What puts the adverse in ‘adverse events’? Patients’ perceptions of post-treatment experiences in osteopathy — A qualitative study using focus groups

Dévan Rajendran a,*, Philip Bright a, Steven Bettles a, Dawn Carnes b, Brenda Mullinger a

a European School of Osteopathy, Research Department, Boxley House, The Street, Boxley, Maidstone, Kent ME14 3DZ, United Kingdom
b Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, 2 Newark Street, London E1 2AT, United Kingdom

1. Introduction

1.1. Background and context

Adverse events are of increasing relevance to manual therapists in today’s climate of evidence-informed practice and critical review (Ernst, 2008; Bronfort et al., 2010). Minor (mild) to moderate adverse events following manual therapy are common, affecting up to half of patients (Cagnie et al., 2004; Rubinstein et al., 2008; Carnes et al., 2010a). Investigations have often adopted a strong practitioner-centric focus in data collection methods and interpretation (Senstad et al., 1997; Thiel et al., 2007) driven, maybe, by the needs of practitioners to comply with professional codes of conduct and provide information on risk, before obtaining valid and informed consent to treat (Langworthy and Cambron, 2007). This is reflected in current literature on classification and standardisation of terminology which revolve around a clinical interpretation of possible adverse events (Rubinstein et al., 2008; Carnes et al., 2010a,b; Carlesso et al., 2010).

Evaluation of responses to manual therapy, however, can be seen from several other viewpoints, most notably those of the practitioner. In our previous feasibility study osteopathic patients self-reported ‘additional effects of treatment’ using a pre-prepared tick-list of possible ‘adverse effects’. The majority (93%) reported at least one ‘post-treatment effect’ over five time points in the week following treatment. Local pain or stiffness were the most commonly reported items (Rajendran et al., 2009). Whereas practitioners might construe these as treatment-related adverse events, the acceptability, attribution and interpretation of such experiences from the patient’s perspective needs exploring.

Across healthcare there is an awareness that the patient’s viewpoint is important for effective practitioner–patient communication; ‘understanding the patient’s perspective’ and ‘sharing information’ are acknowledged elements within the medical encounter (Makoul, 2001; Mauksch et al., 2008) and can be beneficial to health outcomes (Travaline et al., 2005). Within the field of manual therapy, studies have revealed that information and quality of care, reduction in symptoms, and an understanding of their problem underlie patients’ expectations and satisfaction (Pincus et al., 2000; Hills and Kitchen, 2007; Strutt et al., 2008). However, little is known about issues that are important to patients in relation to how they feel after musculoskeletal treatment. Such insights into patient perspectives may enable clinicians to provide patient-centred information and care, and, in the context of a teaching clinic, provide valuable material for teaching and training future practitioners.
The aim of the current study was to investigate how osteopathic patients view post-treatment experiences and what meaning they ascribe to them.

2. Methodology

2.1. Study design

We conducted a focus group investigation to explore the thoughts, feelings, opinions and beliefs of a range of patients concerning post-treatment experiences following osteopathy. The data collected were analysed using qualitative methods. Focus group discussions are recognised as an effective and well-established methodology for exploring and clarifying the views of patients (Kitzinger, 1995).

Three focus groups (FGs) were planned; the topic guide was tested in the first FG to check that it was generating the scope, clarity and depth sought (Arthur and Nazroo, 2003). We collected socio-demographic data on focus group participants to describe our cohort. Approval was obtained from the Research Ethics Committee at the European School of Osteopathy (ESO).

2.2. Participants and recruitment

Participants for the first FG (FG1) were volunteers from the staff and student body at the ESO. Selection criteria were: experience of more than one osteopathic treatment in the last six months. All participants were recruited via email and/or posters.

For the remaining two FGs (FG2 and FG3), convenience sampling was used to identify suitable volunteers among adult patients (> 18 years) who had recently received osteopathic treatment at the teaching clinic of the ESO. There was no attempt to ascertain whether the volunteers had any experience of possible ‘adverse events’. The genders, ages, employment status and experience of osteopathy (first visit to an osteopath > 6 or < 6 months previously) were monitored, as were reasons for non-participation. Inclusion criteria were: fluent in English; not undergoing manual therapy elsewhere; not pursuing any on-going personal injury litigation. All interested patients were provided with a patient information leaflet. Socio-demographic data were collected. To optimise attendance, a £10 store voucher was offered to each participant.

On arrival at the FG, participants were reminded of the study purpose and assured of confidentiality; they provided written consent. All FG discussions took place at ESO premises and were scheduled to last no longer than 90 min. All FGs were audio recorded and transcribed verbatim with identifying terminology anonymised.

2.3. Topic guide and data collection

The topic guide was based on literature review, and experience and findings from our previous pilot survey study (Rajendran et al., 2009). The topic guide was slightly revised after FG1 to promote more discussion about changes in functionality and impact on daily living, and to explore interpretation of the term ‘adverse events’ (see Table 1).

The FGs were moderated by a member of the research team. A second researcher was present to observe and take field notes. The researchers involved in collecting and analysing data all had a background in osteopathy, either as clinicians or academics.

2.4. Analysis and rigour

A framework approach was used to analyse and manage the data (Ritchie and Lewis, 2003). We identified themes and sub-themes. We adopted an interpretive approach to devise conceptual models from the data.

The study team familiarised themselves with the FG transcripts. Two researchers (BM and DC) independently identified emergent sub-themes and themes from the transcripts for the pilot framework; this was tested using the FG2 transcript. It was coded by PB and approximately 20% was independently coded by DR, to assess reliability and validity of the framework. The framework was then modified to reflect the data and promote greater consistency (Table 2). All transcripts were then coded independently, as before, by PB and DR (20% sample). A cycle of coding, meeting, discussing was repeated until agreement was reached and a rationale agreed for future coding, in order to ensure reliability. A third researcher (BM) was available to resolve any discrepancies. An audit trail of the study processes and decisions was recorded.

2.4. Analysis and rigour

A framework approach was used to analyse and manage the data (Ritchie and Lewis, 2003). We identified themes and sub-themes. We adopted an interpretive approach to devise conceptual models from the data.

The study team familiarised themselves with the FG transcripts. Two researchers (BM and DC) independently identified emergent sub-themes and themes from the transcripts for the pilot framework; this was tested using the FG2 transcript. It was coded by PB and approximately 20% was independently coded by DR, to assess reliability and validity of the framework. The framework was then modified to reflect the data and promote greater consistency (Table 2). All transcripts were then coded independently, as before, by PB and DR (20% sample). A cycle of coding, meeting, discussing was repeated until agreement was reached and a rationale agreed for future coding, in order to ensure reliability. A third researcher (BM) was available to resolve any discrepancies. An audit trail of the study processes and decisions was recorded.

Table 1

| 1. Patient’s experiences after osteopathic treatment (prompts: description and nature; timing; effects other than feeling better/improved; narratives of other people) |
| 2. Impact on daily living (prompts: adjustments to normal activities; work/daily living/sport/social life; frame of mind) |
| 3. Acceptability/unacceptability of experiences (prompts: viewed as positive/negative; troublesome; expected or unexpected) |
| 4. Exploring what might be considered a ‘side effect’ or ‘adverse event’ (prompts: how to decide; prompting a complaint) |
| 5. Asking about experiences (prompts: most important effects experienced if surveyed) |

Table 2

| 1. Patient–practitioner encounter |
| 1. Communication |
| 2. Information/advice |
| 3. Trust/relationship |
| 4. Practitioner competence |
| 5. Dissatisfaction/inappropriate care |
| 6. Physical examination/treatment procedures |

| 2. Environment |
| 1. Service provision (i.e. clinic administration)/support/complaints |
| 2. Teaching clinic/continuity of care |
| 3. Service provision (facilities/physical surroundings) |

| 3. Treatment after-effects |
| 1. Personal responsibility/beliefs/behaviours (about effects after treatment) (including pragmatic responses to treatment e.g. hot/cold; adaptive behaviours; coping behaviours) |
| 2. Loss of function (physical)/daily living tasks |
| 3. Coping/tolerance (attitudes e.g. rationalising a negative response) |
| 4. Lack of adverse effects (no response to treatment; ‘no pain no gain’; value for money) |
| 5. Lack of response to treatment |
| 6. Reversal/worsening |
| 7. Pain |

| 4. Expectations of the osteopathic encounter (i.e. things that might colour individual’s experiences post-treatment) |
| 1. Personal past experience of osteopathy (+ve, –ve, modifications based on +ve or –ve experience) |
| 2. Expected outcome of condition (e.g. ‘slipped disc’; ankylosing spondylitis) |
| 3. Expectation of treatment (symptom relief/adverse events) |
| 4. Narrative of others |
| 5. Knowledge and beliefs (theoretical knowledge of physiology/anatomy/pain) |
| 6. Loyalty/expectation of result (suggestion: satisfaction; protection of osteopath | 'Stockholm syndrome') |
| 7. Hypothetical situations regarded as adverse |
3. Results

3.1. Participant characteristics

There were 19 participants (6, 7 and 6 respectively in FGs 1, 2 and 3) aged 19–66 years (mean 45 years), of whom 11 (58%) were females; their characteristics are shown in Table 3. There were three students, two retirees and one person on maternity leave; all others worked, several only part-time. All focus group participants were receiving osteopathic treatment or had done so in the past 6 months; 11 (58%) participants had received six or more treatments in that period. Recruitment of patients with limited exposure to osteopathy proved difficult, with only four participants having first consulted an osteopath within the previous 6 months. Those who declined to participate did so because of lack of time, lack of interest or prior commitments, including work and child-minding (all FGs commenced at 6 pm). The FGs (FG1, 2 and 3) were conducted during a 5 month period (commencing June 2010) and discussions lasted for 47, 75 and 80 min, respectively.

3.2. Emergent themes

We identified four emergent themes encompassing 23 sub-themes from the data. Agreement between the researchers undertaking the coding averaged 65%; no arbitration was deemed necessary. Illustrative quotes are given in Table 4 (identified below in alphabetical order within each numbered theme); these are descriptive ‘first-order’ observations.

3.2.1. Theme I: patient—practitioner encounter

The importance of good communication, trust and respect during the patient—practitioner encounter was very apparent from the FG discussions (Ia, Ib). Some patients felt vulnerable during the practitioner encounter (Ic). Lack of information and consistent understanding were appreciated by participants (I, Ig). Acceptability of specific treatment techniques was very individual and even disliked treatments were often regarded as ‘doing good’ (Ih, II). Differing opinions were voiced about information on potential ‘side effects’ (Ij). In general, patients wanted effective use of their time (and value for money), and the ‘right’ treatment for them (Ik).

3.2.2. Theme II: environment

The clinical environment emerged as a component of the treatment experience that had an impact on the perceived quality of care. Patients wanted a professional service with ready access to appointments, to be seen promptly, be handled efficiently and be able to change practitioner (IIa, IIb, IIc). Different views were expressed, according to personal experiences, regarding the acceptability of teaching-clinic specific characteristics, such as interaction with tutors, and being observed by third parties (IId, IIf). Some participants believed that practitioner competence would develop with time and that students provided “up to date treatment” (IIe). They wanted the see ‘their student’ develop and do well (IIg) although continuity of care when students graduate was raised as an issue (IIh, IIi).

3.2.3. Theme III: treatment after-effects

Participants described one or more of a variety of experiences, during and/or following osteopathic treatment that included pain and stiffness, change in mobility or usual functioning, unexpected or strong emotional responses, and unusual tiredness or feeling relaxed (IIa, IIb, IIc). Changes in underlying symptoms were also mentioned including worsening, no improvement, improvement or resolution (IIId, IIf, IIIf). Interpretation of these experiences in terms of causality and acceptability were influenced by:

- personal beliefs and attitudes (IIg)
- taking personal responsibility with coping strategies and self-management habits (IIIl, IIIi)
- expectations of intensity and/or duration of experiences relative to the underlying condition being treated (see Theme IV).

Some participants expressed a ‘no pain, no gain’ sentiment suggesting that lack of post-treatment discomfort was an indication of sub-optimal treatment and therefore poor value for money (IIj, IIk). Participants with a long-term problem expressed a pragmatic approach, being accepting of a level of on-going discomfort in their lives, and believing in routine osteopathic maintenance treatment as part of their coping behaviour (IIIi).

3.2.4. Theme IV: expectations of the osteopathic encounter

Expectations were associated with each of the previous themes:

- the patient’s encounter with the osteopath (IVa)
- the treatment environment (IVb)
- post-treatment effects (IVc, IVd)

For many participants, expectations based on personal past experiences had a strong influence on their perceptions of treatment effects and after-effects, as they were long-term users of osteopathy. These participants had apparently got used to the way their body responded to treatment and, because they largely expected their post-treatment sequelae, they did not judge them as negative and often regarded them as acceptable (IVe). For them, the narrative of others appeared not to influence their use of osteopathy (IVf). In general, therefore, expectations (and perceptions) were positive, based on a belief that osteopathy was helping...
participants manage a condition that could not be ‘cured’ thus maintaining their independence and quality of life (including work, parenting, social life) (I[v], I[vh]).

Those few participants who were not long-term users of osteopathy had little experience to draw on. Instead, they emphasised the value of being adequately informed on what to expect prior to treatment (such as the need to undress), on possible post-treatment effects (e.g., pain, stiffness, tiredness), and the recommended duration of treatment and likely outcome. For them, lack of such information was likely to influence their expectations and perceptions of treatment and its effects.

Towards the end of each FG, participants had been asked what they would regard as adverse and many found it a difficult concept to articulate. When probed for ‘side effects’ or what might be unacceptable, mainly hypothetical situations were voiced. Pain as a result of treatment was considered a cause for concern (I[v]). The most important negative (adverse) outcome of treatment, hypothetically, was regarded as loss of function, particularly if it had an impact on work or daily activities (I[vk], I[vl]). In addition, treatment-related effects that were unexpected, in nature or intensity, were more likely to be considered unacceptable (I[vm], I[vn]).
Other more unorthodox views of ‘adverse’ experiences were:

- lack of information (IVo)
- lack of respect (IVp)
- poor service provision or value for money (IVq)
- poorly managed expectations (e.g. a mismatch in perceived benefit versus treatment sequelae) (IVr).

3.2.5. Conceptual model: interpretation of patients’ perceptions of post-treatment experiences

It appeared that no one factor dominated patients’ perceptions of what they considered adverse; rather they were influenced by multiple elements from all four themes. To understand what makes a patient perceive of their post-treatment experiences in either a positive or negative light, we therefore conducted a ‘second order’, or level two, analysis and interpretation of our synthesised data. By re-assigning and condensing the previous 23 sub-themes into 19, we developed four main components on which patients base their perceptions, as outlined below and detailed in Table 5. ‘Expectations’ of the treatment and its outcome(s), which may become modified over time.

‘Personal investment’ which recognises that each patient wants to take some personal responsibility for their condition; they seek ‘value for money’; and they develop practitioner loyalty with the investment of time.

‘Osteopathic encounter’, covers all aspects of the patient-practitioner relationship, the treatment environment and experience of care.

‘Clinical change’ embraces all post-treatment symptomatology that patients might experience, whether perceived as related to their underlying condition or to treatment after-effects.

We propose that these four components (designated EPOC) are inter-related (as shown in Fig. 1) under an overarching construct, the patient’s ‘global osteopathic experience’. They explain what influences osteopathic patients’ perceptions of post-treatment experiences. Whether those perceptions are positive, negative or neutral/ambivalent can be modified by EPOC, and can fluctuate.

Table 5

<table>
<thead>
<tr>
<th></th>
<th>E</th>
<th>P</th>
<th>O</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Expectations</td>
<td>Personal investment</td>
<td>Osteopathic encounter</td>
<td>Clinical change</td>
</tr>
<tr>
<td></td>
<td>(from all theme 4 sub-themesa except 4F and 4G)</td>
<td>(from sub-themesa 3A, 3C, 1E and 4F)</td>
<td>(from themes 1 and 2 sub-themesa)</td>
<td>(from theme 3, sub-themesa B, D, E, F, G and sub-theme 4G)</td>
</tr>
<tr>
<td>Acknowledges that patients’ initial expectations may become modified over time, through:</td>
<td>Shows patients seek empowerment by:</td>
<td>Covers:</td>
<td>Pain is often key; but some patients may have:</td>
<td></td>
</tr>
<tr>
<td>- personal past experiences,</td>
<td>- being pro-active about when, how and how often they are treated,</td>
<td>- communication,</td>
<td>- no change or worsening of symptoms</td>
<td></td>
</tr>
<tr>
<td>- changing knowledge and beliefs,</td>
<td>- adopting ‘coping’ strategies (exercises, hot and cold treatment).</td>
<td>- practitioner competence,</td>
<td>- symptom relief without any adverse outcomes.</td>
<td></td>
</tr>
<tr>
<td>- expected impact of any underlying condition,</td>
<td>Reflects patients:</td>
<td>- trust/respect,</td>
<td>Hypothetical situations regarded as adverse.</td>
<td></td>
</tr>
<tr>
<td>- information and advice,</td>
<td>- dissatisfied if do not get perceived ‘value for money’,</td>
<td>- examination and treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- narrative of others.</td>
<td>- want to feel that their time is well spent,</td>
<td>Includes the treatment environment and customer care.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- may express strong loyalty to certain practitioners.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

a See Table 2.

Fig. 1. Conceptual model of influences on an osteopathic patient’s perceptions of their post-treatment experiences. Key: hatched area suggests any alignment between patient perceptions and a clinician-driven definition of an adverse event is small (see text).

(Fig. 1). Our participants did not routinely interpret negative experiences as ‘adverse events’ or as side effects of treatment, but often as a necessary part of their ‘global osteopathic experience’. We suggest, therefore, that any alignment between their perceptions and their practitioner’s interpretation of an adverse event...
therapy using: functional impact; post-treatment pain/symptom severity; timing and duration; ruling out of alternative causes for the response. In contrast to our present study, these authors used direct questioning that probed ‘negative reactions after treatment’, benefit or harm, numeric pain rating and reasons for stopping treatment; in addition, only four of 12 participants had received osteopathy. Despite these differences, there is an apparent concordance between the 11 sub-themes identified by Carlesso et al. as contributing to a definition of adverse events, and the 19 sub-themes used to develop our conceptual model; each study emphasises how contextual factors can influence patient perceptions. Both studies, by exploring the patient’s perspective, add to the debate introduced by Carnes et al. on defining adverse events in manual therapy (Carnes et al., 2010b). From a practitioner-focused Delphi consensus study, three categories of adverse events: major, moderate, or minor and ‘not adverse’, were classified according to duration, severity and seriousness/acceptability. Whereas this hierarchy might be valuable to clinicians, it seems less relevant for patients particularly when considering commonly occurring mild–moderate experiences. Long et al. have shown that variations in interpretation of client-perceived ‘negative responses’ are important to all when interpreting a typology of adverse events, the safety of a complementary therapy (Long et al., 2009). This is in line with our conceptual model, which proposes that there is disparity between what is perceived as adverse by patients, and what might be defined as a minor–moderate adverse event by their practitioner (Carnes et al., 2010b); indeed, it is likely that many such ‘adverse events’ are not viewed by patients as negative at all. Disparities between the perceptions of practitioners and patients concerning other aspects of osteopathic care have been noted elsewhere (Lee-Treweek, 2001; Thornton-Smith and Rajendran, 2010). Therefore, it seems that identifying criteria for establishing what would constitute an ‘adverse event’ from the patient’s perspective is not straightforward but, as called for elsewhere (Strutt et al., 2008; Hsu et al., 2010), is a necessary step towards a better understanding of meaningful patient-centred outcomes; this, in turn, should lead to more effective clinical management.

The strengths of this study include the richness of the data derived from a mixed population (age and gender) of solely osteopathic patients, with a wider socio-economic mix than the employed, well-educated manual therapy patients studied by Carlesso et al. (2011). The emergent themes we have identified are in line with findings from other qualitative studies which have highlighted the importance to patients of expectations (Hills and Kitchen, 2007); of information giving (Sokunbi et al., 2010); of hope, communication, respect and trust within an empathetic relationship (MacPherson et al., 2003; Strutt et al., 2008); and of empowerment (Bishop et al., 2010). There was also strong concordance with the only known study to explore patient perceptions within the context of adverse events in manual therapy (Carlesso et al., 2011).

The influence of the researchers on the design and data analysis for this qualitative study cannot be overlooked. All but one were qualified osteopaths but only one of these worked as a clinic tutor. Some had previous involvement with a clinic-based survey of post-treatment experiences (Rajendran et al., 2009) and DC conducted a systematic review of adverse events in manual therapy (Carnes et al., 2010a). This background may have influenced formulation of the topic guide. The researchers were reflective about any influences on data interpretation; however, as the principal coder of the transcripts (PB) had not been involved in the previous published work, interpretative bias was minimised.
Although our investigation was based within a teaching clinic, we consider many of our findings generalisable since issues relating to continuity of care, practitioner competence and service facilities are not teaching-clinic specific, and expectations of care for patients attending a teaching clinic appear not dissimilar to those of other patients, as discussed earlier. There were, however, some limitations regarding our sample, such as lack of ethnic and geographical diversity, and small sample size. A positivity bias is likely, as many participants were long-term users of osteopathy, committed to this therapeutic modality and often expressing loyalty to the teaching clinic. The use of participants drawn from within the ESO for FG1, from which the analytical framework was generated, may have introduced bias, although no themes emerged from the two later FGs that had not been identified in the first. Finally, our findings are not necessarily applicable to non-returning patients who might have experienced a serious adverse event; the perceptions of this cohort warrant investigation. It should be noted, however, that studying perceptions around serious or major adverse events is likely to be challenging, as the risk of such incidents is very low (Carnes et al., 2010a).

Clinically, our findings are relevant because they provide valuable insight for the practitioner, whether student or qualified, into how all four components (EPOC) of the ‘global osteopathic experience’ can have a profound impact on the patient’s treatment experience and, in particular, on their perception of what is adverse. Thus, throughout the treatment process the practitioner must be aware of their patient’s expectations (E), look at what personal investment is being made (P), relate these to the osteopathic encounter (O) (from service and facilities provision, through the therapeutic relationship, to delivery of specific treatment) and then monitor clinical change (C) within that context. In so doing, the practitioner can enhance positive perceptions of post-treatment experiences and modulate what is perceived as adverse. This proposed conceptual model has relevance for all manual therapists and warrants further testing in other clinical settings.

5. Conclusion

In conclusion, perceptions of experiences following treatment are integral within the global osteopathic experience and evolve within the context of four inter-connected components, designated EPOC: ‘expectations’, ‘personal investment’, the ‘osteopathic encounter’ and ‘clinical change’. There is disparity between the way in which patients perceive these mild—moderate post-treatment experiences and clinical definitions of adverse events. Managing the patient’s overall experience of osteopathy may be an important determinant of perceptions of ‘adverse’ effects.

Acknowledgements

We are grateful to all focus group participants, who made this study possible. Special thanks go to Sarah-Jane Marshall, Dr Janine Leach and Dr Peter Collins for their support and assistance.

References

Anden A, Andersson SO, Rudebeck CE. Satisfaction is not all — patients’ perceptions of outcome of general practice consultations, a qualitative study. BMC Fam Pract 2005;6:43.


Carpenter B, Vitek E, Beersmaa A, Charnier D. How common are side effects of spinal manipulation and can these side effects be predicted? Man Ther 2004;9(3):151–6.


Web references