

A Longitudinal Observational Clinical Study of Neurophysiological and Patient-Reported Responses to a Program of Physiotherapy for Acute and Subacute Low Back Pain

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ABSTRACT

Objectives: The purpose of this study was to document the baseline neurophysiological status (skin conductance activity levels) of patients presenting for physiotherapy with acute and subacute low back pain (symptoms of up to 12 weeks' duration) and to observe the magnitude and direction of sympathetic nervous system (SNS) changes (skin conductance responses [SCRs]) occurring as a result of receiving guideline-endorsed physiotherapy treatment.

Methods: A pragmatic, prospective, longitudinal, observational study recording SNS skin conductance (SC) responses and patient reported outcome measure changes to a program of guideline-endorsed physiotherapy treatment for low back pain symptoms of up to 12 weeks' duration. Sixty patients received a guideline-endorsed physiotherapy treatment program. Continuous neurophysiological recordings of SC activity levels were taken throughout each treatment. Patient reported outcome measure data were extracted from inception, midpoint, and discharge. Within and between treatment analyses determined the nature of SC changes and correlations to longitudinal changes in pain and function. Skin conductance changes were measured within and between treatment episodes at treatment inception, midpoint, and discharge and observed correlations between the magnitude of SCRs, pain abatement (numeric pain rating scale), and functional restoration (Oswestry Disability Index).

Results: Skin conductance changes were significant during all "treatment" periods ($P = .044$), with the greatest magnitude of sympathoexcitatory responses occurring at inception (219%). The treatment modality providing the maximum SNS response was a high-velocity lumbar rotation manipulation. Positive correlations were identified between SCRs, Oswestry Disability Index improvements ($r = 0.82$, $P < .0005$), and pain abatement ($r = 0.459$, $P < .0005$).

Conclusions: Patients with low back pain exhibited neurophysiological treatment responses indicative of a symptom-related neuroplastic state of dorsal horn sensitization that may be receptive to early manual therapy intervention. (*J Manipulative Physiol Ther* 2018;xx:1-11)

Key Indexing Terms: *Low Back Pain; Manipulation, Spinal; Patient Reported Outcome Measures; Sympathetic Nervous System*

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INTRODUCTION

Despite 2 decades of published guidance supporting the use of physiotherapy in the rehabilitation of patients with low back pain (LBP), there continues to be a paucity of empirical knowledge that can support evidence-informed clinical decisions, guide patient choice, and advise policy makers. Indeed, clinical practice guidelines for the management of LBP¹ advocate the use of therapeutic techniques such as manual therapy (MT) and exercise therapies, although the specifics of the treatments remain under debate. Nonetheless, MT treatments are implemented by 73% of United Kingdom physiotherapists² and continue to be integral to multimodal packages of care. Research evidence has provided support

for the use of MTs and exercise therapies on this patient group^{2,3} with improvements, beyond the natural course of symptom resolution, being reported both subjectively; utilizing patient-reported outcome measures (PROMs) of pain intensity⁴ (ie, numeric pain rating scale [NPRS]) and functional disability⁵ (ie, Oswestry Disability Index [ODI]); and objectively or neurophysiologically utilizing immediate changes in measures of sympathetic nervous system (SNS) activity.³ Adaptive changes in neurophysiological responses to guideline-endorsed treatments throughout a course of therapy have yet to be reported; furthermore, no previous study has described observed correlations between neurophysiological responses and traditional PROMs, which may provide preliminary clinical insight into the possible mechanisms of action of a number of therapeutic techniques utilized in this clinical cohort.

In 2009, Bialosky et al⁶ described, in their model of the mechanisms of action of manual therapy for musculoskeletal pain, the links between changes in the measurements of SNS activity and observed pain modulatory responses at both spinal and central levels. Moreover, Perry et al⁷ established that skin conductance (SC) measurements could be reliably recorded between data sessions (intraclass correlation coefficient = 0.99, $P < .005$) with a smallest real difference (SRD) value of 0.315 μmhos (a 4.633% change in SC readings), indicating that any SC change above the SRD could be regarded as an SNS response that is independent of any measurement error or variability, thus representing a real change ascribable to the intervention under investigation. Clinically, Perry et al^{3,7} were the first to describe and compare immediate SNS responses, in both normative and symptomatic groups, to 2 lumbar treatment modalities (manipulation and McKenzie extension in lying exercises⁸). Interestingly, despite similarities in the direction of observed sympathoexcitatory SC responses (SCRs) to treatment, differences in the magnitude of the SNS responses were notable between asymptomatic and symptomatic participants with during-treatment SCRs for the clinical group being 3 times greater than those of healthy groups. This enhanced SCR in the symptomatic group has been suggested to represent an adapted “up-regulated” dorsal horn (DH) with resultant enhancement of neuronal excitability to therapeutic, mechanical stimulation.⁹⁻¹² To date, only immediate SNS responses to lumbar treatments have been reported, with none that have documented and compared PROMs with the longitudinal changes in neurophysiological activity levels within and, uniquely, between treatment episodes lasting for 4 to 8 weeks.

The aims of this study included documentation of the baseline neurophysiological status (skin conductance activity [SCA] levels) of patients presenting for physiotherapy with acute and subacute LBP (symptoms of up to 12 weeks' duration) and observation of the magnitude and direction of SNS changes (SCRs) occurring as a result of receiving

guideline-endorsed physiotherapy treatment (a complex health care intervention) reporting results at 3 data capture points (at inception/commencement of treatment, at mid-point, and at discharge). The secondary aims of the study were to identify potential correlations in changes in SNS status and treatment SCRs to PROM and to identify any “active components” to the therapeutic encounter (notably, to describe the treatments that produced the greatest magnitude of SC response during each encounter).

METHODS

A pragmatic, prospective, longitudinal, observational study design was selected to detect patient neurophysiological responses and PROM changes in response to a program of guideline-endorsed physiotherapy treatment.

Sample Size Calculation and Participant Recruitment

The number of participants required to detect a statistically significant difference ($P < .05$) at 80% power with an effect size of 0.38 (35% mean percentage change [PC] in SCR as a meaningful SCR difference from baseline for the treatment component; standard deviation 92%) was calculated to be 57 patient participants. Anticipating a dropout rate of 10% to 20% (5-13 patients), up to 70 patients needed to be recruited for the study (Fig 1).

Ethical approval was obtained from the University Ethics Committees at Coventry University, the NHS Research Ethics Committee (NREC Ref: 09/H0402/55), and the University Hospitals of Leicester (UHL NHS Trust) Research and Development Office (Ref: UHL 10755).

Patient recruitment, assessment, and treatment took place between July 2009 and May 2011. Good retention of participants meant that during this period, a purposive and convenience sample of 60 patients with LBP was recruited at the physiotherapy department at the University Hospitals of Leicester NHS Trust (Fig 1). Informed consent was obtained from all patients in the study. They satisfied the study criteria (Fig 2) and were assessed as having a mechanical presentation of symptoms with restriction of 1 or more lumbopelvic movements and 1 or more hypomobile lumbar segments on palpation. Patients with red and yellow flags were excluded from the study to maintain cohort homogeneity.

The patients' inception demographic characteristics and PROMs are detailed in Table 1. Participants were informed (prior to attending their appointments) that they were required to avoid certain behaviors, such as consuming food, alcohol, or stimulants (eg, drinks with caffeine and nicotine products¹³) and to avoid heavy exercise 4 hours prior to appointments¹⁴ because these factors are known to alter SNS activity. Participant compliance with these prohibitions was monitored by way of a series of screening questions prior to each treatment session. All participants were adherent to the protocol.

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