(Date of the document: 08.01.2021)

Title of the manuscript: Clinical Efficacy of Local Anesthetic Agents with Interlaminar Epidural Steroid Injection for Chronic Neck Pain: A Prospective, Observational Study

STUDY PROTOCOL AND STATISTICAL ANALYSIS

Patients who were planned to have a cervical epidural injection due to the pain originated from intervertebral disc herniation following examination at the Algology Clinic between 01.01.2022 and 07.30.2022 were included in the study. Patients younger than18, those who were unwilling to participate, those who were pregnant or possibly pregnant, with infection or anatomic variations in the region of the procedure, allergic to the drugs to be used in the procedure and with coagulation disorders were excluded from the study

Demographic data including age and sex, comorbidities, duration of symptoms, and surgical history of the cervical disk were recorded. The hallmarks of cervical disk hernia as evidenced by magnetic resonance imaging (MRI) were documented.

To assess pain severity and functional status, the Numerical Rating Scale (NRS) and the Neck Disability Index (NDI) were used. Treatment success was defined as ≥50% reduction in NRS at one, three, and six months during follow-up.

Operative technique

Cervical ESIs were performed under the guidance of C-arm fluoroscopy imaging by algology specialists with at least five years of experience. An intravenous access was opened with the aim of managing possible complications and side effects. In the operating room, the patient was placed in prone position on the procedure table and a pillow was placed under the chest to ensure the head was in flexion position. The region of the procedure was cleaned with antiseptic solution (povidone-iodine complex) and covered with a sterile drape. Local anesthesia was administered to the region with 3 cc 2% lidocaine to skin and subdermal tissue and patients were left for at least 2 min. The epidural intervention was performed through the C7-T1 interlaminar space with the ‘loss of resistance technique’ using an 18-gauge Tuohy needle. Contralateral oblique images were obtained with the aim of checking the depth of the needle tip. When loss of resistance was felt, a 0.5 to 2 mL contrast agent was administered and

the spread of the contrast material in the epidural space was observed and possible intravenous and subdural/intrathecal spread was excluded. After the needle was ensured to be in the correct position, Group S were administered 6 mg betamethasone (Celestone®, Merck Sharp Dohme İlaçları Ltd. Şti, İstanbul, Türkiye) (1 mL) and 4 mL physiological saline for a 5 mL total injection. Group SLA were administered 6 mg betamethasone (Celestone®) (1 mL), 5 mg 0.5% bupivacaine (Marcaine®, AstraZeneca İlaç Sanayi Ltd. Şti, İstanbul, Türkiye) (1 ml) and 3 mL physiological saline for a 5 mL total injection. After the procedure, all patients were monitored for at least 2 hours and then discharged. The patients were assessed before the procedure and in the first week and at one, three and six months after the procedure.

Statistical Analysis

Study power analysis and sample size calculation were performed using the G*Power version 3.1.9.2 software (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). Using an alpha value of 0.05 and study power 0.95, the number of patients to be included in the sample was 30 patients in the study group and 30 patients in the control group, as prescribed by Manchikanti et al. (8). Finally, a total of 60 patients who met the inclusion criteria were recruited. The patients were divided into two groups as those administered steroids and local anesthetics (Group SLA, n=30) with ESI and those only given steroids (Group S, n=30).

Statistical analysis was performed using the SPSS version 27.0 software (IBM Corp., Armonk, NY, USA). Continuous data were presented in mean ± standard deviation (SD) or median (min-max), while categorical data were presented in number and frequency. The Student *t*-test was used to compare normally distributed variables for independent groups, while the Mann-Whitney U test was used to analyze non-normally distributed variables. The dependent groups t-test was used to analyze data with a normal distribution, while the Wilcoxon signed-rank test was applied to data that did not follow a normal distribution, both before and after the implementation. The Pearson or Spearman correlation analyses were used to examine possible correlations between scale scores and demographic data. A p value of <0.05 was considered statistically significant.