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Chiropractic Care for Nonmusculoskeletal Conditions: A Systematic Review with Implications for Whole Systems Research

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ABSTRACT

Objectives: (1) To evaluate the evidence on the effect of chiropractic care, rather than spinal manipulation only, on patients with nonmusculoskeletal conditions; and (2) to identify shortcomings in the evidence base on this topic, from a Whole Systems Research perspective.

Design: Systematic review.

Methods: Databases included were PubMed, Ovid, Mantis, Index to Chiropractic Literature, and CINAHL. Search restrictions were human subjects, peer-reviewed journal, English language, and publication before May 2005. All randomized controlled trials (RCTs) were evaluated using the Scottish Intercollegiate Guidelines Network (SIGN) and Jadad checklists; a checklist developed from the CONSORT (Consolidated Standards of Reporting Trials) guidelines; and one developed by the authors to evaluate studies in terms of Whole Systems Research (WSR) considerations.

Results: The search yielded 179 papers addressing 50 different nonmusculoskeletal conditions. There were 122 case reports or case series, 47 experimental designs, including 14 RCTs, 9 systematic reviews, and 1 a large cohort study. The 14 RCTs addressed 10 conditions. Six RCTs were rated “high” on the 3 conventional checklists; one of these 6 was rated “high” in terms of WSR considerations.

Conclusions: (1) Adverse effects should be routinely reported. For the few studies that did report, adverse effects of spinal manipulation for all ages and conditions were rare, transient, and not severe. (2) Evidence from controlled studies and usual practice supports chiropractic care (the entire clinical encounter) as providing benefit to patients with asthma, cervicogenic vertigo, and infantile colic. Evidence was promising for potential benefit of manual procedures for children with otitis media and elderly patients with pneumonia. (3) The RCT design is not necessarily incompatible with WSR. RCTs could improve generalizability by basing protocols on usual practice. (4) Case reports could contribute more to WSR by increasing their emphasis on patient characteristics and patient-based outcomes. (5) Chiropractic investigators, practitioners, and funding agencies should increase their attention to observational designs.

INTRODUCTION

The increasing emphasis on evidence-based health care decision-making requires providers to understand the

documented outcomes of their treatments. To better inform this decision-making, the Council on Chiropractic Guidelines and Practice Parameters (CCGPP) developed a process for evaluating the evidence for chiropractic care. Teams of

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TABLE 1. SIGN CHECKLIST⁸

Section 1: Internal validity ^a	
1.1	Study addresses appropriate, clearly focused question.
1.2	Treatment group assignment is randomized.
1.3	Adequate concealment method is used.
1.4	Subjects and investigators are kept "blind" about treatment allocation.
1.5	Treatment and control groups are similar at the start of the trial.
1.6	Only difference between groups is the treatment under investigation.
1.7	Outcomes are measured in a standard, valid, and reliable way
1.8	What percentage of subjects in each treatment arm dropped out before the study was completed? (record %)
1.9	All subjects are analyzed in the groups to which they were randomly allocated (intention-to-treat analysis)
1.10	Where the study is multisite, results are comparable for all sites

Section 2: Overall assessment^b

How well was the study done to minimize bias? How valid is the study? *code +, n, or -*

SIGN, Scottish Intercollegiate Guidelines Network.

^aEach item in Section 1 is to be evaluated using these criteria: Well-covered; adequately addressed; poorly addressed; not addressed (*i.e., not mentioned, or indicates that this aspect was ignored*); not reported (*i.e., mentioned, but insufficient detail to allow assessment*); and/or not applicable.

^bThe overall assessment uses the following ratings:

+, Strong. All or more of the criteria have been fulfilled; *n*, Paper is neither exceptionally strong nor exceptionally weak; -, Weak. Few or no criteria fulfilled.

experts on methodology and practice were formed to address various categories of conditions. This paper reports the results of the compilation of evidence related to chiropractic care for patients with nonmusculoskeletal conditions. We defined these, for this review, as conditions in which the primary symptoms are not related directly to the spine or musculature. For operational purposes, our review specifically excluded headaches, for two reasons: First, headaches were included in the CCGPP category of "cervical spine," and so were addressed by that team; although migraines may not be of musculoskeletal origin, they are often included in headaches studies, along with tension headaches, and it would be difficult to effectively tease out the nonmusculoskeletal and musculoskeletal components. Second, the topic of manipulative treatment of headache is quite extensive, and would result in an unmanageably large paper if combined with the nonmusculoskeletal literature in general.

Previous papers addressing this topic have relied primarily on the results of randomized controlled trials (RCTs), and, because of the paucity of such studies, have concluded that evidence is insufficient.^{1,2} However, recently there has been protest within the scientific community against the near-total reliance on RCTs as a source of evidence.³ Particularly

for "complementary and alternative medicine" (CAM) practices, observational studies reflecting usual practice are gaining credibility.⁴ This is especially relevant to "body-based" practices, which do not lend themselves readily to blinding. In its 2005 report on CAM, the Institute of Medicine recognized the need to develop scientifically rigorous, yet appropriate, methods to study CAM.⁵ Whole systems research (WSR) is a burgeoning methodological perspective that addresses this need.³ It emphasizes the importance of "model validity," that is, congruence between research methodology and the paradigm of the system being investigated.³ Demonstrating the promising nature of WSR, the National Center for Complementary and Alternative Medicine cosponsored a symposium on WSR in 2002.⁶ Application of WSR methods to chiropractic research is as yet only theoretical.⁷

Therefore, we attempted not only to evaluate papers in accordance with conventional standards, but also to view them through a WSR perspective. The specific aims of this review were to (1) evaluate the published evidence on the effect of chiropractic care, rather than spinal manipulation only, on patients with nonmusculoskeletal conditions; and (2) identify specific shortcomings in the evidence base on this topic, with respect to developing a whole systems approach to research on the effects of chiropractic care.

MATERIALS AND METHODS

Paper selection

The initial search was done by an experienced chiropractic college librarian. Full text literature searches were conducted to identify studies that addressed the clinical effects on a specific condition of spinal manipulative therapy (SMT) and/or mobilization (including both chiropractic and osteopathic approaches), and/or general chiropractic man-

TABLE 2. JADAD SCALE^a

	Yes	No
Study was described as randomized.	1	0
Study was described as double-blinded.	1	0
Description of withdrawals and dropouts was provided.	1	0
Methods to generate the sequence of randomization were described and were appropriate.	1	0
Methods to generate the sequence of randomization were described and were inappropriate.	-1	0
Methods of double blinding were described and were appropriate.	1	0
Methods of double blinding were described and were inappropriate.	-1	0

^aScoring: 0-2 = low quality; 3-5 = high quality. From Reference 10.

TABLE 3. MODIFIED CONSORT CHECKLIST^a

1. Power calculation to determine sample size was reported.
2. Required sample size was attained.
3. Methods of blinding were described.
4. Success of blinding was assessed.
5. Baseline characteristics of groups were described.
6. Primary outcome measure was clearly stated.
7. Validity and reliability of primary outcome measure(s) were established.
8. Adequate description of treatment or procedure was included.
9. Therapeutic time was equivalent between groups.
10. Co-interventions were avoided or controlled for.
11. Possible biases in design were described and accounted for.
12. Attrition was less than 25%.
13. Comparison of dropouts versus completers was made.
14. Statistical analysis was appropriate to compare outcomes between groups.
15. Incidence of adverse events was reported.

^a“yes” = 1 point; “no” = 0 points. Scoring: 0–5 = low quality; 6–10 = medium quality; 11–15 = high quality.

agement, which might include procedures in addition to SMT. Papers were excluded if they (1) did not present original data or an analysis of original data (commentaries, editorials, or expert opinion pieces); or if they did not address (2) treatment outcomes; (3) a specific condition; or (4) manual procedures (that is, they were concerned with exclusively nonmanual practices, such as nutritional treatment).

The databases used were PubMed, Ovid, Mantis, Index to Chiropractic Literature, and CINAHL. Search restrictions were human subjects, English language, peer-reviewed journal, and publication before May 2005.

Hand searches and reference tracking were also performed, and the bibliography was assessed by additional content experts.

Terms used were “chiropractic” AND “visceral” OR “nonmusculoskeletal” OR “nonmusculoskeletal;” “manipulation” AND “visceral” OR “nonmusculoskeletal” OR “nonmusculoskeletal.” Additional searches were done for any conditions for which randomized trials were identified.

Evaluation procedures

Papers were classified by the first author (CH) as follows:

- RCT: studies using random assignment to treatment group and making between-group comparisons of an intervention and a comparison treatment to evaluate efficacy. This includes studies using placebo or sham comparison groups as well as those using comparisons of different (usually conventional medical) treatments.
- Systematic review: a literature review with explicitly defined inclusion and exclusion criteria for papers evaluating the quality of the studies.
- Cohort and case control: large observational studies examining risk factors or prognostic factors.

- Other controlled studies:
 - pilot studies: small randomized or nonrandomized studies for the explicit purpose of developing protocols or feasibility, not evaluating efficacy; or studies that were defined by their authors as “pilot studies”
 - quasi-experimental: nonrandomized studies with two or more treatment groups
 - single group interventions: pre-experimental studies performed under controlled conditions
 - other small experimental studies of various designs
- Case series: papers reporting more than 2 cases observed in clinical practice.
- Case reports: papers reporting 1–2 cases observed in clinical practice.

TABLE 4. WHOLE SYSTEMS RESEARCH CONSIDERATIONS^a

	<i>Points if “yes”</i>
1 Intervention included entire clinical encounter (rather than single procedure only)	
1a • Intervention tested “package” of care	1
2 Patient preferences/expectations assessed	
2a • Treatment preference or expectations assessed	1
3 Intervention individualized to the patient	
3a • Practitioner could use clinical judgment to modify procedures	1
3b • Practitioner could use clinical judgment to modify number of visits, duration of care	1
4 Intervention representative of usual practice	
4a • Delivered by experienced practitioners	1
4b • Procedures/protocols based on usual practice, as documented by case reports, case series or large observational studies	1
4c • Principal investigator delivered treatments (–1)	–1
4d • Fees for services were representative of usual practice	1
5 Comparison group representative of “real life”	
5a • “Real-life” comparisons such as no treatment, waiting list, or standard medical care used	1
5b • Sham/placebo procedure same as procedures used in usual practice (such as soft-tissue therapy) (–1)	–1
6 Outcome assessments measured effects important to patients	
6a • Primary outcomes were patient-based measures (pain, function, health status)	1
6b • Satisfaction assessed	1
7 General/systemic/quality of life (QOL) effects assessed	
7a • Health status or QOL instrument administered pre- and postintervention	1
Total	11

^aBulleted items are rated 1 or 0 unless otherwise specified. Total maximum score = 11, with 0–3 rated “low,” 4–7 rated “medium,” and 8–11 rated “high.”

Quality rating

All RCTs were evaluated for quality using the Scottish Intercollegiate Guidelines Network (SIGN) and Jadad checklists.^{8–10} Because these scales do not directly address certain important issues such as sample size and appropriate statistical analysis, we also developed a “modified CONSORT” checklist based on items included in the CONSORT checklist and Singh scale.^{11,12}

The SIGN checklist rates studies as high quality (+), low quality (–), or neutral (0) (Table 1). To simplify comparisons among rating systems, we reported high quality (+) studies as H; neutral (0) as M; and low quality (–) as L. Three coauthors independently rated each study, and the majority rating was used. One of these, a D.C./Ph.D., has been a doctor of chiropractic (D.C.) for 30 years with 15 years’ research experience; one was a D.C./Ph.D. with 18 years in practice and 5 years’ research experience; and one was a D.C./M.D. with 19 years’ practice experience as a D.C. and 8 years as a medical doctor (M.D.).

The Jadad scale rates studies on a scale of 0–5 (Table 2).¹⁰ Two coauthors independently rated each study. One of these raters was the D.C./Ph.D. with 15 years in research, the other a non-D.C. with an M.A. (concentration on demographics and social analysis), with a background in research and systematic reviews. Differences were resolved by discussion.

The modified CONSORT checklist consisted of 15 items (Table 3). This checklist is not validated; we used it only to track the inclusion of specific design items not addressed in the SIGN and Jadad instruments. We included additional detail on specific items in reporting results. Any of the 15 items with fewer than 50% of RCTs included were reported separately. Two coauthors (the same two who used the Jadad scale) independently rated all the studies and resolved differences by discussion.

Whole systems research considerations

We developed a checklist, based on the seminal paper by Verhoef and colleagues,³ of considerations essential to a WSR perspective (Table 4). This checklist was developed as an initial attempt to evaluate the applicability of the results of a conventional systematic review to WSR and usual practice. We gathered input from all coauthors and 3 chiropractors with 10–20 years practice experience in order to operationalize the considerations. For this study, the 2 coauthors who rated RCTs with the Jadad and modified CONSORT checklists independently applied this exploratory checklist to the RCTs rated “high” with the checklists described above. The raters resolved differences through discussion.

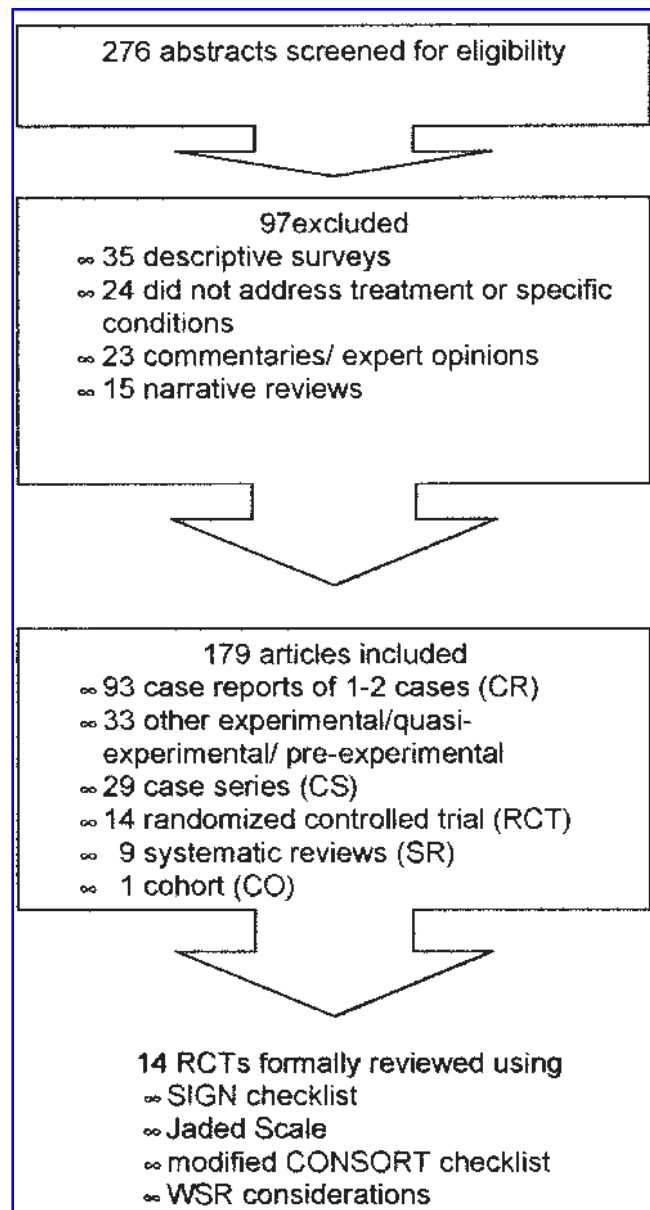


FIG. 1. Flow of citations through the retrieval and screening process.^{1–3}

¹Databases: PubMed, Ovid, Mantis, Index to Chiropractic Literature, and CINAHL.

²User Query: “chiropractic”[MeSH Terms] OR chiropractic [Text Word] AND “visceral” OR “nonmusculoskeletal” OR “non-musculoskeletal;” “manipulation” AND “visceral” OR “non-musculoskeletal” OR “non-musculoskeletal.”

³WSR, Whole Systems Research; SIGN, Scottish Intercollegiate Guidelines Network

Evidence tables

For each condition addressed by at least one RCT, we compiled an evidence table listing all citations, by type of study.

RESULTS

The search yielded a total of 276 papers. Applying the exclusion criteria resulted in 179 papers, as detailed in Figure 1. Table 5¹³⁻¹⁹¹ summarizes the literature by condition and type of study. There were 14 RCTs targeting 10 different conditions.

Table 6 summarizes the evaluation of the RCTs' quality. Six were rated high in all 3 systems. Items on the CONSORT checklist that were least often addressed were reporting of adverse effects (5), power calculation (5), and success of blinding (3).

Table 7 describes the evaluation of the 6 RCTs rated

“high” on the traditional checklists, in terms of WSR considerations. One study (Mills et al.¹³) was rated “high.” Items most frequently contributing to lower scores were (1) lack of assessment of treatment preference or expectations (5/6); (2) practitioner could not exercise clinical judgment to modify number of visits or duration of care (5/6); (3) procedures and protocols were not based on usual practice (5/6); (4) patient satisfaction not assessed (5/6); (4) comparison groups did not reflect real-life practice (4/6).

Tables 8–16 summarize the total body of evidence for each of the 10 conditions for which there was at least 1 RCT.

TABLE 5. SUMMARY OF PAPERS RELATED TO CHIROPRACTIC CARE FOR PATIENTS WITH NONMUSCULOSKELETAL CONDITIONS, BY TYPE OF PAPER AND CONDITION

Condition addressed & reference	Type of paper						Total
	RCT	SR	CO	Other ^a	CS	CR	
Total:	14	9	1	33	29	93	179
Vision ²⁸⁻⁴⁵				1	3	14	18
Asthma ^{14,46-58}	3	1		5	1	4	14
Hypertension ^{15,16,59-68}	2			6	2	2	12
Multiple conditions ⁶⁹⁻⁸⁰		1	1		3	7	12
Vertigo ⁸¹⁻⁹¹	1	1		3	4	2	11
Dysmenorrhea/PMS ^{17-20,92-97}	1	2		5	1	1	10
Infantile colic ^{21,22,27,98-102}	2	1		1		4	8
Otitis media ^{13,103-109}	1			1	3	3	8
Infertility/amenorrhea ¹¹⁰⁻¹¹⁷						8	8
ADHD/learning disabilities ¹¹⁸⁻¹²³				1	4	1	6
Chronic pelvic pain ¹²⁴⁻¹²⁹				2	1	3	6
Dysfunctional nursing ¹³⁰⁻¹³⁵				1		5	6
Nocturnal enuresis ^{23,136-139}	1	1		1		2	5
Constipation ¹⁴⁰⁻¹⁴⁴						5	5
Chronic obstructive pulmonary disease ¹⁴⁵⁻¹⁴⁸					2	2	4
Seizures ¹⁴⁹⁻¹⁵²						4	4
Visceral-related pain/disorders ¹⁵³⁻¹⁵⁶		2		1		1	4
Pneumonia ^{24,157}	1			1			2
Arrhythmia/ECG abnormalities ^{158,159}					1	1	2
Parkinson's ^{160,161}				1		1	2
Depression ¹⁶²				1			1
Phobia ²⁶	1						1
Bowel/bladder dysfunction ¹⁶³					1		1
Cerebral palsy ¹⁶⁴					1		1
Crohn's ¹⁶⁵				1			1
Jet lag ²⁵	1						1
Multiple sclerosis ¹⁶⁶					1		1
Ulcer ¹⁶⁷				1			1
Upper respiratory infection ¹⁶⁸					1		1
Other ^b						23	23

^aIncludes pilot studies, quasi-experimental (nonrandomized) designs, single-group interventions and other small experimental or pre-experimental designs.

^bConditions for which there were 1–2 case reports each, with no other types of study: 2 case reports: dysphonia,¹⁶⁹⁻¹⁷⁰ eczema/psoriasis,^{171,172} encopresis,^{173,174} hearing loss/tinnitus;^{175,176} one case report: anxiety¹⁷⁷ aphasia,¹⁷⁸ autism,¹⁷⁹ cancer pain,¹⁸⁰ cystic hygroma,¹⁸¹ diabetes,¹⁸² diabetic polyneuropathy,¹⁸³ Down syndrome,¹⁸⁴ Erb syndrome,¹⁸⁹ urinary tract infection,¹⁹⁰ vertebrobasilar ischemia.¹⁹¹

ADHD, attention deficit hyperactivity disorder; PMS, premenstrual syndrome; RCT, randomized controlled trial; SR, systematic review; CO, cohort study; CS, case series; CR, case report; ECG, electroencephalogram.

TABLE 6. EVALUATION OF RCTs^a

<i>Citation</i>	<i>SIGN</i>	<i>Jadad</i>	<i>Mod. CONSORT</i>	<i>Power calculation?</i>	<i>Success of blinding assessed?</i>	<i>Occurrence of adverse effects reported?</i>
Balon 1998 ⁵⁶	H	H	H	Yes	Yes	Yes
Goertz 2002 ¹⁶	H	L	H	Yes	No	No
Guiney 2005 ¹⁴	H	L	M	No	No	No
Hondras 1999 ¹⁸	H	H	H	Yes	No	Yes
Karlberg 1996 ⁸⁹	H	L	M	No	No	No
Mills 2003 ¹³	H	H	H	Yes	Yes	Yes
Nielsen 1995 ⁵⁷	H	H	H	Yes	No	Yes
Noll 2000 ²⁴	H	H	H	No	No	Yes
Olafsdottir 2001 ²⁷	H	H	H	No	No	No
Peterson 1997 ²⁶	L	H	L	No	No	No
Reed 1994 ¹³⁸	L	L	L	No	No	No
Straub 2001 ²⁵	H	L	M	No	Yes	No
Wiberg 1999 ¹⁰¹	M	H	M	No	No	No
Yates 1988 ⁶⁸	M	L	M	No	No	No

RCT, randomized controlled trials; SIGN, Scottish Intercollegiate Guidelines Network.

^aH = high quality; M = medium/neutral quality; L = low quality.

TABLE 7. WHOLE SYSTEMS RESEARCH CONSIDERATIONS^a

	<i>Balon</i> ⁵⁶	<i>Hondras</i> ¹⁸	<i>Mills</i> ¹³	<i>Nielsen</i> ⁵⁷	<i>Noll</i> ²⁴	<i>Olafsdottir</i> ²⁷
Intervention tested “package” of care	0	0	1	0	1	1
Treatment preference/expectations assessed	0	0	0	1	0	0
Practitioner could use clinical judgment to modify procedures	1 ^b	0	1 ^h	1	1	1
Practitioner could use clinical judgment to modify number of visits, duration of care	1 ^c	0	0	0	0	0
Delivered by experienced practitioners	1	0 ^e	1	1	1 ^l	1
Procedures/protocols based on usual practice, as documented by case reports, case series, or large observational studies	0	0	0	0	0	1 ⁿ
Principal investigator delivered treatments (−1)	0	0	0	0	0	0
Fees for services were representative of usual practice (NS = 0)	NS	NS	1 ⁱ	NS	1 ⁱ	NS
“Real-life” comparisons such as no-treatment, waiting list, or standard medical care used	0	0	1	0	0	1
Comparison procedure also used in usual practice (−1)	−1 ^d	−1 ^f	0	−1	−1 ^m	0
Primary outcomes were patient-based measures (pain, function, health status)	0	1	1 ^j	1	1	1
Satisfaction assessed	0	0	1	0	0	0
Health status or QOL instrument administered pre- and postintervention	1	1 ^g	1 ^k	1	0	0
Total	3	1	8	4	4	6

^aScore 1 if “yes” unless otherwise specified; maximum score is 11, with 0–3 = low; 4–7 = medium; 8–11 = high. NS, not specified. “NS” was counted as 0. QOL, quality of life.

^bSome latitude allowed in procedures, but all were diversified technique (high-velocity low-amplitude; HVLA) spinal manipulative therapy (SMT) with adjacent soft-tissue treatment, with no additional procedures allowed.

^cAllowed range of 20–36 visits over fixed (4 mo) treatment period.

^dComparison treatment was soft tissue massage accompanied by low-amplitude, low-velocity impulses applied to “nontherapeutic” contacts, avoiding joint cavitation.

^eMajority of treatment provided by chiropractic residents.

^fComparison treatment HVLA SMT with 200–400 N. force; active treatment HVLA SMT with 750 N force.

^gMenstrual Distress Questionnaire, assessing multifactorial items related to dysmenorrhea.

^hThe only restriction was that HVLA procedures were not used.

ⁱPatients were provided usual hospital inpatient care throughout study.

^jAOM (acute otitis media) episodes, antibiotic use, surgery.

^kInformation on behavior, sleep habits, mood, and attention collected.

^lFor all patients, students performed standardized portion of intervention, experienced doctors of osteopathy the nonstandardized portion.

^mComparison treatment was light touch to same regions for same time and at same intervals.

ⁿReference group of 14 doctors of chiropractic agreed on procedure for intervention.

TABLE 8. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH ASTHMA

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 406)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Balon 1998 ⁵⁶	RCT	80 (ages 7–16)	Chiropractic FS HVLA SMT + soft-tissue massage vs. simulated SMT + soft-tissue massage	No significant improvement in lung function measures in either group; symptoms, B-agonist medication use, and QOL improved in both groups	None
Guiney 2005 ¹⁴	RCT	140 (ages 5–17)	Osteopathic mobilization (ribs) + myofascial release vs. sham touch	Significant improvement in peak expiratory volume in treatment group only; difference between groups not analyzed for significance	Not reported
Nielsen 1995 ⁵⁷	RCT/ crossover	31 (ages 18–44)	Chiropractic FS drop-assisted HVLA SMT vs. sham drop-assisted manual pressure	Lung function measures and bronchodilator use unchanged; symptom severity and bronchial hyperreactivity improved in both groups	No adverse effects related to SMT
Ernst 2001 ⁸⁰	SR ^a	Reviewed Balon and Nielsen trials	—	Clinical improvements in both groups; no significant differences between groups	—
Hondras 2001 ⁵⁸	SR	Reviewed Balon and Nielsen trials	—	Insufficient evidence	—
Nilssen 1998 ⁵⁵	Retrospective case series	79 patient records (ages 2–63)	Chiropractic SMT, private practice	Patient-perceived improvement 1 mo, 5 treatments; younger age and less severe symptoms associated with more rapid improvement	Not reported
Bronfort 2001 ⁵³	Pilot RCT	36 (ages 6–17)	Chiropractic HVLA SMT vs. sham (manual pressure over spinal contact point, no thrust)	Groups not compared. Active group: quality of life and severity substantially improved; no changes in lung function	Not reported
Brockenhauer 2002 ⁵²	Crossover	10 (age >18; mean 47)	OMT vs. sham (pressure to paraspinal area + range-of-motion of arms)	Thoracic excursion significantly increased after OM, but not sham	None
Jamison 1986 ⁵⁴	Single-group pretest/post-test	15 (ages 8–45)	Chiropractic SMT, mobilization, manual soft-tissue treatment, exercise, home advice	Voluntary reduction or elimination of medication in 11/5; no change in spirometry	Not reported
Peet 1995 ⁵¹	Single-group pretest/post-test	8 (ages 4–12)	Chiropractic Biophysics Technique analysis and Mirror Image adjustments	Voluntary reduction or elimination of medication in all; peak flow meter reading performed by chiropractor improved	Not reported

(continued)

TABLE 8. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH ASTHMA (CONT'D)

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 406)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Lines 1993 ⁵⁰	Case series	3 (ages 2, 5, 30)	Chiropractic care + diet/lifestyle advice to eliminate allergens	Reduction of symptoms, episodes, medication use with 2-year follow-up	Not reported
Garde 1994 ⁴⁶	Case report	1 (age 6)	FS chiropractic SMT	Stopped use of inhaler	Not reported
Hunt 2000 ⁴⁷	Case report	1 (age 4)	Instrument-assisted (upper cervical specific) SMT to C-spine	Symptoms improved with 2-month treatment plan; 2 year follow-up with resolution of symptoms	Not reported
Killinger 1995 ⁴⁸	Case report	1 (age 18)	Palmer upper cervical SMT to previously traumatized segments	Improvement in health status	Not reported
Peet 1997 ⁴⁹	Case report	1 (age 8)	Chiropractic SMT, 8 visits during 2.5 weeks	Discontinued medication; 4-month follow-up	Not reported

RCT, randomized controlled trials; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; HVLA, high-velocity, low-amplitude; FS, full spine; OMT, osteopathic manipulative therapy; QOL, quality of life.

^aThis systematic review (SR) addressed studies on various conditions, not asthma only.

Asthma

Three papers reported on adverse effects (Table 8); all 3 reported that there were no adverse effects related to SMT. Physiological measures did not improve in any of the experimental studies except one (Guiney),¹⁴ in which peak expiratory volume improved in the treatment but not control group; however, between-groups difference was not analyzed for statistical significance. In all studies, symptoms were reported to improve and in most, medication use decreased.

Hypertension

Two papers reported on adverse effects (Table 9); both of these reported that there were no adverse effects related directly to SMT. However, in 1 (Morgan et al.),¹⁵ 6 patients were withdrawn because of unacceptable increases in blood pressure; medication had been withdrawn prior to enrollment. Most papers described application of manual procedures to the cervical and thoracic areas. Some papers reported decreases in blood pressure and decreases in medication use, but results were not consistent across studies. The Goertz RCT,¹⁶ although not rated as highly with the Jadad checklist because of its pragmatic study design, was highly generalizable to practice and tends to support a conclusion that chiropractic care is not of great clinical utility to a broad population of hypertensive patients.

Vertigo

One paper reported on adverse effects; there were no adverse effects for SMT in that study (Table 10). In 8 of 10 studies, dizziness was accompanied by neck pain (NP) and/or cervical spine dysfunction. In the other 2, patients with NP or cervical spine dysfunction were compared to those without. In general, patients with dizziness accompanied by neck pain and/or cervical spine dysfunction appeared to benefit from SMT and other manual procedures, although the controlled studies did not have adequate sample sizes to indicate statistically significant outcomes.

Dysmenorrhea and premenstrual syndrome

Dysmenorrhea. One study reported on adverse effects (Table 11). These were transient low back soreness in both the treatment (3) and sham treatment (2) group. All 4 studies used a comparison procedure that was very similar to that of the SMT group. For 3 of these, the main difference was that the amount of biomechanical force was less; for the other (Snyder and Sanders¹⁷), the comparison treatment was applied to a different, presumably nonaffected, area. Primary outcomes were measured 1 hour post-treatment for 2 studies (Hondras et al.¹⁸ and Kokjohn et al.¹⁹); in the Snyder study, they were measured at the end of 3 months of treatment and after a 3-month, no-treatment follow-up period. Across studies, patients receiving an intervention applying any amount of biomechanical force, even slight, showed some improvement; the sys-

TABLE 9. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH HYPERTENSION

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 491)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Goertz 2002 ¹⁶	RCT	140 (ages 25–60; systolic BP < 160; diastolic BP 85–99)	HVLA SMT, physical modalities + diet intervention by DC vs. diet intervention by dietician	No significant difference between groups; small decreases in BP in both	Not reported
Yates 1988 ⁶⁸	RCT	21 (ages 35– 60)	Instrument- assisted SMT T spine vs. sham (instrument set on zero), vs. no treatment	Significant decrease, systolic and diastolic BP immediately post- treatment in treatment group compared to sham and control	Not reported
Morgan 1985 ¹⁵	Crossover	29 (mean age/group: 48/50 yrs)	Mobilization of C1/occiput; T1– 5 and T11–L1 vs. soft-tissue massage (performed by osteopath)	No significant change in either group	6 patients withdrew because of BP increase above 150/110
Wagnon 1988 ⁶⁷	Crossover	18 high- aldosterone hypertensive (ages 20–50)	HVLA SMT (Gonstead) of C2, T9, L5 vs. no treatment	Significant drop in serum aldosterone after HVLA; no significant change in BP	Not reported
Plaughter 2002 ⁶⁶	Pilot study	23 (ages 24– 50)	HVLA SMT (Gonstead) vs. light massage vs. no treatment	No statistical analysis because of small sample size and nonequivalence of groups	No adverse events
Knutson 2001 ⁶⁵	Nonequivalent comparison group	54 (ages 20– 83)	SMT upper C (group with postural distortion) vs. no treatment (group without postural distortion)	Significant drop in systolic BP immediately after adjustment; no change in diastolic	Not reported
Johnston 1995 ⁶⁴	Cohort	61 (ages 23– 77)	Patients followed up at 3–10-yr interval for presence of spinal dysfunction pattern (C6T2T6) in hypertensives	80% of hypertensives had persistent pattern of spinal dysfunction	NA
Fichera 1969 ⁶³	Non equivalent comparison group	35 normal BP, 22 hypertensive (age NS)	Soft-tissue OMT to C and T paraspinal musculature	Greater decrease in BP in hypertensive group	Not reported
Goodman 1992 ⁶²	Case series	8 (age NS)	SMT to occiput/C1	6 of 8 had decrease in systolic and diastolic BP after 2 months of care	Not reported
Connelly 1998 ⁶¹	Case series	3 (ages 73, 41, 74)	Cranial adjusting— sacro-occipital technique	BP decreased during 6 mo. except in 73- year-old, in whom diastolic was normal at baseline	Not reported

(continued)

TABLE 9. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH HYPERTENSION (CONT'D)

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 491)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Plaugher 1993 ⁶⁰	Case report	1 (age 38)	SMT (Gonstead) C6– 7, T3–4, T7–8;	BP reduced after 3 treatments; MD reduced medications; after 7 treatments MD discontinued all medications; BP normal at 18 mo follow-up	Not reported for SMT
McGee 1992 ⁵⁹	Case report	1 (age 46)	HVLA SMT to C and T (Pierce- Stillwagon) for 8-week interval	BP decreased after 1 treatment; MD cut medication dose in half at 4.5 wks; maintained at 8 weeks	Not reported

RCT, randomized controlled trials; DC, Doctor of Chiropractic; MD, Medical doctor; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; OMT, osteopathic manipulative therapy; HVLA, high-velocity, low-amplitude; C, cervical vertebrae; T, thoracic vertebrae; L, lumbar vertebrae; BP, blood pressure; NS, not specified; NA, not applicable.

TABLE 10. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH VERTIGO

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 348)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Karlberg 1996 ⁸⁹	RCT	17 (ages 26– 49) with NP and dizziness	PT (soft-tissue treatment; mobilization, relaxation techniques, home exercise, ergonomics) vs. waiting list control	Trend toward less postural sway in treatment group; dizziness frequency and intensity significantly reduced in treatment group compared to control	Not reported
Galm 1998 ⁹¹	Non equivalent group, pretest/ post-test	50 (ages 19– 78) with dizziness	31 patients with C spine dysfunction, HVLA SMT, mobilization and PT; 19 without cervical spine dysfunction, PT	24/31 improved in SMT group vs. 5/19 in PT only group	Not reported
Grod 2002 ⁸⁶	Observational	36 chiropractic patients (ages 12– 72), 19 with NP and 17 without NP	No intervention; patients' perception of verticality assessed	NP patients, significantly greater error in perception of verticality than those without NP	NA
Heikkila 2000 ⁸⁷	Single- subject design pilot study	14 (ages 22– 54) with C- spine dysfunction and dizziness	HVLA SMT by manual medicine practitioner vs. acupuncture vs. no treatment	Reduction in dizziness greatest after SMT	Not reported
Rogers 1997 ⁸⁸	Nonrand- omized, matched pilot study	20 chiropractic patients with NP (age NS)	HVLA SMT vs. stretching exercises	SMT group showed greater improvement in head repositioning (cervical kinesthesia)	4/10 in exercise group, increase in pain; none in SMT group
Reid 2005 ⁹⁰	SR	—	Manual therapy	Level 3 evidence ^a	—

TABLE 10. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH VERTIGO (CONT'D)

Citation	Study type	Patients (total n = 348)	Interventions	Summary of outcomes	Adverse effects
Fitz-Ritson 1991 ⁸⁴	Case series	112 chiropractic patients (age 15–56) with neck trauma and vertigo	“Standard chiropractic care” to cervical spine for 18 treatments	101/112 symptom free, 11 had decreased vertigo, 5 no change	Not reported
Wing 1974 ⁸⁵	Case series	80 (age 40–60) with NP and vertigo	SMT, support collar, postural advice; treatment time unspecified	53% complete remission of vertigo; 35% improvement to extent medications discontinued	Not reported
Cote 1991 ⁸³	Case series	3 (ages 65, 62, 30) chiropractic patients with NP and vertigo	1. 65 yr old: BPPV and vertigo 20 years; 8 treatments/3 wks with vestibular rehabilitation exercises, mobilization to suboccipital area, soft tissue to C musculature. 2. 62 y old: cervical SMT and soft tissue 3. 30 yr old, cervical SMT and soft tissue	1. Complete remission at 3 wks maintained at 18 months 2. complete remission after 2 wks, maintained with occasional vertigo for 6 years, relieved by SMT 3. complete remission after 1 month, maintained for 3 years with one recurrence relieved by SMT	Not reported
Bracher 2000 ⁸²	Case series	15 (ages 27–82) vertigo patients (14 with NP)	C and T SMT; electrotherapy, biofeedback, C ROM exercise; labyrinth sedation medication (9/15)	Median 5 treatments/2 wks; 9/15 complete remission; 3/15 improved and medications stopped; 3/15 not improved	Not reported
Cronin 1997 ⁸¹	Case report	1 (age 64) chiropractic patient with NP, vertigo, hypertension	C mobilization and traction 1 visit; SMT C1-2 and T for 3 visits	Vertigo resolved after first SMT, maintained at 3-month follow-up	Not reported

RCT, randomized controlled trials; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; HVLA, high-velocity, low-amplitude; C, cervical vertebrae; T, thoracic vertebrae; BPPV, benign paroxysmal positional vertigo; ROM, range of motion; NP, neck pain; NS, not specified; NA, not applicable.

^aLevel 3 evidence defined as limited evidence derived from generally consistent findings in one or more lower quality RCTs.

tematic review (Cochrane collaboration group²⁰) concluded that active treatment was no more effective than sham, but possibly more effective than no treatment.

Premenstrual syndrome. None of the papers reported on adverse events (Table 11). Three of the 4 papers reported on treatment; all used high-velocity, low-amplitude (HVLA) SMT over at least 3 menstrual cycles. Results were inconsistent among studies, and the systematic review indicated that evidence was insufficient to make a recommendation.

Infantile colic

One paper reported on adverse effects (Table 12). This study (Klougart et al.²¹) reported no adverse effects to SMT

among 316 infants. A variety of SMT techniques were used among the 8 studies, most specifying a modification of force to accommodate treating infants; 1 study used instrument-assisted SMT (Leach²²). Both full-spine and localized SMT were utilized. Results were consistent in the direction of improvement with SMT; 1 systematic review judged the evidence insufficient, whereas the other indicated that, although SMT did not appear to be superior to placebo/sham treatment, it appeared that the delivery of chiropractic care resulted in improved parent-reported outcomes.

Otitis media

Two papers reported on adverse effects (Table 13). There were no adverse effects but some parent-reported positive side

TABLE 11. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH DYSMENORRHEA AND/OR PREMENSTRUAL SYNDROME (PMS)

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 308 women)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Dysmenorrhea					
Hondras 1999 ¹⁸	RCT	138 (ages 18–45)	Chiropractic HVLA SMT (> 750-N force to thoracolumbar spine and sacroiliac) vs. low-force lumbar mimic maneuver (<400-N force); primary outcomes 1 hour post-treatment	VAS and prostaglandin decreased, both groups over time. No significant between-groups difference	3 in SMT and 2 in mimic group transient (24 hours) lumbar soreness
Thomason 1979 ⁹⁴	Pilot study	8 (ages 17–35)	HVLA SMT vs. sham with instrument vs. no treatment	SMT group, symptoms improved	Not reported
Kokjohn 1992 ¹⁹	Pilot study	45 (ages 20–49)	HVLA SMT vs. low-force mimic maneuver	Improvement; both groups; significantly greater, SMT group	Not reported
Snyder 1996 ¹⁷	Randomized comparison study	26 (mean age/group, 27/26 yrs)	Low-force SMT (Toftness technique), 2–3 treatments/wk for 3 months with 3-month follow-up	Treatment group only improved on menstrual distress questionnaire. No between-groups comparisons	Not reported
Proctor 2002 ²⁰	SR	—	SMT	No more effective than sham, but possibly more than no treatment	—
PMS					
Walsh 1999 ⁹⁵	Observational study	54 with PMS, 30 without PMS (ages 18–49)	None; participants evaluated by non-blinded assessors for presence of spinal clinical findings	PMS patients showed higher prevalence of spinal clinical findings	NA
Walsh 1999 ⁹⁶	Crossover trial	25 (ages 20–47)	HVLA SMT and soft tissue vs. sham with instrument, 2 times per week for at least 3 menstrual cycles	Significant improvement in menstrual distress with treatment delivered first, either active or sham	Not reported
Stevinson 2001 ⁹²	SR	—	CAM therapies (reviewed Walsh study)	Insufficient evidence	—
Wittler 1992 ⁹⁷	Case series	11 (ages 23–42)	HVLA FS SMT (Gonstead), 4 menstrual cycles	Self-reported improvement in all symptoms at end of study period	Not reported
Stude 1991 ⁹³	Case report	1 (age 35)	HVLA lumbar spine SMT (side posture), 12 wks	PMS symptoms improved except for back pain and dizziness	Not reported

RCT, randomized controlled trials; SR, systematic review; CAM, complementary and alternative medicine; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; HVLA, high-velocity, low-amplitude; C, cervical vertebrae; T, thoracic vertebrae; FS, full spine.

TABLE 12. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH INFANTILE COLIC

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 467)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Olafsdottir 2001 ²⁷	RCT	96 (ages 3–9 wks)	Chiropractic mobilization and SMT vs. being held by nurse	Parent-reported improvement in crying time in both groups	Not reported
Wiberg 1999 ¹⁰¹	RCT	50 (ages 2–10 wks)	Chiropractic SMT and counseling vs. inactive medication and counseling	Colic diaries interpreted by blinded observer; no dropouts SMT group; 9 in control group. Parent-reported improvement in crying time in both groups, significantly greater in SMT group	Not reported
Klougart 1989 ²¹	Prospective single group observational	316 (ages 2–16 wks)	Chiropractic SMT	Substantial decrease in crying time after 2 wks of treatment	None
Ernst 2003 ¹⁵⁵	SR ^a	Reviewed Wiberg and Olafsdottir studies	—	Insufficient evidence	Not reported
Hughes 2002 ¹⁰²	SR	Reviewed Wiberg, Olafsdottir, Klougart, 1 unpublished abstract	—	No evidence of efficacy compared to placebo; evidence of fewer parent-reported hours of crying with chiropractic care	Not reported
Killinger 1998 ⁹⁸	Case report	1 11-month-old	2 treatments, chiropractic SMT Upper Cervical Specific toggle recoil	Late-onset colic with developmental delay after gum surgery; remission of colic at 3-wk follow-up, with improvement in coordination and activity.	Not reported
Leach 2002 ²²	Case report	2 (ages 6 and 9 wks)	Instrument-assisted (PULSTAR) SMT to thoracic spine	Crying decreased 50% after 1 session in 6-wk-old; after 4 sessions in 9-wk old; eliminated after 10 days; no recurrence at 30-day follow-up	Not reported
Pluhar 1991 ⁹⁹	Case report	1 infant (age 12 wks)	Chiropractic SMT: T7 (HVLA, Gonstead) and C1 (instrument assisted), 3 × at 2-wk intervals	Remission of symptoms after each treatment	Not reported
Van Loon 1998 ¹⁰⁰	Case report	1 infant (age 12 wks)	Chiropractic SMT (diversified and Webster) to occiput and cervical spine; craniosacral therapy; 4 × 2 wks	Remission of symptoms maintained at 6 months (without additional treatment).	Not reported

RCT, randomized controlled trials; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; HVLA, high-velocity, low-amplitude; C, cervical vertebrae; T, thoracic vertebrae.

^aThis systematic review (SR) addressed studies on various conditions, not infantile colic only.

TABLE 13. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH OTITIS MEDIA

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 465)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Mills 2003 ¹³	RCT	57 (ages 6 mo–6 yrs)	Routine medical care plus FS osteopathic mobilization and soft-tissue procedures vs. routine care only	Treatment over 6 mo; significantly fewer episodes AOM and surgical procedures in mobilization group compared to control	No adverse effects; several positive effects (relaxation/good naps)
Sawyer 1999 ¹⁰⁹	Pilot study	22 (ages 6 mo–6 yrs)	HVLA SMT vs. light-touch sham	No statistical analysis because of small sample	No serious effects; transient 1 case muscle soreness and 1 case transient irritability in SMT group; 1 case excessive crying in sham group
Fallon 1997 ¹⁰⁶	Case series	332 (ages 1 mo–5 yrs)	HVLA SMT to occiput and other segments + soft tissue to SCM; average 4–6 treatments	Normal otoscopic exam at 1 wk. No patient-oriented outcomes except recurrence: 11–30% recurrence in 6 mo	Not reported
Froehle 1996 ¹⁰⁷	Case series	46 children (ages 0–5; minimum age NS in months)	SOT + modified AK; terminated when improved	43% improved with 1–2 treatments; 75% within 10 days; 93% within 3 wks	Not reported
Fysh 1996 ¹⁰⁸	Case series	5 children (ages 1–5)	HVLA SMT C2; treatments ≤ 5	Time to resolution (normal otoscopic exam and reduction of fever) range: 3 days–8 weeks	Not reported
Peet 1996 ¹⁰³	Case report	1 (age 5)	SMT using CBP techniques; 24 treatments/6 mo	One recurrence during 6-month period	Not reported
Phillips 1992 ¹⁰⁴	Case report	1 (age 2)	Instrument assisted SMT to C1	Drainage and pain improved 3 days after treatment	Not reported
Thomas 1997 ¹⁰⁵	Case report	1 (age 1)	SMT (diversified) over 6-month period	Episodes decreased after 8 wks of treatment	Not reported

RCT, randomized controlled trials; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; HVLA, high-velocity, low-amplitude; AOM, acute otitis media; C, cervical vertebrae; SCM, sternocleidomastoid muscle; SOT, sacro-occipital technique; AK, applied kinesiology; CBP, chiropractic biophysics technique; NS, not specified.

effects reports in the Mills et al. study;¹³ these were relaxation or a good nap after the treatment. One case of transient muscle soreness and 1 of transient irritability related to SMT were reported in the Sawyer et al. study. A variety of manual treatments were used in the 8 papers, ranging from HVLA SMT to osteopathic mobilization and soft-tissue procedures. Several different chiropractic techniques were described, including diversified, Gonstead, Sacro-Occipital, and Chiropractic Biophysics. Results were consistent in the direction of improvement with manual procedures, although in the 6 case

series/reports, the natural course of the illness cannot be differentiated from possible treatment effects. In the single RCT, significantly fewer surgical procedures were found in the osteopathic mobilization group, compared to usual medical care.

Nocturnal enuresis

One paper reported on adverse effects (Table 14). In this study (LeBoeuf et al.²³), there were 2 cases of transient pain (headache or low back) that resolved after 2 weeks of soft-

TABLE 14. SUMMARY OF EVIDENCE FOR CHIROPRACTIC CARE AND/OR SPINAL MANIPULATION FOR PATIENTS WITH NOCTURNAL ENURESIS

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 219)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Reed 1994 ¹³⁸	RCT	46 (ages 5–13)	HVLA FS SMT vs. sham (impulse instrument set on zero) delivered by chiropractic students	Patient-reported wet nights not significantly different between groups; significantly improved within treatment group but not within control group	Not reported
LeBoeuf 1991 ²³	Prospective outcome study	171 (ages 4–15)	SMT, both groups; one served as waiting-list group with treatment delayed for 2 wks; maximum of 8 treatments, all delivered by chiropractic students	After adjusting for baseline wet nights, no significant effect of treatment found with logistic regression	2 reported: 1 case, headaches and NP, 1 LBP; both resolved after 2 weeks soft-tissue treatment
Glazener 2005 ¹³⁹	SR	Reviewed Reed and LeBoeuf	—	Insufficient evidence, but “promising and warrants further research”	Mild and self-limiting
Blomerth 1994 ¹³⁶	Case report	1 (age 8)	SMT to L; 1 treatment	Symptoms resolved; occasional recurrences resolved with additional treatment	Not reported
Gemmell 1989 ¹³⁷	Case report (time series)	1 (age 14)	3 wks sham (light massage to LB); 4 weeks SMT to L5–S1 only (toggle recoil), 1–2 treatments/wk	No improvement during sham, substantial increase in dry nights with treatment	Not reported

RCT, randomized controlled trials; SMT, spinal manipulative therapy delivered by chiropractor unless otherwise specified; HVLA, high-velocity, low-amplitude; FS, full spine; L, lumbar vertebrae; SR, systematic review; NP, neck pain; LBP, low back pain.

tissue treatment. Results were generally consistent in the direction of no treatment effect; the systematic review judged the evidence insufficient but promising.

Pneumonia

One paper reported on adverse effects (Table 15). In that study (Noll et al. 2000²⁴), 2 patients withdrew from the study because of transient joint and muscle soreness after osteopathic manipulative therapy (OMT) and mobilization. Both studies involved hospitalized patients aged 60 and older, and used OMT, mobilization, myofascial release, and other soft-tissue treatment. Hospital stays and courses of intravenous antibiotics were shorter in the treatment group than in the control group, which received light touch.

Jet lag and phobia

Each of these conditions had only 1 RCT with a very small sample size, and no other studies of any type supporting it (Table 16). The RCT on jet lag²⁵ showed no sig-

nificant effects, but with a sample size of 15 distributed into 3 groups, no conclusions can be made on this topic. The RCT on phobia,²⁶ with 18 patients distributed into 2 groups, reported a statistically significant difference in a Visual Analog Scale measuring intensity of emotional response, although not in pulse rate reduction, in the manipulation group compared to the sham group. No information was provided on the amount of change in this outcome measure that represents a clinically significant change.

DISCUSSION

There are several limitations to this study. First, the number of studies on chiropractic care and/or SMT and other manual therapies for patients with nonmusculoskeletal conditions is relatively small, and the quality of the studies is generally not high. The literature selection was limited to English. It is possible that some studies were missed; however, we used hand searching and input from content experts to ensure a comprehensive search. Another limitation is the

TABLE 15. SUMMARY OF EVIDENCE FOR MANIPULATION FOR PATIENTS WITH PNEUMONIA

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 79)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Noll 2000 ²⁴	RCT	58 hospitalized patients 60+ (mean age/group: 77/78)	OMT, mobilization and soft-tissue therapies including myofascial release (C, T, R) vs. control (light touch) by osteopathic students	Significantly shorter hospital stay and significantly shorter duration IV antibiotics in OMT group (2 days)	2 withdrew from OMT group because of transient joint and muscle soreness
Noll 1999 ¹⁵⁷	Pilot study	21 hospitalized patients 60+ (mean age/group: 79/83)	OMT and soft tissue (including myofascial release) vs. light touch vs. no manual treatment	No statistical analysis because of small sample; treatment group had 2 days' shorter stay, 4 days' shorter course of IV antibiotics; and no deaths (control group, 2 deaths)	Not reported

RCT, randomized controlled trials; OMT, osteopathic manipulative therapy; C, cervical vertebrae; T, thoracic vertebrae; R, ribs; IV, intravenous.

possibility of bias in evaluating the studies. We attempted to avoid this by using accepted checklists. A specific limitation to the WSR checklist is that it has not been validated; it must only be viewed as a first attempt to developing a systematic method of representing a WSR perspective.

CONCLUSIONS

Implications for chiropractic practice

We have drawn several conclusions, from a pragmatic perspective, regarding our first specific aim, to evaluate the published evidence on the effect of chiropractic care on patients with nonmusculoskeletal conditions.

1. The adverse effects reported for SMT for all age groups and conditions were rare and, when they did occur, transient and not severe.
2. Evidence from both controlled studies and usual practice is adequate to support the "total package" of chiropractic care, including SMT, other procedures, and unmeasured qualities such as belief and attention, as providing benefit to patients with asthma, cervicogenic vertigo, and infantile colic.
3. Evidence was promising for the potential benefit of manual procedures for children with otitis media and for hospitalized elderly patients with pneumonia.

4. Evidence did not appear to support chiropractic care for the broad population of patients with hypertension, although it did not rule out the possibility that there may be subpopulations of hypertensive patients who might benefit.
5. Evidence was equivocal regarding chiropractic care for dysmenorrhea and premenstrual syndrome; it is not clear what level of biomechanical force is most appropriate for patients with these related conditions. It does appear that an extended duration of care, over at least 3 menstrual cycles, is more likely to be beneficial.
6. There is insufficient evidence to make conclusions about chiropractic care for patients with other conditions.

Implications for whole systems research in chiropractic

Regarding our second specific aim, to identify specific shortcomings with respect to developing a whole-systems approach to research on the effects of chiropractic care, we have identified the following issues:

1. All studies, from case reports to RCTs, should routinely report adverse effects.
2. Most published RCTs investigating chiropractic care for nonmusculoskeletal conditions have not relied on usual practice in designing their intervention protocols. Some RCTs were designed without benefit of any published ob-

TABLE 16. SUMMARY OF EVIDENCE FOR MANIPULATION FOR PATIENTS WITH PHOBIA OR JET LAG

<i>Citation</i>	<i>Study type</i>	<i>Patients (total n = 79)</i>	<i>Interventions</i>	<i>Summary of outcomes</i>	<i>Adverse effects</i>
Jet lag Straub 2001 ²⁵	RCT	15 (ages 16–21)	Chiropractic drop-assisted SMT (C) vs. sham (impulse instrument set on zero) vs no treatment	No between-group differences in mood, sleep, or jet lag	Not reported
Phobia Peterson 1997 ²⁶	RCT	18 college students (mean age/group: 25/32)	Impulse instrument procedure (T) vs. sham (instrument set on zero)	Pulse rate not significantly different between groups; VAS assessing emotional discomfort significantly lower in treatment vs. sham	Not reported

RCT, randomized controlled trials; SMT, spinal manipulative therapy; C, cervical vertebrae; T, thoracic vertebrae; VAS, Visual Analogue Scale.

servational studies, case series, or case reports. Even in the absence of observational studies, it is possible to demonstrate that the protocol represents usual practice; for example, the Olafsdottir et al.²⁷ infantile colic study used a “reference group” of 14 practicing chiropractors to establish the treatment protocol. We recommend that, in the interest of generalizability, investigators carefully review existing observational studies and reports, as well as consult practitioners with experience treating patients with the condition of interest, and design their intervention protocols to reflect these.

3. Case series and case reports could increase their utility in several ways:
 - a. Report patient-based outcomes using validated instruments (rather than focusing on clinician-based outcomes);
 - b. Specifically address occurrence of adverse effects;
 - c. Describe patient characteristics in greater detail;
 - d. Routinely include measures of expectation, satisfaction, and other attitudinal assessments.
4. The RCT design is not necessarily incompatible with WSR. For example, 1 of 6 RCTs scoring high on conventional RCT checklists also scored high with our preliminary list of WSR considerations. Considerations in designing RCTs that are both rigorous by conventional standards yet are consistent with WSR are as follows:
 - a. In reporting the results of intervention studies, investigators should specify whether care was provided free of charge and/or patients received incentives for par-

ticipating. Cost is an important consideration, and free care and/or incentives may affect the generalizability of results.

- b. As described above, RCT protocols should have greater reliance on procedures and treatment schedules found in usual practice.
- c. “Real-life” comparison groups such as no-treatment or standard care are more generalizable; furthermore, using soft-tissue treatment or other procedures that are also used in everyday practice as shams or placebos may confound results.
- d. Routinely including patient-based functional outcome measures, satisfaction, and quality of life provides more multifactorial information on treatment effects.
- e. Routinely including measures of patient and practitioner preference and expectation provides important information on psychosocial aspects of the clinical encounter that may affect outcomes.
5. Educate chiropractic investigators, practitioners, and funding agencies as to the value (or in some cases, the existence of) observational designs such as cohort and case-control studies, to avoid use of scarce resources on premature and sometimes poorly conceived RCTs.

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