Consent in osteopathic practice

Steven Vogel

LOS July 14
Aims

• Review expectations of 2012 Practice Standards
• Principles and definitions of consent
• Discuss current practice and results from CROaM study
• Share practice, identify obstacles and strategies for problem solving
• Share further resources
Consent in osteopathy: A cross sectional survey of patients’ information and process preferences

Glen Daniels a,*, Steven Vogel b

a Osteopathic Health Centre, Prestige House, 84 Queen’s Road, Essex, IG9 5BS, UK
b Research and Quality, The British School of Osteopathy, 275 Borough High Street, London SE1 1JE, UK

Received 16 June 2011; revised 3 April 2012; accepted 14 April 2012

KEYWORDS
Osteopathy; Manipulation; Osteopathic medicine; Patient preference; Consent; Informed consent; Survey

Abstract  Background: Consent is an ethical and legal requirement for any therapeutic process. It is the responsibility of healthcare practitioners to respect patients’ rights of autonomy and to receive their consent. The United Kingdom law currently states that all relevant risks, which a reasonable patient would want to know, must be told to them. Consequently the General Osteopathic Council’s (GOsC) “Code of Practice” includes specific expectations in this area. As a result risk disclosure and informed consent has become of increasing importance within osteopathy, particular in today’s increasingly litigious society. Osteopathy is a patient centred approach to healthcare; as such research to determine patients’ expectations and preferences is needed.

Objective: To explore and describe patients’ preferences of consent procedures in a sample of UK osteopathic patients.

Methods: A cross sectional survey using a new questionnaire was performed incorporating paper and web-based versions of the instruments. 500 copies were made available, (n = 200) to patients attending the British School of Osteopathy (BSO) clinic, and (n = 300) for patients attending 30 randomly sampled osteopaths in the South East of England.
The survey by Daniels and Vogel, even though it touches upon an important topic, avoids the truly pertinent questions. It therefore looks to me a bit like a fig leaf shamefully hiding an area of potential embarrassment.

http://edzardernst.com/2013/01/informed-consent-is-a-serious-threat-to-osteopaths-and-other-alternative-practitioners/
Practice Standards

• A: Communication and Partnership
• B: Knowledge, Skills and Performance
• C: Safety and Quality in Practice
• D: Professionalism
Osteopathic Practice Standards

• **Standard A3**
  Give patients the information they need in a way that they can understand

• **Guidance**
  – That patients may stop treatment / exam, realistically expect from you as an osteopath
  – Material or significant risks, including no treatment, alternatives to treatment
Osteopathic Practice Standards

• **Standard A4**
  You must receive valid consent before examination and treatment

• **Guidance**
  – Patients understand nature, purpose and risks of the examination or treatment proposed
  – Where diagnostic exam and treatment delivered simultaneously – explain your approach
  – Consent orally or in writing, or may imply consent (This will vary from patient to patient based on what is being proposed or performed)
Osteopathic Practice Standards

• **Standard C8**
  You must receive valid consent before examination and treatment

• **Guidance**
  – Records accurate, comprehensive, easily understood….
  Records of consent, consent forms

Also D8 Support colleagues and cooperate with them to enhance care…
  Observer or student present record consent
Underpinning principles

- Autonomy

- Beneficence

When can these principles clash?
Autonomy - beneficence

• Recent child case in UK brain cancer chemotherapy ok, radiotherapy no consent given to court….

• In osteopathy exercise interventions, manipulation….pelvic floor…

• “Patient may not think its plausible and not want the technique”

• “Get them to ask for the technique – orientate the conversation”
Definition

- Voluntary - sufficient information for an informed decision and include nature of condition, treatment options, risks, effects, benefits
- Risks, benefits and alternatives
- … one competent to act, receives information, understands and acts voluntarily
Patient osteopath partnership

- Benefits
- Risks
- Alternatives

Communication
Patient Needs
Preferences

- Receive Consent
- Examination
- Treatment
- Record Consent
Process

Prerequisites

- Information:
  - Risks Benefits Alternatives
  - Voluntariness
  - No-coercion
  - Competence
  - Understanding

Decision making

- Discussion
- Opportunity to ask questions
- Compare and contrast information
- Retention of information

Consent or reject intervention
Special situations

• Presumed capacity > 18 YOA
• Lacks capacity impairment eg learning disability, or problem at the time that makes pt unable to make decision – anxiety or shock
• Understand, retain, weigh up, communicate decision
• Children
• Sensitive areas
BSO team

Steven Vogel  Principal Investigator
Tom Mars  Research Fellow
Sam Keeping  Research Administrator
Tamsin Barton  Researcher assistant

Professor Martin Underwood  Warwick Medical School
Professor Sandra Eldridge  Barts and The London School of Medicine and Dentistry
Professor Tamar Pincus  Royal Holloway, University of London
Ms Nadine Köhler  Barts and The London School of Medicine and Dentistry
Dr Rob Froud  Barts and The London School of Medicine and Dentistry
Overview of design

- Practitioner survey
  - Risk assessment, management and experience of serious adverse events

- Patient survey
  - Experience of treatment and outcomes
    - treatment reactions
    - 6 week follow-up outcomes

- Interview study
  - Practitioners and Patients
  - Interpret and explore treatment reactions

THE BRITISH SCHOOL OF OSTEOPATHY
Cross sectional survey: All UK osteopaths

• Postal follow up non responders

Prospective cohort study: New and ongoing patients

• Pre-treatment
• Day one after treatment
• Day two after treatment
• 6 week (postal follow up to non responders)

Nested qualitative interview studies patients and osteopaths
Information giving and consent

Difficulty in talking about unpleasant treatment reactions when preparing new patients for cervical HVT

Difficulty in talking about unpleasant treatment reactions when preparing returning patients for cervical HVT
Informing patients – Benefits, Risks, Outcomes/No treatment

- Benefits of the recommended treatment
- Risks of the recommended treatment
- Outcomes of no or alternative treatments

Never
Always
<table>
<thead>
<tr>
<th>Did the osteopath talk about:</th>
<th>Yes</th>
<th>%</th>
<th>No</th>
<th>%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td></td>
<td>n</td>
<td></td>
<td></td>
</tr>
<tr>
<td>New pat</td>
<td>195</td>
<td>86.3</td>
<td>31</td>
<td>13.7</td>
<td>226</td>
</tr>
<tr>
<td>Reasons for examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New pat</td>
<td>190</td>
<td>84.1</td>
<td>36</td>
<td>15.9</td>
<td>226</td>
</tr>
<tr>
<td>Rtn pat/new symp</td>
<td>174</td>
<td>68.5</td>
<td>80</td>
<td>31.5</td>
<td>254</td>
</tr>
<tr>
<td>Rtn pat/ongoing</td>
<td>781</td>
<td>59.7</td>
<td>527</td>
<td>40.3</td>
<td>1,308</td>
</tr>
<tr>
<td>Likely benefits of treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New pat</td>
<td>107</td>
<td>50.0</td>
<td>107</td>
<td>50.0</td>
<td>214</td>
</tr>
<tr>
<td>Rtn pat/new symp</td>
<td>81</td>
<td>34.9</td>
<td>151</td>
<td>65.1</td>
<td>232</td>
</tr>
<tr>
<td>Rtn pat/ongoing</td>
<td>414</td>
<td>33.6</td>
<td>817</td>
<td>66.4</td>
<td>1,231</td>
</tr>
<tr>
<td>Likely risks of treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New pat</td>
<td>103</td>
<td>48.4</td>
<td>110</td>
<td>51.6</td>
<td>213</td>
</tr>
<tr>
<td>Rtn pat/new symp</td>
<td>98</td>
<td>41.5</td>
<td>138</td>
<td>58.5</td>
<td>236</td>
</tr>
<tr>
<td>Rtn pat/ongoing</td>
<td>443</td>
<td>35.7</td>
<td>798</td>
<td>64.3</td>
<td>1,241</td>
</tr>
</tbody>
</table>

New patients recall more discussion
Risks and alternatives lowest levels of recall – 50% at best
Summary

• Discussing unpleasant reactions C spine most difficult

• Osteopaths report high frequencies of receiving consent – new patients > returning

• Variable methods used, more formal HVT, small proportion do not discuss consent

• Patients report lower levels than osteopaths but again new patients > returning patients

• Risks and alternatives least recalled by patients
• Examples
  – Mechanical low back pain
  – When
  – Information
• Familiar patient in a hurry
• Anxious patient
• Neck pain…
What are the challenges?

• Consider obstacles to consent process with respect to treating the neck
• Note two or three of these down
What osteos said: Uncertainty, understanding

- It's still uncertain as to what the risk is… don’t relate to osteo”
- They didn’t actually realise was that at that time, what I was doing was getting consent…”
- I find it difficult to actually give them all the details and I probably to be honest I withhold some of the information about what might happen…
- …I legally have to verbalise that to you
What osteos said: Communication and partnership

• .. logically consent is important … apart from the legal side, its important in terms of patient cooperation and trust

• … every patient that comes to my clinic signs a form to the effect that they’re consenting to treatment, and the mere fact that they have presented and come in voluntarily is an implied assent, sorry, consent
What osteos said: -ve perceptions

• … if people are so frightened of giving treatments and you make the patient so frightened of having perfectly valid treatment, then you know we lose so much..

• … always wonder how much of the reaction is led by suggestion

• An unworkable position to have to explain every procedure and any possible reaction or response
Opportunities

- Partnership, rapport, empathy
- Shared decision making
- Information that patients need, relevant to them, in a format they can understand
- Practitioner – shared – patient: which model suits the patient and practitioner? .... What suits you as a practitioner?
What patients said

• .. No he’s never said anything about risk of treatment, no, no
• I can’t remember probably at the beginning of treatment

• He does tell me you might be stiff for a couple of days
• He wouldn’t hurt me
• I have faith that he only do the right thing
• … assume that if I’ve taken my top off and I’ve laid on the bed, I’ve given permission.
What patients that complain say

‘The treatment to my back all happened very quickly. During this, I do not remember [osteopath] explaining what she was doing in any great detail or offering any explanations as to why she was carrying out this treatment.’

[Osteopath] did not explain what he was doing on this occasion. He has explained it to me in the past and so I think he knows that I know what he is doing.’

‘[Osteopath] said that there was a bit of stiffness in my neck. She said she would try to correct this and that I would hear another ‘pop’. Again, [osteopath] did not explain the details of what she was doing or why she was doing it. She moved my head from the left to the right a couple of times, while her hands were still covering my ears, and I heard the ‘pop’.’
• [Osteopath] didn’t explain what he was doing and why, but because I have known him for so long I just left it to him and was happy chatting to him generally.’

• ‘[Osteopath] did not examine me any more than that and did not explain to me what he was about to do. [He] then yanked my foot in a violent way, I think he did this two or three times.’
Summary

• Concerns about type and impact of information to be given
• Difficulties being understood
• Range of patient views, faith, attendance and memory
• Positive empathy and relationship building – mediates interpretation of events, forewarned is forearmed
HEAD TO HEAD

Should we abandon cervical spine manipulation for mechanical neck pain? Yes

Benedict Wand and colleagues argue that the risks of cervical spine manipulation are not justified, but David Cassidy and colleagues (doi:10.1136/bmj.e3680) think it is a valuable addition to patient care

Benedict M Wand associate professor¹, Peter J Heine research fellow², Neil E O’Connell lecturer³

¹School of Physiotherapy, University of Notre Dame Australia, 19 Mouat Street, Fremantle, WA 6959, Australia; ²Warwick Clinical Trials Unit, Division of Health Sciences, University of Warwick, Coventry, UK; ³Centre for Research in Rehabilitation, Brunel University, Uxbridge, UK

Cervical spine manipulation (a high velocity, low amplitude, end range thrust manoeuvre) is a common treatment option for mechanical neck pain, yet research on cervical spine manipulation is often conflicting. Some studies have shown that it is efficacious, whereas others have shown it to be ineffective or even harmful. A Cochrane review noted that the increased risk after chiropractic treatment may be an artefact of patients seeking care for neck pain resulting from existing cervical pathologies, and not from the treatment itself.
Manipulation and C’sp (1)

- But most recent evidence GP risk equivalent to Chiro risk (Cassidy et al 2008)
- Prodromal or dissection in situ cause of presentation accounts for risk
Manipulation and C’sp (2)

- Recent systematic review (Haynes et al 2012)
- Considerable imprecision for all studies
- Conclusive evidence absent for strong association and also lacking for no association
- Uncertainty – “advise patients of a possible increase in risk of rare form of stroke… also applies to other neck movements”
- Back to patient preference
Manipulation and C’sp (3)

• Clear that need for vigilance for vascular causes of neck and head pain
• Individual patients need high levels of clinical reasoning and professional judgement with patient
• Not easy to have clear and simple do it like this rules....
International Framework for Examination of the Cervical Region for potential of Cervical Arterial Dysfunction prior to Orthopaedic Manual Therapy Intervention

Authors: Rushton A, Carlesso L, Flynn T, Hing W, Rivett D, Kerry R.
Clinical reasoning and making decisions

- Complex clinical scenario
- No easy rules
- Involves uncertainty and making the best clinical judgement
- Sharing information with patient and involving them in your decision making
- Like the rest of osteopathy
- All part of being a health care professional
International Framework for Examination of the Cervical Region for potential of Cervical Arterial Dysfunction prior to Orthopaedic Manual Therapy Intervention

Authors: Rushton A, Carlesso L, Flynn T, Hing W, Rivett D, Kerry R.

http://www.ifompt.com/ReportsDocuments.html
Recording consent

• Written and verbal consent equivalent
• Contemporaneous notes key
  – Record of care
  – Hand over care to others
  – Ability to reflect on practice
  – Defence if complaint
  – Note risks explained to patient, consent received or declined
  – Remember these notes might be needed years later – who will remember more accurately pt or prct?
Challenge for practitioners

• To provide sufficient information for patients to make an informed choice of action (autonomy)

• To balance with desire to achieve good outcomes (beneficence)

• Osteopaths need knowledge of risk, illness, disease, contra-indications, effectiveness of interventions, assessment of patient progress, etc: High level clinical skills and reasoning

• Individual calculations with individuals includes uncertainty – characteristic of professional action
Prior to attending

New Patient: Consultation

Follow up

Leaflet, e-info: nature of treatment and exam

- Process: wide range of health question, examination – ask questions at any stage
- Specifics of exam – may involve pain/discomfort – pt may stop
- Verbal consent
- Information: diagnosis, treatment options (include alternatives), perceived benefits – ask if models helpful? – check understanding, assess baseline knowledge
- Information: common minor adverse events and rare major – communicate risk, check understanding – offer choices and opportunity to ask questions – pt may stop
- Verbal consent before treatment: note risks, benefits and alternatives discussed and receipt of consent
- Conclusion: further questions, further info future treatment – tie in to treatment plan.

- Continue offering choices and verbalising actions
- Re-iterate opportunity for questions – pt may stop
- Revisit pt preferences for repeat of information as above, or
- Preference of new information if new examinations/treatments
Further resources

• IJOM papers – consent and CAD (Taylor and Kerry 2010)
• GOsC and GMC … regulator papers and guides – AOA Board guidance
• Adverse events projects and other GOsC funded work on NCOR website
• Adverse events and risk information and repository – NCOR website in development
Masterclass

A ‘system based’ approach to risk assessment of the cervical spine prior to manual therapy

Alan J. Taylor*, Roger Kerry

Division of Physiotherapy Education, University of Nottingham, Hucknall Road, Nottingham, NG5 1PB, UK

A R T I C L E   I N F O

Article history:
Received 8 April 2010
Accepted 26 May 2010

Keywords:
Manual therapy
Manipulations
Neck
Cervical spine
Physical therapy
Osteopathy
Chiropractic
Atherosclerosis

A B S T R A C T

This paper presents a clinical overview and update of cervical arterial dysfunction (CAD) for osteopaths and other clinicians who treat patients presenting with cervical pain and headache syndromes. An overview of a ‘system based’ approach to the concept of vertebrobasilar arterial insufficiency (VBI) is covered, with reference to assessment procedures recommended by commonly used guidelines. We suggest that the evidence supporting contemporary practice remains limited and present a more holistic approach to considering cervical arterial dysfunction. This ‘system based’ approach considers typical pain patterns and clinical progressions of both vertebrobasilar, and internal carotid arterial pathologies. Attention to the risk factors, pathomechanics and haemodynamics of arterial dysfunction is also given. We suggest that consideration of the information provided in this updated ‘Masterclass’ will enhance clinical reasoning with regard to differential diagnosis of cervical pain syndromes and prediction of serious adverse reactions to treatment.

© 2010 Elsevier Ltd. All rights reserved.
International Framework for Examination of the Cervical Region for potential of Cervical Arterial Dysfunction prior to Orthopaedic Manual Therapy Intervention

Authors: Rushton A, Carlesso L, Flynn T, Hing W, Rivett D, Kerry R.

http://www.ifompt.com/ReportsDocuments.html
What are the challenges?

• Consider obstacles to consent process with respect to treating the neck
• Note two or three of these down
• Note some actions you can take next week to address some of these obstacles practically
Thank you for your attention
Questions?

Acknowledgements: Research team and colleagues at the BSO
Majority funding GOsC, BSO contribution
Roger Kerry, Associate Professor, Nottingham University – Slides on CAD