies' levels at 1., 3., 6., and 12. months. When we compare the 6. month control, the mean VAS values have decreased of $4,2 \pm 2,3$ for patients have L4-5 level discopathy, $2,7 \pm 1,9$ for patients have L-S1 level discopathy and a decrease of $4,8 \pm 2,2$ for the group of two levels discopathy were observed. Although this was not statistically significant ($p = 0,05$), the highest decrease was observed in the group that showed both levels herniation. Also, there was no decrease in ODI values. VAS and ODI values according to the lumbar disc herniation levels examined, and the patients had no differences in pain scales for single and multipl-dose CESI groups (Table 1).

The most common complication, back pain appeared in 9 patients. Headache was the second most common complication and presented in 6 patients. Headache and the back pain which presented after CESI procedure was transient and treated in 24 hours. 2 patients suffered from insomnia in the first night following the injections.

Table 1. Decrease of the preinjection scale values based on months.

| * | L4-5 | | L5-S1 | | L4-5/L5-S1 | | p |
|---------------|--------------------|------------|--------------------|------------|--------------------|------------|-------|
| | mean±std deviation | min-max | mean±std deviation | min-max | mean±std deviation | min-max | |
| 1. month VAS | 4,7±2,6 | (-0,2)-8,3 | 3,8±2 | 0,4-6,5 | 5,3±2,4 | (-0,1)-7,9 | 0,198 |
| 3. month VAS | 4,8±2,5 | (-0,3)-7,7 | 3,5±2,3 | (-0,2)-6,4 | 5,1±2,4 | (-1,1)-8,1 | 0,23 |
| 6. month VAS | 4,2±2,3 | (-0,6)-7,4 | 2,7±1,9 | (-0,2)-5,4 | 4,8±2,2 | (-0,5)-7,6 | 0,05 |
| 12. month VAS | 2,9±1,9 | (-1)-6,1 | 2,5±1,6 | 0,3-4,4 | 3,3±1,8 | (-0,5)-7,4 | 0,387 |
| 1. month ODI | 35,3±20,1 | (-12)-62 | 34,1±13,2 | 18-59 | 42,2±19,2 | (-18)-70 | 0,189 |
| 3. month ODI | 34,3±20,5 | (-8)-56 | 37,0±14 | 14-52 | 39,1±19,4 | (-20)-68 | 0,694 |
| 6. month ODI | 31,1±19,4 | (-8)-62 | 27,6±12,4 | 10-46 | 35,2±17,6 | (-20)-64 | 0,355 |
| 12. month ODI | 19,1±22 | (-18)-64 | 19,1±12 | 4-35 | 24,4±17,4 | (-30)-52 | 0,531 |

DISCUSSION

Low back pain is a common chronic disorder. Many treatment modalities have been described for lumbalgia. CESI is the alternate option for patients who presented with acute lumbar disc herniation. CESI has also become an important injectional treatment technique (3, 7, 8). Epidural steroid injections without fluoroscopy guidance were first used in 1952 for lumbar radicular pain and have been a part of management of persistent unilateral or bilateral lumbar radiculopathy since the last half a century, and have significantly increased since 2000 (3, 7, 8). Reports of lower pack pain have increased from 3.9%-10.2 from 1992 to 2006 (9). Several studies showed that epidural injections are the most preferred procedures of all interventional treatment techniques for the management of spinal pain (5, 10). There are many indications to perform CESI, these include: lumbosacral sciatica due to disc herniation, foraminal or lateral canal stenosis, radiculopathies, epidural fibrosis and spinal instability (4, 5). Pain originated from lumbar discopathy is classically thought to be the compression of neural tissues by the herniated disc material (4, 11). As a result of the compression an ischemia and axonal damage occurs, but other studies shed light on the inflammatory mediators related to this pain mechanism (11). Epidural steroid injections remove or inhibit the synthesis of these mediators resulting in the reduction of neural tissue oedema and venous congestion (12, 13).

VAS and ODI are used to determine the clinical improvement of the patients. There was no significant difference between VAS and ODI

values in both groups before the procedure. 6.-month VAS was found to be significantly lower in groups with multipl-dose CESI compared to the single-dose groups ($p=0,034$). ODI was also low in multipl-dose CESI groups but it was not statistically significant ($p=0,268$). 1., 3. and 12. month values were similar in both groups. We can say with certainty that multiple dose procedures have a positive effect at 6. month results, but does not appear to make a difference on the long term results of the patients. Patients were also checked for benefit from treatment according to discopathy levels. There was no significance in pain scores according to L4-5 or L5-S1 level hernia, but it was observed that multipl level discopathy received greater pain relief.

In literature, many cases have been reported, but there is also clear evidence for CESI (3, 4). In 2014, the Food and Drug Administration stated that epidural steroid has serious side effects that may be rare but are also potentially serious, these include: Stroke, paralysis, umbar epidural hematoma, blindness, allegic reactions, backpain, headache, insomnia, euphoria, facial erythema, nausea, and death (7, 8). Lower back pain is the most common complication. In our study, CESI increased quality of life resulting in only 9 patients reporting postoperative lower back pain and 6 reporting transient headaches. The headaches and back pains are usually transient as our study reported. 2 patients suffered from insomnia in the injection night. 3 patients had hypotension after treatment and rapidly normalized with intravenous 0.9% sodium chloride. The multiple-dose CESI had better

outcomes at 6. month when compared with single dose CESI. Our study emphasizes the highlights of the sixth month benefits of multiple dose CESI according to our clinic experience. Nowadays, there is no consensus for treatment of the lumbar sciatica. In many centers, patients are referred for surgical interventions if no benefit is received from conservative methods. In these cases CESI should be considered as a minimally invasive, effective and alternate method (11,12,13).

CONCLUSION

In this study, 6. month results have found that multiple dose CESI has better outcomes in terms of pain relief in patients with lumbar radiculopathy when compared to those who underwent single dose CESI. These minimally invasive alternate methods to surgery may be considered if the patient qualify for conventional surgery

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