

OVERVIEW

Most forms of treatment carry some risk of harm to the patient. While chiropractic procedures are considered comparatively safe, special caution is warranted with certain conditions. These include, for example, vertebral artery syndrome, herniated disc, and bone weakening processes.

Prevention of complications from treatment is facilitated when good professional judgment is exercised and quality care is provided. Elements common to all primary care practitioners include sufficient history taking and record keeping, thorough examination, timely re-evaluation procedures throughout the course of case management, good communication with the patient and appropriate response in the event that an unexpected incident does occur. With serious manipulative accidents, it is of critical importance that the intervention or procedure associated with the onset of the complication not be repeated.

Some of the complications reported in the literature could have been prevented. The development of acceptable preventative strategies to minimize future risk should be directed by methods of consensus, illuminated by continuous evaluation of research, protocol experience, and risk management and peer review programs. The expected goal of establishing guidelines for standards of practice is to assist practitioners to set and abide by standards which improve all aspects of patient care.

The scope of manipulative incidents and reactions may range from short-term pain and stiffness to cerebrovascular accidents arising from a dissecting aneurysm. This review of complications of and contraindications to high-velocity thrust procedures outlines various clinical conditions requiring treatment modification. Other manual procedures (e.g., soft tissue and low force technique procedures) are not addressed in this chapter. Guidelines for sound clinical management and prevention are recommended.

II. DEFINITIONS

Complication: The unexpected aggravation of an existing disorder or the onset of an unexpected new disorder as a result of treatment.

Classification of Complications.

- a) **Adverse Effect:** Any detrimental result of an action or treatment.
- b) **Reaction:** A slight or benign adverse effect of short duration usually lasting no more than a few days.
- c) **Accident or Incident:** An unexpected event occurring by chance, unknown causes, carelessness, negligence, or a combination thereof, resulting in serious or permanent impairment, injury, or fatality. The onset of signs and symptoms may be immediate or a day or two following the treatment.

d) **Indirect Complication:** Delay of diagnosis and appropriate treatment as a consequence of using a procedure or treatment that, in retrospect, has proven to be of no benefit for the condition.

Contraindication—Absolute: Any circumstance which renders a form of treatment or clinical intervention inappropriate because it places the patient at undue risk.

Contraindication—Relative: Any circumstance which may place the patient at undue risk unless treatment approach is modified.

Effectiveness: Effectiveness refers to the potential any given procedure or group of procedures has to produce a desired effect under actual conditions of use.

Iatrogenesis: Disorders or complications caused by health care providers.

Instability: An unstable joint condition resulting in damage or symptoms under the influence of physiologic loading.

Joint Dysfunction (Manipulable lesion, subluxation, functional spinal lesion): Decreased or aberrant joint mobility for which manipulation is indicated. In this context the term excludes states of hypermobility or instability.

Management: A plan of action for treatment of the patient in accordance with diagnosis, progress, and expectations of outcome.

Manual Therapy: Broadly described as a skilled manual method of movement of the soft tissues and articulations. May include all manual procedures, such as massage, muscle energy and strain-counterstrain techniques, trigger point therapy, joint mobilization, manipulation, and articular adjustment.

- a) **Stretching:** Techniques that attempt selectively to apply tensile forces along the length of specific ligaments or muscles. Loads used are quasistatic and are thought to bring about increased flexibility of the appropriate joint through passive means. Relaxation of muscle spasm and creep deformity of the elastic elements in connective tissues are commonly assumed mechanisms of action.
- b) **Mobilization:** Passive movement within the physiologic joint space, administered by a clinician for the purpose of increasing overall range of joint motion.
- c) **Soft Tissue Procedures:** A variety of manual techniques for soft tissue. As muscles and noncontractile structures lose function and elasticity, they have an effect on joint function. Most soft tissues are richly innervated with a variety of proprioceptive mechanisms, and often chiropractic application of soft tissue procedures will follow a traditional chiropractic rationale of attempting to improve a clinically identifiable aberrant neurologic reflex or pain pattern. Such work may be used in conjunction with other adjunctive or manipulative approaches. Some practitioners use a

variety of soft tissue procedures for nonarticular purposes as well (e.g., abdominal pressure points may be stimulated in a constipated patient).

d) High-Velocity Thrusting: Techniques involving movement of the selected joint to its end range of voluntary motion, followed by the application of an impulse loading. These methods are among the most common in chiropractic practice and are often referred to as "manipulation" or "adjustment" to differentiate them from less dynamic procedures.

Motion Segment: The smallest functional unit, made up of two adjacent articulating surfaces and contiguous and intervening soft tissues.

Negligence: Breach of the legal duty of care placed on all practitioners to exercise reasonable care and skill in the circumstances.

Risk Management: A systematic preventative strategy to minimize patient harm and practitioner liability through education and the development of guidelines for practice.

Safety: Safety refers to a judgment of the acceptability of any risk in a specified situation during the application of a specific procedure or group of procedures provided by an individual with specified and appropriate training.

Specialist: A health care provider who has obtained a professionally accepted or recognized level of additional training and competence with respect to specific procedures or disorders.

III. LIST OF SUBTOPICS

Conditions selected have come from a review of the scientific and medicolegal literature as well as insurance claim information.

A. Articular Derangements

1. Arthritides
 - i) Acute arthropathies
 - ii) Subacute and chronic ankylosing spondylitis
 - iii) Degenerative joint disease
 - iv) Spondylolysis and spondylolisthesis
2. Dislocation, fractures, instability
3. Os odontoideum
4. Articular hypermobility
5. Postsurgical joint
6. Acute joint injury
7. Scoliosis

B. Bone Weakening and Destructive Disorders

1. Juvenile osteochondroses
2. Osteoporosis, osteomalacia

3. Bone tumors
4. Malignancy
5. Infection of bone and joint

C. Circulatory and Cardiovascular Disorders

1. Vertebrobasilar, etc.
2. Aneurysm
3. Bleeding disorders

D. Neurological Disorders

1. Myelopathy, cauda equina syndrome

IV. LITERATURE REVIEW

Over the past two decades there has been a rapid growth of literature on manipulation-induced accidents or injuries (Dvorak 1991; Patjin, 1991; Schmitt, 1991; Terrett, 1990; 1987; Grieve, 1986; Gotlib and Thiel, 1985; Schmidely and Koch, 1984; Gutmann, 1983; Dvorak and Orelli, 1982; Ladermann, 1981; Gatterman, 1981; Jaskoviak, 1980; Kleynhans, 1980; Livingston, 1971). There can be little doubt that the elevated level of reporting arises from a general increase in awareness of complications by all professionals interested in spinal manipulative therapy. Because some alleged "consequences" are consistent with the natural history of a condition, anecdotal or polemic reports must be distinguished from those that provide objective evidence of true manipulation-induced injuries. Some case reports of injury have proven to be unfounded upon further unbiased inquiry.

Complications that do occur in a chiropractic office setting may be attributed to the following (Shekelle et al. 1991):

- misdiagnosis
- presence of coagulation dyscrasias
- cervical manipulation
- presence of a herniated nucleus pulposus
- improper technique application

The relative harm caused by therapeutic procedures used by chiropractic practitioners may be appreciated by reviewing claims of malpractice. The National Chiropractic Mutual Insurance Company listed the six most common claims in 1990 as:

- disc problems - 29%
- failure to diagnose - 13%
- fracture - 9%
- soft tissue - 7%
- cerebrovascular accidents - 6%
- aggravation of prior condition - 4%

Review of claims made in Canada from 1978 to 1985 revealed that cervical injuries represented 34% of the frequency and 50% of the total cost of claims. The second most reported claim was lumbar injury accounting for a frequency of 19% and cost of 26% of all claims made. Common reasons for malpractice claims against practitioners were inappropriate treatment and poor patient communication. Aside from the treatment of functional disorders of the spine and extremities, other pre-existing and unrecognized conditions are a significant factor in some accident claims. (Canadian Chiropractic Protective Association — CCPA Claims Review, to 1985).

A more recent CCPA Claim Review, for the period January 1986 to December 1990, revealed the following:

Lumbar spine injury	36 (23% of claims)
Rib Fracture	29 (19%)
Neck Injury	24 (16%)
Soft tissue/non-spinal injury	26 (13%)
CVA	12 (8%)
Other *	24 (16%)

* fee dispute, patient perception of general injury, failure to diagnose, improper treatment, practitioner concern over lawsuit)

With respect to the frequency of complications, Ladermann (1980) identified 135 case reports of serious complications over a 30 year period from 1950-1980, a time period during which tens of millions of manipulations were administered by a variety of practitioners. Kleynhans (1980), analyzing some of these case studies, outlined a number of likely practitioner-related causes of adverse reactions and suggested three main factors: lack of knowledge or diagnostic error; lack of technique skill; and lack of rational clinical attitude in case management. These causes could well account for a number of iatrogenic injuries reported in the literature, e.g., pathological fractures (Austin, 1985; Holta, 1942), ruptured abdominal aneurysms (Kornberge, 1988), electrotherapy burns and injuries, etc.

Jaskoviak (1981) and Terrett (1987) specifically dealt with case reviews on the adverse effect of cervical manipulation where verteobasilar insufficiency was evident. Gutmann (1984), Terrett (1987), Theil (1991) and Schmitt (1991) have recently described or studied the biomechanical effects of head and neck movement and cervical manipulation in association with vertebral artery injury. Manipulation has been identified as only one of many activities or health care procedures that may result in damage to the vertebral artery. However, it has been the one most extensively reviewed and discussed. (Pratt-Thomas and Berger, 1947; Gutmann 1957, 1962, 1971, 1984; Smith and Estridge, 1962; Maigne, 1969; Houle, 1972; Lewit, 1972; Giles, 1977; Henderson, 1979, 1991; George et al., 1981; Terrett, 1982, 1983, 1987; Hulse, 1983; Fast et al., 1987; Henderson and Cassidy, 1988; Martienssen and Nilsson, 1989; Raskind and North, 1990).

It is thought that cervical rotation combined with extension and traction may have some obstructive effect on perfusion of

the vertebral artery on the contralateral side of rotation. If the ipsilateral artery is diseased or hypoplastic, symptoms of hind brain ischemia may occur because the dominant healthy artery is under partial physiological compression, resulting in a loss of sufficient or compensatory blood flow. If trauma to the arterial wall does occur, thrombus formation may be the result. Further, this may lead to stroke or stroke-like complications in susceptible patients. While incidence figures vary, it is generally agreed that the risk of serious neurological complications is extremely low, and is approximately one or two per million cervical manipulations. Structural abnormalities, particularly where mechanical instability, pathological bone disorders, dislocations and fractures of the cervical spine are present may also lead to mechanical strain of the vertebral arteries (Terrett, 1987; Kleynhans, 1980; Jaskoviak, 1981; Ladermann, 1981).

Other cervical manipulative complications, which are rare but have either been reported or described in the literature, include Horner's syndrome, diaphragmatic paralysis, cervical myelopathy secondary to meningeal hemorrhage, pathological fracture of a cervical vertebra and cervical disc protrusions (Dabert et al., 1970; Rinsky et al., 1976; Krewalramani, 1982; Hefner, 1985; Grayson, 1987; Gatterman, 1991). Dislocation in the upper cervical spine due to inflammatory or traumatic rupture of the transverse atlantal or alar ligaments warrants particular caution (Yochum and Rowe, 1980, 1987; Jeffreys, 1980; Sandman, 1981; Redlund-Johnell, 1984).

Though rarely reported in the literature, empirically the most common complaint of manipulation of the thoracic region occurs when forceful or poorly applied manipulations cause costovertebral strains, rib fractures and costochondral separations (Grieve, 1986). Excessive thoracolumbar torque in the side posture position as well as inappropriately applied posterior to anterior techniques may cause thoracic cage injuries particularly in the elderly.

Lower back injury alleged to have occurred following spinal manipulative therapy has been reported in patients with pre-existing disc herniation or prolapse (CCPA Claim Review, 1990; Bromley, 1989; Gallinero and Cartesegna, 1983). While it is suggested that the forces required to cause a disruption of the annular fibers of the healthy intervertebral disc well exceed that of a rotational manipulative thrust (Adams and Hutton, 1981, 1983; Farfan, 1983; Gilmore, 1986; Triano, 1991), some disc herniation/protrusion may certainly be aggravated by an inappropriately applied manipulative maneuver, as it may be by other simple activities of daily living such as bending, sneezing, lifting. The most frequently described severe complication is compression of the cauda equina by massive midline nuclear herniation at the level of third, fourth or fifth intervertebral disc (Lehmann et al., 1991; Malmivivaara and Pohjola, 1982; Kleynhans, 1980; Hooper, 1973).

Of the thirty cauda equina complications associated with manipulation reported in the French, German and English literature over an 80 year period, only eight were allegedly related to chiropractic treatment (Ladermann, 1980). Had these patients not been manipulated, the outcome may have been the

same with menial effort or impulsive strain replacing the rupturing effect alleged to arise from the manipulation. However, this clinical outcome does stress the need for particular care in this susceptible subgroup of patients.

Psychological factors including pain intolerance, hysteria conversion reactions, hypochondriasis, malingering, etc., require special consideration, since the presence of neuromusculoskeletal symptoms may be of secondary importance. Aside from the risk of creating a dependency for care that may or may not be indicated, treatment itself may aggravate or contribute to real or imagined harm.

V. ASSESSMENT CRITERIA

Complications may occur spontaneously or arise as a result of chiropractic treatment. The risk of these complications may vary within subgroups of patients based on their clinical presentation. The main focus for the prevention of complications is the recognition of well known and established indicators or "red flag" signs and symptoms, which may require careful assessment and reassessment, changes in treatment plan, or other appropriate action such as emergency care or referral to another health care specialist. Ignoring these "red flag" indicators increases the likelihood of patient harm.

The literature and clinical experience show that the most common therapeutic procedure in chiropractic practice, and the one most likely to result in complications, is the adjustment or high-velocity manipulative thrust. The following assessment criteria and recommendations relate to this procedure applied to, or adjacent to, the anatomical site of pathology.

Assessment criteria developed and used in this chapter relate to:

- a) Rating of conditions
- b) Severity of complication
- c) Quality of evidence
- d) Level of contraindication: based on the above factors and the probability of complication

A. Rating of Conditions:

Type I:

A condition for which high-velocity thrust procedures have been shown to be comparatively safe and effective so long as an adequate diagnosis has been made and a therapeutic trial is rationally applied (e.g., upper cervical dysfunction/subluxation associated with tension headaches).

Type II:

A type I condition is present but may be coincident with another related or unrelated condition requiring modification of procedures and/or further diagnostic assessment (e.g., upper cervical joint dysfunction/subluxation accompanied by

widening of the atlantodental interval or inflammatory causes affecting the area). Careful clinical judgment is required in high-velocity thrust procedures may be relatively or absolutely contraindicated.

Type III:

Type I or II conditions are present but considered negligible compared with clinical evidence of another pathological problem requiring further diagnostic assessment and referral to another health care professional (e.g., cervical joint dysfunction/subluxation and local metastatic bone tumor). As the risk of serious harm far outweighs benefit, the therapeutic procedure may be absolutely contraindicated.

B. Severity of Complication:

Minimal Level:

Any complications of high-velocity thrust procedures may be considered minimal, with slight objective evidence of worsened signs usually lasting a maximum of several days (Reactions such as short term pain and stiffness or, infrequently, a mild chronic pain disorder alleged to arise from aggravation of a pre-existing problem). These reactions are rarely reported in the literature/claim reviews, given the brief duration of mild symptoms experienced by patients and the superimposed natural history of the presenting complaint. High-velocity thrust procedures are not generally contraindicated. Treatment modifications may have to be anticipated in exceptional cases.

Moderate Level:

Level of harm is generally moderate, characterized by more-or-less serious but usually reversible harm lasting weeks to months. Effects are temporary and/or residual in nature (e.g., broken rib, uncomplicated disc herniation, radiculopathy, foot drop). Depending on all factors (e.g., frequency of complications, benefits) high-velocity thrust procedures may be relatively or absolutely contraindicated.

High Level:

Evidence suggests risk of a high level of harm. The complication or accident may be serious and/or permanent, particularly in susceptible patients. (e.g., stroke, cauda equina syndrome). High-velocity thrust procedures may be relatively contraindicated with careful treatment modification, or absolutely contraindicated given patient history, diagnostic tests and/or other information obtained during a trial of therapy.

C. Quality of Evidence:

Evidence on the risk of complication arising from chiropractic treatment and particularly high-velocity thrust procedures comes from case reports, surveys, literature reviews, and insurance and legal claims records. There needs to be further systematic study of the incidence, severity and man-

of complications. Present classification of quality of evidence is:

Class I:
Evidence provided by surveys, systematic studies, literature reviews, and detailed clinical case reports published in refereed journals.

Class II:
Evidence provided by other case studies or reviews, or consensus expert opinion from legitimate consensus-building efforts.

Class III:
Evidence provided by expert opinion and one or more case reports.

D. Level of Contraindication:

Having regard to all of the individual assessment criteria already discussed, the following overall ratings are used:

No Contraindication

Relative Contraindication: high-velocity thrust procedures may be used with appropriate care and/or modification.

Relative to Absolute Contraindication: careful clinical judgment dictates whether contraindication is relative or absolute with each specific patient.

Absolute Contraindication

Example: As an example of the complete rating system:

Noncomplicated Low-Back Pain:

No contraindication to high-velocity thrust procedures.

Risk-of-Complication Rating:

Severity (if harm did occur): Minimal

Rating of Condition: Type I

Quality of Evidence: Class I

This rating system assumes no negligence or error on the part of the practitioner. Tolerance to treatment may sometimes, but not always, be estimated by provocative or premanipulative testing.

In the examples below it is assumed that traditionally and commonly used high-velocity, low-amplitude thrusts (adjustment/manipulation) are administered to, or immediately adjacent to, the segmental level where both the manipulable subluxation/dysfunction and/or the condition has primarily manifested itself.

VI. RECOMMENDATIONS

Note: General health problems which have been described in the literature as either contraindications to or complications of high-velocity thrust procedures include the following con-

ditions. It should be understood that the listed conditions are not necessarily those for which high-velocity thrust procedures are intended. Rather they may be coincidentally present in a patient undergoing treatment. The fundamental object of treatment is a manipulable joint lesion (subluxation, dysfunction, blockage).

A. Articular Derangements:

1. Acute rheumatoid, rheumatoidlike and nonspecific arthropathies including acute ankylosing spondylitis characterized by episodes of acute inflammation, demineralization, ligamentous laxity with anatomic subluxation or dislocation, represent an **absolute contraindication** to high-velocity thrust procedures in anatomical regions of involvement.

12.1.1 Risk-of-Complication Rating:

Severity: Moderate to High Condition Rating:

Type III

Quality of Evidence: Class II, III

Consensus Level: 1

2. Sub-acute and/or chronic ankylosing spondylitis and other chronic arthropathies in which there are no signs of ligamentous laxity, anatomic subluxation or ankylosis are **not contraindications** to high-velocity thrust procedures applied to the area of pathology.

12.1.2 Risk-of-Complication Rating:

Severity: Minimal

Condition Rating: Type I, II

Quality of Evidence: Class II, III

Consensus Level: 1

3. Degenerative joint disease, osteoarthritis, degenerative discopathy and spondyloarthrosis are **not contraindications** to high-velocity thrust procedures to the area of pathology but treatment modification may be warranted during active inflammatory phases.

12.1.3 Risk-of-Complication Rating:

Severity: Minimal

Condition Rating: Type I, II

Quality of Evidence: Class II

Consensus Level: 1

4. In patients with spondylolysis and spondylolisthesis caution is warranted when high-velocity thrust procedures are used. These conditions are **not contraindications**, but with progressive slippage they may represent a **relative contraindication**.

12.1.4 Risk-of-Complication Rating:

Severity: Minimal to Moderate

Condition Rating: Type I, II

Quality of Evidence: Class II

Consensus Level: 1

5. Acute fractures and dislocations, or healed fractures and dislocations with signs of ligamentous rupture or instability, represent an **absolute contraindication** to high-velocity thrust procedures applied to the anatomical site or region.

12.1.5 **Risk-of-Complication Rating:**
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

6. Unstable os odontoideum represents an **absolute contraindication** to high-velocity thrust procedures to the area of pathology.

12.1.6 **Risk-of-Complication Rating:**
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

7. Articular hypermobility, and circumstances where the stability of a joint is uncertain, represent a **relative contraindication** to high-velocity thrust procedures to the area of pathology.

12.1.7 **Risk-of-Complication Rating:**
Severity: Minimal
Condition Rating: Type I, II
Quality of Evidence: Class II, III
Consensus Level: 1

8. Postsurgical joints or segments with no evidence of instability are **not a contraindication** to high-velocity thrust procedures but may represent a **relative contraindication** depending on clinical signs (e.g., response, pretest tolerance or degree of healing).

12.1.8 **Risk-of-Complication Rating:**
Severity: Minimal
Condition Rating: Type II
Quality of Evidence: Class III
Consensus Level: 1

9. Acute injuries of osseous and soft tissues may require modification of treatment. In most cases, high-velocity thrust procedures to the area of pathology are **not contraindicated**.

12.1.9 **Risk-of-Complication Rating:**
Severity: Minimal to moderate
Condition Rating: Type I, II
Quality of Evidence: Class I, II
Consensus Level: 1

10. The presence of scoliosis is **not a contraindication** to high-velocity thrust procedure.

12.1.10 **Risk-of-Complication Rating:**
Severity: Minimal
Condition Rating: Type I, II

Quality of Evidence: Class II, III
Consensus Level: 1

B. Bone Weakening and Destructive Disorders

1. Active juvenile avascular necrosis, specifically of the weight bearing joints (e.g., Perthes' disease) represents an **absolute contraindication** to high-velocity thrust procedures to the area of pathology.

12.2.1 **Risk-of-Complication Rating:**
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

2. Demineralization of bone warrants caution with the use of high-velocity thrust procedures. This represents a **relative contraindication** to high-velocity thrust procedures to the area of pathology.

12.2.2 **Risk-of-Complication Rating:**
Severity: Minimal to Moderate
Condition Rating: Type II
Quality of Evidence: Class II, III
Consensus Level: 1

3. Benign bone tumors may result in pathological fractures and therefore represent a **relative to absolute contraindication** to high-velocity thrust procedures to the area of pathology.

12.2.3 **Risk-of-Complication Rating:**
Severity: Low to Moderate
Condition Rating: Type II, III
Quality of Evidence: Class III
Consensus Level: 1

4. Malignancies represent conditions for which high-velocity thrust procedures to the area of pathology are **absolutely contraindicated**.

12.2.4 **Risk-of-Complication Rating:**
Severity: Moderate to High
Condition Rating: Type III
Quality of Evidence: Class II, III
Consensus Level: 1

5. Infection of bone and joint represents an **absolute contraindication** to high-velocity thrust procedures to the area of pathology.

12.2.5 **Risk-of-Complication Rating:**
Severity: Minimal to High
Condition Rating: Type III
Quality of Evidence: Class II
Consensus Level: 1

Respiratory and Cardiovascular Disorders

Clinical manifestations of vertebrobasilar insufficiency **do not** warrant particular caution and represent a **relative contraindication** to cervical high-velocity thrust procedures to the region of pathology.

- 12.3.1 Risk-of-Complication Rating:**
Severity: Minimal to High
Condition Rating: Type II, III
Quality of Evidence: Class I, II, III
Consensus Level: 1

When a diagnosis of a significant aneurysm involving a major blood vessel has been made, a **relative to absolute contraindication** may exist for high-velocity thrust procedures within the area of pathology.

- 12.3.2 Risk-of-Complication Rating:**
Severity: High
Condition Rating: Type III
Quality of Evidence: Class III
Consensus Level: 1

Bleeding is a potential complication of anticoagulant therapy or certain blood dyscrasias. Patients with these disorders represent a **relative contraindication** to high-velocity thrust procedures.

- 12.3.3 Risk-of-Complication Rating:**
Severity: Minimal to High
Condition Rating: Type II
Quality of Evidence: Class III
Consensus Level: 1

Neurological Disorders

Signs and symptoms of acute myelopathy or acute cauda equina syndrome represent an **absolute contraindication** to high-velocity thrust procedures applied to the anatomic site of involvement.

- 12.4.1 Risk-of-Complication Rating:**
Severity: High
Condition Rating: Type II, III
Quality of Evidence: Class I, II
Consensus Level: 1

* Most dysfunctions or disease processes have variations or phases. Levels of severity and probability have been assigned on the basis that the condition displays usual and classical signs and symptoms. The difficulty in precisely detailing the degree or severity and probability of an individual patient's overall physical and psychological response both to the condition and therapeutic procedure (subtleties of force, amplitude, direction, patient positioning, etc.) is acknowledged. Nevertheless, ratings have been assigned based on the literature and

the current consensus process. These provide a starting point which will require ongoing review and refinement.

Some conditions, such as scoliosis, are not level-specific and high-velocity thrust procedures used apply more to a region than a level.

VII. COMMENTS, SUMMARY OR CONCLUSION

This chapter provides an analytical framework and specific interim guideline recommendations with respect to complications of and contraindications to manipulative thrust procedures. At present, detailed systematic studies on this subject are lacking and the recommendations made are based on information from clinical reviews and case reports, as well as from expert opinion and consensus methods. One objective of this chapter is to encourage productive debate leading to firmer commitment on risk management protocols.

The recommendations made must be continuously re-evaluated in light of ongoing research and clinical experience. Cooperative intradisciplinary and interdisciplinary research will be necessary to determine the true extent of the nature and occurrence of iatrogenic complications in chiropractic practice. The development of a central registry system capable of generating comprehensive research data would be valuable, and would facilitate the establishment of more detailed and refined guideline recommendations in the future.

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X MINORITY OPINION

None.

資料 9

Chapter 13 - Contraindications And Complications

Chapter Outline

- I. Overview
- II. Definitions
- III. List of Subtopics
- IV. Literature Review
- V. Assessment Criteria
- VI. Recommendations (Guidelines)
- VII. Comments, Summary or Conclusions
- VIII. References
- IX. Minority Opinions

I OVERVIEW [Top]

Most forms of treatment carry some risk of harm to the patient. While chiropractic procedures are considered relatively safe, special caution is warranted with certain conditions. These include, for example, vertebral artery syndrome, disc herniation, and bone weakening processes.

Prevention of complications from treatment is facilitated when good professional judgment is exercised and quality care is provided. Elements common to all primary care practitioners include good history taking, detailed record keeping, appropriate examination, timely re-evaluation procedures throughout the course of case management, good communication with the patient and appropriate response in the event that an unfortunate incident does occur. When complications from a manipulation occurs, it is of critical importance that the intervention or procedure associated with the onset of the complication not be repeated.

The development of acceptable preventive strategies to minimize future risk should be directed by methods of consensus, supported by continuous evaluation of research, protocol experience, risk management, and peer review programmes. The expected goal of establishing guidelines for standards of practice is to assist practitioners to set and abide by standards which improve all aspects of patient care.

The scope of manipulative incidents and reactions may range from aggravation of the presenting complaint to cerebrovascular accidents arising from a dissecting aneurysm. This review of complications of and contraindications to high-velocity thrust procedures outlines various clinical conditions requiring treatment modification. Other manual procedures (e.g., soft tissue and low force technique procedures) are not addressed in this chapter. Guidelines for sound clinical management and prevention are recommended.

II DEFINITIONS [Top]

Complication: The unexpected aggravation of an existing disorder, or the onset of an unexpected new disorder as a result of treatment.

Classification of complications:

- a) Adverse effect** - Any detrimental result of an action or treatment.
- b) Reaction** - A slight or benign adverse effect of short duration usually lasting no more than a few days.
- c) Accident or Incident** - An unexpected event occurring by chance, unknown causes, carelessness, negligence, or a combination thereof, resulting in serious or permanent impairment, injury, or fatality.
- d) Indirect complication** - Delay of diagnosis and appropriate treatment as a consequence of using a procedure or treatment that, in retrospect, has proven to be of no benefit for the condition.

Contraindication - absolute: Any circumstance which renders a form of treatment or clinical intervention inappropriate because it places the patient at undue risk.

Contraindication - relative: Any circumstance which may place the patient at undue risk unless treatment approach is modified.

For definitions see the Glossary at the end of this publication.

Effectiveness

Iatrogenesis

Instability

Manipulable lesion (joint dysfunction, functional spinal lesion, subluxation)

Management

Manual Therapy

See also High-Velocity Thrusting; Manipulation; Mobilization, Soft Tissue Procedures; and Stretching.

Motion Segment

Negligence

Risk Management

Safety

Specialist

III. LIST OF SUB-TOPICS [Top]

Conditions selected have come from a review of the scientific and

medicolegal literature as well as insurance claim information.

A. Articular Derangement

1. Arthritides
 - a) Inflammatory arthritis
 - b) Sub-acute and chronic ankylosing spondylitis
 - c) Degenerative joint disease
 - d) Spondylolysis and spondylolisthesis
2. Fractures, dislocations, and ligamentous instability
3. Atlanto-axial instability
4. Articular hypermobility
5. Post-surgical joint
6. Acute joint and soft tissue injuries
7. Scoliosis

B. Bone Weakening and Destructive Disorders

1. Juvenile osteochondroses
2. Osteoporosis and osteomalacia
3. Benign bone tumours, tumour-like and dysplastic bone lesions
4. Malignancy
5. Infection of bone and joint

C. Circulatory and Cardiovascular Disorders

1. Vertebrobasilar insufficiency syndrome
2. Aneurysm
3. Bleeding disorders

D. Neurological Disorders

1. Myelopathy and cauda equina syndrome

IV LITERATURE REVIEW AND DISCUSSION [Top]

Over the past two decades there has been a rapid increase in the literature on manipulation-induced accidents or injuries (Haldeman and Rubinstein 1993, Dvorak 1991, Patijn 1991, Schmitt 1991, Frumkin and Baloh 1990,

Terrett 1990, 1987, Fast et al. 1987, Mas et al, 1987; Sherman et al. 1987, Grieve 1986, Dvorak and Orelli 1985, Gotlib and Thiel 1985, Schmidley and Koch 1984, Gutmann 1983, Gatterman 1981, Ladermann 1981, Jaskoviak 1980, Kleynhans 1980, Krueger and Okazaki 1980, Schellhas et al. 1980, Livingston 1971). This interest suggests that the elevated level of reporting arises from a general increase in awareness by all professionals interested in spinal manipulative therapy. Some alleged consequences are consistent with the natural history of a condition and thus, anecdotal or polemic reports must be distinguished from those which provide objective evidence of true manipulation-induced injuries. Some case reports of injury have proven to be unfounded upon further unbiased inquiry.

Complications that do occur in a chiropractic office setting may be attributed to the following (Shekelle et al, 1991):

- misdiagnosis
- presence of coagulation dyscrasias
- cervical manipulation
- presence of a herniated nucleus pulposus
- improper technique application

The relative harm caused by therapeutic procedures used by chiropractors may be appreciated by reviewing claims of malpractice. The National Chiropractic Mutual Insurance Company (1990) listed the six most common claims as:

- disc problems - 29%
- failure to diagnose - 13%
- fracture - 9%
- soft tissue injury - 7%
- cerebrovascular accidents - 6%
- aggravation of prior condition - 4%

A review of claims made in Canada from 1978 to 1985 revealed that cervical injuries represented 34% of the frequency and 50% of the total cost of claims. The second most reported claim was lumbar injuries accounting for a frequency of 19% and a cost of 26% of all claims made. The most common causes for malpractice claims against chiropractors were inappropriate treatment and poor patient communication. Aside from the treatment of functional disorders of the spine and extremities, other co-existing and unrecognized conditions are a significant factor in some accident claims (Canadian Chiropractic Protective Association - CCPA Claim Reviews, 1978 to 1985). A more recent CCPA Claim Review for the period beginning January, 1986 to December, 1990 revealed the following:

Lumbar spine injury 36 (23% of claims)

Rib fracture 29 (19%)

Soft tissue/non-spinal injury 26 (13%)

Cervical spine injury 24 (16%)

Cerebrovascular accidents 12 (8%)

Thoracic spine injury 8 (5%)

*Other 24 (16%)

(*fee dispute, patient perception of general injury, failure to diagnose, improper treatment, practitioner concern over lawsuit)

With respect to the frequency of complications, Ladermann (1981) identified 135 case reports of serious complications over a thirty year period between 1950 and 1980. During this time period, tens of millions of manipulations were administered by a variety of practitioners. Kleynhans (1980), analyzing some of these case studies, outlined a number of likely practitioner-related causes of adverse reactions. Three main factors were identified: lack of knowledge or diagnostic error, lack of technique skill, and lack of rational clinical attitude in case management. These causes may well have accounted for a number of the iatrogenic injuries reported in the literature, e.g., pathological fractures (Austin 1985, Holta 1942), ruptured abdominal aneurysms (Kornberg 1988), and sensorineural hearing loss (Brownson et al. 1986).

Terrett (1987) and Jaskoviak (1981) specifically dealt with case reviews on the adverse effect of cervical manipulation where vertebralbasilar insufficiency was evident. Schmitt (1991), Thiel (1991), Terrett (1987), and Gutmann (1985) have recently described or studied the biomechanical effects of head and neck movement and cervical manipulation in association with vertebral artery injury. Manipulation has been identified as one of many activities or health care procedures that may result in damage to the vertebral artery. However, manipulation in association with vertebral artery injury has been the most extensively reviewed and discussed (Henderson 1992, 1979, Raskind and North 1990, Frumkin and Baloh 1990, Martiensen and Nilsson 1989, Henderson and Cassidy 1988, Fast et al. 1987, Terrett 1987, 1983, 1982, Gutmann 1985, 1971, 1962, 1959, Hulse 1983, George et al. 1981, Giles 1977, Houle 1972, Lewit 1972, Maigne 1969, Smith and Estridge 1962, Pratt-Thomas and Berger 1947).

It is thought that cervical rotation combined with extension and traction may have some obstructive effect on perfusion of the vertebral artery. Several studies suggest that the vertebral artery on the contralateral side of rotation comes under partial physiological compression (Thiel 1992, Schmitt 1991, Andersson et al. 1970, Selecki 1969, Toole and Tucker 1960). If the ipsilateral artery is diseased or hypoplastic, symptoms of hind brain ischaemia may occur as a result of a loss of sufficient or compensatory blood flow. A recent study suggests that cervical rotation combined with extension and traction may in fact obstruct flow in either vertebral artery (Koskas et al. 1992). If trauma to the arterial wall does occur, thrombus formation may be the result. Further, this may lead to stroke or stroke-like complications in susceptible patients. While incidence figures vary, it is generally agreed that the risk of serious neurological complication is extremely low and is approximately 1 or 2 per million cervical manipulations (Henderson 1992, Terrett 1987, Dvorak and Orelli 1985, Gutmann 1983, Jaskoviak 1980). Structural abnormalities particularly where mechanical instability, pathological bone disorders, dislocations and fractures of the cervical spine are present may also lead to mechanical injury of the vertebral arteries (Terrett 1987, Jaskoviak 1981, Ladermann 1981, Kleynhans 1980).

Other cervical manipulative complications, which are rare but have either been reported or described in the literature include diaphragmatic paralysis, cervical myelopathy secondary to meningeal haemorrhage, pathological fracture of a cervical vertebra and cervical disc protrusions (Gatterman 1991, Grayson 1987, Heffner 1985, Kewalramani et al. 1982, Rinsky et al. 1976, Dabbert et al. 1970). Instability in the upper cervical spine due to inflammatory or traumatic rupture of the transverse, atlantal or alar ligaments warrant special consideration in susceptible patients (Yochum and Rowe 1987, 1980, Redlund-Johnell 1984, Sandman and Sandman 1981, Jeffreys 1980). Atlanto-axial instability is suggested when the distance between the posterior aspect of the anterior arch of the atlas and the anterior aspect of the odontoid process exceeds 3mm in adults or 5mm in young children, or an osseous distance that changes considerably between flexion and extension (Chapman and Nakielny 1984). Besides inflammatory arthritis and trauma, atlanto-axial instability can also be present in congenital anomalies such as os odontoideum in patients with Down's, Morquio's, or Klippel Feil syndromes.

Though rarely reported in the literature, empirically the most common sequelae of manipulation to the thoracic region occurs when forceful or poorly applied manipulations cause costovertebral sprains, rib fractures and/or costochondral separations (Haldeman 1993, Grieve 1986). Excessive thoracolumbar torque in the lateral recumbent position as well as inappropriately applied posterior to anterior techniques may also cause thoracic cage injuries, particularly in the elderly.

Low-back injury alleged to have occurred following spinal manipulative therapy has been reported in patients with pre-existing disc herniation or prolapse (CCPA Claim Review 1990; Bromley 1989, Gallinaro and Cartesegna 1983). While it is suggested that the forces required to cause a disruption of the annular fibres of the healthy intervertebral disc well exceed that of a rotational manipulative thrust (Cassidy et al. 1993), Triano 1991, Gilmore 1986, Farfan 1983, Adams and Hutton 1983, 1981), some disc herniation/protrusions may be aggravated by an inappropriately applied manipulative manoeuvre as it may be by other simple activities of daily living such as bending, sneezing, and/or lifting. Manipulation as a form of treatment of patients with lumbar disc herniation is used by chiropractors. There are several uncontrolled descriptive studies and single case reports of the successful treatment of lumbar disc herniation by manipulation (D'Ornano et al. 1990, Quon et al. 1989; Martin 1988, Kuo and Loh 1987, Chrisman et al. 1964, Mensor 1955, Henderson 1952). There is only one controlled clinical trial which compared oscillatory rotational manipulation to conventional physiotherapy in the treatment of lumbar disc herniation. The results favoured the manipulated group on all outcome measures (Nwuga 1982).

In most cases of lumbar disc herniation, the effect of manipulation is to help relieve back pain; to allow for improved ambulation and thus offer greater comfort to the patient (Cassidy et al. 1992). Manipulation for lumbar disc herniation when appropriately applied is a safe treatment in cases where there are no signs of increasing neurological deficit or cauda equina syndrome (Cassidy et al. 1993).

The most frequently described severe complication is compression of the cauda equina by massive midline nuclear herniation at the level of the third, fourth or fifth intervertebral disc (Lehmann et al. 1991, Malmivaara and Pohjola 1982, Kleynhans 1980, Hooper 1973). Of the twenty-nine cases of cauda equina syndrome associated with manipulation collected in

the French, German and English literature reported over a period of 80 years, only eight were allegedly related to chiropractic treatment (Haldeman and Rubinstein 1992, Ladermann 1981). In most cases it was impossible to determine whether manipulation was a precipitating factor or merely coincidental to the onset of cauda equina syndrome. Had these patients not been manipulated, the outcome may have been the same with menial effort or impulsive strain replacing the rupturing effect allegedly to have arisen from the manipulation. However, until further conclusive evidence is available, this clinical outcome does stress the need for particular care in this susceptible sub-group of patients.

V. ASSESSMENT CRITERIA [Top]

Complications may occur spontaneously or arise as a result of chiropractic treatment. The risk of these complications may vary within subgroups of patients based on their clinical presentation. The main focus for the prevention of complications is the recognition of well-known and established indicators or "red flag" signs and symptoms which may require careful assessment and reassessment, changes in treatment plan, or other appropriate action, such as emergency care or referral to another health care specialist. Ignoring these "red flag" indicators increases the likelihood of patient harm.

When assessing whether any particular therapeutic procedure is safe and effective, two major interdependent factors require consideration: the patient's overall condition in association with the specific complaint for which the patient sought care and secondly, the risk associated with the application of a therapeutic procedure in any given situation.

The literature and clinical experience suggest that the most common therapeutic procedure in chiropractic practice, and the one most likely to result in complications, is the adjustment or high-velocity manipulative thrust. The following assessment criteria and recommendations relate to this procedure applied to, or adjacent to, the anatomical site of pathology.

Assessment criteria developed and used in this chapter relate to:

- A) Severity of complication.
- B) Rating of a condition.
- C) Quality of evidence.
- D) Level of contraindication - based on the above three factors.

A. Severity of Complication:

Minimal Level:

Minor or temporary intensification of symptoms may occur following high-velocity thrust procedures. These reactions are rarely reported in the literature/claim reviews, given the brief duration of mild symptoms experienced by patients and the superimposed natural history of the presenting complaint. Generally, there is no contraindication to high-velocity thrust procedures.

Moderate Level:

Level of harm is generally moderate, characterized by fairly serious, but usually reversible harm lasting weeks to months. Effects are temporary and/or residual in nature (e.g., broken rib, uncomplicated disc herniation, radiculopathy, foot drop). Depending on all factors (e.g., frequency of complications, benefits) high-velocity thrust procedures may be relatively or absolutely contraindicated.

High Level:

Evidence suggests that there may be a high level of risk of harm. The complication or accident may be serious and/or permanent, particularly in susceptible patients (e.g., stroke, cauda equina syndrome). Serious complications are rare but perhaps under-reported in the literature. High-velocity thrust procedures may be relatively contraindicated requiring careful treatment modification or absolutely contraindicated given patient history, diagnostic tests and/or other information obtained during a trial of therapy.

B. Rating of Conditions:**Type I Condition:**

A condition for which a high-velocity thrust procedure has been shown to be comparatively safe and effective so long as an adequate diagnosis or clinical impression has been made and a therapeutic trial is rationally applied (e.g., upper cervical dysfunction associated with tension headaches).

Type II Condition:

A Type I condition is present but may be coincident with another related or unrelated condition requiring modification of a therapeutic procedure and/or further diagnostic assessment (e.g., lumbar spine joint dysfunction associated with a Grade 2 spondylolisthesis). Careful clinical judgment is required as high-velocity procedures may be relatively or absolutely contraindicated.

Type III Condition:

Type I or II conditions are present but considered negligible compared with clinical evidence of another pathological problem requiring further diagnostic assessment and referral to another health care professional or specialist (e.g., cervical joint dysfunction and local metastatic bone tumour). As the risk of serious harm far outweighs benefit, the therapeutic procedure may be absolutely contraindicated.

C. Quality of Evidence:

Evidence on the risk of complication arising from chiropractic treatment, particularly high-velocity thrust procedures comes from case reports, surveys, literature reviews, and insurance and legal claim records. There needs to be further systematic study of the incidence, severity and management of complications. Present classification of quality of evidence is:

Class I:

Evidence provided by well-designed prospective studies such as randomized controlled trials, cohort studies, and case-control studies published in refereed journals.

Class II:

Evidence provided by surveys, systematic studies, literature reviews, and detailed clinical case reports, or consensus expert opinion from legitimate consensus-building efforts published in refereed journals.

Class III:

Evidence provided by expert opinion and one or more case reports.

D. Level of Contraindication:

Having regard to all of the individual assessment criteria already discussed, the following overall ratings are used:

No Contraindication.

Relative Contraindication - high-velocity thrust procedures may be used with appropriate care and/or modification.

Relative to Absolute Contraindication - careful clinical judgment dictates whether contraindication is relative or absolute with each individual patient.

Absolute contraindication.

Example: As an example of the complete rating system for non-complicated mechanical low-back pain: **no contraindication** to high-velocity thrust procedures.

Risk-of-Complication Rating:

Severity (if harm did occur): Minimal

Condition Rating: Type I

Quality of Evidence: Class I

This rating system assumes no negligence or error on the part of the practitioner. Tolerance to treatment may sometimes, but not always, be estimated by provocative or pre-manipulative testing.

In the following examples it is assumed that traditional and commonly used high-velocity, low-amplitude thrusts (manipulation/adjustment) are administered to, or immediately adjacent to, the segmental level where the manipulable lesion (joint dysfunction, subluxation) has primarily manifested itself.

VI. RECOMMENDATIONS (GUIDELINES) [Top]

NOTE: General health problems which have been described in the literature as either contraindications to or complications of high-velocity thrust procedures include the following conditions. It should be understood that the manipulative procedures are not necessarily intended for the following listed conditions. Rather they may be co-incidentally present in a patient undergoing treatment. The fundamental object of treatment is a manipulable lesion (subluxation, joint dysfunction, functional spinal lesion).

A. Articular Derangement:

1. Arthritides

13.1 Inflammatory arthritis such as rheumatoid arthritis, seronegative spondyloarthropathies including acute ankylosing spondylitis characterized by episodes of acute inflammation, demineralization, ligamentous laxity with anatomic subluxation or dislocation, represent an **absolute contraindication** to high-velocity thrust procedures in anatomical regions of involvement.

Risk-of-Complication Rating:

Severity: Moderate to High

Condition Rating: Type III

Quality of Evidence: Class III

Consensus Level: 1

13.2 Sub-acute and chronic ankylosing spondylitis and other chronic arthropathies in which there are no signs of ligamentous laxity, anatomic subluxation or ankylosis are **not contraindications** to high-velocity thrust procedures applied to the area of pathology.

Risk-of-Complication Rating:

Severity: Minimal

Condition Rating: Type I, II

Quality of Evidence: Class III

Consensus level: 1

13.3 Degenerative joint disease, osteoarthritis, degenerative spondyloarthropathy and facet arthrosis are **not contraindications** to high-velocity thrust techniques to the area of pathology but treatment modification may be warranted during active inflammatory phases.

Risk-of-Complication Rating: