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The use of validated outcome measures in the chiropractic care of pregnant patients: A systematic review of the literature



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ABSTRACT

Keywords:
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Background: Healthcare systems recognize the need to incorporate patient-reported outcomes as part of their clinical and research measures. We performed this review on the use of validated outcome measures in the chiropractic care of pregnant patients.

Methods: Pubmed, CINAHL, Medline, Index to Chiropractic Literature and MANTIS were searched for (1) primary investigation reports (i.e., case reports, case series, case control, randomized controlled trials and survey or surveillance studies) published in English; (2) involving the care of pregnant patient(s) and (3) utilizing a valid outcome measure.

Results: Our review found 8 articles using the Patient's Global Impression of Change, the NRS, the Oswestry, Bournemouth, Fear Avoidance Belief and Quebec Disability questionnaires, PROMIS-29 and the Measure Yourself Medical Outcome Profile.

Conclusion: Despite their heterogeneity and inconsistency of use in the studies reviewed, our findings demonstrate some measure of effectiveness in the chiropractic care of pregnant patients.

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1. Introduction

Healthcare providers, including chiropractors, patient advocates, regulatory agencies, third party payers and policymakers recognize the need for valid outcome measures (i.e., accurate and meaningful capture and interpretation of patient data) to not only evaluate the effectiveness of care but also provide a mechanism by which the performance (i.e., cost, safety) of healthcare providers can be measured and improve their clinical quality [1].

Of interest in this article is the use of valid outcome measures in the chiropractic care (i.e., the use of spinal manipulation/adjustment and adjunctive therapies) of pregnant women. There is a rich tradition in chiropractic on the care of pregnant women that goes back to its founder, DD Palmer [2]. Despite extensive clinical experience in the care of pregnant patients, the recent systematic

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review by Alcantara et al. [3] found studies consisting mostly of case reports/series, surveys and reviews of the literature with a handful of cohort studies. To date, 5 systematic reviews [3–7] on chiropractic and pregnancy care have been published. This disproportionation may reflect both the complexity of care and the pathophysiology involved in pregnancy-related morbidities for this patient population. Furthermore, the exact mechanisms of the effect of chiropractic care in this patient population remains relatively unknown and as such speak to the need for more research.

Towards safe and effective interventions, we again echo the sentiment that there is a need by all healthcare providers to use validated outcome measures. Outcome measures such as pain levels and functional health status using the Visual Analogue Scale (VAS), the Numerical Rating Scale (NRS), the Roland Morris Disability Questionnaire (R-MDQ), the Oswestry Low Back Pain Disability Index (Q-LBPDI) and the Short Form-36 (SF-36) (see Table 2) are measures commonly used in chiropractic, with reviews examining their use in clinical practice [8–15]. However, to the best of our knowledge their use in the chiropractic care of pregnant patients has not been examined. To address this deficit and in

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 Table 1

 Summary of studies on the chiropractic care of pregnant patients utilizing validated outcome measures.

Reference	Study design	Sample	Outcome measure	Results/conclusions
Peterson et al. [16]	Prospective cohort	A total of 108 patients (average age = 32.96 years) presenting at an average week of gestation at 26.21 weeks.	NRS O-LBPDI	Compared to baseline PGIC measures, 52% of the subjects 'improved' at 1 week, 70% at 1 month, 85% at 3 months, 90% at 6 months and 88% at 1 year. Significant reductions in NRS and OSW scores were observed from baseline to comparative measures in patients presenting with low back and pelvic pain.
George et al. [17]	RCT	A sample size of 169 pregnant patients with an average age of 27.3 years (treatment group) versus 26.6 (control group).	NRS QDQ	The addition of chiropractic to usual obstetrics care resulted in clinically and statistically significant improvements in NRS and QDQ scoring in patients presenting with low back and pelvic pain.
Alcantara et al. [18]	Prospective case series	Six subjects with average age at 33.33 years and average parity at 0.33 with mean week of gestation at 20.	PROMIS-29	The PROMIS scoring demonstrated pregnant patients under chiropractic care improved in the domains of fear/anxiety, pain interference and satisfaction with social roles) and decreased in physical functioning and sleep disturbance domains.
Murphy et al. [19]	Prospective cohort	Pregnant women (N = 115) presenting with low back pain, pelvic pain or both were examined before and after a trial of chiropractic care. The average age was 29.9 years and mean gestation at 25. 2 weeks.	BDQ NRS FABQ-Act	At end of treatment and long-term follow-up, the NRS and BDQ scores improved significantly. The greatest improvements were in those patients presenting with posterior pelvic pain. No discussion was provided on the use results of the FABQ-Act outcome measure.
Andrew et al. [20]	Prospective case series	Three pregnant women with presenting complaint of pelvic girdle pain	MYMOP2	The MYMOP2 demonstrated consistency of response for recording and evaluating women's experiences and the chiropractic findings.
Skaggs et al. [21]	Prospective cohort	A cohort of pregnant women ($N = 599$) at an average age of 22.7 years, average weight of 177.41 lbs. and average week of gestation at 17.1 weeks.	Sleep NRS	Clinically important changes in the NRS and improvement in sleep were observed with chiropractic care.
Lisi [22]	Retrospective case series	A cohort of pregnant women (N = 17) at an average age of 32.4 years and average gestational age of 27 weeks presenting with complaints of low back pain.	NRS	The mean NRS decreased from 5.9 to 1.5 at termination of care. The average time to clinically important pain relief was 4.5 days at an average no. of visits of 1.8. The total no. of visits averaged 5.6. None of the 17 women reported any adverse effects.
Guadagnino [23]	Retrospective case series	12 patients aged 14–34 years	NRS	During care, the average VAS pain rating ($0 = \text{no pain}$; $10 = \text{worst pain}$) was 4.25 compared with 7.58 at baseline

keeping with the principles of evidence-informed practice, we performed a systematic review of the literature on the use of validated outcome measures in the chiropractic care of pregnant patients.

2. Methods

A search strategy was devised using the following key terms: "chiropractic AND pregnancy." For our electronic search, we utilized the following databases: Pubmed (1966-2014), CINAHL (1966–2014), Medline (1966–2014), Index to Chiropractic Literature (1984–2014) and MANTIS (1966–2014). Additionally, chiropractic journals (i.e., Journal of Manipulative and Physiological Therapeutics, Journal of the Canadian Chiropractic Association, Clinical Chiropractic, and The Chiropractic Journal of Australia) were hand-searched for the last five years for possible relevant materials. Two of the authors independently reviewed the title and abstracts of all articles generated from the electronic search as well as from the reference lists of relevant articles. The full manuscripts of reports relevant to the chiropractic care of pregnant patient were retrieved by applying the following set of eligibility criteria: (1) the study was a primary investigation/ report (i.e., case reports, case series, case control, randomized controlled trials and survey or surveillance studies) published in a peer-reviewed journal in the English language; (2) part or all of the study population involved the care of pregnant patient(s) and (3) a validated outcome measure was used.

3. Results

Our review revealed 84 articles describing chiropractic care during pregnancy. Of these, 8 articles met our inclusion criteria [16–23] (See Table 1). Five of these were prospective in nature [16,18–21], 2 were retrospective [22,23] while one involved a randomized clinical trial [17]. The following is our narrative analysis of the literature.

Peterson et al. [16] recently published their findings with pregnant patients presenting for chiropractic care with complaints of low back or pelvic pain. In addition to patient sociodemographics, baseline Numerical Rating Scale (NRS) and Oswestry Low Back Pain Disability Index (O-LBPDI) data (see Table 2) were collected. Comparative measures were collected in addition to the Patient's Global Impression of Change (PGIC) (see Table 2) at 1 week and at 1 and 3 months since initiating care. At 6 months and 1 year since initiating care, only the PGIC and NRS scores were collected. Patients responding "better" or "much better" were categorized as "improved" while other responses were scored as "not improved." The authors recruited 115 subjects for the study. Compared to baseline PGIC measures, 52% of the subjects 'improved' at 1 week, 70% at 1 month, 85% at 3 months, 90% at 6 months and 88% at 1 year. Significant reductions in NRS and O-LBPDI scores (p < 0.0005) were also observed from baseline to comparative measures. The authors concluded that pregnant patients undergoing chiropractic treatment experienced clinically relevant improvements in their low back or pelvic pain but with no single variable was strongly predictive of "improvement" based on logistic regression modeling.

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