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Original article

Short-term pain evolution in chronic low back pain with Modic type 1 changes treated by a lumbar rigid brace: A retrospective study

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ABSTRACT

Background: Blocking the lumbar or lumbosacral spine with a custom-made rigid lumbar brace, based on the mechanical origin of active discopathy, is a therapeutic option for low back pain, but no study has yet defined its applicability in low back pain.
Objective: To assess the pain evolution of individuals with non-specific chronic low back pain associated with Modic type 1 changes treated with custom-made rigid lumbar brace.
Methods: This was a retrospective observational study conducted in the Physical Medicine and Rehabilitation unit at Clermont-Ferrand University Hospital, France, between January 2014 and December 2016. Inclusion criteria were adults with non-specific chronic low back pain associated with Modic type 1 changes on the lumbar or lumbosacral spine confirmed by MRI. Patients had 4 consultations with the physician (baseline, 5 weeks, 3 months, and 5 months). The brace was progressively withdrawn at 3 months. The main outcome was pain improvement of at least 30% at 3 months (visual pain scale). The secondary outcome was an improvement of at least 50%. We also studied the association between pain improvement at the 2 thresholds (30 and 50%) and clinical data, level of Modic type 1 changes, and pain recurrence after withdrawal of the brace.
Results: Among the 174 patients who wore the brace, 62 were included in the study; 49/62 (79%) showed improvement of at least 30% at 3 months. Two months after brace withdrawal, pain recurred for 30/46 patients (16 missing data). No sociodemographic, clinical or radiographic criteria were associated with pain evolution.
Conclusion: In the present study, a rigid lumbar brace worn for 3 months was associated with a 30% reduction in pain for 79% of patients with chronic low back pain and active discopathy. However, the retrospective open and uncontrolled design of our study limits our interpretation about a specific treatment effect. A prospective randomized controlled trial is needed to clarify the effect of a rigid lumbar brace in this condition.

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Innovation

- Lack of international guidelines on the management of non-specific low back pain with Modic type 1 changes.
- First study to assess pain evolution in low back pain with Modic type 1 changes when treated with lumbar rigid brace.
- Immobilization by lumbar rigid brace is a non-invasive treatment with few side effects.

1. Introduction

Low back pain secondary to active discopathy represents a subset of individuals with non-specific chronic low back pain (NS cLBP). It is qualified by some authors as a clinical and radiological syndrome with MRI showing abnormalities in intervertebral-disc subchondral bone and adjacent vertebral-endplate subchondral bone [1–3]. The underlying mechanism remains unclear and debated (mechanical, local infection, genetic [3–5]). The mechanical hypothesis found its origin in the Modic et al. initial study [1], linking Modic changes (MC) types 1 and 2 to degenerative disc disease. The term "active discopathy" refers to a specific clinical, biological and MRI profile of MC type 1 [3] because of the inflammatory process that defines it.

In the absence of international guidelines on the management on NS cLBP with MC type 1, different therapeutic strategies have been described. The main goal is to accelerate the transition to MC type 2, which is supposedly less painful [5]. The estimated time to expect a transition from type 1 to type 2 is at least 1 year [1,6].

Bracing the lumbar or lumbosacral spine with a custom-made rigid lumbar brace (CRLB), based on the mechanical origin of active discopathy, is a therapeutic option [7]. To our knowledge, no study has yet defined the applicability of the brace to LBP other than a pre-surgical evaluation [8].

In this retrospective study, we aimed to evaluate the evolution of pain in individuals with NS cLBP and MC type 1 who wore a CRLB.

2. Methods

2.1. Study sample

We included all outpatients with NS cLBP and MC type 1 on the lumbar or lumbosacral spine who received treatment in the Physical Medicine and Rehabilitation unit of Clermont-Ferrand University Hospital, France, from January 1, 2014 to December 31, 2016.

CRLB prescription concerned individuals with inflammatory pain, morning stiffness, night awakening pain, pain resistant to non-steroidal anti-inflammatory drugs or analgesics steps 1 and 2 on the WHO pain ladder, and MC type 1 confirmed by MRI. Exclusion criteria concerned individuals with spondylolisthesis associated with MC type 2, did not wear the brace for at least 3 months or did not want to wear one.

2.2. Study design

This was a retrospective observational and single-centered study. In our practice, CRLB prescription and follow-up requires 4 consultations with the physician (baseline, 5 weeks, 3 months, and 5 months). The different outcomes were determined according to these 4 consultations. During the first consultation, the patient was examined by the physician to confirm the diagnosis and the indication for CRLB, then the prosthetist took measurements to design the brace, which was delivered directly to the patient 2 weeks later. There was no specific interference with the usual treatment besides CRLB prescription. The second consultation was 5 weeks later to assess tolerance (skin lesions, digestive intolerance or any other discomfort) and pain evolution; the CRLB was also modified if needed. At the third consultation, at 3 months, progressive withdrawal began with a physiotherapy prescription. The fourth consultation was 2 months after withdrawal of the brace. Co-interventions did not vary over time.

2.3. Custom-made rigid lumbar brace

The CRLB consisted of 4-mm – thick polyethylene braces, monovalve, with an anterior opening and Velcro® fastening. The same prosthetist (*Orthopédie Moderne*) used computer-aided design to make all CRLBs. Recommendations regarding the total time of immobilization was 3 months. No pantaloon cast was used; limited mobility regarding L5-S1 was guaranteed in part by the CRLB anterior shape that limited body flexion. The patient was asked to wear the brace all day and to take it off if lying down. Information concerning the use and maintenance of the CRLB was given to the patient by the physician and prosthetist during the initial consultation. This information was given once again when the CRLB was delivered. Patients were encouraged to continue their everyday life activities. After 3 months, progressive withdrawal of the CRLB was started, associated with standardized physiotherapy based on stretching and spine flexor and extensor strengthening.

2.4. Data collection

Data were collected from medical files completed during each consultation. During the first consultation, clinical and sociodemographic data were collected (pain evaluated by visual pain scale [0–10 mm], constant level of pain intensity, night pain, morning stiffness). During the third consultation, participants were asked to define the percentage improvement in pain and for the last consultation, were asked if pain recurred after the withdrawal of the brace.

2.5. Outcomes

We studied the percentage improvement in pain described after wearing the CRLB for 3 months (recorded during the third consultation) compared to the pain felt at the first consultation. Outcomes assessment were based on self-administered questionnaires. The main outcome was defined as an improvement in pain of at least 30%. The secondary outcome was an improvement of at least 50%. We also studied the association between improvement in pain at these 2 levels (30% and 50%) with clinical data, level of MC type 1, and pain recurrence after withdrawal of the brace.

2.6. Statistical analysis

Statistical analyses involved using Stata v13 (StataCorp, College Station, TX, USA). The tests were two-sided, with type I error set at $\alpha = 0.05$. Continuous data are expressed as mean (SD) or median (interquartile range [IQR]) according to statistical distribution (assumption of normality assessed by the Shapiro–Wilk test). The percentage improvement in pain was analyzed by sociodemographic, clinical and radiologic characteristics of participants by Student *t* test or Mann–Whitney test if the assumptions of the *t* test were not met: (1) normality and (2) homoscedasticity studied by the Fisher–Snedecor test. The results are expressed as effect sizes and 95% confidence intervals. Then, the rate of improvement in pain was classified into 2 classes ($> 30\%$ or $\leq 30\%$) and compared between groups by Chi^2 or Fisher's exact test. This rate was

determined according to the literature and the minimal important change [9]. The same statistical analyses were applied for rate of improvement in pain dichotomized according to a 50% threshold. Finally, the relation between quantitative variables was analyzed by correlation coefficients: Pearson or Spearman according to the statistical distribution (data not shown). As described by several authors [10] readers should balance a study's statistical significance with the magnitude of the effect size, the quality of the study and findings from other studies. For these reasons, statistical analyses were performed without correction of type I error.

2.7. Ethics

This was a retrospective observational study. Diagnostic and therapeutic decisions were according to usual practice. This study was conducted according to the principles of the declaration of Helsinki and was approved by our institutional review board (no. IRB00008526, 20/12/2017).

2.8. Role of the funding source

The study was funded by Clermont-Ferrand University hospital. Orthopédie Moderne had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

3. Results

3.1. Patients

In total, 174 patients received a CRLB from January 1, 2014 to December 31, 2016; 62 participants were included in the study (Fig. 1). The mean (SD) age was 47 (7.7) years. Mean baseline pain was 6.7/10 (1) (calculated from 48 patients). Sociodemographic, clinical and MRI characteristics are in Table 1.

3.2. Outcomes

Overall, 49/62 (79%) participants showed improvement in pain of at least 30% (median 50 [IQR 30–70]). Also, 39/62 (62.9%) showed improvement in pain of at least 50%. The mean (SD) improvement percentage after 3 months of immobilization with the CRLB was 49% (25.1). Table 2 illustrates the improvement in pain along with the effect size according to different parameters. The percentage improvement in pain did not differ by clinical and MRI characteristics. Pain recurred for 30/46 (65.2%) participants after CRLB withdrawal (16 missing data). The non-significant results were confirmed by multivariable analysis with multiple linear regression.

3.3. Adverse events

We did not record any adverse events secondary to the use of the brace.

4. Discussion

We found that a rigid lumbar brace worn for 3 months was associated with a 30% reduction in pain for individuals with cLBP and active discopathy. No clinical, sociodemographic or radiographic factors or medical history of disc surgery were associated with pain evolution at 3 months. However, the retrospective open and uncontrolled design of our study limits our interpretation about a specific treatment effect.

We found good tolerance of the CRLB. Only 2 patients stopped wearing it prematurely because of an increase in pain. This conservative treatment has few side effects, which are mainly cutaneous, psychological impact and potential cardio-respiratory and digestive physical constraint. Furthermore, lumbosacral or lumbar braces do not lead to spinal muscular atrophy [11].

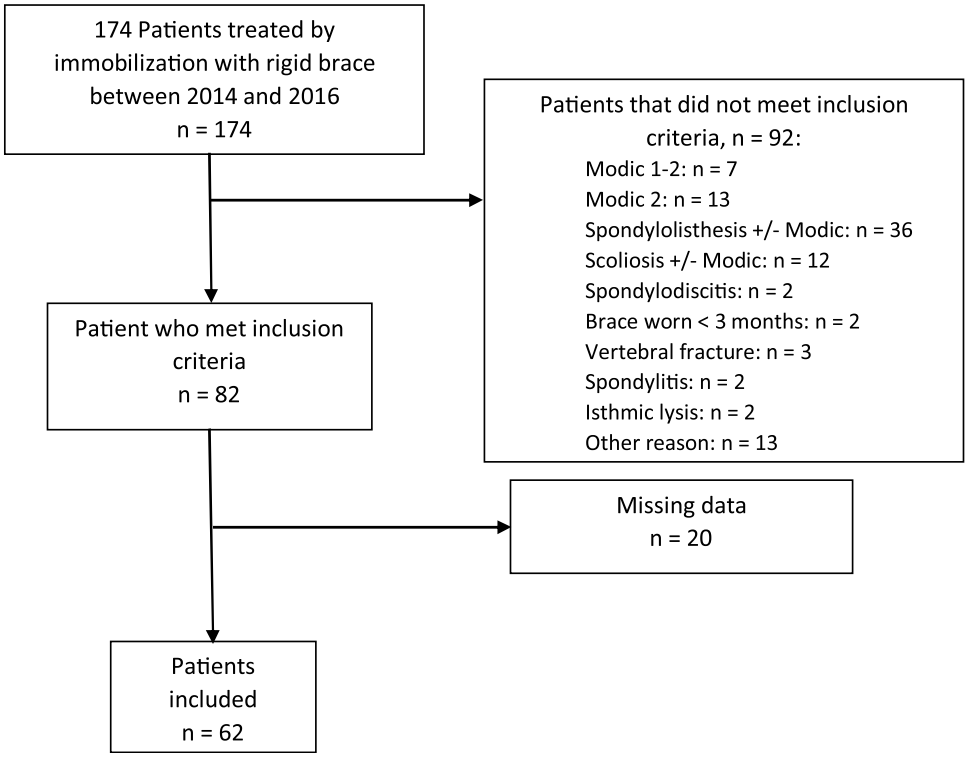

Fig. 1. Flow of participants in the study.

Table 1
Sociodemographic, clinical and MRI characteristics of patients with chronic low back pain at baseline.

Sex (F/M) ($n = 62$)	22/40 (35.5/65.5%)
Occupation ($n = 62$)	
Physical	31 (50%)
Sedentary	14 (22.6%)
Mixed	15 (24.2%)
Retired or invalidity	2 (3.2%)
Time of pain evolution ($n = 62$)	
< 6 months	3 (4.9%)
6–12 months	11 (17.7%)
> 12 months	48 (77.4%)
Disc surgery history ($n = 62$)	17 (27.4%)
Modic type 1 level ($n = 62$)	
L2L3	1 (1.6%)
L3L4	3 (4.9%)
L4L5	17 (27.4%)
L5S1	35 (56.4%)
Multiple levels	6 (9.7%)
Night-time awakenings due to pain ($n = 48$)	39 (81.2%)
Morning stiffness > 15 min ($n = 50$)	41 (82.0%)

We determined the minimal time that the CRLB had to be worn (3 months) according to the healing delay for vertebral micro fractures [12]. Despite the amount of missing data concerning this variable, pain recurrence after CRLB withdrawal remains high. Nevertheless, this pain recurrence suggests an effect of CRLB on pain evolution, in the short term. We were not able to assess the pain at 5 months because of missing data in medical files (fourth consultation).

CRLB treatment has been the concern of expert opinion or practice investigations. MC is the main pathology leading to CRLB prescription in clinical practice [7]. For instance, patients responding positively to CRLB probably have MC type 1.

In the absence of any consensus regarding the care management of these patients with cLBP with active discopathy, it seems relevant to remind about the main treatment described and their efficiency.

Concerning non-invasive treatments, as compared with active physiotherapy, resting and non-rigid braces did not differ over a 10-week course [14]. The mean percentage improvement in pain after 10 weeks in the resting and brace group was 11% versus 12% in the active physiotherapy group. This study did not specifically focus on MC type 1. In 2015, Jensen et al. [15] conducted a secondary analysis of these data [14] by isolating MC type 1 but did not find any significant results.

We did not find any study focusing on the efficiency of oral analgesic treatments (non-steroidal anti-inflammatory drugs [16], corticosteroids [17]) specifically in cLBP with MC type 1. Furthermore, there was no effect with the prescription of oral antibiotics. A study found a significant improvement in pain after 100 days of amoxicillin-acid clavulanic [18], with a mean improvement of 25% at the end of treatment and about 45% after 1 year. However, this effect was not confirmed in a recent prospective study [19]. Pain was significantly improved at 6 months and 1 year after treatment by intravenous pamidronate, with a mean improvement of 46% and 51%, respectively. This study involved only 10 patients and was not randomized. A randomized controlled trial comparing zoledronic acid versus denosumab versus placebo did not show any significant improvement in pain at 6 months [21]; another randomized controlled trial is in process [22]. A recent prospective study confirmed the efficiency of intradiscal corticosteroid infiltrations in the short term with pain as an outcome [23], giving more credit to previous results in the literature [24,25], with a mean improvement in pain of 24% at 3 months. However, pain was described as worse at 3 months after infiltrations.

Comparing these different treatments is difficult because of different study designs and populations studied. Furthermore, the retrospective nature of our study does not allow for a direct comparison in terms of efficiency.

The presence of MC type 1 could be a prognostic factor of better response to lumbar vertebral fusion as compared with MC types 2 and 3. Posterior lumbar fusion with an interbody cage seems efficient for pain in the long term in the presence of MC type 1 (mean improvement in pain of 64% at 3 years [26]). However, there are contradictory results in the literature.

A systematic review did not determine whether the presence of MC affected the results of spine surgery: evidence was shown for a negative correlation between clinical characteristics and discectomy and positive correlation after total disc replacement. Proof was not sufficient to conclude versus arthrodesis.

Our study has several limitations. The size of our sample was small. A positive response could have been due to the natural course of the disease, which is currently unpredictable, but also to a possible placebo effect that we could not control for in this retrospective study. Another limitation is the missing data, which prevented from assessing a mean visual analog scale score for pain (VASp). Not having a reliable VASp score led us to choose the minimum clinically important improvement (MCII) as an outcome instead of the patient acceptable symptom state (PASS). Tubach et al. [29] reported that the MCII and PASS are similar across diseases (including LBP) and countries, whatever the outcome. The absence of data regarding functional outcome or other psychosocial data, which are key points in pain chronicity, is also a limitation. Patients were not systematically asked to stop their professional activity, which could have led to a confounding effect between those at rest and those pursuing activities.

Despite the numerous limitations that are inherent to a retrospective study, mainly due to missing data, this is the first study to our knowledge, to assess the pain evolution of NS sLBP with MC type 1 treated with CRLB. Finally, acceptance of the CRLB

Table 2
Percentage improvement in pain by different variables.

	Percentage improvement in pain	*P*	Effect size [95% CI]
Sex (F/M)	50 [35–70]/50 [30–60]	0.46	−0.23 [−0.75–0.29]
Disc surgery history (Y/N)	50 [25–50]/50 [30–75]	0.13	0.42 [−0.14–0.98]
Time of pain evolution (months)			
< 6	50 [10–60]	0.37	−0.45 [−1.11–0.21]
6–12	40 [20–70]		
> 12	50 [40–70]		
Night awakening pain (Y/N)	50 [25–70]/50 [45–75]	0.52	0.24 [−0.48–0.97]
Morning stiffness			
≤ 15 min	50 [30–60]	0.35	−0.41 [−1.13–0.32]
> 15 min	50 [40–70]		

Data are median (interquartile range). 95% CI: 95% confidence interval; F: female; M: male; no. Mann–Whitney test.

is probably a major factor of efficiency, because only patients who wore the CRLB were evaluated, which prevented from assessing the acceptability. We believe that acceptance and tolerance was good because braces were custom-made, which diminishes the rate of side effects regarding the tolerance and contributes to treatment observation.

5. Conclusion

In the present study, we found a 30% reduction in pain at 3 months in 79% of patients with cLBP and active discopathy treated with a rigid lumbar brace worn for 3 months. However, the retrospective open and uncontrolled design of our study limits our interpretation of a specific treatment effect. Immobilization with CRLB is a non-invasive approach, so it is an interesting treatment. Randomized controlled trials are necessary to confirm these results and to specify the best indication for immobilization with a CRLB in NS cLBP with MC type 1. Functional outcome should also be considered in further studies.

Disclosure of interest

The authors declare that they have no competing interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org10.1016/j.rehab.2018.06.008.

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