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Is ultrasound-guided caudal steroid injection effective in the management of lower lumbar radicular pain? A two-center prospective observational study on 150 patients

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Journal Pre-proof

Lower lumbar radicular pain is a benign and frequent condition [1], mostly induced by disk herniation or osteoarthritis. The management of lower lumbar radicular pain is a public health problem [2], with multimodal management. Lumbar epidural steroid injections are considered as a treatment but their effectiveness remains controversial, with conflicting results [3–5]. Injection via the caudal hiatus route (CH) under ultrasound (US) guidance has gained popularity because of accessibility or US equipment, absence of irradiation, feasibility and very few complications reported [6].

A pragmatic prospective observational two-center (Rennes and Nantes University Hospitals) study was performed to evaluate the effectiveness of a single steroid (corticivazol) epidural injection delivered under US guidance via the CH on lower lumbar radicular pain. The primary outcome for success was achieving a numerical pain rating scale score (NPRS $\leq 3/10$ at day 30 (D30) after epidural injection. The secondary endpoints were achieving a NPRS $\leq 3/10$ at D30 without opiates and NSAIDs, level of analgesic and NSAIDs consumption, absence from work and occurrence of adverse events. Factors related to efficacy were not well established.

One hundred and fifty patients were enrolled [Appendix A, Table S1 and Figure S1; See the supplementary material associated with this article online]. Compared to the baseline (10% of patients with NPRS score $\leq 3/10$, not excluded in the final analysis), 31% at 10 days (D10) post-injection ($p < 0.001$) and to 37% at D30 ($p < 0.05$) reported a NPRS score $\leq 3/10$ (Figure 1). The proportion of patients achieving this objective without consuming opioids or NSAIDs was 23% at D10 and D30 ($p < 0.001$). Opioid and NSAIDs consumption decreased significantly between baseline, D10 and D30. During follow-up, patients did not report any adverse events. We found no clear predictive factors for the efficacy of epidural injections at D10 and D30 after injection (Table 1).

Previous studies using the CH found some conflicting results on steroid injection effectiveness on radicular pain [7,8], mainly because the heterogeneity of the populations studied and the frequency of monitoring (first evaluation at 6 weeks [7] or 3 months [8]). In our study, consistent with Nandi *et al.* [9] study, epidural injections of steroids through the CH appeared to be effective in relieving lower lumbar radicular pain induced by herniated disk on a native spine pain in the short term (1 month). It was an important pragmatic point because the first and main objective of the epidural injection is to alleviate as soon as possible severe or resistant pain—in a pathology frequently associated with spontaneous favorable medium-term evolution [10]. Similar to the literature reported, we were unable to identify any predictive factors for the efficacy of CH injections [3]. No serious adverse events during the follow-up were observed, confirming the safety of this route.

In conclusion, a single CH epidural steroid injection under US guidance improved significantly the radicular NPRS in about one-third of the patients. Patients and clinicians should be aware of the results when discussing therapeutic options for this condition. The usefulness of a second injection 10 days after the first injection for patients who are insufficiently responsive to the first injection should be specifically investigated.

Competing interests: No conflict of interest in relation to the results of this work is reported by all authors.

Ethical approval information: All patients were informed of the objectives and procedure of the study and gave their consent. The study was approved by the ethics committee of Rennes university hospital (Avis n°18.38, Oct 2015).

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Appendix A. Supplementary data

Supplementary data (Table S1, Figure S1) associated with this article can be found in the online version at ...

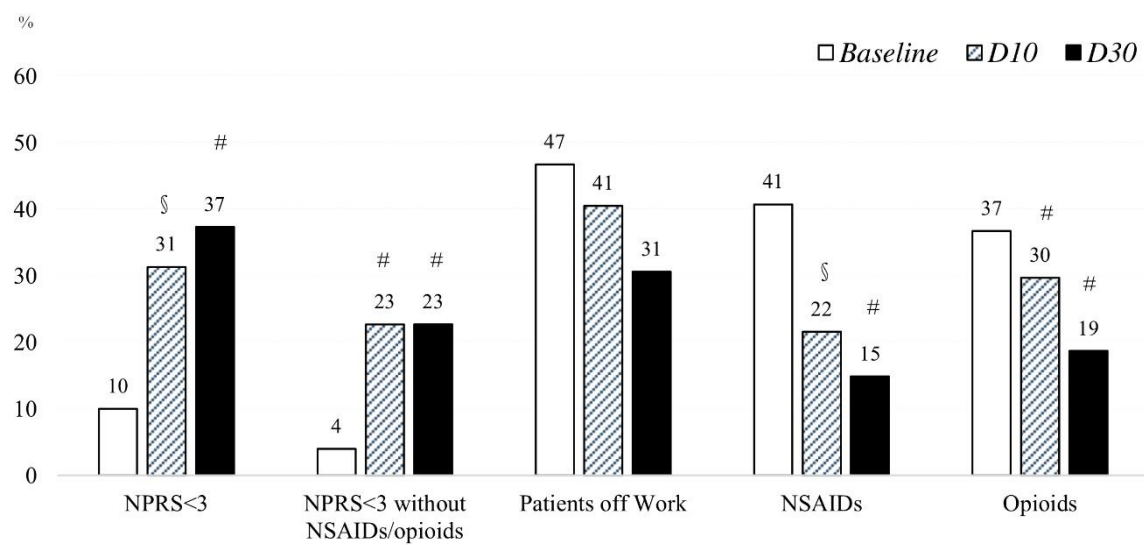
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Figure 1: Epidural injection efficacy on root pain, analgics consumption and professional activity.
Difference compared to baseline with § = $p < 0.05$ and # = $p < 0.01$).

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Figr-1



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	Factors of efficacy at D30 (NPRS<3/10)	
	OR (IC95%)	OR (IC95%)
Age < 45 years	1.26 (0.62-0.57)***	1.06 (0.53-2.10)***
Male Gender	2.40 (1.17-4.93)*	2.63 (1.32-5.24)**
Root S1	0.85 (0.42-1.70)***	1.07 (0.55-2.09)***
Root pain < 6 weeks	1.07 (0.48-2.37)***	1.61 (0.76-3.43)***
Severe pain (NPRS>7/10)	0.32 (0.46-0.72)**	0.52 (0.26-1.05)***
Disk herniation	2.16 (0.75-6.17)***	3.04 (1.07-8.64)*
Foraminal conflict	2.94 (1.25-6.90)***	1.44 (0.62-3.34)***
Operated Spine	1.01 (0.36-2.85)***	1.26 (0.47-3.34)***

*p < 0.05 ; **p < 0.01 ; ***NS

Table 1: Factors associated with the efficacy of cortivazol epidural injection via the CH under ultrasound at D10 and D30.

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