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Annotated bibliography of the biomedical literature pertaining to chiropractic, pediatrics and manipulation in relation to the treatment of health conditions

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Biomedical literature retrieval, both indexed and non-indexed, with respect to the application of manipulative therapy with therapeutic intent and pediatric health conditions (ages 0 to 17 years) yielded 66 discrete documents which met specified inclusion and exclusion criteria. There was one experimental study (RCT's), 3 observational (cohort, case control) studies and 62 descriptive studies (case series, case reports, surveys, literature reviews). An independent rating panel determined consistency with a modified quality of evidence scale adopted from procedure ratings system 1 of Clinical Guidelines for Chiropractic Practice in Canada. Results indicate minimal Class 1 and Class 2 and some Class 3 evidence for a variety of pediatric conditions utilizing the application of manipulation with therapeutic intent.
(JCCA 1995; 39(3): 159–177)

KEY WORDS: chiropractic, manipulation, pediatric, child.

Une recherche de la littérature médicale, indexée ou non-indexée, portant sur l'utilisation de manipulations comme traitement pour états de santé pédiatriques (0 à 17 ans) a servi à répertorier 66 documents qui répondaient à des critères spécifiques d'inclusion ou d'exclusion : 1 texte portant sur une expérience (RCT), 3 sur des observations (cohorte, dossiers de contrôle) et 62 descriptions (enquête, revue de litérature, rapports de cas). Une tribune d'experts indépendants a reconnu la constance des résultats en utilisant l'échelle de qualité modifiée du système de classement 1 du «Guide de pratique chiropratique au Canada». De ces résultats, on remarque un minimum de Classe 1 et Classe 2 et la présence de quelques Classe 3 pour une variété d'états pédiatriques en utilisant la manipulation à titre d'usage chiropratique.
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MOTS-CLÉS : chiropratique, manipulation, pédiatrique, enfant.

Introduction

A literature search was undertaken in order to accurately assess the nature and depth of the biomedical information available with respect to paediatric conditions generally treated with spinal manipulative therapy and more specifically related to the practice of chiropractic.

Literature retrieval at its best, can be an exceptionally difficult and demanding task. For our purposes in this study, both the indexed and non-indexed biomedical literatures were scanned, fully realizing that retrieval in both areas has its limitations. Annotating the relevant literature has its purpose based partly in identifying, appraising and ultimately assimilating information (evidence) in an effort to assist the clinician by narrowing the substantial gap between the clinical research and clinical practice environments.

Methodology

With respect to the indexed literatures, we interacted with three computer based systems, namely Medline, Chirolars and Index to the Chiropractic Literature (ICL). Medline contains some 3000 journals of the 40,000 worldwide scholarly publications in the biomedical field and would generate a fair representation of the indexed literatures from 1966 onward. Chirolars contains references from approximately 700 biomedical publications, and ICL from approximately 16 chiropractic publications. Chirolars and ICL are more profession specific with respect to chiropractic and manipulation and for that reason one would expect the anticipated yield would be greater. Interestingly, in this particular search, it was Medline that yielded the greatest number of documents.

The non-indexed literature was scanned manually and is an exceptionally time consuming task, but nevertheless warranted for the sake of completeness.

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In searching the computer based systems, the following key words (subject headings/descriptors) were utilized:

Medline – 1. exp child and 2. chiropractic de
Chirolars – 1. paediatrics de and 2. manipulation de or chiropractic de
ICL – 1. paediatrics

The headings pediatrics and chiropractic yielded 0 documents in the Medline search and therefore narrower subject headings were required. The term pediatrics has a wide variety of confusing descriptors which include the following: neonate, newborn, infant, toddler, child, juvenile, adolescent and teenager. For the purposes of this study, we adopted the standard listed in the Merck Manual of Diagnosis and Therapy:[1]

neonate – newborn to 1 month
infant – 1 month to 1 year
child – 1 to 12 years
adolescent – 13 to 17 years

The search retrieved a total of 321 articles, each of which were initially screened by a single assessor to determine eligibility according to established inclusion criteria. (Table 1)

Table 1
Summary of indexed and non-indexed literature retrieval

Source	Documents retrieved
Medline	102
Chirolars	67
ICL	72
Manually	80
Total	321

The total number of distinct documents retrieved which met both the inclusion, and the exclusion criteria was 66.

The following constituted the inclusion criteria necessary for each article to be considered eligible.

Inclusion criteria

1 the document retrieved must pertain to the subject matter of chiropractic, osteopathy, medicine, physical therapy, manipulation or pediatrics;
2 the document retrieved must relate and be material to the application of manipulation as a therapeutic intervention with respect to pediatric conditions;
3 the relevant information must pertain to the pediatric age range of 0 to 17 years.

As well, the following constituted exclusion criteria, which would eliminate documents from the study, again determined by the same single assessor.

Exclusion criteria

1 the document retrieved was not relevant to the subject matter or had nothing to do with chiropractic, manipulation or pediatrics (i.e. Boline et al.; Callahan et al.; Hsieh et al.; Liebl and Butler) or was inconsistent with the inclusion criteria;
2 the document retrieved was relevant to the subject matter but was highly anecdotal, highly speculative or was editorial in nature (i.e. Bagnell; Cichoke; Fysh; Monti; Mega; Fernandez) and was published in the popular literature as opposed to the scholarly literature;
3 the document retrieved involved pediatric subjects but made only clinical or epidemiological observations, without any manipulative treatment (i.e. Greko and Thayer; Good and Mikkelsen; Taylor; Taylor, Green-Deslauriers and Tanaka; Ebrall);
4 the document retrieved involved pediatric subjects but the statistics were not clearly defined with respect to the pediatric subjects (i.e. Fitzritson; Cox and Schreiner; Cox, Fromelt and Schreiner; Parker, Tupling and Pryor; Parker and Tupling);
5 the document retrieved was of a generalized nature which included pediatric subjects in a limited capacity without making specific conclusions related to pediatric age groups (i.e. McKellow; Shekelle; Nyiendo and Haldeman);
6 the document retrieved involved identification of a pediatric condition as a contraindication to manipulative treatment (i.e. Taylor, Green-Deslauriers and Tanaka);
7 the document retrieved involved highly anecdotal identification of an adverse pediatric outcome (i.e. Sperry and Pfalzgraf; L'Ecuyer);
8 the document retrieved had no discernible translation or English abstract (i.e. Falkenau; Ivanichev and Popelianskii; Krasilnikoff).

Following these determinations, the 66 acceptable articles were categorized according to the nature and depth of the information, in the format which appears below. (Table 2)

Articles were submitted to a rating panel of three clinicians at CMCC and they were asked determine consistency with respect to a quality scale. In determining an appropriate quality scale for evaluating the literature, we gave consideration to the methodology previously utilized by Assendelft, Koes et al.[2] as well as Sackett.[3] We deemed their approaches to be too stringent having regard to the nature of material being investigated in this study. However, with respect to weighing the evidence, we accept Sackett's ranking of evidence.[3] (Table 3) For our purposes we felt it would be reasonable and prudent to adopt the quality scale (procedure ratings – system 1) utilized in the Clinical Guidelines for Chiropractic Practice in Canada, and

Table 2
Summary of literature retrieval by study design, source and condition

Category of information	Literature source (peer reviewed scholarly publication, questionable or non peer reviewed)					Condition		
	MD	DC	DO	PT	Total Documents	NMS	non-NMS	both
Experimental studies (random clinical trials)	0	1	0	0	1	none	yes	none
Observational studies (cohort, case control)	0	2	1	0	3	none	yes	none
Descriptive studies	13	48	0	0	61	yes	yes	
(case series	1	6						
case report,	6(12)	28(40)						
survey,	6	6						
literature review)		8						
Editorial/Commentary/ Letter	1	0	0	0	1	no	no	yes

MD – medical
DC – chiropractic
DO – osteopathic
PT – physical therapy
NMS – neuromusculoskeletal

originating from RAND. (Table 4)

A randomized trial (randomized controlled trial, randomized clinical trial, RCT) was defined as an experiment in which subjects are randomly allocated to receive or not receive an experimental preventive, therapeutic or diagnostic procedure and then followed to determine the effect of the intervention.[7]

A cohort study was defined as a prospective investigation of the factors that might cause a disorder in which a cohort of subjects (a group of persons with a common set of characteristics) who do not have evidence of an outcome of interest, but who are exposed to the cause are compared with a concurrent cohort of subjects who are also free of the outcome but are not exposed to the cause. Both cohorts are then followed to compare the incidence of the outcome variable.[7] While Sackett,[3] Portney and Watkins,[8] and Gehlbach[9] characterize cohort (follow-up) studies as prospective in nature, Haley[10] characterizes them as most commonly prospective and uncommonly retrospective.

A case control study was defined as a study which compares the frequency of clinical findings or causal factors in a group of cases and a group of controls. This type of study is retrospective in nature.[7] While Sackett[3], Portney and Watkins,[8]

Table 3
Ranking of evidence[3]

Strength	Method
Strongest	Randomized clinical trial
	Cohort study
	Case control study
Weakest	Case series

Table 4 Quality of Evidence Scale[7] (modified)

Class 1: Evidence provided by one or more well designed controlled clinical trials; or well designed experimental studies that address reliability, validity, positive predictive value, discriminability, sensitivity and specificity.

Class 2: Evidence provided by one or more well designed **controlled,** observational clinical studies, such as case-control, cohort studies, etc; or clinically relevant basic science studies that address reliability, validity, positive predictive value, discriminability, sensitivity, and specificity; and published in refereed journals.

Class 3: Evidence provided by expert opinion, descriptive studies or case reports, **surveys, literature reviews.**

Table 5 Summary of study designs

Category of information	Methodology	Direction of inquiry	Randomization	Control
Experimental study design	RCT	prospective[3]	yes	yes
Observational study design	Cohort (follow-up)	prospective[3] both[10]	no	yes
	Case control (backward)	retrospective[3] both[10]	no	yes
Descriptive study design	survey	retrospective	no	no
	case series/ case report	retrospective	no	no

and Gehlbach[9] characterize case control studies as retrospective in nature, Haley[10] characterizes them as most commonly retrospective and uncommonly prospective.

A descriptive study was defined as a prospective[3] study investigating the response of a series of patients to a given treatment according to methods carefully worked out in advance, and does not compare itself to a control group or to a placebo treated group.[7]

A case report (study) was defined as a type of descriptive research in which one individual or unit was studied in depth.[8] A case series is an expansion of a case report (study) in which observations of several similar cases are reported.[8] Sackett cautions that case series/reports while thought provoking, are prone to over interpretation because of methodologic weakness.[3]

A survey was defined as a method of collecting descriptive data composed of a series of questions posed to a group of subjects usually with the intent of generalizing sample responses to describe a larger population.[8] It involves measuring a set of parameters in one pass through a population or sample of subjects.[10]

We considered class 1 to be scientific/experimental evidence, class 2 to be clinical/observational evidence and class 3 to be

evidence which would have far less weight attached to it and described as opinion, speculative, anecdotal, descriptive or empirical.

We have attempted to summarize in brief format, the types of study designs (Table 5) noting that there is some variance by author.[3,8,9,10]

It may be argued that reviews of the literature have value in the valid conclusions that they draw with respect to any assessment of the available literature based information because they express opinion evidence (class 3). The review of literature allows the researcher to learn from the trials of others. The results of each study contribute to an accumulated knowledge and thereby stimulate further research.[8] For purposes of our study we allocated surveys and literature reviews to class 3, as well as letters.

The reader is advised that with respect to the issue of complications and contraindications related to the therapeutic intervention of manipulation, that the Clinical Guidelines for Chiropractic Practice in Canada[7] has a separate and distinct rating system dealing with quality of evidence and the classes of evidence are at variance with system 1 (Table 4). In relation to exclusion criteria 6 and 7 of our study we felt that our intent was not compromised with the instructions given to the rating panel.

Following the determinations reached by the rating panel, consensus levels of agreement were then calculated. We adopted the following levels:

level 1 – 3 clinicians in full agreement
level 2 – 2 clinicians in agreement
level 3 – 0 clinicians in agreement

At least 2 of 3 clinicians had to agree on the class of evidence in order to determine final placement of the document.

Results

The results demonstrate that initially, 66 discrete articles met our inclusion and exclusion criteria. With respect to the quality scale applied to these articles, and having regard to Sackett's ranking of evidence (Table 3), the results indicate that the class of evidence is primarily Class 3 and secondarily Class 1 and 2. Only 1 experimental study (chiropractic), 3 observational studies (2 chiropractic, 1 osteopathic) which by definition are controlled and 61 descriptive studies (13 medical and 48 chiropractic) were retrieved. Of the 61 descriptive studies, 8 were literature reviews, 12 were surveys, 7 were case series formatted, 6 separate medical documents detailed 12 case reports and 28 separate chiropractic documents detailed 40 case reports. It is interesting to note that two of these medical documents (Breen; Weiner) were authored by chiropractors. There was 1 letter detailing a variety of conditions. Given the low quality and quantity of evidence, little weight can be attached and it would therefore be improper to generalize the few successful outcomes to the population at large. It should be noted that one of the panel members took exception to our inclusion of literature reviews and surveys within class 3 evidence.

Of the 66 documents submitted to the rating panel of clinicians the following determinations were made:

Table 6

Class of evidence	Documents	Consensus level of agreement
1	1	level 2
2	3	level 1, level 2
* 3	62	level 1, level 2

Discussion

Aker has recently reported on the utilization of four computerized literature databases in the field of manual medicine.[4] Using identical or similar search terms, searches for english literature on efficacy of manual therapy to the cervical spine were conducted in CHIROLARS, CINAHL (Cumulative Index to Nursing and Allied Health Literature), EMBASE (Exerpta Medica) and MEDLINE (Index Medicus). Of 1457 total citations from the 4 databases, 767 (52.6%) were deemed relevant. The following distribution of relevant articles and randomized controlled trials yielded 17 discrete RCT's as an outcome measure:

Database	Relevant citations	RCT's
Chirolars	376	11
CINAHL	8	1
Embase	191	11
Medline	192	11

The author concludes in part that reviews of the literature in manual medicine require searching of at least 2 computerized databases, and that Medline is the most efficient database to search but alone will only retrieve 65% of the accessible clinical trials on a topic.

In a further study on the effective utilization of computerized chiropractic literature databases, McDermaid and Aker conclude that no single database can function in a stand alone capacity and recommend both Medline and Chirolars be used for database searching in chiropractic research.[5]

Our retrieval methodology is consistent with the recommendations of Aker[4] and McDermaid and Aker[5] in that we utilized Medline, Chirolars and ICL in our computerized search strategy. We were able to retrieve 33(50%) discrete documents

mechanically and 33(50%) discrete documents manually.

In searching the literature based information, there are various limitations which apply and may skew outcome measures. The limitations which we considered in a general sense, that equally apply to this study, were the following:

1 Primarily only the English literature was searched and cited. The German, French, Russian, Norwegian and Danish literature may have good evidence;
2 Some papers spoke in general terms with no direct application to pediatric patients. Ages were not specified in some articles (i.e. Wiles and Diakow) or good quality evidence pertained only to adults (i.e. Nielson, Bronfort el al.);
3 Data was confusing and we were unable to isolate or identify meaningful pediatric statistics (i.e. Changjiang et al., Nilsson and Christiansen, Thomas et al.);
4 Some papers made no direct reference to manipulation as an intervention utilized by any manipulative practitioner (i.e. Dubousset);
5 Proceedings were excluded since they had not undergone the rigors of the publication process or come under the scrutiny of peer review (Proceedings of National Conference on Chiropractic and Pediatrics 1991, 1992, 1993, 1994, ICA; Lewit and Rychlikova, Proceedings IXth Congress Int Fed Man Med 1975; Esch);
6 Some articles are either unpublished or are currently in the process and may or may not be detected by retrieval of the literature based information;
7 It may be argued that there is the potential for single assessor apprehension of selection bias with respect to inclusion and exclusion determinations.

With regard to table 2, we attempted to stratify study design with both the source and nature of the literature. One could successfully argue that this categorization is purely discretionary and therefore invalid, but our intent was simply to provide a preliminary indicator of quantification in as fair and impartial a manner as possible.

In the category of neuromusculoskeletal conditions (NMS), the reader should not draw the inappropriate conclusion that the chiropractor (or other practitioner), was treating the patient for the condition listed, but instead and keeping within each specific context, that the chiropractor may have been treating a particular condition, or may have been treating a patient concurrent with a particular condition. (i.e. Mierau et al., Nykoliation et al.). As well, the distinction between NMS and non-NMS conditions may not be a truly valid stratification. Some chiropractors would argue that all the conditions discussed are in fact NMS conditions in etiology, and most if not all are simply the effects or expressions of aberrant neurophysiology.

Conditions listed or described in the 66 discrete documents primarily include but are not limited to the following: scoliosis, congenital torticollis, juvenile arthritis, strabismus, foot inversion, neurologic performance (learning, behaviour, attention), enuresis, Erb's palsy, infantile colic, asthma, esophoria, fever, shoulder impingement, encopresis, neurogenic bladder, bronchitis, atelectasis, birth trauma, back pain, neck pain, headache, otitis media, seizure, tetraparesis, Bell's palsy, constipation, disk herniation, lumbar fracture, hemiparesis, Osgood Schlatter, radial head subluxation, and developmental delay. Each of these conditions would have a degree of weight attached to it depending on the source, the peer review process and the fully realized responsibility of scholarly journal editors as gatekeepers to the permanency of script.

We note with interest a case report (18-year-old female) in the Frach, Osterbauer and Fuhr document that we draw attention to in relation to the cross reference of Schrode and two cases of Bell's palsy.

Table 4, the quality of evidence scale, is at variance with the Clinical Guidelines for Chiropractic Practice in Canada and was modified for our purposes firstly in Class 2 to capture "controlled" as opposed to "uncontrolled" studies, and secondly in Class 3 to include surveys and literature reviews.

With regard to table 6, the experimental study (Reed et al.) in class 1 has a level 2 consensus in that one panel member felt the document fell below the standard defined for class 1 evidence, arguing the study was not well defined and utilized a sham treatment as a control. Another panel member argued this was a random comparative study as opposed to a random clinical trial. The absence of level 1 consensus stretches the credibility of the evidence. While panel members may debate over one particular study, the argument is mute within the overall context of our intended purpose. With respect to the observational studies in class 2, Giesen et al. had level 2 consensus while both Leboeuf et al., and Frymann et al. had level 1 consensus.

In 1992, Rupert reviewed the chiropractic, osteopathic and medical literature related to pediatrics.[6] The literature based information scanned (Chirolars, ICL and CRAC) with respect to chiropractic focused on 10 peer reviewed chiropractic periodicals as well as the popular chiropractic literature. Chirolars, the only computer based system at the time, was the primary source of information retrieval and in contrast to this study, pediatric was defined as 0 to 12 years of age. As well, there was no quality of evidence scale or independent rating mechanism. Rupert validly concluded that studies utilizing acceptable experimental design are virtually non-existent. That conclusion, seemingly continues to remain in full force.

Conclusion

The biomedical information available through literature based retrieval with respect to pediatric health conditions and manipulation as a therapeutic intervention is scattered, fragmented, lacks sufficient methodological rigour and remains primarily at the empirical or anecdotal level. Health care practitioners utilizing manipulation with therapeutic intent have some distance to go in substantiating on a scientific basis (Class 1) the successful outcomes realized on a daily empirical basis in the

clinical environment. In comparison to other professions, chiropractic appears to have taken an initial leading role in reporting manipulative therapy as a therapeutic intervention with respect to certain pediatric conditions.

Given the limitations of this analysis and keeping within its specific context, there is only very limited or weak class 1 and class 2 evidence currently with respect to either NMS or non-NMS pediatric conditions and the application of manipulation in its traditional sense as a therapeutic intervention. There is some class 3 evidence supporting a variety of both NMS and non-NMS conditions of which most notable we mention congenital torticollis, asthma, Erb's palsy, infantile colic and enuresis.

Scientific inquiry demands rigid protocols. The majority of standard treatments given by all health providers for all disorders, whether these disorders be minor or lifethreatening, have not been validated by scientific evidence.[7] Eddy claims only about 15% of medical methods of intervention are supported by solid scientific evidence, partly because only 1% of the articles in medical journals are scientifically sound and partly because many treatments have never been assessed at all.[11] Some comment is warranted with respect to the exclusion list of documents, which we have provided for ease of reference. Peer review is by no means a secure discipline. While the validity, efficacy[12] or reliability[14] of peer review has never been scientifically tested within the publication process, the intent is nevertheless clear – collegial accountability. In recent decades, the nature of clinical evidence has changed in three important ways: the standards for gathering it, the tools for analyzing it, and the social context in which it is used.[12] While the scientific testing of peer review is an area ripe for investigation by scholarly journal editors and while consensus methodology in producing statements can be a suspicious process, Eddy submits that agreement of the experienced without evidence is a poor basis for producing advice.[11] In contrast, however Gitelman, raises the concern that reductionistic guidelines are being applied to a holistic profession.[13]

In the past, evidence based practice depended on the case report and on expert opinion. However, there has been a shift from the standard of anecdotal clinical information to the standard of population driven clinical trials (RCT), and increasingly now, professions are expected to base their decisions on the evidence rather than on authority. Davidoff, Hynes, Sackett and Smith argue that there is a widening chasm between what doctors ought to do and what they are actually doing.[15] Rosenberg and Donald submit that authoritarian clinicians see evidence based practice as a threat since it may expose their current practices as obsolete or occasionally even dangerous.[16]

The reader is advised that a major study (RCT) is in progress entitled "A randomized controlled trial of chiropractic care for chronic childhood asthma" designed to evaluate the effectiveness of chiropractic management of asthma in paediatric populations. The study, a collaborative effort between CMCC, LACC, and McMaster University, is funded by the Consortium for Chiropractic Research and the researchers are Dr. Jeff Balon, Dr. Malcolm Sears, Dr. Peter Aker, Dr. Ted Crowther, Mr. Clark Danielson and Dr. Gerald Cox. Dr. David Sackett serves as research design consultant.

There is an urgent need for a general shift in the scholarly literature pertaining to pediatrics and chiropractic so that the quality of evidence is enhanced and could be reasonably applied against the more rigorous scales utilized by Koes and Sackett. The science aspects of chiropractic need to be accelerated in order to substantiate the successful applications and outcomes of the clinical aspects of chiropractic.

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