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Effect of High-Volume Saline Flushing in Lumbar Transforaminal Epidural Steroid Injection: Interim Analysis of A Randomized Controlled Trial

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Introduction

- Several studies have suggested that the injection volume itself has analgesic effects and higher volumes are associated with better outcomes in lumbar Transforaminal Epidural Steroid Injection (TFESI)
- The proposed mechanism : injected fluid volume leads to the lysis of neural adhesions
- The purpose of our study : to examine the effect of **high volume saline injection** on lumbar TFESI in patients with single-level herniated lumbar disc disorder

Subjects

- Prespecified **interim analysis** of an ongoing RCT
- **Subjects**

Inclusion

- moderate to severe radicular pain (NRS≥4)
- With a diagnosis of single-level herniated lumbar disc disorder on spine MRI

Exclusion

- Patients with a history of prior spinal surgery
- Any history of spinal intervention over the previous 6 months
- Need for TFESI at ≥2 levels
- Those with oral steroid use
- Those with or suspicious of systemic infections

Methods

- **Methods**

Randomly assigned to either a **high volume saline (HS) group** or a **control group**

- HS Group (High-volume Saline injection)

Step 1. Initial epidural contrast injection

Step 2. High-volume Saline injection (20 ml)

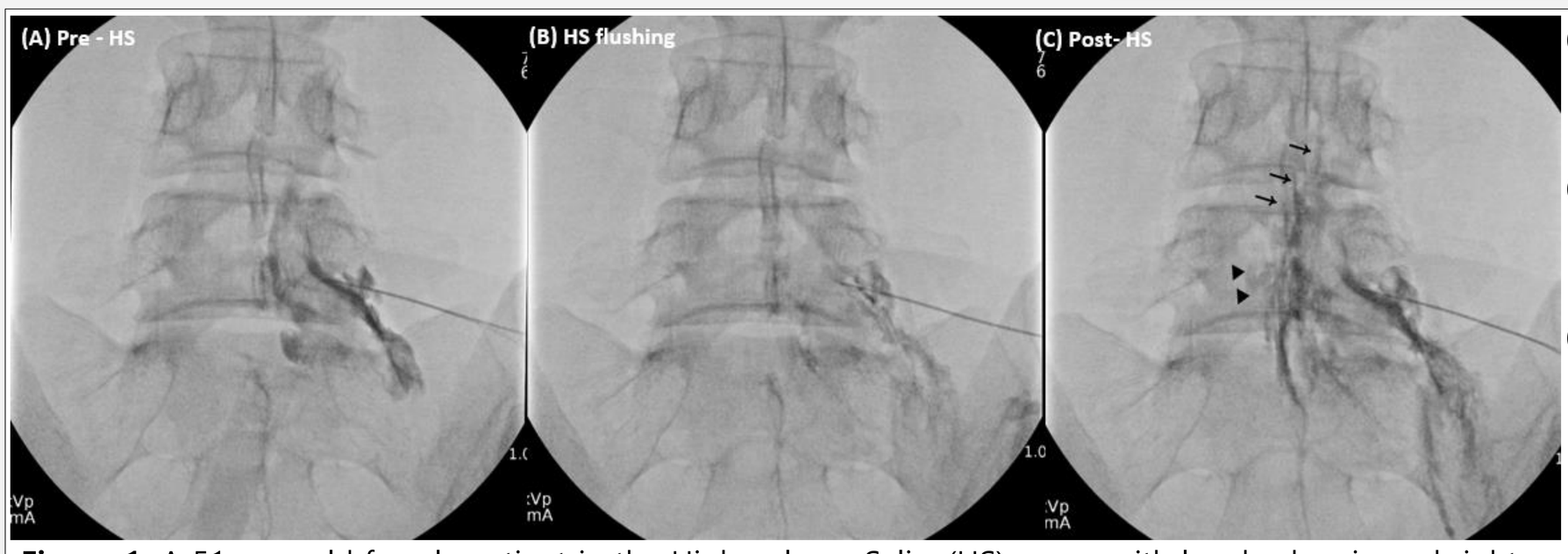
Step 3. Contrast and epidural dexamethasone injection

- Control Group

conventional TFESI with contrast and epidural dexamethasone injection

- **Outcome measure**

- Brief pain inventory (BPI) : 4 pain severity item (current, worst, least , average) (worst, least and average pain in last 24 hours) at baseline and 4weeks
- Oswestry Disability Index (ODI) at baseline and 4weeks



(A)Step 1 : Initial epidural contrast injection (demonstrating contrast confined to the distal epidural space)

(B)Step 2 : High-volume saline injection (20mL) performed after the initial contrast injection.

(C)Step 3 : Post–high-volume saline injection contrast injection demonstrating additional proximal epidural spread (arrow) and contralateral epidural spread (arrowhead).

Figure 1. A 51-year-old female patient in the High-volume Saline(HS) group with low back pain and right-sided radiating pain underwent TFESI with an additional 20 mL saline injection.

Results

Table 1. Baseline characteristics of participants

Variables	Groups		* P value
	High volume Saline(n=13)	Control (n=15)	
Age (years)	59.69(14.89)	63.60(16.19)	*0.514*
Gender M : F	4:9	7:8	*0.390*
Pfirrman grading, n (%)			*0.328*
Grade 1	0 (0)	0 (0)	
Grade 2	0 (0)	0 (0)	
Grade 3	5 (38.46)	8 (53.33)	
Grade 4	6 (46.15)	3 (20)	
Grade 5	2 (15.38)	4 (26.67)	
Foraminal stenosis grading, n (%)			*0.421*
Grade 1	6 (46.15)	7 (46.67)	
Grade 2	5 (38.46)	3 (20)	
Grade 3	2 (15.38)	5 (33.33)	
ODI (0-50)	16.00(8.25)	14.67(5.96)	*0.625*
BPI			
worst pain (NRS 0-10)	6.62(2.06)	6.47(1.60)	*0.832*
least pain (NRS 0-10)	2.92(1.61)	2.93(1.49)	*0.986*
average pain (NRS 0-10)	5.38(1.39)	5.00(1.00)	*0.403*
current pain (NRS 0-10)	4.85(2.44)	4.73(1.16)	*0.875*
Physical funtion			
gait speed (sec)	4.73(2.07)	4.99(1.29)	*0.690*
Sit to stand (sec)	9.48(4.06)	9.16(2.62)	*0.804*

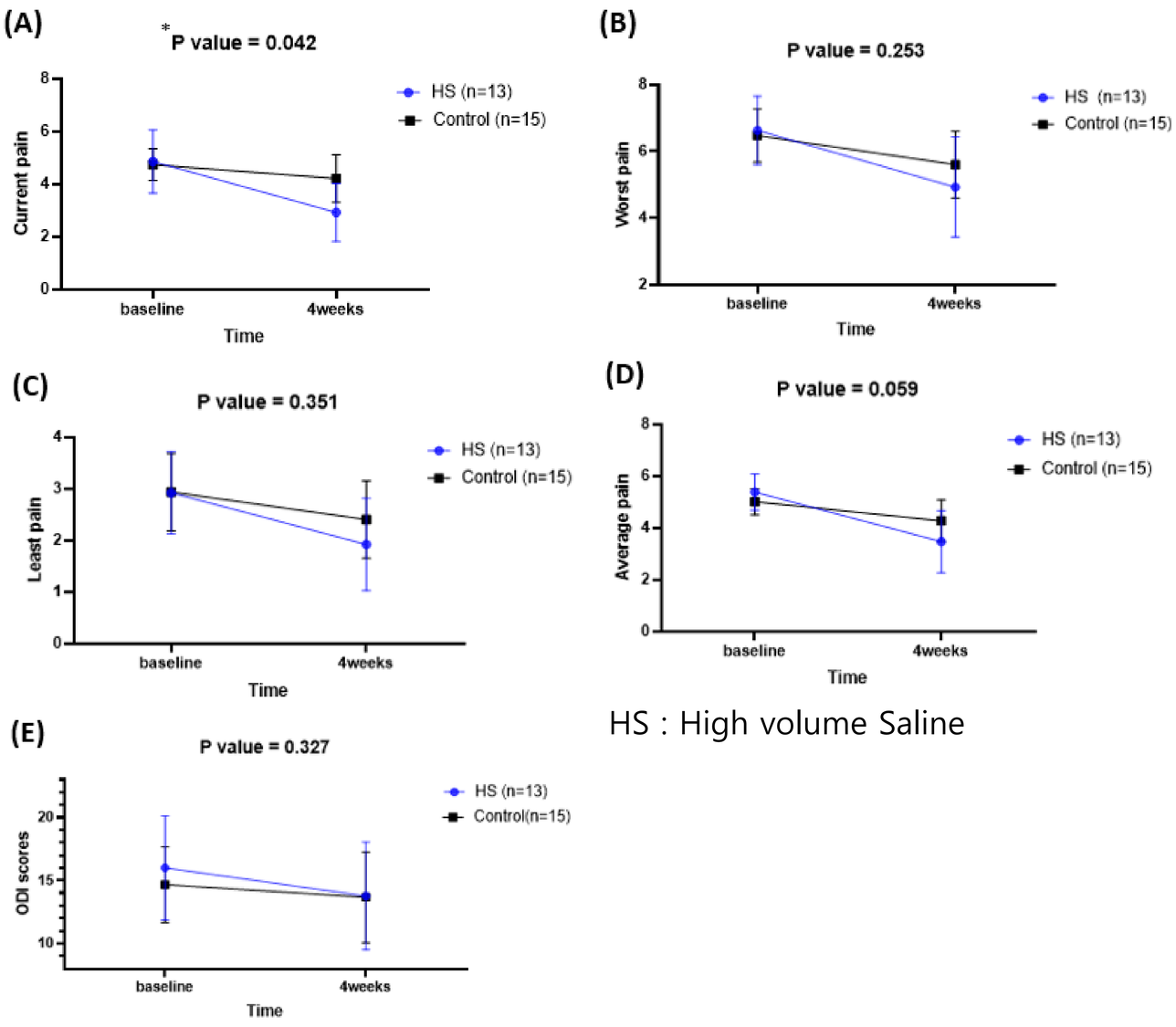
Values are mean ± SD or n (%).
* Using Chi-square test for categorical variables or Student t-test for continuous variables.
ODI, Oswestry Disability Index; BPI, Brief Pain Inventory ; NRS, Numerical Rating Scale

- Baseline characteristics (Age, Sex, Pfirmann and foraminal stenosis grading, ODI, BPI) were comparable between groups. **(Table 1)**

- **No severe adverse events** (infection and paralysis) were observed in either group.
- The number of patients with **aggravated pain** was 3(23.8%) in HS group and 5(33.33%) in control group.(*P=0.55*)
- The number of patients with **rescue injection** (defined as a secondary TFESI within 4-12 weeks) was 6(46.2%) in HS group and 9(60%) in control group.(*P=0.464*)
- The incidence of mild-to-moderate adverse events did **not** differ significantly between the two groups.

Figure 2. Changes in (A) current pain, (B) worst pain, (C) least pain, (D) average pain, (E) ODI scores from baseline to 4weeks.

Pain scores : ranged from 0 to 10 (with higher scores indicating more pain)
ODI scroes : ranged from 0 to 45 (with higher scores indicating more disability)



HS : High volume Saline

- The **HS group** tended to have a greater reductions across all domains of the BPI and ODI scores
  : **Current pain (-1.92 vs -0.53,*P=0.042)**
  Worst pain (-1.69 vs -0.87,*P=0.253*)
  Least pain (-1.00 vs -0.53,*P=0.351*)
  Average pain (-1.92 vs -0.73,*P=0.059*)
  ODI (-2.23 vs -1.00, *P=0.327*)
  : Statistically significant between-group difference was observed only in the **current pain(*P=0.042). (Figure 2)**

Conclusion

- This **interim analysis** of an ongoing randomized trial suggests that forceful injection of high-volume saline may provide greater improvement in **current pain at 4weeks** compared with conventional lumbar TFESI.
- These findings should be interpreted cautiously, and definitive analysis involving the complete randomized population and longer follow-up will be required to confirm the comparative effects of the interventions.