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Lumbosacral immobilization following glucocorticoid intradiscal injection in patients with chronic low back pain and active discopathy: A feasibility study

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Abstract.
BACKGROUND: In people with chronic low back pain (cLBP) and active discopathy, glucocorticoid intradiscal injection (GC IDI) reduces LBP in the short-term. Lumbosacral immobilization may be useful to obtain long-term results.
OBJECTIVE: To assess the feasibility of a lumbosacral immobilization using a pantaloon cast following GC IDI in people with cLBP sand active discopathy.
METHODS: We conducted a retrospective feasibility study. Participants were allocated to experimental or control groups by preferences. The experimental group received lumbosacral immobilization using a custom-made pantaloon cast worn continuously for one week following a GC IDI of 25 mg of prednisolone acetate. The control group received GC IDI alone. The primary endpoint was the feasibility of lumbosacral immobilization assessed by the rate of refusal and early withdrawal of the cast.
RESULTS: Twelve patients were offered lumbosacral immobilization following GC IDI: the rate of refusal was 3/12 (25.0%) and was 3/9 (33.3%) of early withdrawal. Mean (95% CI) acceptability of the procedure was 55.0 (26.9–83.1)/100 in the experimental group ($N = 6$) and 61.6 (25.1–98.2)/100 in the control group ($N = 6$).
CONCLUSIONS: We found high rates of refusal and early withdrawal of the lumbosacral immobilization using a pantaloon cast following GC IDI in people with nonspecific cLBP and active discopathy.

Keywords: Chronic low back pain, Modic 1, active discopathy, intradiscal therapy, glucocorticoid, lumbar brace

1. Introduction

In patients with non-specific chronic low back pain (cLBP) and active discopathy, a single glucocorticoid intradiscal injection (GC IDI) decreases LBP intensity in the short-term [1,2]. This effect is not sustained, suggesting that besides inflammation, other adverse factors could contribute to symptoms [3,4]. Increased shear

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forces on adjacent vertebral endplates can promote disc activation [3]. Therefore, targeting biomechanical adverse factors could be relevant. A retrospective study of 62 patients with cLBP and active discopathy suggested that a rigid lumbar brace worn for three months could reduce LBP intensity [5]. However, lumbar bracing following spinal GC injection has never been studied.

For knee joints, in the absence of knee immobilization, an increased diffusion of Yttrium 90 outside the joint has been reported following intra-articular injection [6]. In patients with inflammatory rheumatic diseases, immobilization of the knee following GC intra-articular injection is associated with longer clinical improvements [7,8]. Similarly, in patients with cLBP and active discopathy, lumbosacral immobilization following GC IDI may prolong GC IDI positive effects. Before evaluating the efficacy of this approach, we assessed its feasibility in a pilot study.

2. Methods

2.1. Design overview

We conducted a retrospective single-center controlled open-label study. Our study is reported in accordance with the CONSORT 2010 statement [9].

2.2. Setting and participants

Participants were consecutively screened among patients referred to the Department of PRM of a French tertiary care center (Cochin Hospital, Paris, France) to receive GC IDI for active discopathy. The sample was selected by convenience based on the number of eligible participants in the specified period. Inclusion criteria were LBP $>$ 3 months, LBP intensity $>$ 40/100 on a self-administered numeric rating scale (NRS, 0 = no pain, 100 = maximal pain), Modic 1 changes at a single lumbar level, MRI $<$ 6 months, failure of first-line treatment and indication of GC IDI by a multidisciplinary team. Exclusion criteria were pregnancy, allergy to prednisolone acetate or contrast, current local or systemic infection, current fever, bleeding disorder, current anti-coagulation or systemic GC, sedimentation rate $>$ 20 mm at first hour, history of disc surgery or nucleolysis at the Modic 1 level in the previous 6 months, specific LBP, motor deficit, uncontrolled psychiatric disorder, Modic 1 changes at multiple lumbar levels and insufficient proficiency in French.

2.3. Treatment allocation and allocation concealment

Treatment was allocated by preference of the participant after information about the expected benefits and burden of the pantaloon cast was provided. Participants, care providers, data collectors, outcome assessors and data analysts were not blinded.

2.4. Experimental group

Patients in the experimental group received a GC IDI of 25 mg of prednisolone acetate, as previously described in [1], followed by lumbosacral immobilization, starting right after the GC IDI, using a pantaloon cast, worn continuously for one week. The immobilized lower limb was the most painful or the preferred one in the absence of pain in the leg. The pantaloon cast was custom-made by an experienced orthoprosthesist. In short, the material was a resin allowing suitable trunk circular bandage up to xyphoidal apophysis extended by a unilateral mid-thigh circular bandage, making a one piece brace impeding hip motion (Fig. 3). To reduce the risk of skin damage, layers of Jersey tissue and cotton were placed under the resin. Sharp edges were covered with an adhesive elastic band. Once wearing the brace, the patient was instructed to walk for 2 h to test the tolerance of the brace. In case of discomfort, sharp edges and overpressure areas were corrected. Only the orthoprosthesist could remove the brace using an oscillating cast saw, a Henning plaster retractor and a Brown plaster shear. In case of immediate or delayed intolerance ($<$ 1 week), despite appropriate modifications and upon patients' request, the brace was removed. Advice was given to reduce the burden of the pantaloon cast in activities of daily life.

2.5. Control group

Patients in the control group received GC IDI alone (i.e. patients who primarily refused the pantaloon cast or those who wore it less than 7 days), as previously described in [1].

2.6. Outcome measures

The primary outcome was the feasibility of lumbosacral immobilization following GC IDI. It was assessed by the rates and reasons of refusal and early withdrawal ($<$ 1 week) of the cast, the nature of adverse events and the acceptability of the overall procedure (i.e. GC IDI alone in the control group or GC IDI

Table 1
Demographical and clinical characteristics of the participants

	Experimental group ($N = 6$)	Control group ($N = 6$)	Both groups ($N = 12$)
Women, n (%)	5 (83.3)	2 (33.3)	7 (58.3)
Age (years), mean (SD)	43.5 (6.7)	46.7 (8.8)	45.1 (7.6)
Body mass index (kg/m^2), mean (SD)	24.6 (2.8)	24.0 (4.2)	24.3 (3.5)
Higher education, n (%)	5 (83.3)	5 (83.3)	10 (83.3)
Currently working, n (%)	3 (50.0)	6 (100.0)	9 (75.0)
Symptom duration (years), mean (SD)	5.8 (4.4)	2.2 (23.0)	4.0 (3.6)
Low back pain intensity (NRS, 0–100), mean (SD)	66.7 (10.3)	66.7 (13.7)	66.7 (11.5)
Radicular pain intensity (NRS, 0–100), mean (SD)	50.0 (29.0)	15.0 (15.2)	32.5 (28.6)
Previous treatments, n (%)			
Analgesicss	6 (100.0)	6 (100.0)	12 (100.0)
Non-steroidal anti-inflammatory drugs	6 (100.0)	5 (83.3)	11 (91.7)
Lumbar brace	6 (100.0)	4 (66.7)	10 (83.3)
Physiotherapy	6 (100.0)	4 (66.7)	10 (83.3)
Multidisciplinary rehabilitation	4 (66.7)	2 (33.3)	6 (50.0)
QBPDS (0–100), mean (SD)	44.2 (12.6)	49.7 (16.4)	46.9 (14.2)
SF-12 PCS (9.95–70.02), mean (SD)	55.8 (10.2)	51.7 (7.5)	53.8 (8.8)
SF-12 MCS (5.89–71.97), mean (SD)	56.8 (12.5)	53.6 (20.1)	60.2 (16.3)
HADs depression (0–21), mean (SD)	5.8 (3.3)	7.2 (4.5)	6.5 (3.7)
HADs anxiety (0–21), mean (SD)	9.1 (1.2)	7.8 (4.5)	8.5 (3.1)
FABQ physical activity (0–24), mean (SD)	16.8 (2.8)	13.2 (7.4)	15.0 (5.6)
FABQ work (0–42), mean (SD)	26.8 (4.7)	10.0 (9.8)	18.4 (11.4)

No missing data. FABQ: Fear-Avoidance Beliefs Questionnaire; HADs: Hospital Anxiety and Depression scale; MCS: Mental Component Score; NRS: Numerical Rating Scale; PCS: Physical Component Score; QBPDS: Quebec Back Pain Disability Scale; SF-12: Short Form 12 Health Survey.

plus pantaloon cast in the experimental group) using a self-administered NRS (0 = absent, 100 = maximal) at the end of follow-up. Secondary outcomes were mean changes from baseline in LBP intensity assessed by a self-administered NRS at 1 week, 1, 2, 3, 4, 5 and 6 months. In LBP-specific activity limitations were assessed by the self-administered Quebec Back Pain Disability Scale (0 = no limitation, 100 = maximal limitation) [10–12]. Health-related quality of life (HRQoL) was assessed by the physical component (9.95 = worse HRQoL, 70.02 = best HRQoL) and the mental component (5.89 = worse HRQoL, 71.97 = best HRQoL) scores of the self-administered 12-Item Short Form Health Survey [13]. Clinically significant symptoms of anxiety and depression were assessed by the anxiety and depression subscales of the self-administered Hospital Anxiety Depression scale (0 = no symptoms, 21 = maximal symptoms) [14] at 3 months.

2.7. Statistical analysis

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Quantitative variables were described with means (95% CI) or standard deviation (SD) and qualitative variables were described with absolute and relative frequencies. Missing data were imputed using the Last Observation Carried Forward method. Descriptive analyses were performed using MYSTAT 12 version 12.02.00. We did not pre-specify comparative analyses because they would have been be biased.

2.8. Ethical consideration

The study was carried out in accordance with the Declaration of Helsinki. The investigator provided oral and written information, and all participants provided written informed consent. *Engagement de conformité* to MR-1 was declared to the *Commission Nationale de l'Informatique et des Libertés* (No. 2210232). According to the *Loi Jardé* of March 5, 2012 and its application decree (No. 2016–s1537) of November 16, 2016, retrospective studies do not require a formal approval by an institutional review board in France.

3. Results

3.1. Patients

From 14 December 2016 to 25 July 2017, 13 patients with cLBP and active discopathy were referred for GC IDI, 12/13 (92.3%) met the eligibility criteria and were consecutively enrolled (Fig. 1). The mean age was 45.1 (7.6) years, mean symptom duration 4.0 (3.6) years and mean LBP intensity 66.7 (11.5)/100 (Table 1).

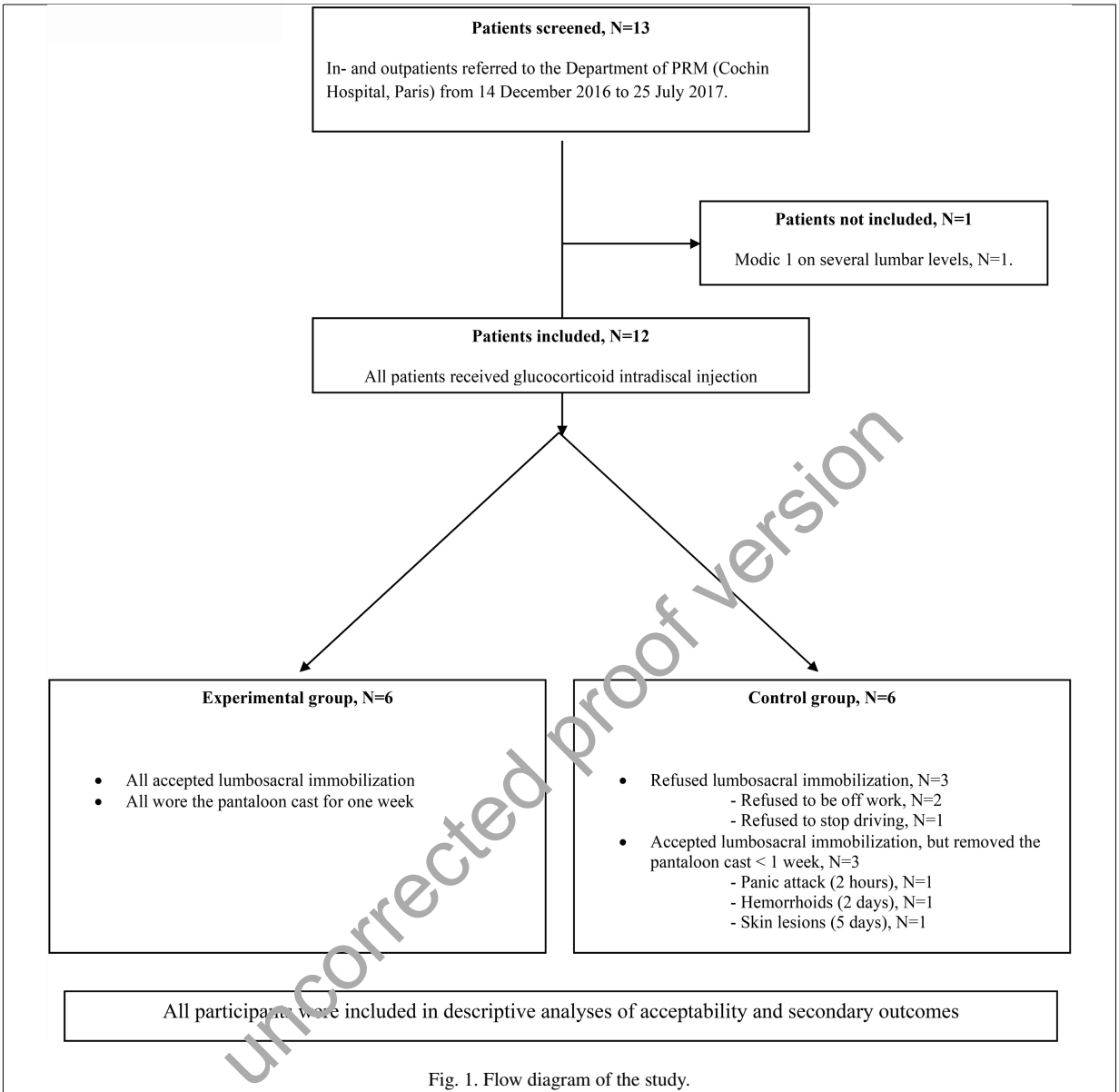

Fig. 1. Flow diagram of the study.

3.2. Primary outcomes

Overall, 3/12 (25.0%) patients refused the lumbosacral immobilization: two refused to be off work and one refused to stop driving for one week. Among the nine patients who accepted, 3/9 (33.3%) eventually had the cast removed within a week because of mild reversible adverse events: one after 2 h because of a panic attack, one after two days because of hemorrhoids and one after five days because of skin lesions. Only 6/12 (50.0%) patients wore the cast for one week and were analyzed in the experimental group (Fig. 1). At the end of the follow-up, mean acceptability of the overall procedure was 55.0 (26.9–83.1)/100 in the experimental group ($N = 6$) and 61.6 (25.1–98.2)/100 in the control group ($N = 6$).

3.3. Secondary outcomes

In the experimental group, an early increase of LBP intensity occurred within one, at the time of cast removal, and one month after GC IDI. In the control group, it occurred between one and three months (Fig. 2). In both groups, changes in secondary outcomes were of the same magnitude (Table 2).

Table 2
Secondary outcomes at three months

	Experimental group ($N = 6$)	Control group ($N = 6$)	Both groups ($N = 12$)
Low back pain intensity (NRS, 0–100)	−13.3 (−21.9;−4.7)	−15.0 (−35.7;5.7)	−14.2 (−23.4;−5.0)
QBPDS (0–100)	−4.3 (−12.9;4.1)	−7.8 (−20.7;5.0)	−6.1 (−12.5;0.3)
SF-12 PCS (9.95–70.02)	5.0 (−5.5;15.5)	0.8 (−10.9;12.5)	2.9 (−3.6;9.5)
SF-12 MCS (5.89–71.97)	6.2 (−1.9;14.2)	2.5 (−12.8;17.8)	4.3 (−2.8;11.5)
HADs depression (0–21)	1.7 (−1.7;5.0)	−0.2 (−1.8;1.5)	0.8 (−0.9;2.4)
HADs anxiety (0–21)	0.0 (−2.4;2.4)	0.2 (−2.2;2.5)	0.1 (−1.3;1.5)

Values are mean (95% CI) absolute difference between 3 months and baseline. Missing variables were imputed using the Last Observation Carried Forward. QBPDS: Quebec Back Pain Disability Scale; HADs: Hospital Anxiety and Depression scale; MCS: Mental Component Score; NRS: Numerical Rating Scale; PCS: Physical Component Score; SF-12: Short Form-12 Health Survey.

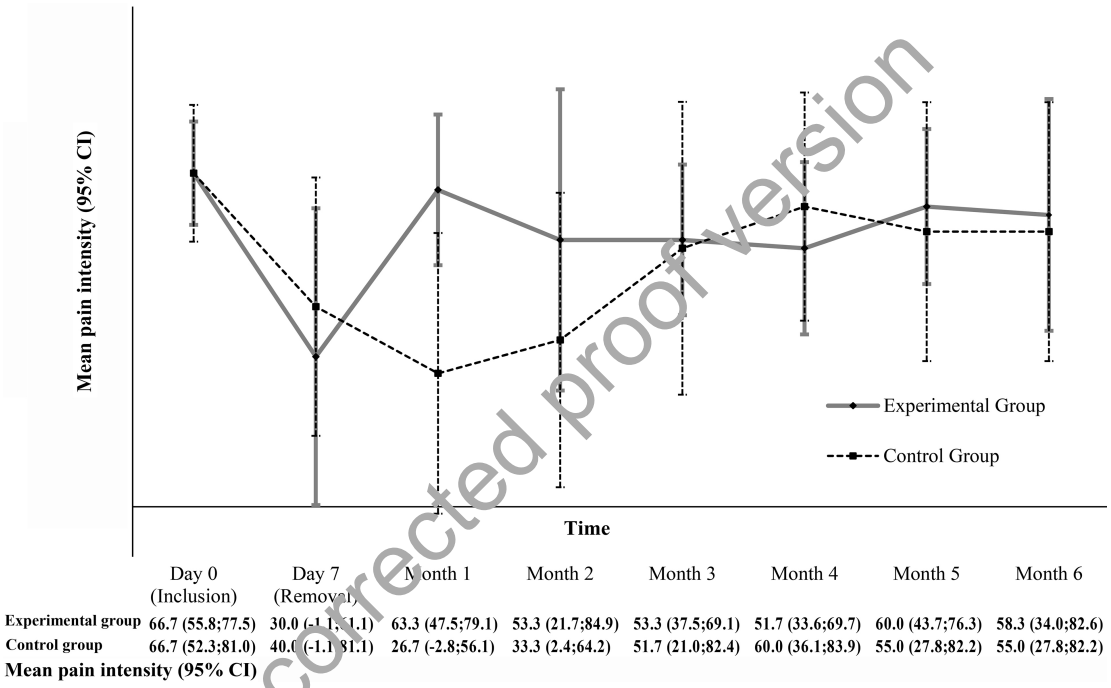

Fig. 2. Evolution of mean low back pain intensity.

3.4. Safety

No serious adverse events occurred.

4. Discussion

We found high rates of refusal and early withdrawal of lumbosacral immobilization and low scores of acceptability in both groups. Some characteristics of our population may explain our results.

Because wearing the cast required a one week sick leave and may have limited many activities of daily living (e.g. sitting, driving, taking care of oneself), some patients refused to participate. In this population, the burden of treatment was probably higher than the burden of the disease. Measures to reduce the latter could have included a shortening of the immobilization period to 48 h, comfortable material such as polyethylene could have been used for the knee [7,8,15], the use of a hip hinge could have allowed the patient to sit, as well as the use of a rigid lumbar brace without hip immobilization. In fact, the benefits of adding unilateral hip immobilization to lumbar immobilization are debated [16]. Recommendations inspired by those of the International Society on Scoliosis Orthopedic and Rehabilitation Treatment could also have been implemented to improve adherence [17].

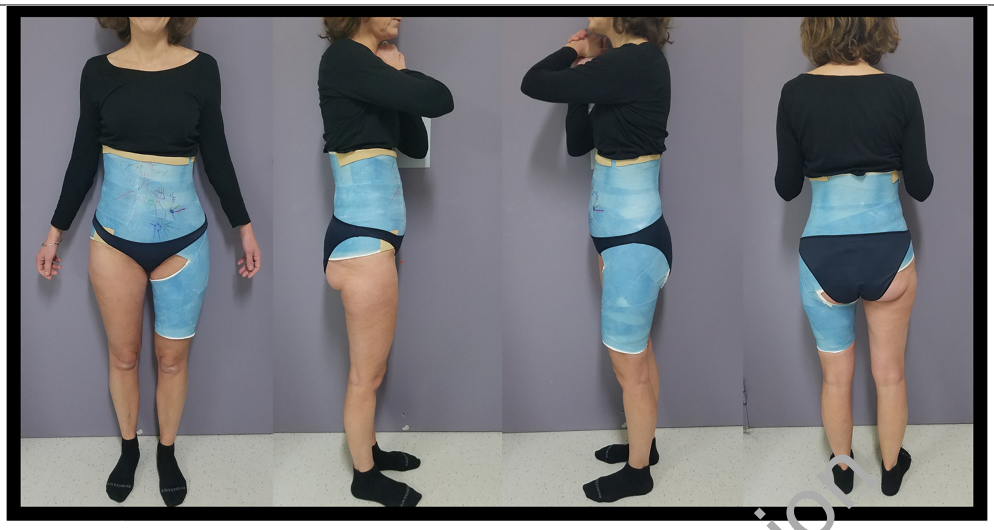

Fig. 3. Therapeutic pantaloon cast.

In the control group, mean changes in mean LBP intensity were similar to those previously reported and the acceptability was consistent with our previous findings [1], attesting the validity of our control group. In the experimental group, the rebound effect after GC IDI occurred much earlier than expected. In addition, variations in secondary outcomes were of the same magnitude in both groups. Altogether, our results suggest that lumbosacral immobilization does not add value to GC IDI.

Our study has limitations. Its design was exposed to risks of biases and we cannot draw conclusions about the treatment effect. The retrospective design was exposed to measurement biases, the absence of blinding to performance and detection biases, and the allocation by preference to volunteer biases and confounding factors, as reflected by the uneven between-group distribution of baseline characteristics. We selected our sample by convenience and did not calculate a sample size based on an efficacy hypothesis. Therefore the interpretation of our results is limited by small and convenience sampling effects. Finally, participants were recruited from a tertiary care center and were not representative of French people with chronic LBP and active discopathy.

In summary, lumbosacral immobilization using a pantaloon cast following GC IDI in patients with chronic LBP and active discopathy is not feasible. Whether this measure adds value to GC IDI is questionable.

Conflict of interest

The authors have no conflict of interest to report.

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