Adverse Events in Manual Therapy

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Why study adverse events in manual therapy?

- Codes of conduct to seek consent
- Informed consent and knowledge of risks
- Definition of adverse events applicable to manual therapy
- The literature bias to manipulation and vascular accidents
- Adverse events vary in degrees of severity and duration

AIMS

1) To define an adverse event

2) To review the evidence about incidence, risk, and nature and type of adverse events that occur with manual therapy

What is an adverse event?

Incontinence

Sharp pain

Death

Cervical artery dissection

Numbness

Vascular accident

Fracture

Nausea

Bruising

Tingling

Aches

Dizziness

Being disrespected

Being inappropriately touched

Fatigue

Parasthesia

Referred pain

Neuralgia

Muscle soreness

Un-resolving pain

Coma

Blurred vision

Stroke

Falling off plinth

Consensus Study

- Delphi approach:
  Concept developed in the 1950s in the USA as an approach to seek consensus about issues where there is poor clarity or controversy

We brainstormed

We asked participants to classify some symptoms and signs

We asked a ranged of different professionals to classify descriptors of outcomes of treatment

Agreed definition of adverse events

Adverse Event	Duration	Severity	Descriptor
Major	Medium/long term	Moderate/severe	Unacceptable Requires further treatment Serious Distressing
Moderate	Medium/long term	Moderate	
Minor	Short term	Mild	Non-serious Function remains intact, Transient/reversible No treatment alterations required Short term consequences Contained
Not adverse	Short term	Mild	

Systematic review of adverse events

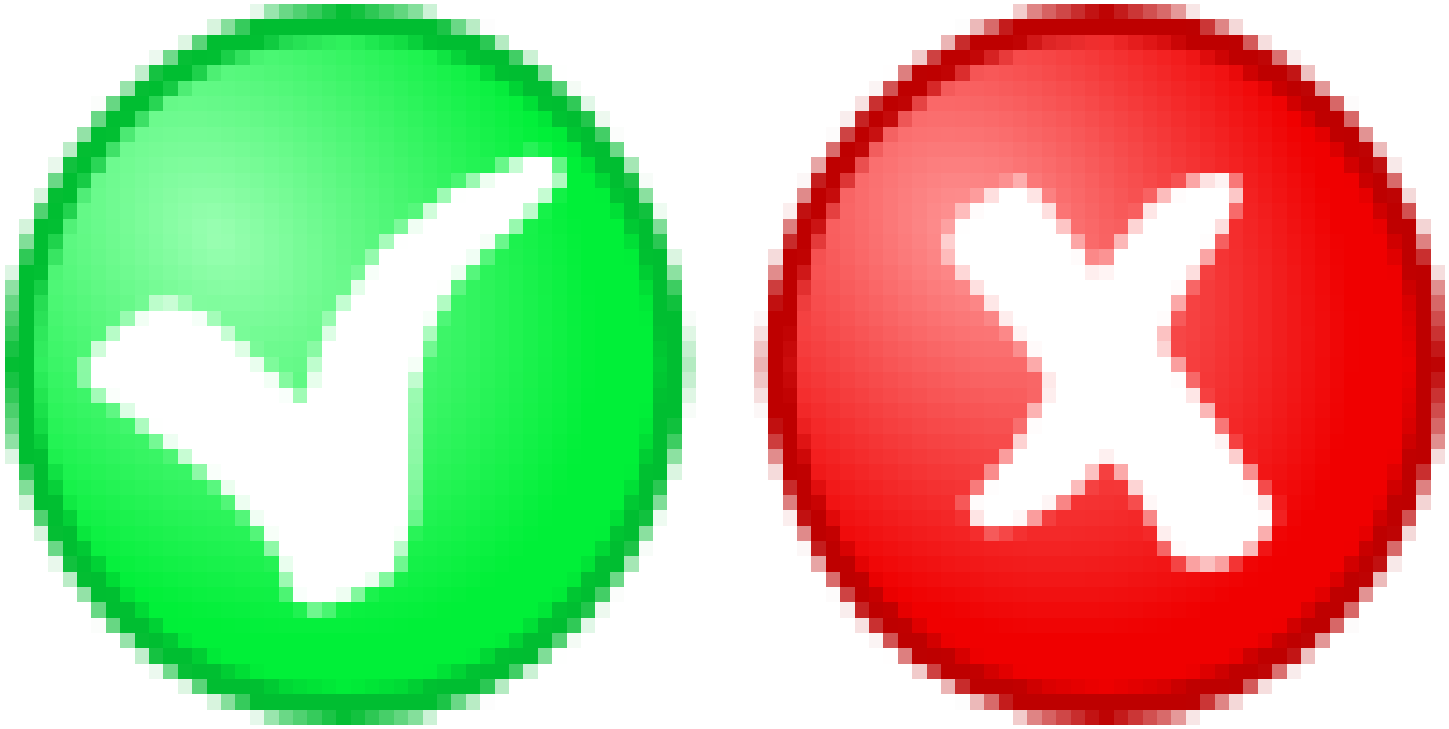
What is a manual therapist ?

What is manual therapy?

Systematic review protocol/method

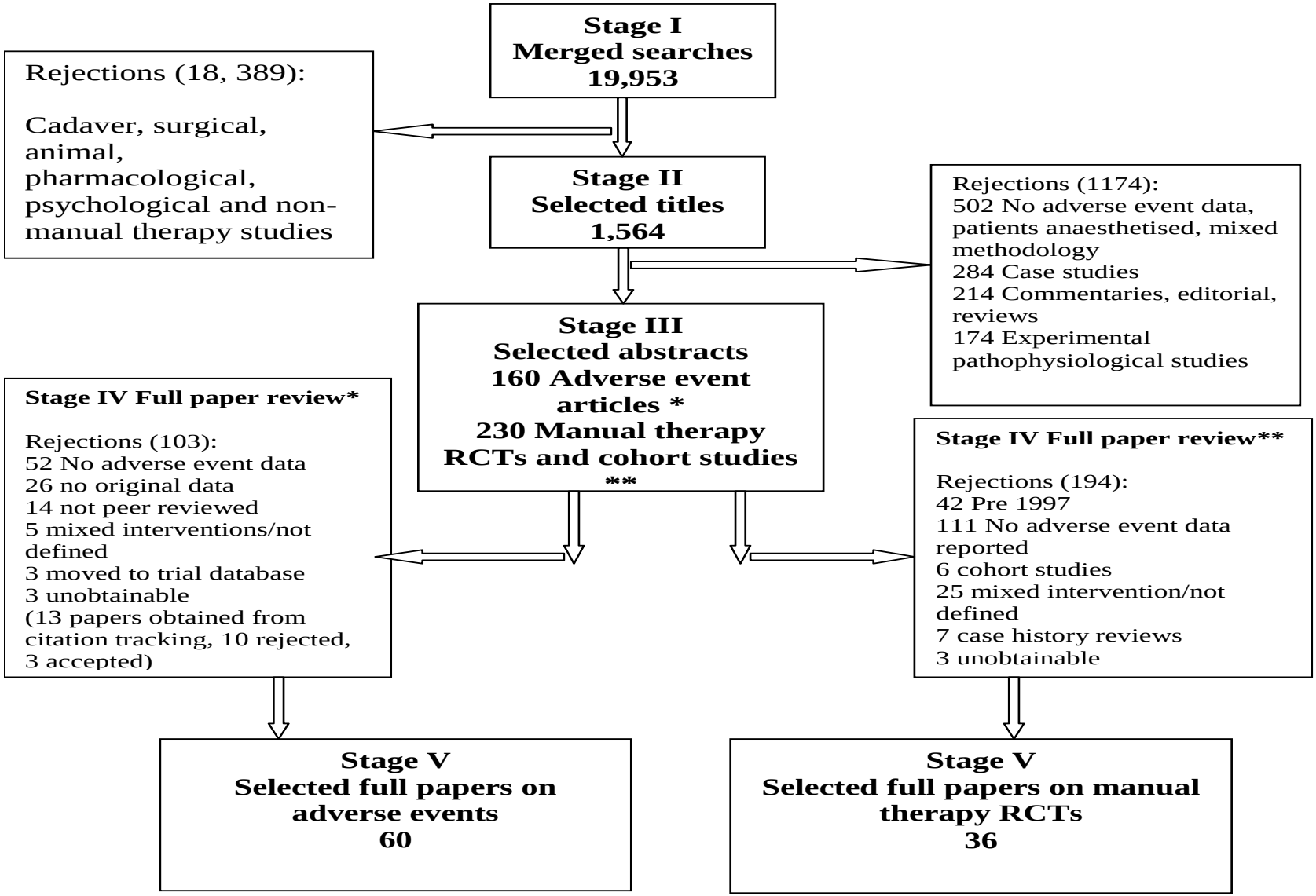
- Inclusion, exclusion criteria
- Search terms
- Databases
- Selection
- Quality appraisal
- Data extraction
- Data analysis

Inclusion and exclusion criteria



Databases

	Hits TM	Hits DC
Main databases		
PubMed	4059	7401
OVID (inc chiroaccess)	2812	7056
Science Direct	1187	824
ISI Web of Science	249	242
Wiley Interscience	119	824
Index of Chiropractic Literature	968	259
PEDro	213	330
Other databases		
Taylor and Francis Informaworld	685	
Cambridge Journals		445
Ostmed	Non-operational	
AMED		233
JAMA		851
Total excluding duplicates	9,960	15,991
Total combined excluding duplicates	19,953	



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Results

Sources data

Grouped data from two sources:

• Observational, case control and cohort studies (e.g. prospective cohort studies)

Questionnaire surveys, both individual data and population data (60 articles)

• Randomised Controlled Trials (RCTs) (36 articles)

Data extraction (non RCT)

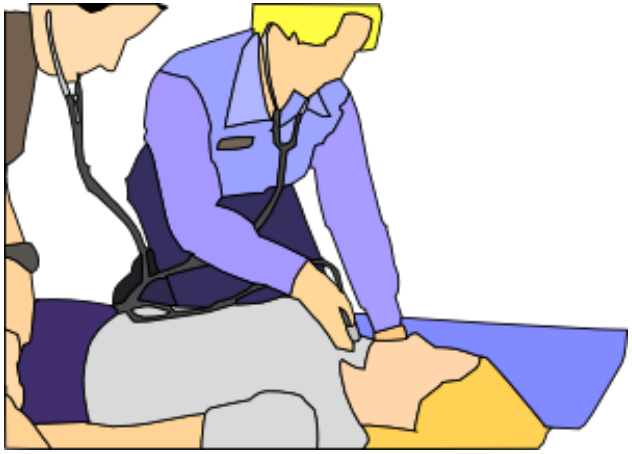
- **Incidence data** – the rate or frequency of adverse events occur with manual therapy over a period of time

- **Risk factors** - the occurrence of adverse events with any other variable or factors

- **Nature and type** of adverse events – onset and duration

Incidence data

Varies according to the reporter: The patient



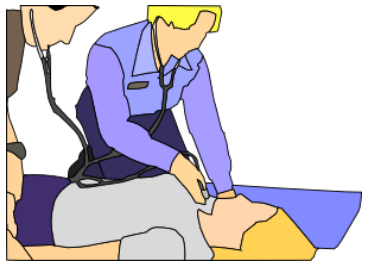
Incidence data

Varies according to the reporter: therapist administering the manual therapy

Incidence data

Varies according to the reporter: Clinicians treating patients after they have had manual therapy

Incidence data – Patient reports:



- Patient reports from prospective cohort studies (9)

- Minor and moderate adverse events reported after treatment ranged from 30% to 61%

- Mean ~ 46% of patients report minor to moderate adverse events after manual therapy

- Major adverse events were reported, range between 0 to 0.1%

Incidence data – Manual therapist reports:

- 4 studies retrospective questionnaire surveys

- Therapists reports of patients' experiencing adverse events ranged from 19 to 99 %

Incidence data – Clinician reports:

- 4 studies retrospective questionnaire surveys

• Neurologists reported that between12 and 29% of their patients sought treatment as a result of adverse events after manual therapy

Incidence data - RCTs:

- 36 articles reporting 30 studies

- 16 studies (N=1,543) did not report any adverse events occurring as a result of manual therapy

- No major adverse events, deaths or vascular insults occurred in any of the RCTs

Incidence data - RCTs:

- 14 RCTs (N=5,532) reported adverse events.

- Mild or moderate adverse events were recorded in:

  5.5% (155/2,797) of the manual therapy treatment participants and

  6.4% (175/2,735) with controls, sham and other interventions

Incidence data – Population data

- Deaths (3 studies) incidence:
  - 0-1:400,000 – 3,606,870,000 cervical spine manipulations over one year

- Cervical artery complications (12 studies)
  - 1: 100,000 – 601 million cervical spine treatments

- Major complications (excluding CADs) (9 studies)
  - 1: 8,500 – 1,562,000 cervical spine treatments
  - 1: 20,125 – 100,000,000 lumbar manipulations

Relative risk of adverse events

• We looked at the risk of adverse events occurring with manual therapy and with other interventions:

- Exercise
- Drug / medication
- GP care
- Passive / control interventions

What is a relative risk?

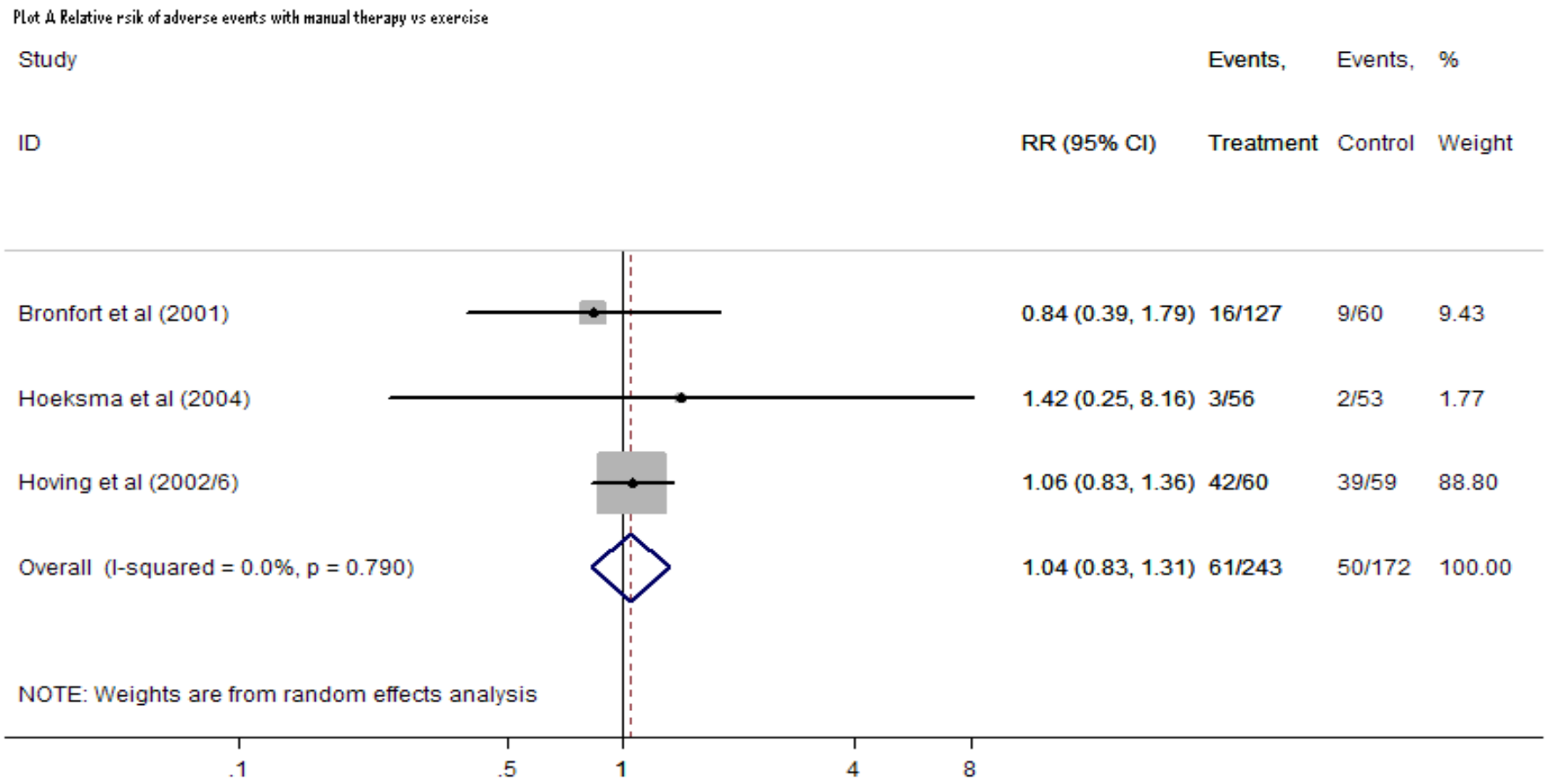
- Relative risk – indicates the risk of an event relative to exposure

- Relative risk calculated by dividing (A/B)/(C/D)

- Confidence interval set at 95%

	Number of adverse events occurring	Total in group
Manual therapy	A	B
Other therapy	C	D

Relative risk (RR) for adverse events with manual therapy vs exercise



More risk with exercise

More risk with manual therapy

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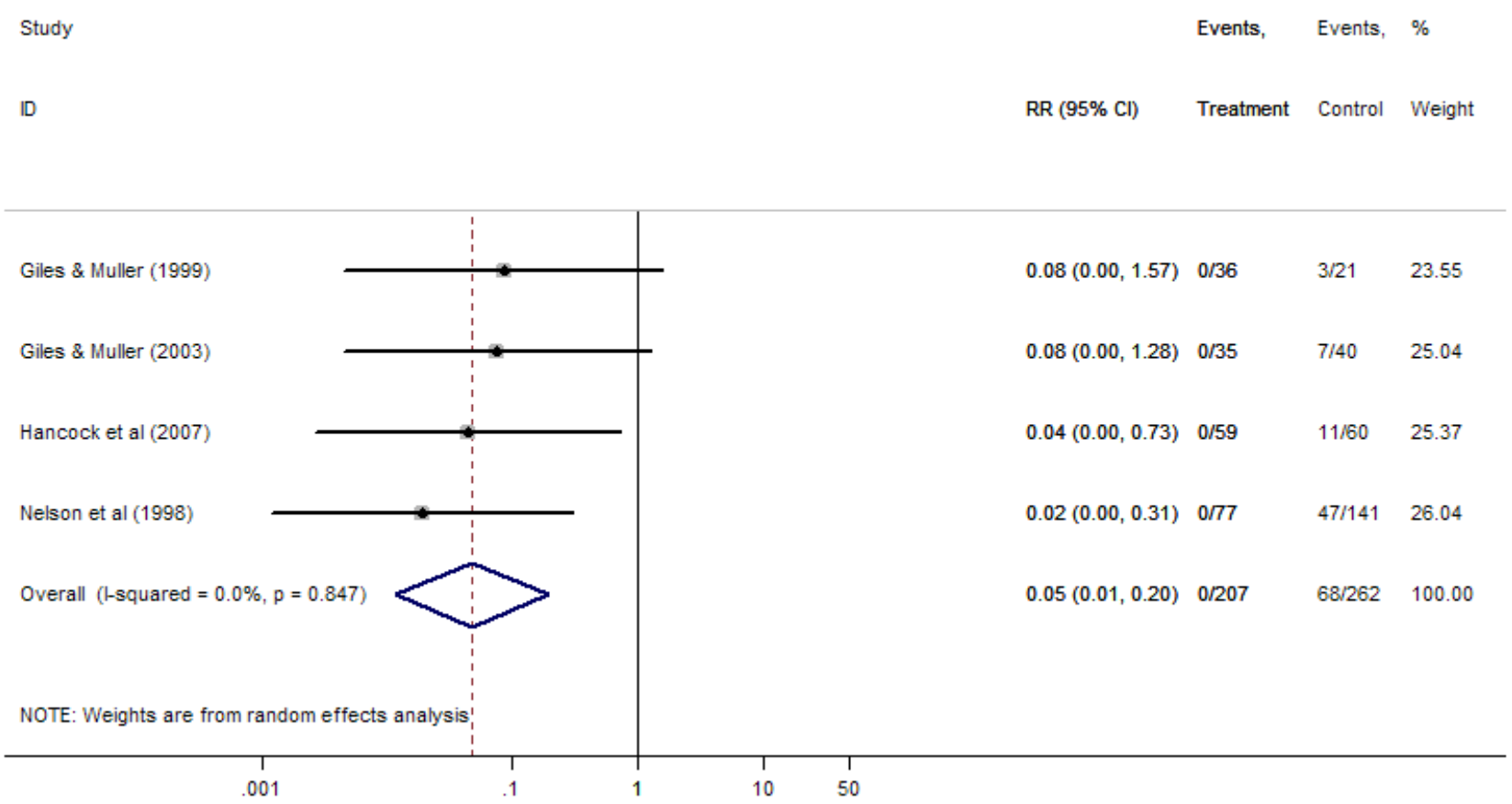
RR for adverse events with manual therapy vs medication, drug use



More risk with meds

More risk with manual therapy

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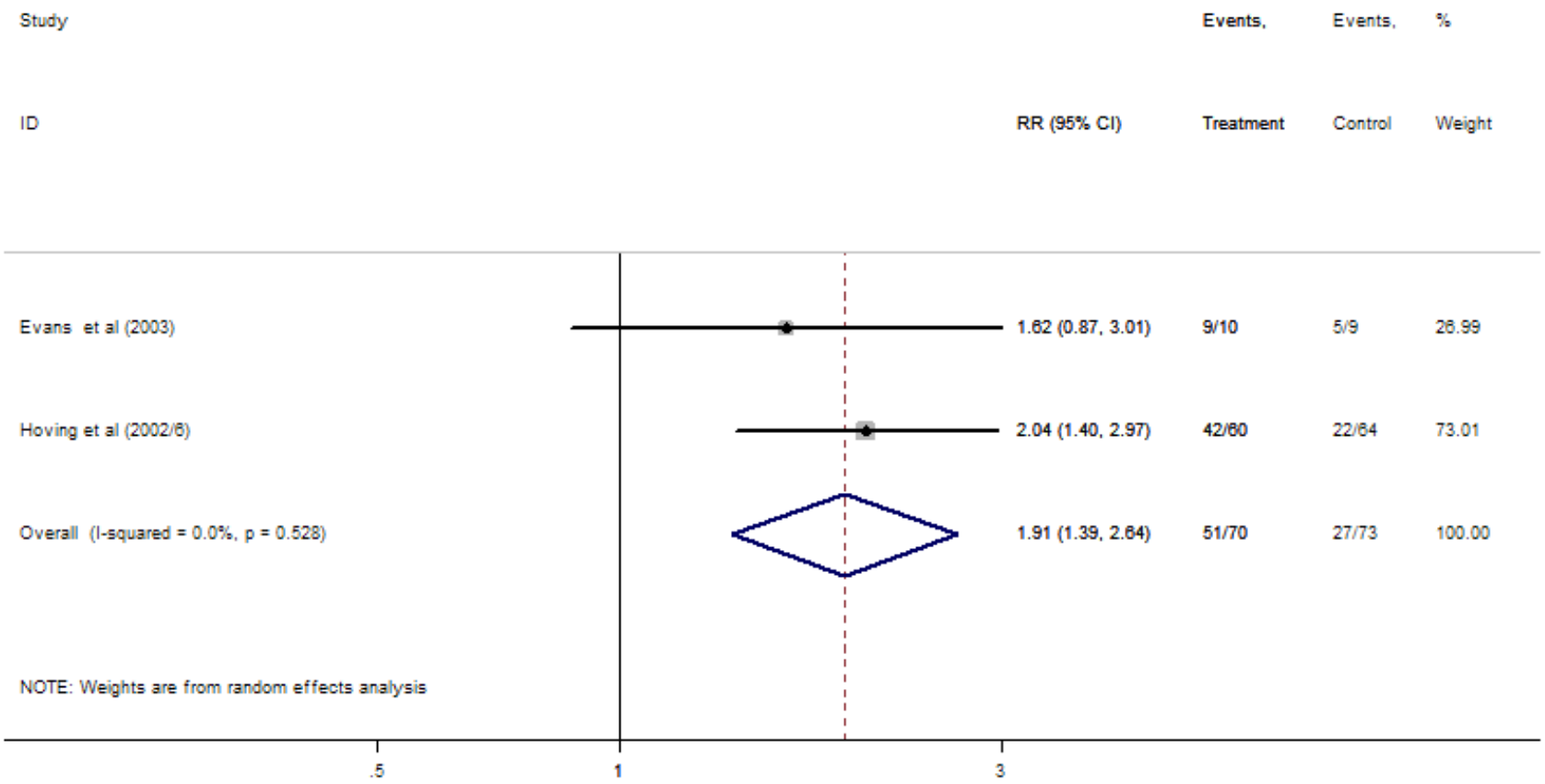
RR for adverse events with manual therapy vs GP care



More risk with GP care

More risk with manual therapy

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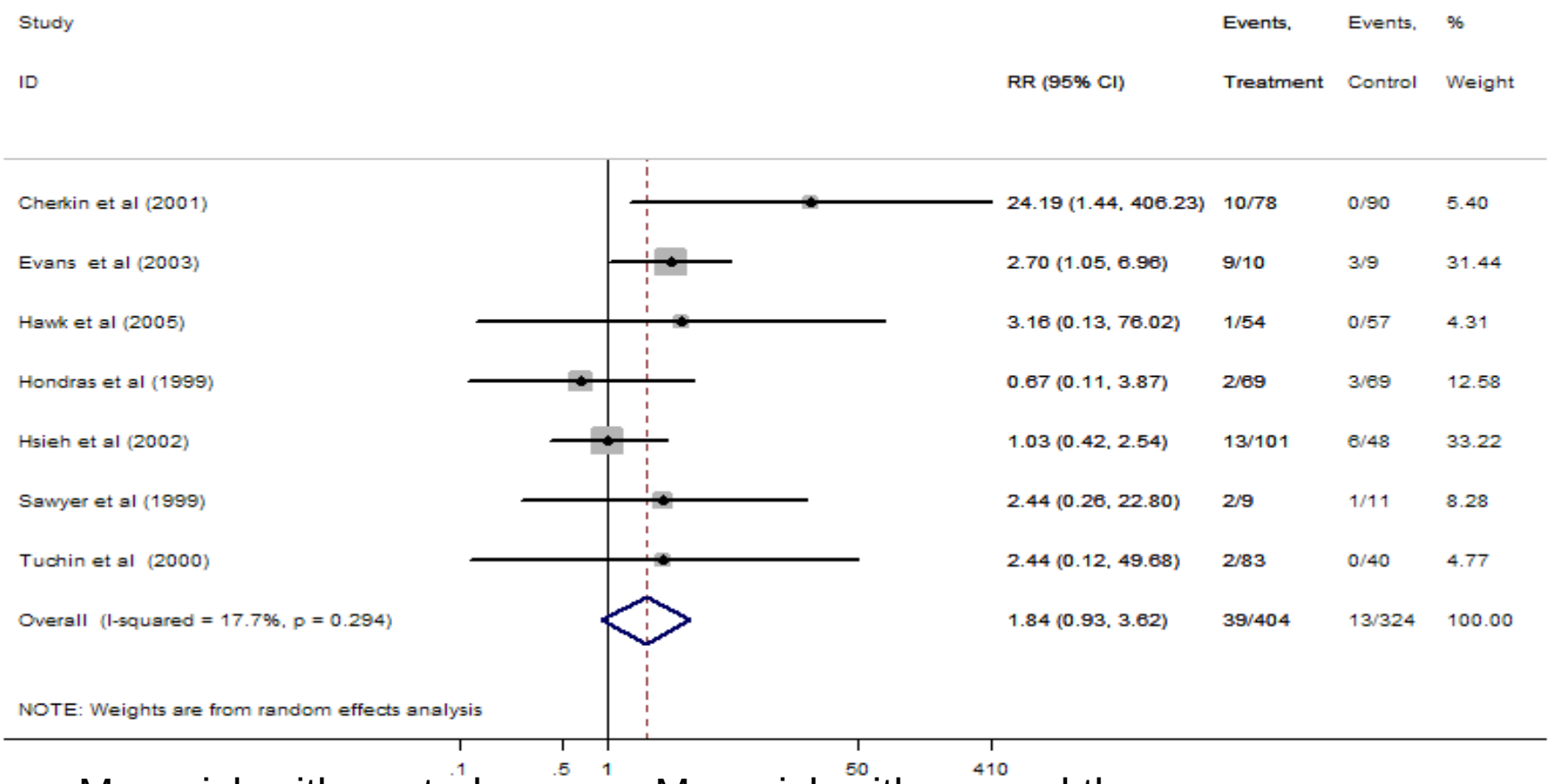
RR for adverse events with manual therapy vs passive / control interventions



More risk with control

More risk with manual therapy

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Risk factors associated with adverse events occurring with manual therapy

- Likely factors associated with manual therapy and vascular complications include:

  - upper cervical manipulation (2/2 studies)

  - neck pain/stiffness prior to treatment (4/5 studies)

  - seeing a manual therapist or primary care physician (3/4 ` studies)

  - being female (3/4 studies)

Risk factors associated with adverse events occurring with manual therapy

• Likely risk factors for reporting any adverse events post-manipulation include:

- first manual therapy treatment session (3/3 studies)

- being female (3/5 studies)

- regular medication use (1/1 study)

Risk factors associated with adverse events occurring with manual therapy

• Possible risk factors for both vascular and non-vascular adverse events:

- rotation cervical manipulation (3/4 studies)

- infection (1/1 study)

Nature and type of adverse events associated with manual therapy

- Most minor, moderate non vascular adverse events occur within 48 hours of treatment

  - (Mean 84%, Range 65% - 100%)

- Most resolve within 24 hours

  - (Mean 67%, Range 55% - 83%)

Nature and type of adverse events associated with manual therapy

- 15% to 27% of patients report that adverse events have a major effect on their daily living

- Non fatal vascular complications can produce substantial morbidity but death is extremely rare

What can we tell our patients?

1. About half of patients are likely to experience some minor to moderate short lived adverse event(s) after manual therapy treatment

2. Most minor and moderate adverse events resolve within 48 hours

3. Adverse events are most likely to be reported after the first treatment and by females

Summary of key findings

4. Risk of major adverse events such as stroke with manipulation are low, estimates suggest around:

1 per 100,000 to 1,000,000 manipulations or
1 per 50,000 to 100,000 patients.

(the risk of having a stroke in the general population is around 100 stokes per 100,000 or 1 per 1,000 people per year)

Summary of key findings

5. Upper neck and rotational manipulations and maneuvers of the neck appear to be the treatment most commonly associated with an increased risk of cervical artery injury

6. Warning signs potentially indicating higher risk of vascular injury and contra indicate manipulation are:

- sudden onset of unusual severe headache
- pain stiffness in the neck
- previous mechanical trauma
- history of cardiovascular insufficiency

Summary of key findings

7. The symptoms of vertebrobasilar dissections are neck pain and/or headaches that precipitate patients seeking care from either manual therapists or their GP

Conclusions

- The data was diverse, quality varied.

- Predominance of literature from chiropractors.

- Risk of major adverse events are very low but may increase with recent trauma, upper cervical and rotation manipulation.

Conclusions

• Risk of minor and moderate adverse events is high (around half of those having manual therapy), but the effects are mild and short lived.

• Risk compared to other medical treatments may be equivalent or better.

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Conflict of interest: Funding body (GOsC), TM, DC, RF are trained Osteopaths

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