

Chapter 8

Methods:

The Search for, Levels of, Ratings of, and Grading of Evidence

Accrual of Clinical Studies Documents

Four ICA members paid a recent chiropractic graduate to travel to Davenport, Iowa. For 2.5 months, she made daily visits to the Library of Palmer Chiropractic College. Palmer Chiropractic College has one of the best Archive Libraries in Chiropractic. Additionally, a few Palmer students were paid, by the aforementioned Chiropractors, to find and copy the clinical studies that could be located with the help of the Palmer College Librarians. Besides searching different literature indexes, hand searches were performed on newsletters, old texts, old journals, etc.

Levels of Evidence

Clinical studies can be of four different levels of evidence depending on the number of subjects studied, randomization, whether control subjects are included, and the sophistication of the research design. Some guidelines include consensus of committee members as evidence. This consensus is, “personal opinion”, and should not supersede any published clinical studies.

While some groups choose to include “Personal Opinion” (“Level 5”) as evidence, as discussed in Chapter 1 of this document, ICA is going to use the definitions provided by the United States Department of Health and Human Services. Recall that there are only 4, “Levels of Evidence”, recognized by the United States Department of Health and Human services at <http://www.ahrq.gov/>:

- **Level 1.** *Randomized controlled trials*—includes quasi-randomized processes such as alternate allocation.
- **Level 2.** *Non-randomized controlled trial*—a prospective (pre-planned) study, with predetermined eligibility criteria and outcome measures.
- **Level 3.** *Observational studies with controls*—includes retrospective, interrupted time series (a change in trend attributable to the intervention), case-control studies, cohort studies with controls, and health services research that includes adjustment for likely confounding variables.
- **Level 4.** *Observational studies without controls* (e.g., cohort studies without controls, case series without controls, and case studies without controls)

Searching for the Evidence

For the beginning searches for evidence of chiropractic care, we included all levels of evidence (Levels 1, 2, 3, and 4) in computer searches. It was our goal to locate every original clinical study involving patients receiving chiropractic care. For additional studies, our representative, Dr. Nicole Knapp, worked closely with the Palmer Chiropractic College Librarians to search by hand all recent and old text books, recent and old journals, and chiropractic newsletters.

Since systematic reviews and meta-analyses are not original patient studies, these were located and included in our data base, but not rated.

The Chiropractic, Orthopedic, Physical medicine, Osteopathic, Physical Therapy, and Manual Medicine fields were searched using the following citation indices:

A. Search Indices/Engines Used for Data Collection:

1. Pub Med through Medline
2. MANTIS <http://www.healthindex.com/> ,
3. The Index to Chiropractic Literature <http://www.chiroindex.org/#results> ,
4. Google's beta version of their "scientific" search engine available for free use: <http://www.scholar.google.com>,
5. Chiropractic technique texts
6. Hand searches at the Palmer College of Chiropractic Library of Chiropractic Magazines, Journals, and Newspapers.
7. Hand searches of Chiropractic Research Conference Proceedings

B. Search Topics and Key Word Search

The search topics included the following:

1. Chiropractic
2. Chiropractic Adjustment
3. Chiropractic Manipulation
4. Spinal Manipulation
5. Spinal Manipulative Therapy
6. Manipulation
7. Chiropractic Case Study
8. Chiropractic Case Report
9. Chiropractic Clinical Study
10. Randomized Clinical Trial
11. Nonrandomized Clinical Trial
12. Clinical Control Trial
13. Cohort Study
14. Case Series
15. Chiropractic observational studies

C. Study Inclusion Criteria for Guideline Analysis and Production:

Studies were included if they fit the following criteria:

1. Original chiropractic study with patient outcomes (Systematic reviews and meta analysis were not included in the rating of studies);
2. Chiropractic source, which included spinal manipulation or spinal adjustment
 - (a) Any technique system or chiropractic technique text book
 - (b) Any journal article which included a clinical study with any of the key words listed above;
3. Physical Medicine, Osteopathic, Physical Therapy, and Manual Medicine care which included any of the key words listed above.

D. Journals & Texts Searched by hand (besides Index Searches):

Chiropractic texts were searched by hand for clinical studies. Additionally, due to the fact that some journals, depending on their date of publication, may not have had adequate key words, journals were hand searched for chiropractic clinical studies that may have been missed during computer searches. To be thorough without redundancy over the search period of 2.5 months, Dr. Knapp made lists of the journals that were hand searched. This list is provided below:

Table 1: Hand searched journals

1. Advances in Chiropractic	32. Chiropractic Sports Medicine	61. McA Journal
2. American Chiropractor	33. Chiropractic Technique	62. National Journal of Chiropractic
3. American Journal Chiropractic Medicine	34. Christian Chiropractic Journal	63. New England Chiropractic Journal
4. American Journal Clinical Chiropractic	35. Chronic Headache Pain	64. New Mexico Chiropractic Journal
5. Annals of the Swiss Chiropractic Assoc	36. Clinical Chiropractic	65. North Carolina Chiropractic Journal
6. Arkansas Chiropractic Journal	37. Colorado Chiropractic Journal	66. Ohio Chiropractic Physician Assoc J
7. Australian Chiropractic Journal	38. Connecticut Yankee	67. Oklahoma Chiropractic Journal
8. Australian Journal of Chiropractic	39. Digest of the Chiropractic Economics	68. Oregon Chiropractic Physicians Assoc
9. British Journal of Chiropractic	40. Dynamic Chiropractic	69. Osca Journal
10. Bulleting European Chiropractors Union	41. Ejournals	70. Palmer Green Books
11. California Chiropractic Association J	42. European Journal of Chiropractic	71. Palmer Journal of Research
12. California Chiropractic journal	43. Inter Chiro Assoc Review Chiropractic	72. Philosophical Constructs for Chiro Prof
13. Canadian Chiropractic Journal	44. Internist (original Internists)	73. Research Forum
14. CCA news	45. J American Chiropractic Association	74. South Dakota Chiro Assoc Newsletter
15. Chiropractic	46. J Australian Chiropractic Association	75. Spine 1975-1985 (no articles found)
16. Chiropractic and Osteopathy	47. J Canadian Chiropractic Association	76. Spine 1986-2006
17. Chiropractic Approach to TMJ	48. J Clinical Chiropractic Pediatrics (JCCP)	77. Staging Wellness
18. Chiropractic Archives	49. J Kansas Chiropractic Association	78. Tennessee Chiropractic Journal
19. Chiropractic Australia (uncataloged)	50. J Manipulative & Physiol Therapeutics	79. Texas Chiropractic Association
20. Chiropractic Conversations	51. J of National Chiropractic Association	80. Texas Journal of Chiropractic
21. Chiropractic Economics	52. J Pennsylvania Chiropractic Society	81. The Chiropractor
22. Chiropractic Educator	53. J Sports Chiropractic & Rehabilitation	82. The National Chiropractic Journal
23. Chiropractic Family Physician	54. Journal Manual & Manipulative Therapy	83. Thermography Journal
24. Chiropractic History	55. Journal of Chiropractic	84. Today's Chiropractic
25. Chiropractic Internists	56. Journal of Chiropractic Education.	85. Topics Diagnostic Radio & Adv Imaging
26. Chiropractic Journal	57. Journal of Chiropractic Humanities	86. Topics in Clinical Chiropractic
27. Chiropractic Journal of Australia	58. Journal of Chiropractic Medicine	87. United Chiropractors Assoc of Australia
28. Chiropractic Pediatrics	59. Journal of NeuroMusculoskeletal System	88. United Chiropractors of Washington
29. Chiropractic Report	60. Journal Vertebral Subluxation Research	89. Upper Cervical Monograph
30. Chiropractic Research Journal		90. Wisconsin Chiropractic Association J
31. Chiropractic Society of Washington		

Critically Appraising the Evidence (Rating of Evidence)

While there are numerous published articles, systematic reviews or meta-analyses, with different rating methods of Level 1 evidence (RCTs) on Spinal Manipulative Therapy (SMT), to the best of our knowledge, we found only two publications that rate Level 2-4 studies.^{1,2}

Usually, the rating methods of Level 1 (RCTs) studies do not apply to Levels 2-4 studies, and especially do not apply to Observational Studies (Levels 3 & 4). Empirical research has shown that quality scores, (which are numeric scores based on arbitrary weights given to each item in a scale), are arbitrary, unreliable, biased, and hard to interpret.² Instead of quality scores for Observational Studies, Juni et al suggested that a check list be used in which rating is done by whether an item is present or not present, such as “met, partially met, not met”. This is the same recommendation made in a Consensus Statement by the Meta-analysis Of Observational Studies in Epidemiology (MOOSE) Group published in JAMA in 2000.¹

In this document, we decided to follow many of Juni’s suggestions for rating Observational Studies and RCTs.² By giving a point for each important item that is present in a particular study, a rating method which is not biased can be performed. Instead of having committee meetings to have all members read and rate clinical studies by arbitrary weights in a scale, our ICA Committee met and had consensus on items that, when present, provide details necessary to determine exactly

- (a) what the patient population was,
- (b) what was done in the methods, and
- (c) what outcomes were reported in order that a study may be exactly replicated by any future study.

A data base was engineered in File Maker Pro that contained questions for the reader/rater (ICA Best Practices Committee Member) of Clinical Studies (Level 1-4 publications) to answer. A point was assigned to items if they were present in the study. These were broken into five categories:

- A. Research Design,
- B. Subject Characteristics,
- C. type of intervention,
- D. frequency and duration, and
- E. care outcomes.

Elimination of Bias with Criteria for Rating Articles

There is much bias possible when guideline committees vote on the ranking/rating of published studies. To eliminate this possible bias, the ICA-BPPG Executive Committee met to determine what items, when present in manuscripts, are, “*essential*”, to reading, understanding, replicating, and extrapolating from a clinical study. For any Clinical study (including a Case Study), the following items in Table 2, if appropriate for that type of study, are needed.

Table 2
List of and Rating of Essential Information in Clinical Studies

Research Design	Level 1 RCT	Level 2 NRCT	Level 3	Level 4		Possible Points
	Yes = 4 No = 0	Yes = 3 No = 0	Yes = 2 No = 0	Yes = 1 No = 0		4
Blinded	Statistical Analysis Performed	Statistics: p-values	Power Analysis	Matching Controls	Long Term Follow-up?	
Yes = 2 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Greater than 1 year = 2 .5-1 Year = 1 Less than .5 years = 0	8
Intervention	Previous Failed care?	Technique Provided?	Modalities Described?	Frequency of Care?	Duration of Care?	
	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	5
Subject data	Gender	Age	Height	Weight	Demographics	
	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0	5
Pre-Post Outcome Measures	Outcome Measure Used	Functional Outcome Measure Used	Structural Outcome Measure Used			
	Yes = 1 No = 0	Yes = 1 No = 0	Yes = 1 No = 0			3
Highest Possible Rating						25

A data base and computer program in File Maker Pro was written by Leonard Siskin, DC (New Jersey) to collect data and rate each article. After the articles were read by Committee members, said individuals entered data into the program from the articles. If *essential* data were entered by a Committee member, then the computer program assigned points to the manuscript by how many *essential* items were present. Thus, the rating of articles was not by voting, but rather by if an article provided *essential* information.

Grading the Evidence

The Agency for Healthcare Research and Quality (AHRQ) addressed the diversity of evidence grading systems.³ AHRQ states, “Specifically, they assessed 20 systems relating to systematic reviews, 49 systems for RCTs, 19 for observational studies, and 18 for diagnostic test studies. For final evaluative purposes, the authors focused on scales and checklists. In addition, they reviewed 40 systems that addressed grading the strength of a body of evidence (34 systems identified from their searches and prior research and 6 from various EPCs). The systems reviewed totals more than 121 because several were reviewed for more than one grid.”³

Regarding the choosing a specific method of evidence rating, the authors state, “In the authors' judgment, those who plan to incorporate study quality into a systematic review, evidence report, or technology assessment can use one or more of these 19 systems as a starting point, being sure to take into account the types of study designs occurring in the articles under review.”

Of the 19 recommended systems, a modification of Harbour and Miller⁴ was chosen for the ICA rating system. Harbour and Miller⁴ had modified the grading system reported by the Agency for Healthcare Research and Quality (AHRQ).⁵ Our system for grading the evidence is summarized in Table 3.

Since the results of well done Case Studies have been consistent with the results of RCTs, it was decided to derive a rating method based on RCTs and Case Studies. In the ICA's computer program for entering data from clinical papers, points were awarded according to Table 2. Twenty-five is the maximum possible points for a manuscript to attain and this is very difficult to achieve. The average RCT in our ICA data base received 16 points.

To derive a rating scale A-D, it was decided to divide the total points for any health condition by 16 points, termed the RCT equivalent. If two RCTs were performed on a certain health condition or if there was one RCT and the RCT equivalent (total of Level 2-4 evidence divided by 16) is equal to or higher than 7.0, then ICA has determined that this health condition is well supported by clinical evidence. Table 3 delineates this ICA rating scale. For examples of this new rating method, consider some health conditions in Table 4 from Table 1 in upcoming Chapter 10:

Table 3: ICA's Rating of the evidence.

Scale	Description
A	Well Supported by clinical evidence of either: 1. At least 2 positive RCTs OR 2. One RCT & 1 NRCT with positive results OR 3. one RCT and RCT Equivalent ≥ 7.0
B	Supported by clinical evidence of either: 1. One Good quality positive RCT OR 2. One NRCT with good Results and $2.1 \leq \text{RCT Equivalent} \leq 6.9$ OR 3. RCT Equivalent ≥ 7.0
C	Supported by clinical evidence of $2.1 \leq \text{RCT Equivalent} \leq 6.9$
D	Supported by clinical evidence of one or more Level 2-4 studies: $0.1 \leq \text{RCT Equivalent} \leq 2.0$

Table 4: Examples of ICA's Rating Scale for Chiropractic care of Health Conditions

	Keywords	Level I	Level II	Level III	Level IV	Total Points	RCT Equivalent	ICA Rating
1.	Abdominal Pain	0	0	0	11	118	7.4	B
2.	Acromegaly	0	0	0	1	11	.7	D
3.	ADD/ADHD	0	0	1	14	162	10.1	B
4.	Allergy	1	0	0	14	172	10.8	A
5.	Amyotrophic Lateral Sclerosis	0	0	0	1	12	.8	D
6.	Anemia	0	0	0	6	52	3.3	C
7.	Angina	0	3	0	5	84	5.3	B
8.	Ankle (Pain/Injury)	5	1	1	12	235	14.7	A
9.	Ankylosing Spondylitis	0	0	0	3	34	2.1	C
10.	Aneurysm	0	0	0	1	12	.8	D
11.	Anxiety	1	0	0	5	78	4.9	B
12.	Aphasia	0	0	1	3	33	2.1	C
13.	Apnea	0	0	0	2	21	1.3	D
14.	Appendicitis	0	0	0	4	38	2.4	C
15.	Arrested Development	0	0	0	1	6	.4	D
16.	Arteriosclerosis	0	0	0	1	12	.8	D
17.	Arthritis	0	0	1	16	176	11	B
18.	Asthma	4	0	2	32	430	26.9	A
19.	Auditory Neuropathy	0	0	0	1	9	.6	D
20.	Autism	2	0	0	5	83	5.2	A
21.	Autonomic Dysfunction	0	0	0	3	30	1.9	D

References

1. [Stroup DF, Berlin JA, Morton SC, Olkin I, Williamson GD, Rennie D, Moher D, Becker BJ, Sipe TA, Thacker SB](#). Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA. 2000 Apr 19;283(15):2008-12.
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3. United States Department of Health and Human Services. Agency for Healthcare Research and Quality. Systems to Rate the Strength of Scientific Evidence. Evidence Report/Technology Assessment: Number 47. Accessed 03/27/2008. <http://www.ahrq.gov/clinic/epcsums/strengthsum.htm>
4. Harbour R, Miller J. A new system for grading recommendations in evidence based guidelines. BMJ 2001;323:334-336.
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