Study protocol. Statistical analysis and results.

Title: Identification of Epidural Space: A Comparison Study Between Contrast Spread and Loss of Resistance Techniques

REB tracking number: 19-06-002

Date of document: 07/17/2020

The study protocol.

The study participants were patients of Astoria Pain Management, New York, USA (age 28–72 years) with a clinical diagnosis of cervical radiculitis. The Canadian SHIELD Ethics Review Board approved this study (July 18, 2019. REB tracking number: 19-06-002), conducted from August 19, 2019, to October 8, 2019. Patients were eligible for the study if they met the criteria for cervical ESI, which included clinical and recent MRI findings confirming the diagnosis of cervical radiculitis and inadequate pain relief with conservative care for more than 3 months. Other criteria were if the procedure was covered by medical insurance, and if they signed informed consent. Patients were excluded from the study if they were taking anticoagulants or had serious comorbidities such as congestive heart failure.

The patients were divided into two groups of 20 each and underwent CESI with either an 18G or a 25G Tuohy needle. Patient selection for the18G and 25G groups was not random. For example, the preference was given for a 25G needle when the procedure was performed at the C5-6 level (25G/18G = 15/4) and for an 18G (18G/25G = 16/5) when the needle was inserted at C6-7 or C7-T1 level. The smaller needles were favored for females (25G/(25G+18G) = 17/24) vs. males (25G/(25G+18G) = 3/16). The skin was anesthetized with 1% lidocaine in the 18G group but not in the 25G group. All CESIs were performed utilizing the fluoroscopy only method when the needle was navigated from the skin toward the epidural space under contralateral oblique fluoroscopy, and the

contrast spread technique was employed for epidural space identification. After radiological confirmation of the epidural spread, LOR was tested using an Epidrum® device (Exmoor Innovations Ltd., Somerset, UK). Subsequently, accompanied by the radiology assistant, I observed the Epidrum for 30 seconds or more; if the Epidrum deflated, the result was positive. However, if the device remained inflated, the result was reported as negative. The collected data was then analyzed.

Statistical analysis and Results.

There were three investigations:

1) Within group 1; 18G (LORT vs. CST),

2) Within group 2; 25G (LORT vs. CST); and

3) Between groups 1 and 2 (LORT 1 vs. LORT 2).

The Confidence Interval Test for Proportion to estimate the confidence interval (CI) between LORT and CST within groups 1 and 2 was employed. The 95% CI was [0.385, 0.815] for group 1 (LORT 60%; 18G) and [-0.031, 0.231] for group 2 (LORT 10%; 25G), confirming that LORT showed a statistically significant lower rate of epidural space detection than CST within each group (Table 1).

Table 1. The 95% Confidence Interval test for proportions of epidural space detection by LORT within 18G and 25G groups.

	x	n	p	Margin of error for 95% CI	Lower Limit	Upper Limit
LORT 18G	12	20	60	0.215	0.385	0.815
LORT 25G	2	20	10	0.131	-0.031	0.231

Rate of epidural space detection by CST in both groups is 100%. The 95% Confidence Interval test for proportions confirmed that epidural space detection by LORT is significantly lower than the CST. x–positive results, n–number of patients, p–percentage of positive results.

The z-test for independent proportions was utilized to compare the epidural space detection between LORT 1 (group 1; 18G) and LORT 2 (group 2; 25G). Since CST detected 100%, it was employed as a benchmark to conduct a hypothesis test of proportion, using H_0: ρ = 1; Ha: ρ < 1. There was a statistically significant difference between the proportions of epidural space detection by LORT with 18G compared to 25G needles: z = 3.31, p < 0.001, Cohen's h = 1.13 (Table 2).

Table 2. Z-test for independent proportions for the difference in the epidural space detection by LORT between 18G and 25G groups.

		x	n	p
LORT 18G		12	20	60
LORT 25G		2	20	10
Significance level	Pooled proportion	z	p-value	Effect size Cohen's h
0.05	0.35	3.31	0.0009	1.13

CST=20 (100%) was employed as a benchmark. Since p-value: 0.0009 < 0.05, H_0 was rejected. As Cohen's h > 0.8, the difference in LORT detection rate between 18G and 25G needles is large.