

SEPTEMBER 2019 VOLUME 17 ISSUE 3

PAIN NEWS

A PUBLICATION OF THE BRITISH PAIN SOCIETY



Death of the little brain

Pain management efficacy

Pain, suffering and death in health professionals

Procedures for discogenic pain

Real world trial of cannabis for pain

Pain and sleep

ISSN 2050-4497



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PAIN NEWS SEPTEMBER 2019

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PAIN NEWS is published quarterly. Circulation 1300. For information on advertising please contact

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London EC1Y 1SP, UK.

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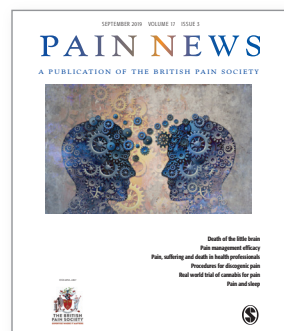
Email rajeshmunglani@gmail.com

ISSN 2050-4497 (Print)

ISSN 2050-4500 (Online)

Printed by Page Bros., Norwich, UK

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The late visit and the unexpected visitor

Rajesh Munglani *Editor, Pain News*



The second day

His expression looked pained; despite all the hours he had been on duty, and the cursory way he had looked at me previously, clearly the junior doctor had now dropped all his other commitments and for the first time his eyes stared directly at me, undistracted by the urgency of the care of others, despite the investigation results or the clamorous bleep or alarms in

A&E; he spoke gently, taking his time.

'It looks like a tumour in the left cerebellum', he said. *The words swam in my head.*

'I need to talk to my boss'. He rushed out, cubicle paper screen wafting irritatingly lazily and ineffectively in the swift movement out, a poor apology for privacy, it wafted again, my response to these life-changing words shared with the rest of suffering humanity in the casualty department, an imperfect barrier between myself and the rest of Bedlam.

My mind, however, surprisingly content: three thoughts popped out with a surprising piercing clarity of thought: a life lived until 56; a devoted wife; and 4 loving daughters, and I thought about it all, at peace, at peace with myself, before an untimely intrusion pierced my thoughts again, saying 'I forgot to do these; to check your cerebellar signs'.

He made me touch each of my index fingers from my nose to his jerkily moving index finger, flapping my hands, one up then down upon the back of the other and then making me move each ankle up and down the other shin, rushing out and, barely before the paper curtain had time to settle, he said 'The boss wants you to have a CT contrast', – the 'boss' was clearly not far away; perhaps listening on the end of a phone – then also adding with a beaming smile, 'and I will be your porter this time'. I was the momentary centre of attention of the rushed junior doctor for the second time.



Credit: Henry Ossawa Tanner.¹

The first day

Less than 24 hours previously, I had been thinking about reorganising my life (again) and how to make it less busy. As usual, no firm decisions made.

Deadlines achieved: telephone conference; finishing a report; 5,000m rowing on a machine; half an hour, also crammed with an episode of the addictive series 'Billions'; bag packed and late again to visit my recently widowed mother.

Deadlines not achieved: only three items of work left on my 'To do list' (mental note: *to be done by end of today*), followed by a rushed journey to London, remembering not a thing of it, contemporaneous weather, scenery, life passed by quickly, unnoticed, to arrive traffic-worn, 2 hours late.

She smiled, having waited all morning for this moment, opening the door, painfully shuffling with rheumatoid joints, I, sitting, grabbing a moment to answer a hundred new emails before she, shuffling, brought in some kebabs. Hungry from the late morning exercise; not being breakfast-fueled, grabbing greedily at the beautifully spiced steaming kebabs, before she slowly, deliberately, effortfully returned to the kitchen to find the home-made mint sauce. I continued to answer my emails, barely acknowledging the immense and painful efforts she had made, served lovingly on the metal tray: saffron rice, thinly sliced red onion, and spiced meat.

Would you like a drink? she said, returning, offering strong tea, tannin rich wine, and fresh pomegranate seeds, blood red crunchy, sweet, tart and astringent, the sort I liked. Guiltily I realised I had eaten 8 of the 10 kebabs on the plate before she had even returned and, reluctantly, I left two and pointed to them and to her and said, 'You must have some, too'. 'It is a full moon; I cannot eat meat', she replied.

I finished the remaining two, felt for a moment like the rabbit that had caught up, just for a moment, just having passed the hare of constant demand and I, feeling the need to rest, announced 'Much meat on the stomach is heavy', I reasoned aloud, 'especially with a glass of red wine' and with a growing calmness that, just for a moment, I knew I could stop. 'Do you mind if I take a rest?' I asked predictably. She smiled, knowing me well; I, as usual, flipping from 100 miles an hour to dead stop and back again in an instant.

I went upstairs and began slowly to feel unwell and drifted into a very deep and disturbed sleep. I awoke abruptly covered in sweat, a heavy migraine, I thought, pounding on one side – did I really drink too much? Sweating, feeling sick and dizzy, I went downstairs slowly, uncharacteristically, holding on to the bannister.

'The hospital sent me this, what should I stop?' she asked. I looked at the long list of medication that would need to be discontinued before her painful ankle injections for her even more painful arthritis. With horror, I noticed I couldn't read the print and then suddenly an overwhelming, nauseating desire to lie down overcame me, within an instant my shirt drenched with sweat, and I said to her weakly, 'I will look at this later, I think I'm going to be sick; can you bring me a bowl?' She looked concerned and slowly walked to get the bowl she used for her ankles morning and evening, bathing them with oil and water to soothe the inflamed joints, making them a little more bearable, reducing her excruciating suffering just a little.

While she was gone, such gut-wrenching desire to be sick overwhelmed me and a complete inability to move my head; a

few seconds, perhaps an eternity later, she brought the bowl to me and slowly with one hand I brought it to my head, resting on the right arm of the big chair. There then followed 6 hours of the most intense vomiting ever experienced, but combined with an absolute inability to move my head. 'I am dying', I thought.

My first concern was not to worry my mother, recently bereaved, I, unwilling to blame the kebabs, thoughts turning to my brother coming the next day.

'Perhaps we should not serve him this for the moment', I said in the lightest, most gentle tone I could muster, continuing to vomit dark sinister indeterminate fluid laced with blood. She looked worried and said, 'Shall I call the doctor?'.

'No, I'm sure it will pass'.

After 6 hours, I looked at the sofa two metres away and with all the effort I could muster, still vomiting, launched, collapsing on to it, left side of head onto the sofa arm, and my head hit the soft cushion with a spasm of dizziness and nausea and retched again, this time with nothing to bring up.



Credit: Ernst Ludwig Kirchner.³



Credit: Wassily Kandinsky.²

For 12 hours, I did not move, my mother covered me with a blanket and lay down on the other sofa, watching for me to move. In the middle of the night, painfully crawling up to the bedroom with no sense of balance, I lay down. The pounding in my head was accompanied by a complete, concerning absence of pain in my stomach and no diarrhoea. I crawled, all four limbs moving. Instinctively, self diagnostically, I noted pain: left ear, head on chin: just; neck: stiff, yes, but not meningism; photophobia: a little; stomach pain: none.

A self-diagnosis of labyrinthitis, reassured by this – 'Bugger', I thought, 'That is probably at least a few days, if not a week off work'.

The late visit and the unexpected visitor

Assuming sympathetic system in overdrive, accounting for the sweat, a torrential equatorial which had drenched my clothes, my trousers and all the bedsheets – labyrinthitis *definitely* and perhaps some acute poisoning and sympathetic overdrive. I fell into a fitful sleep.

The third day

24 hours, still at home, later my brother, towering over my weak, huddled form, having arrived from Bristol, said 'I am calling 111'. The two young female paramedics came over to me, I looking older, more tired, foetal-positioned but covered in slimy liquid like I'd just been born, but dying. 'I have never cannulated a doctor before', giggled one. In my drenched nauseated state, I could only think that must've been some pickup line re-phrased. I thought to myself, 'Well, if I can think about *that* I can't be *that* ill'.



Credit: Max Weber.⁴

In a dream-like blur, the next few hours passed, the primitive shock absorbers on the bone-rattling ambulance mingling with the cacophony of the jungle-like noises within the ambulance, alarms, beeps, and squeaky equipment.

The second day

The repeat CT scan with contrast showed in fact I had suffered a primary dissection of the left vertebral artery, starving the cerebellum – one of the '*little brains*', it was described to me – of the vital oxygenated pulsating blood it needed to survive from heart beat to heart beat. In the 24 hours since the dissection, my body re-forged a bloody path, the last time being in my mother's womb when first made, as I lay there in a deep labyrinthine-induced sweat – a re-bleed, giving a mixed CT picture, cloaking it

with the appearance of an unwelcome imposter, a cancer, a crab enveloping the cerebellum, concerning the doctors that something autonomous and alien was growing deeper within. But it was simply the body trying to deal with the dying brain, flooding the area in a desperate attempt, reinvigorating my nerves with new blood; for the life is in the blood, it says in Deuteronomy.

The fourth day

Hillingdon, to Northwick Park, to Addenbrooke's Hospitals. On the way a thin, wiry Consultant, nurses calling him the inevitable Dr Raj, with immaculate English, soulful dark eyes, and an obviously attractive empathic air explained to me that 'it's not your fault, and no one knows why this has happened. These vertebral dissections happen in younger people of an active age, but to stop it happening again you would need to be anticoagulated for six months'.

In a desperate fog-like state, with a pounding left headache and left ear pain, I try to remember the other easily retrieved facts slipping off his well-rehearsed medical tongue. 10% die; locked-in syndrome in some; eventual [good?] recovery in about 90%. An unmistakable professional mark of one who has dealt with such cases previously, reassuring in that fact: '*he has seen it all before*', one so versed in the life-changing tragedies of others. The world was now surreal. Dr Raj also mentioned *en passant* that there had been some midline shift, which might explain some of my confusion, and the danger period was from 48 to 72 hours. Well, I was on day 4 at least.

My wife was desperate to get me back to Cambridge; the doctors in Northwick Park could not name the time as their attempts to contact the Cantabrigian hospital bed managers far out East proved, inevitably, typically futile in the search for spare beds.

The fifth day

I was told then it could be a week or longer to wait for a transfer ... In fact, it was a few hours later. An unexpected early lone message left on a ward ansaphone told the ward staff I would be transferred to Cambridge 'within minutes', message relayed first by one rushed nurse, like Pheidippides, a hemerodromos, or an Athenian runner-messenger, followed by another announcement, a nurse who confusingly reported it would be 12 hours later at 6am, with a 24 hour journey. Uncertainty set in, which I accepted with the grace and stoicism that accompany one who has surrendered, to be led, willingly or unwillingly to his unknown fate.

The sixth day

I arrived in Addenbrooke's to find that the person next to me was a tall, lithe young chap, a festival dancer who cycled everywhere, who had suffered the same type of cerebellar infarct [as me] from the same condition of a dissected vertebral artery in the cervical spine. Desperate for reassurance, he wanted to know from the

doctors whether he could dance again. 'No reason not to' came one authoritative, abrupt medical reply: 'one week off'.

The days in Addenbrooke's passed quickly and in a blur, the usually quiet rehabilitation unit being regularly disturbed by the lack of beds and the incessant merry-go-round of patients from hospital ward to hospital ward, as they struggled to cope. Two hours sleep was considered a luxury. Disturbance, if not by an OT or a physiotherapist, was then by a call from another patient asking for drinks or the loo or the incessant bleep and alarm of a drip monitor.

My brain, apparently said to have more potential connections than atoms in the universe (*seriously, how can this be so?*) responded quickly; the immense but fragile learning power switched off the absence of signal from the left cerebellum and the intense continuous nausea, abated initially only by drugs, was slowly replaced over the next few days by a feeling of nausea only when standing and moving my eyes. Lying in the bed just for an instant, I felt completely normal, my reading ability had come back, I could scan words again and comprehend them. What if I had lost some of that ability?



Commiphora myrrha tree, one of the primary trees from which bitter myrrh is harvested. Credit: Franz Eugen Köhler.

One medical friend came to tell me about his decision to stand for a political party, another breezily saying 'you've only lost one of the little brains-[the cerebellum] – the big ones [the cerebrums] still work: 'you will be fine in the end'.

The pain has subsided, the dizziness is passing, the Zimmer frame discarded, though on walking now I feel like a drunkard at closing time, with a short concentration span, but what now



Credit: Rembrandt Harmenszoon van Rijn.⁶

remains is a deeper, unequivocal understanding of what it is to be human and to be alive, a transient fragile condition that can be wiped out in an instant and, along with those gifts, a gift to suffer and feel pain.

I never understood why, along with the gifts of gold and healing frankincense, the gift of the bitter myrrh was also given; given at Jesus' birth and offered to him at his death: to know that life is not to be taken for granted, to have had a short, much unexpected visitation from death, makes me more alive than ever. I am grateful for all these gifts.

We are pleased to consider contributions from patients, health professionals or indeed health professionals who have been or are patients, loosely based around the experience of pain and suffering in everyday life. Ed.

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Jenny Nicholas



It is our autumn issue already; does anyone else agree that the time has just flown by?

Dr Arun Bhaskar, your new President has written to update you on several developments within the Council and at headquarter (HQ). Please do read his message and consider how you might support your Society.

While work continues to strengthen your Society from within, we are delighted with the volume and quality of

submissions to *Pain News* (and *BJP*!). I thoroughly enjoy reading through all of the submissions that Raj as Editor selects for each issue and the variety of topics that are covered.

So what do we have in store for you this time?

- Well, we've whetted your appetite with two out of three articles on Peripheral Neuromodulation, and this issue sees the third and final instalment on 'peripheral nerve stimulation in other regions including autonomic nerves,' which continues to discuss the applications of peripheral

nerve stimulation in different parts of the body. We hope you've enjoyed this series of longer articles and we will be continuing with this format as you will see.

- We introduce the first of a three-part series on 'Being Mindful of Mindfulness' by Dr Sangram Patil. In part 1, he explores the role of Vipassana in the history and evolution of modern mindfulness techniques.
- A challenging topic to discuss is that of 'suicide in doctors and other healthcare professionals'. Dr Clare Gerada introduces us to the Practitioner Health Programme, a confidential service for doctors and dentists with mental health and addiction problems.
- 'Treatment of Discogenic Back Pain and Sciatica in Daily Practice: Report of 100 Sequential Cases of Interventional Spinal Pain Treatment with DISC-FX' By Dr Hammond, C Hess and C Oram who present their findings.
- Katie Whale and Rachel Gooberman-Hill talk us through 'Why sleep matters to pain research'.

We would love to hear from as many of our members and colleagues as possible who have informative, thought-provoking and interesting viewpoints and articles to share.

Also, we'd love to hear your feedback on your newsletter? Are there any articles which have inspired you or helped your practice? Please do let us know!

Arun Bhaskar



Dear Friends
I trust this finds you well. I sit down to write this in the midst of the long-awaited summer while our colleagues in Europe are experiencing a heat wave. Some of you would have known by now that Dr Raj Munglani, Editor-in-Chief, had an unexpected left vertebral artery dissection followed by a cerebellar stroke and is recuperating well from it. Raj had already ensured that the publishing of

the next issues is not compromised and I thank the Editorial Team for stepping up to support him. On your behalf, I am wishing Raj a speedy recovery and the indication is that he will be back with us in fine form very soon.

We have had a few developments in the few months. I had mentioned in my previous communication that we do not have an elected Council member representing our colleagues in clinical psychology and I am pleased to announce that Dr Patrick Hill will be the co-opted member. Mr Martin Hey also recommended to the Council that it would be in the interest of the British Pain Society (BPS) to have a co-opted member from the Physiotherapy Council representing the wider physiotherapy colleagues involved in pain management. The Council has ratified this and is awaiting the recommendation from the Physiotherapy Council. Prof Sam Eldabe is now the Chair of the Scientific Programme Committee (SPC) and is putting together a team that will deliver the next Annual Scientific Meeting (ASM). The Patient Liaison Committee requires a Chair and this is being addressed. Dr Andreas Goebel is planned to take over from Prof Eldabe as the Chair of the Science Committee and also become a co-opted member of the Council. Dr David Pang, who is leading on the National Awareness Campaign, suggested that there should be a patient co-chair for the campaign and the Council supports this suggestion also.

The ASM 2019 was a success in terms of delegate experience as well as a modest success from a financial standpoint. This is as much as we could reasonably expect in the circumstances. We generated better industry support than expected and this contributed towards loss mitigation, which was one of the prime reasons for holding the ASM in London. I would like to thank the delegates as well as our industry colleagues for their support in making the ASM a success. Some of the Council members and the Secretariat worked incredibly hard to help organise the meeting in a short period of less than 4 months. The support of an external event organiser, Mr Ciaran Wazir also helped in achieving some of the financial targets. The feedback from the membership (from those who attended and those who were unable to attend), overseas delegates and our industry colleagues is that London is also the preferred venue for ASM 2020. The cadaver workshop which was held for the first time this year was a success and there has been feedback about having new topic-based sessions at the ASM. Prof Eldabe and his team will examine this proposal. Dr Ashish Gulve will be the Executive Officer supporting the SPC in organising the London-based ASM 2020 and would be liaison between the various stakeholders. I am aware this is disappointing news for colleagues in the North and the West of the British Isles, but at this stage when we are having significant financial challenges, it seems financially more sound to be based in London. We will also ensure that the regional meetings are supported; Dr Ashish Gulve along with Prof Sam Ahmedzai, Chair of the Education Committee, are organising a meeting in York on 17 September and are also supporting the Welsh Pain Society meeting organised by Dr Christian Egeler and Prof Neeraj Saxena later in the year. We are also looking to support several other regional meetings in the future.

The Executives are evaluating the current financial situation facing the Society and this was shared at the Council meeting. Although the situation is not as bad as the message from Liam Byrne, the former Chief Secretary of the Treasury of Gordon Brown's Labour government, to his successor at No. 2, Liberal Democrat MP Daniel Laws, 'I am afraid to tell you, there is no money left', it still puts us in a tight situation. Dr Glyn Williams has stepped down as Honorary Treasurer and the Council has nominated Dr Ashish Gulve, to take on the position of Interim Honorary Treasurer. Ashish has outlined some of the details in

Arun Bhaskar



Burnout in health professionals.

Credit: AntiMartina.

his message to the membership. We had looked at a hybrid model of part-outsourcing the ASM 2019, which contributed towards the meeting's success. We also looked at fully outsourcing the ASM for 2020, but the costings of the latter were such that it was not in the best interests of the Society. The Council has agreed to go ahead with the model that helped turn around the situation this year. Traditionally, 60% of the workload of the BPS Secretariat was in organising the ASM, limiting their time and attention to other important activities including engaging and providing support to the members. It was therefore agreed at the Council meeting that with this new arrangement, only 30% of the Secretariat activities is anticipated to be required for the ASM and the rest of the time would be focussed on supporting the membership and Council/SIG/Committee activities. We have also taken several measures to cut down on the financial outgoings of the Society, and now we need to focus on generating some much-needed funds to support the Society in its current form as a multidisciplinary organisation. On behalf of the BPS Dr Ayman Eissa, Honorary Secretary is negotiating with various stakeholders in the changing landscapes on how pain management is delivered across the country. Along with Ayman, Prof Roger Knaggs is also continuing to support the membership recruitment and retention programme.

I have been attending various meetings on behalf of the Society. The Chronic Pain Policy Coalition organised a meeting on 25 June and this was hosted by Lord Luce at the House of Lords. The various stakeholders attending the meeting acknowledged the importance of raising the awareness of pain as a healthcare problem. I would like to thank Lord Luce, Prof. Andrew Baranowski, Dr Martin Johnson and Mr Neil Betteridge for continuing to champion the cause on behalf of Pain Medicine. The Pain Management Programme SIG is having

their meeting in Bristol and again this is a meeting that should be widely publicised both within the United Kingdom and abroad as it offers good value for a specialised subject in a multidisciplinary setting. The Headache SIG will hold their meeting on 7 October at Churchill House, London. It was discussed at Council how the SIGs should be liaising with the rest of the Society. One of the suggestions is the formation of an Early Careers SIG; this was suggested by Dr Victoria Tidman and we are looking at our junior colleagues across the various disciplines to come forward and support the formation of this SIG that would ensure future colleagues are mentored and supported.

There have been several articles in recent times on 'burnout' in medical professionals, not just in doctors alone; the latest of which are from *British Journal of General Practice* (Hall LH et al. (2019)) and also an article by Ellis and Crighton in the July issue of *Bulletin*, the Newsletter of RCoA (https://www.rcoa.ac.uk/system/files/Bulletin116_web.pdf). Figures from the GMC and from a National Survey (McClelland et al.) state that up to 85% anaesthetists in training are at the risk of burnout compared to 25% of the doctors in training as a whole. This would certainly apply to pain trainees, consultants and specialist MDT colleagues who are beginning their careers in pain medicine, but senior colleagues are also facing challenges due to the demand on pain services. Professional indemnity organisations like Medical and Dental Defence Union of Scotland (MDDUS) have identified that symptoms of burnout or reduced wellbeing is one of the main reasons for complaints and litigation due to delayed or missed diagnosis or failure to initiate appropriate treatment. The Philosophy & Ethics SIG has been holding successful meetings annually with delegates attending from all corners of the world. The SIG members were informed that they should bring in their experience and share with the wider membership of the Society. They have suggested a support group for professionals in pain medicine facing burnout during the course of their work and we shall be hearing more about it soon.

We are looking at ways to ensure that all our colleagues involved in Pain Medicine in the United Kingdom seriously consider joining as members of the BPS. Your support in this matter would be invaluable. We also heard very helpful suggestions about increasing the membership fees in line with salary banding for 2 years to tide over the current situation. However, this would also be reflected in what the Society gives back in return to its members in various ways. This was presented at the Council meeting and it was decided that we put this forward to the membership before any final decision is taken on this matter. On another note, we wish to engage with and employ the considerable talents of our members. Please do speak to any member of the Council or the Executives or write to me personally at akbhaskar@btinternet.com to consider putting yourselves forward for various roles within the Society. I look forward to hear from you.

Dr Ashish Gulve



Dear Colleagues,

I would like to thank you all for electing me as a Council Member of the British Pain Society (BPS) in May 2018.

From June 2019, I have accepted the honour of also becoming the Interim Honorary Treasurer of the Society.

As some of you may be aware, the Society has been in financial decline over last 4–5 years with five to six-figure losses being registered year-on-year.

This has been due to

dwindling membership numbers and attendance at Annual Scientific Meetings (ASMs). Changes in regulations and declining ASM attendance have also resulted in reduced industry funding.

The BPS promotes education, training, research and development in all fields of pain. BPS is a valued multidisciplinary organisation that is highly recognised at many levels of policy and decision making, including at the Department of Health, NICE, NIHR, Clinical Reference Groups and others. This has made our Society unique in representing the interests of all disciplines involved in pain management at a national and international level.

In order to fulfil these roles, we need to employ staff (the BPS Secretariat). The income for BPS is generated by membership fees and surplus, if any, from the ASM. Unfortunately, both these sources of income have been declining over the years, despite cutting costs and considerable reorganisation income has been less than expenditure for a number of years.

In 2019, we managed to reduce the projected loss to a certain extent. However, the Society still has very limited reserves and we need to turn the Society around financially urgently to avoid dissolution and insolvency.

The BPS Council is determined to ensure that the Society will continue to function effectively and be a valuable resource to



each and every member of our Society. We want to ensure that the Society is responsive to our members' needs so that they are getting good value for their money.

Unless we take drastic, urgent actions over next 12–24 months, we cannot guarantee survival of the Society. It is impossible to achieve this without your support.

We need your help and support in the following ways:

1. Maintain your BPS Membership at the correct banding.
2. Encourage all your colleagues to become BPS members.
3. Attend the ASM and encourage your teams to attend also. There is something for everyone at the ASM!
4. We are considering revising the fee structure to increase financial stability, but this would be only after discussing with all of you.
5. *Charitable donations* to help turn around the Society. This can be done as a gift aid. As an expression of our gratitude, the Society will regularly publish a list of donors and their gifts (if not anonymous), on the website and in *Pain News*.

Donations can be made online at: <https://www.britishpainsociety.org/donate/>

The British Pain Society 2019 Meetings & Events



**THE BRITISH
PAIN SOCIETY**
EXPERTISE WHERE IT MATTERS

Pain Management Programmes SIG Bi-ennial Conference

“Placing the Spotlight on the Biopsychosocial”

11th & 12th September 2019

Bristol

The theme of the conference is "Placing the Spotlight on the Biopsychosocial" and will feature excellent plenary talks and a diverse choice of workshops.

A social event including drinks and canapés will be held at Bristol Museum & Art Gallery on Wednesday 11th September between 18:00-21:00.

North of England Regional Meeting

17th September 2019

York

The British Pain Society will be hosting the first of a series of regional study day events in York on 17th September 2019.

The day will feature talks on neuromodulation, pain in cancer survivors and will explore the future of pain services.

Headache SIG Annual Meeting

7th October 2019

London

The British Pain Society will be hosting the 3rd Headache Special Interest Group Meeting on Monday 7th October 2019 in London.

Talks include **“How important is psychology in management of headache symptoms”** **“CGRP receptors, what’s new?”** and a session focusing on **“Neuromodulation in Headache”**.

The meeting will also feature a Multidisciplinary workshop as well as a Hands on Botox workshop.

Cancer Pain Study Day

8th October 2019

London

This will be the fourth time that the Society has held a study day on this important and diverse topic. Previously we have explored basic science, oncology, pain/palliative medicine, mechanisms of cancer pain, and the role of the WHO ladder. Join us once again for further discussion as we continue to explore the many facets of cancer pain.

Further details for all our meetings can be found on our events listing page:

www.britishpainsociety.org/mediacentre/events/

Have your say and contribute to *Pain News* today

Pain News is the newsletter for members of the British Pain Society and we welcome member and non-member contributions to share your news with the wider membership and beyond.

Do you have a news item to share?

Perhaps a professional perspective, or informing practice piece?

We'd love to hear from you so drop the Editor an email today at: rajeshmunglani@gmail.com

Pain News is published four times per year.

The Editorial Team; Dr Rajesh Munglani, Dr Margaret Dunham and Jenny Nicholas, CEO, welcome submissions for consideration of inclusion. Thoughtful pieces on Pain Medicine and related subjects including personal opinions, original work and reviews will be considered. By submitting an article, potential authors are agreeing to active editorial input to ensure conformity to house style, clarity and reasoned debate.



Citation for Dr Frances Cole for the award of Honorary Membership of the British Pain Society

Dr Dee Burrows *Clinical Nurse Specialist*



It is my great pleasure to present this citation for Dr Frances Cole for the award of Honorary Membership of the British Pain Society.

Frances became a GP in 1981 and then trained to be a Cognitive Behavioural Therapist in 1994.

She worked in South Tyneside as a GP in 1989-1994, and she describes sitting, during a 3 a.m. home visit, with a lady with 'terrible chronic pain following spinal surgery many years previously'. She quotes 'we both sat and looked at each other in a common desperation'. Frances decided subsequently to train in CBT in Newcastle and the lady gradually learnt to become more active and started swimming ... and so began Frances' journey as a Pain Rehabilitation Specialist. Discovering CBT enabled her to have a practical person centred model and approaches to address chronic pain in everyday frontline practice.

Frances is passionate about improving the quality of life for people with pain and believes whole-heartedly in patient-centred self-management approaches. Her contribution to pain self-management has been outstanding. Her influence in

primary and community care pain management is immeasurable.

23 years ago, in 1996, Frances started the first CBT multidisciplinary pain rehabilitation service in primary care in the United Kingdom. She is fervent, in not only advocating but also demonstrating the value of the multidisciplinary team in the management of people with chronic pain. As such, she has taught, inspired and encouraged countless doctors, physiotherapists, psychologists, pharmacists and nurses. Her influence on their thinking and practice is exceptional. She has been a mentor to many of us.

Frances currently supports the GP Red Whale training programmes to reach numerous primary care clinicians to enable them to manage chronic pain confidently and safely. In 12 months, she and colleagues have reached over 3,000 GPs around the United Kingdom via CPD updates. Her talks at the four RCGP Pain Education Conferences have always proved the most popular, as she demonstrates the skills needed by GPs to assess and manage people with pain.

Frances believes firmly in the contribution of Expert Patients in enabling person-centred pain self-management throughout the United Kingdom. Just this week, an Expert Patient told me that Frances' 'willingness and enthusiasm to publicise patient's stories, to help both clinicians and patients, was amazing and not something that happens enough'. As well as Expert Patients, she is generous in her inclusion of healthcare professionals in developing and delivering her programmes.

In 2005, Frances won a regional NHS Modernisation award for the development and implementation of a pain health needs assessment tool. She is an early adopter and passionate about getting commissioning and service delivery models correct. She has been a sounding board for and influencer of many projects and commissioning Pain Services around the United Kingdom in both primary and secondary care. In 2011, Frances won a National NHS Clinical Leadership Award for her pain work.

Frances is a co-author of the CBT self-help guide *Overcoming Chronic Pain*. First published in 2005, it has since been chosen twice in 2013 and 2017 as a patient resource for

Citation for Dr Frances Cole for the award of Honorary Membership of the British Pain Society

the Reading Well Agency Books on Prescription, for GP's and other practitioners in NHS England.

Frances has been instrumental in the development and widespread use of the Pain Toolkit and the Pain Management Plan. She worked with Pete Moore to develop and support the Pain Toolkit and a range of self-management tools, including app-based resources. The Pain Toolkit and resources have not only influenced practice in the United Kingdom, with 250,000 copies distributed nationally in 2011 alone, but also had an international reach, with the Pain Toolkit available in 21 different languages.

Frances commissioned through Bradford Primary Care Trust in 2010, the CBT workbook *The Pain Management Plan* with Professor Bob Lewin, York University. This workbook is designed for partnership working with patients in both home and community settings and is also used in secondary care Pain Management Services. Over 200 practitioners have been trained in its use, across more than 35 NHS providers. Frances researched the application and validity of the Plan in three sites using health outcome measures. She is committed to measuring outcomes from a patient-centred perspective, focussing not just on usual measures of pain intensity, pain-related distress and dysfunction but on what is important to the individual in terms of their values and goals.

More recently, she co-developed self-management digital resources through www.pain-sense.co.uk to enable wider access to knowledge and skills on pain management that include the Pain Toolkit and Pain Management Plan.

In 2017, Frances wrote and published the book *Introduction to Living Well with Pain, 10 footsteps to guide self-management*. Subsequently, in response to requests from GPs and other Primary Care colleagues, for an easily accessible online resource to support pain self-management interventions, she went onto develop *and fund* the Live Well with Pain website (www.livewellwithpain.co.uk). The site has received extremely positive feedback and continues to widen its reach, providing self-management knowledge, skills and resources to clinicians across Primary Care. The resources include valued advice and support on how to successfully reduce opioid prescribing, building on the work she undertook in 2008/2009 with Joan Hester, Cathy Stannard, Gill Chumbley and others on, the then, emerging issue of safe opioid prescribing by primary care clinicians.

France's work with the British Pain Society exemplifies her commitment to the world of pain. She is a past Chair of the Pain Management Programme Special Interest Group and led

members in focusing on measuring patient outcomes and reviewing the Pain Management Programme Guidelines. She has been and currently again is a co-opted member of the Primary and Community Care Special Interest Group, where her support and ideas are greatly valued.

Barriers and the words 'I cannot' are not known to Frances; she is the epitome of a 'can do' person and appears to be able to find funding, large and small, for her varied initiatives. She is driven by ensuring that the needs, values and goals of people with pain are central to their treatment and promote self-management. She is an excellent role model in this endeavour.

Her influence on primary and community care is beyond measure. Her educational materials reach thousands of patients and practitioners. Her mantra is self-management and, to this end, she has taught, inspired and encouraged countless practitioners across the multidisciplinary team. Yet, despite her vast knowledge, skills and experience, she is modest, approachable, welcoming and a joy to work with. She puts people at their ease and her compassion for others is exceptional. I feel deeply honoured to have had the opportunity to present this citation.

Unfortunately, Frances cannot join us today. She is away on a remote island off the North West coast of Scotland, and in her words 'on checking transport options it sadly is hopeless' for her to be with us. Nevertheless, ladies and gentleman, please join me in congratulating Dr Frances Cole for her commitment to improving the self-management of people with pain and the extremely well-deserved award of Honorary Membership of the British Pain Society.

Dr Jim Huddy came forward to accept the award and share a few words from Frances;

"Thank you for this award. For me the award is really for all those who worked with me to create ways that help people with pain live well in spite of pain. The British Pain Society, especially the PMP SIG and more recently Primary Care and Community Care SIG have enabled me as a generalist clinician become confident to innovate, deliver and create services and resources that make a difference most of the time.

Thank you to the Society for this wealth of knowledge and shared experience.

Finally, people and the person matter more than the pain, this crucial focus I learnt from Cicely Saunders, founder of Hospice Movement and that focus from my early training, guided my clinical work always. Thank you."

Citation for Prof Roger Knaggs for the award of Honorary Membership of the British Pain Society

Felicia Cox *Lead Nurse*



It is with great pleasure that I deliver this citation to support the award of Honorary Membership of the British Pain Society (BPS) to Prof Roger Knaggs. Roger was described in an interview with the *Pharmaceutical Journal* in 2016 as 'The pain reliever', which for those who know him well is an understatement. His footprint is everywhere.

After graduating from the University of Sunderland, Roger completed his pre-registration training in the pharmaceutical industry and in a hospital pharmacy. He originally came to Nottingham from the North East to study the physicochemical properties of opioids, working under Nick Shaw and Dave Barrett and was awarded his PhD in 1997. Since then he has been an anaesthesia and pain management directorate pharmacist at Nottingham University Hospitals NHS Trust and most recently an Associate Professor in Clinical Pharmacy Practice at the University of Nottingham. He successfully stood for election in June 2011 to the Council of the BPS, having been a co-opted member having represented The Royal Pharmaceutical Society (RPS) for a number of years. Roger has held the post of Honorary

Secretary since 2016 and been a member of the Scientific Committee since 2012.

He was instrumental in the development of PAIN (Pharmacist Analgesia Interest Network) and is the immediate past chair of the United Kingdom Clinical Pharmacy Association (UKCPA) Pain Management Group.

Roger is a Faculty Fellow of the RPS. He represents the RPS on pain management issues in both online and traditional media, including regular comment for BBC Regional Radio. He describes himself as having a good face for radio. He is a past chair of the UKCPA Pain Management Group. In 2016, he was the first non-medic elected as a Fellow of the Faculty of Pain Medicine of the Royal College of Anaesthetists in 2016.

He teaches a wide variety of disciplines and his main research interest relates to the appropriate use of analgesic medicines and associated clinical outcomes and healthcare utilisation. One of his early studies investigated the prescribing and clinical outcomes in primary care after opioid recommendation for chronic non-cancer pain from a pain clinic. This work won the UKCPA Napp Pain Award in 2005. Other topics have included topical lidocaine, the effectiveness of acupuncture and intramuscular stimulation for persistent pain, patient evaluation of services for chronic pain and oral analgesic prescribing after major surgery.

More recently, he has been studying trends in regional opioid prescribing for persistent non-malignant pain and has run opioid management clinics. Roger has been instrumental in developing a large number of educational resources including but not limited to editing and authoring modules for the FPM e-pain resource, Opioid 10 e-learning modules, FPM patient information leaflets, Opioids Aware resources and has also co-edited a number of books and is most importantly my co-editor of the *British Journal of Pain*. He has recently been appointed to the Home Office Advisory Council on the Misuse of Drugs and has been working on the cannabis medicinal products working group.

Citation for Prof Roger Knaggs for the award of Honorary Membership of the British Pain Society, 2019

On the international front, he was a task force member on developing the IASP curriculum on pain for pharmacy and has been a regular contributor to workshops on opioids both for the BPS and IASP as well as contributing to EFIC.

Roger is always keen to stress that medicines are just one part of supporting with patients with persistent pain.

You need to be able to have a conversation with a patient about their mood, their sleep and other issues that we might not delve into on a regular basis. I see a lot of my role is about putting medicines into perspective. It's about getting the patients to think about what impact that pain is having and taking time to work with them in terms of what they would actually want to achieve.

One might say he supports the biopsychosocial model of pain management.

How and when his wife Kate manages to schedule time to spend with him is a mystery as he always seems to be on a train somewhere in the United Kingdom coming from or going to a meeting. He is an avid walker (at altitude) and can be found walking in Switzerland or Austria while on his rare holidays. In addition to singing with the Nottingham Harmonic Society, Roger is a keen reader of autobiographies.

Considering his major contribution to the pharmacology of opioids, being a champion for the safe use of medicines and the management of adult persistent pain, in addition to his major contribution to this Society, Roger Knaggs is richly deserving Honorary Membership of the BPS.

The pain of death: when suicide occurs in doctors and other health care professionals

Clare Gerada *Medical Director, Practitioner Health Programme*



Introduction

Doctors have higher rates of suicide compared to the general population, especially so among female doctors. Death through suicide leaves those who are bereaved especially isolated. The author runs a service for those bereaved following the death through suicide or sudden accidental death of a doctor. This group has grown as increasing numbers of friends, relatives and colleagues ask for support to help them overcome the pain of death.

This article will discuss the issue of doctors and mental illness, suicide and the special problems faced by the bereaved.

Doctors and mental illness

Across the world, whether in a publicly or privately funded health system, whatever age, level of seniority or stage of training, doctors have high rates of mental illness, especially depression, anxiety and post-traumatic stress disorder.^{1,2} They also have higher rates of suicide compared to the general population. The suicide rate for doctors has been variably estimated at between 2 to 5 times the rate of the general population.^{3,4} In a systematic review, Lindeman et al.⁵ estimated physicians' relative suicide risk at 1.1 to 3.4 for men and 2.5 to 5.7 for women compared with those for the general population and at 1.5 to 3.8 for men and 3.7 to 4.5 for women compared with those for other professionals. An Australian survey found that approximately a quarter of doctors reported having had thoughts of suicide prior to the last 12 months (24.8%) and 10.4% having had thoughts of suicide in the previous 12 months. Thoughts of suicide are significantly higher

in doctors compared to the general population and to other professionals (24.8% vs 13.3% vs 12.8%).⁶

The reasons why doctors have high rates of mental illness and suicide are complex.

Of course, a medical degree does not exempt a doctor from developing a mental illness. In fact, in many ways, it increases it. Doctors are chosen for personality traits which predict good doctoring. They are perfectionist, obsessional and have martyrdom traits. But in times of stress, these traits increase the risk of mental illness, leaving doctors feeling guilty for issues beyond their control, blaming themselves rather than the system for failures in care. Working so close to death, despair and disability also increases the risk of mental illness, especially if the doctor lacks a confidential space to discuss the emotional impact of their work. Access to, and the means to know how to use, dangerous drugs adds to the risk of addiction and contributes to the high rate of suicide through poisoning found among doctors. Finally, complaints and the process which follows are often the root cause of a doctor who has killed him or herself. Despite having high rates of mental illness, doctors have poor access to care. There are organisational barriers – for example, frequent changes of address due to training rotations means it is difficult to register with or sustain a relationship with a general practitioner or have care from a psychiatrist. Fear that one's career might suffer if a doctor discloses a mental illness also acts as a powerful barrier to seeking timely help. The shame of disclosure of a mental illness – of having in some way 'let the side down' (usually meaning the professional norms of not becoming unwell) – means doctors would rather suffer in silence than disclose their mental illness or addiction. Sadly, shame can push doctors over the edge to suicide.

Practitioner Health Programme

The Practitioner Health Programme (PHP) is a confidential service for doctors and dentists with mental health and addiction problems and was set up to address the many

The pain of death: when suicide occurs in doctors and other health care professionals

barriers doctors face in seeking appropriate help. The service was established in 2008, and by 2019, nearly 8,000 doctors and dentists have presented for care. Around 80% of these health professionals have mental health problems – most often depression, anxiety or symptoms indistinguishable from post-traumatic stress disorder. The remaining 20% are those with addiction problems (alcohol accounts for the majority), bipolar disorder or complex comorbidities. All specialties have presented, though general practitioners, psychiatrists and paediatricians are over-represented and surgeons under. Suicide is at the heart of the service. Funding for the service was established following an Inquiry into the deaths of Daksha Emson and her 3-month-old baby in what was termed a ‘double suicide’. Daksha was a talented young psychiatrist, who had throughout her life suffered from severe bipolar disorder. Following the birth of her first child, Freya, she developed a relapse. The severity of her relapse went unnoticed by the array of health professionals who were caring for her – the subsequent Inquiry did not set out to blame a single person, but the system which treated Daksha differently from other patients, only because she was a doctor. The recommendations of the Inquiry into the deaths of Daksha and Freya highlighted the barriers to care which doctors face, due to personal, professional and institutional stigma, and led a decade later to the establishment of PHP.

PHP and death through suicide

The vast majority of patients who attend PHP show significant improvements in their mental health, return to work or training and social functioning, and if addicts, achieve high rates of abstinence. Many doctors, when followed-up as part of an independent study, attributed to PHP not just saving their careers, but also their lives.⁷ However, over the years, despite our care, sadly patients of PHP have taken their own lives. Although small in number, each death bears heavily on our service as we take responsibility for any failings on our part which might have contributed to their deaths. We mourn their deaths and take time out, as a group of clinicians and administrators, to talk about our contact with the deceased and their impact on their own patients. We record their deaths in a Memorial Album, held at PHP. Coming together has helped us to make sense of their deaths and, where needed, to learn from them. We also invite relatives to meet us to join us in the process of learning.

The bereaved

While suicide among doctors is higher than an age-matched group (and higher still in female doctors),^{8,9} it is still a rare occurrence and as such those left behind often feel isolated, stigmatised and alone. Bereavement following suicide is a

lonely experience, and the grief following a suicide is complex. When death occurs, there is always the familiar constellation of feelings: denial, angry protest, searching, despair and recovery leading to the establishment of new attachments seen following any death.¹⁰ However, when death is due to suicide, this is complicated by the additional dimension of stigma and shame. Sufferers experience what Feigelman et al.¹¹ have called the ‘wall of silence’ – the absence of caring or interest, or conversely an unwelcome array of unhelpful and awkward advice given by well-meaning friends or colleagues. Relatives of the dead become wary of talking about their loss, unsure of the reaction of those being told and paradoxically steering clear of the mention of suicide when talking to others to avoid creating undue distress in those being told. This is more so where the individual who has killed themselves is from a community such as medicine, where it is so counter to expectations. No one expects a healer to kill him or herself; this is at dissonance to the archetype of the powerful healer, and by some is seen as a betrayal to professional values.

Suicide, more so than death through other causes, also leaves the bereaved with feelings of self-denigration, blame and self-recrimination – often articulated by sentences which begin ‘what if ...?’. There is the further dimension if the bereaved are also health professionals, with the question often asked that given medical/nursing training why they could not have spotted the distress/depression or worsening addiction and done something about it before it was too late?

I blame myself, for not going into that room earlier. I blame his daughters for not encouraging him to get more help when I was pleading with them. I blame his family for not asking him how he was doing when he was feeling so low, and for not visiting him when they were less than an hour away. I blame his doctor for not calling in his refill for medication ‘because he needs to be seen first’ and I blame his therapist for not including me in his treatment, to make me aware of this possibility and giving me ways to help him in his depression. And, I blame society for placing such a negative stigma on mental health that those who are affected have to carry the burden alone for fear of judgment. So many to blame, but really. It won’t change anything. The end is still the same. (This extract is from an online self-help group – Blame and Suicide¹²)

The taint of shame and stigma so often at the root cause of suicide is therefore transmitted to those surviving relatives – especially where both the dead and the bereaved are health professionals. Shame hides in dark places and, if not spoken about, feelings fester and guilt grows. There can be no true sympathy without sharing, but there are few places where the bereaved following the suicide of a doctor can find true

The pain of death: when suicide occurs in doctors and other health care professionals

compassion, and the bereaved fear being judged – which sadly is commonplace. Where the bereaved try to get help from support groups, they find they receive mixed responses from other group members. Doctors (in particular general practitioners and psychiatrists) are often blamed by Inquiries and Inquests for the suicide of patients, and this blame can be transmitted to those attending support groups for those bereaved following suicide, vicariously being held responsible for the 'health system' who had failed their relatives.

Those bereaved following the death of a health professional more often than not work within the same health system as their dead friend/colleague/relative and this complicates an already difficult grieving process. All parties (the dead and the survivors) might have a personal as well as a professional relationship with local services, and this makes it difficult to untangle where responsibility might lie if the lead clinician is also a personal friend or close colleague.

The bereavement group

To help with the process of mourning, PHP has established a support group for those bereaved following suicide or sudden accidental death of a doctor, nurse, dentist or medical student. The group has been running for a year. It meets every 2 months. The groups are held in grand medical establishments – the British Medical Association, The Royal Society of Medicine and Royal College of General Practitioners have been recent venues. It seems fitting that the group does meet in such places – as a homage to the recent dead, reinforced by the presence of the long since dead represented by portraits, plaques and works of art scattered around each room. It feels as if the doyens of the past are looking benevolently on the grieving below.

The group membership is open to any friend, family or colleague who has been bereaved, whether or not a previous patient of PHP. Members include those who are recently bereaved (one member attended only 3 days after her partner died) or those bereaved many years before. One attendee, for example, came to talk about her father who had died many years ago, but never disclosed before. The group is advertised through word of mouth, via PHP communications and other doctor-support group networks and via social media. There is no requirement to come for more than one event (though members are welcome to come repeatedly). The requirements are that once the decision is made to attend, that the member comes on time and stays for the full duration. I try and meet all new members to explain the group process, understand a little about their own personal circumstances and to ensure that I am alert to any issues that might be important for the working of the group. There is no charge to attendees – costs are born

by PHP. Around 20 individuals come at each time – with a fairly cohesive core group. Among those attending are mothers, fathers, siblings, colleagues, children and friends of the deceased. Ages range from early 20 years to middle 70 years. Although not a therapy group per se, it nevertheless follows therapeutic lines. It is facilitated by me (C.G.) and an experienced group analyst. The members and facilitators sit in a circle. After introductions, any dialogue is open and free association is encouraged. Two 90-minute facilitated groups are run, with space before, during and after for informal networking. Refreshments are an essential part – and I make sure these are provided and that the meeting ends with lunch.

The bereavement group allows for 'healthy' mourning and a space where the wall of silence can be broken and where denial and inconsolable preoccupation with the lost loved one can be transformed into dialogue which helps the grieving process. The supportive environment, alongside friends, family, belief system, social group, work network or therapist, can ease the passage from grief to recovery.

The group allows authenticity in grief. What is spoken at each group varies, but is invariably along the themes of loss, mourning and recovery.

Creative outcomes following bereavement

The generosity and creativity of those who have been bereaved is humbling. Group members reach out to each other and to others who ask, offer support and advice. The bereaved have established charities to prevent suicide, fundraised for other charities, established virtual and real support systems for junior doctors and given talks, written articles and attended workshops and conferences. Giving to others helps in the healing process.

Preventing suicide

In the absence of any national initiatives, PHP has been working with senior policy makers, health professionals, trade unions and the bereaved to help put in place systems and practices to prevent suicide among health professionals. This means addressing the causes of distress – for example, the complaints process, the burden of regulation and inspection and the need to create spaces where doctors and health professionals can come together to talk about their work. Without these changes, the numbers taking their own life will continue to grow and, sadly, the need for groups such as the one run by PHP will become even more necessary.

Acknowledgements

For details of the PHP/Bereavement, visit <https://php.nhs.uk/>.

The pain of death: when suicide occurs in doctors and other health care professionals

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Why sleep matters to pain research

Katie Whale *Research Fellow, NIHR Bristol Biomedical Research Centre, University Hospitals Bristol NHS Foundation Trust and University of Bristol*

Rachael Gooberman-Hill *Professor, NIHR Bristol Biomedical Research Centre, University Hospitals Bristol NHS Foundation Trust and University of Bristol*



Credit: George Peters.

Sleep and health

We are in the midst of a sleep crisis. Our current work and lifestyle environments are normalising poor sleep with substantial negative impacts on our health. In recent years, surviving on minimal sleep has often been seen as something to be proud of or even touted as a badge of honour. Famous figures such as Margaret Thatcher, who purportedly only slept a few hours a night, are seen as role models for productivity and efficiency; never mind the impact this lifestyle may have had on their health. Paying attention to one's sleep routine or going to bed early is viewed as a defiant act of 'self-care'. Sleeping 8 or 9 hours a night is not viewed as a positive health behaviour or mandatory for the body and brain to function but is frequently stigmatised as laziness or indulgence.

Research on sleep has linked sleep deprivation to poorer mental health,¹ obesity,^{2,3} cancer,^{4,5} diabetes,⁶ heart disease,⁷ and a myriad of other health conditions. In the United Kingdom,

an estimated £40 billion is lost in revenue due to sleep deprivation each year.⁸ Our poor relationship with sleep and disregard for its importance is now not only affecting our individual health but is having a substantial impact on our economy.

Growing recognition of the importance of sleep and its health benefits has led to a boom in the commercial sleep industry. Barely a week goes past without seeing a new advert for the latest mattress in a box which guarantees idyllic uninterrupted restful hours, a new smartphone app promising to enable a peaceful repose, pillow sprays, supplements, weighted blankets,⁹ even robots to teach breathing techniques;¹⁰ the list goes on. There are more sleep products than ever before, and people are buying in. A 2017 McKinsey report estimated the sleep-health industry to be worth between \$30 and \$40 billion, with a yearly growth rate of 8%.¹¹

Sleep and pain

Most of us know that sleep is good for us, and many of us want to have more of it, but why should research into chronic pain pay particular attention? The issue is that sleep deprivation and interrupted sleep are substantial problems for people who live with chronic pain (pain that lasts or recurs for more than 3 months). Between 67% and 88% of individuals with chronic pain experience sleep disruption and insomnia,^{12,13} and at least 50% of people with insomnia report chronic pain.¹⁴ Hence, there is known to be a relationship between sleep and pain. Experimental, cohort and longitudinal studies have all demonstrated that restricted sleep is linked to greater pain. Poor sleep therefore not only affects general health but has a direct impact on pain response and experience. Thus, improving sleep in people living with chronic pain has the potential to deliver great benefit to many.

The evidence base

Experimental studies focusing on short-term sleep restriction and acute pain have consistently reported that sleep deprivation in healthy subjects, in particular slow wave sleep restriction, is associated with increased acute algogenic responses to nociceptive stimuli.^{12,15} However, experimental

studies have been criticised for their lack of generalisability to people with chronic pain. Experimental methods often enforce temporary sleep restriction to reduce total sleep time by either keeping participants awake longer before sleep or waking them early, and acute pain tests, such as pressure, heat or ice. These methods do not necessarily evoke the experiences of disturbed sleep of people living with pain, which include multi-nocturnal waking. Some studies have partially addressed this by using 'forced awakening' techniques. These forcibly awaken participants multiple times per night to mirror the sleep patterns more commonly experienced by people with pain. Smith and colleagues conducted a study in which otherwise healthy women were awakened at 8 intervals during the night over an 8 hour sleep period. This restricted their total sleep time to 280 minutes (just over 4.5 hours). Compared with a restricted sleep group (same total sleep time but uninterrupted) and a control group who slept for 8 hours, forced awakening resulted in greater next-day spontaneous pain reports and reduced conditioned pain modulation.¹⁶

Prospective longitudinal studies focusing on the effect of sleep on future pain have reported similar results. Studies in people who experience headaches and migraines have shown that elevated insomnia symptoms increase the risk of exacerbating existing headache and in developing new headache symptoms at long-term follow-up ranging from 1 to 12 years.^{17–19} A population-based study in Norway found that insomnia symptoms at baseline significantly increased the risk of developing chronic musculoskeletal pain at 17-year follow-up.²⁰ Cohort studies in women undergoing caesarean have found that pre-operative sleep quality is associated with more severe pain when moving and increased analgesic intake following surgery.²¹ In addition, a history of sleep disturbance prior to injury in burns patients has been shown to be correlated with greater pain during the night, pain in the morning and pain during debridement procedures.²²

In addition to the negative impact on physical pain symptoms, reduced sleep has detrimental effects on psychological wellbeing and coping. Experimental work has shown that reduced sleep over a period of 12 days reduces optimism, sociability and psychosocial functioning, in particular at the beginning and end of the day.²³ Poor sleep also has clear links with depression and pain catastrophising, both of which have established associations with pain coping and contribute to an increased pain experience.^{24–26}

A reciprocal relationship between sleep and pain

The dominant view of the relationship between sleep and pain is that they are reciprocally related, that is, reduced sleep increases pain and increased pain reduces sleep. However, studies exploring the reciprocal, bidirectional relationship

between sleep and pain suggest that there is temporal precedence for sleep over pain. Studies of adolescents with a range of chronic pain complaints have found that total sleep time and wake after sleep onset were associated with next-day pain reports. However, pain was not prospectively associated with any sleep measure within the study.²⁷ In contrast, a prospective UK-based study and a longitudinal Norway-based study both found that widespread chronic pain predicted the incidence of disturbed sleep and insomnia over a 3-year period.^{28,29} These findings show that while the evidence for pain disrupting sleep is less clear-cut than the evidence for poor sleep increasing pain, there is still a case for a bidirectional relationship, albeit a potentially unbalanced one.

A possible reason for the conflicting findings about the reciprocal relationship between pain and sleep is the variation in pain pathways and treatment for nociceptive pain and neuropathic pain. Nociceptive pain is caused by actual or potential damage to tissues, such as a cut, burn or damage to joints such as osteoarthritis.³⁰ Neuropathic pain is caused by changes or damage to the nerves themselves and affects the way that pain signals are sent back to the brain.³⁰ Neuropathic pain can result from prolonged nociceptive pain, such as chronic pain conditions or a result of damage during surgical procedures such as joint replacement. Chronic pain is commonly treated with traditional painkillers and anti-inflammatory medications;³¹ these medications lessen the nociceptive pain experience but have little impact on neuropathic pain symptoms.

A recent study exploring the bidirectional relationship between pain and sleep in joint replacement patients found that neuropathic pain symptoms were a stronger predictor of sleep disturbance than nociceptive joint pain. Predictive analysis of pain and sleep demonstrated that the impact of joint pain on sleep was moderated by medication use, but neuropathic pain scores were associated with the development of sleep disturbance even after adjustment for joint pain.³² These data suggest that for individuals who experience nociceptive pain only, medications used to treat this are likely to mediate the impact that their pain has on their sleep. However, for individuals who experience both nociceptive and neuropathic pain, such as some chronic pain populations, these medications will only mediate for one of these pain responses. These findings demonstrate that there is a strong likelihood of sleep disturbance due to neuropathic pain.

Interventions to improve sleep

Findings from research to date highlight why interventions to improve sleep could be of such great benefit to people with pain. Although there are many medicines that can help with management of nociceptive pain – such as pain relief and anti-inflammatory medicines and steroids – neuropathic pain is harder

Why sleep matters to pain research

to manage with medication. Medicines for neuropathic pain include antidepressants and anticonvulsants, both of which can come with unwelcome side effects, and opioids about which there are growing concerns. Sleep interventions offer a complementary approach by targeting the other side of the relationship: improving sleep to decrease pain, rather than focusing on the pain symptoms as the first target for management.

Current treatment approaches for insomnia may offer a starting point. Alternative interventions to pharmacotherapy such as psychological interventions, complementary therapies, social and physical activity and sleep aids are gaining increasing traction as a cost-effective sustainable approach. The most common of these is cognitive behavioural therapy for insomnia (CBT-I) which has been shown to be equally effective or even superior to pharmacotherapy.³³ CBT-I can be done on an individual basis or in a group and is applied through a course of sessions commonly consisting of psychoeducation and sleep hygiene information, sleep restriction, relaxation, stimulus control and cognitive therapy. The evidence for the effectiveness of CBT-I for improving sleep for people with chronic pain is promising.³⁴ CBT has been shown to be effective in the treatment of back pain, in particular for reduced fear of movement and pain and improved pain management.³⁵ A recent systematic review and meta-analysis of sleep interventions in patients with osteoarthritis and spinal pain also found CBT to be of the most effective interventions for improving sleep.³⁶

Despite increasing knowledge, the development and application of sleep interventions for improving chronic pain still has some way to go. Given the evidence base for the link between sleep and pain, it might be tempting to move straight to implementation. However, one of the driving forces behind the sheer range of commercial sleep products is that the multiple dimensions of sleep and variation in individual sleep problems means that there is no 'one size fits all' approach for improving sleep. In order to be effective, robust intervention development must first explore the factors that are associated with poor sleep and identify which of those have the greatest scope for change, within particular patient populations.³⁷ There are a number of different chronic pain populations, including people experiencing back pain, migraine, fibromyalgia, arthritis, sickle cell disease, chronic post-surgical pain and multiple sclerosis, all of which come with different profiles of pain and sleep experience. It is crucial that we understand the specific issues affecting each group in order to develop targeted interventions tailored to patients' needs. Targeted and carefully designed interventions have a better chance of patient acceptability, engagement and effectiveness. Researchers can work together to conduct robust studies that include multiple approaches, such as qualitative work, wearable sleep monitors, and sleep diaries, in order to identify the key issues that affect sleep and pain.

Conclusion

Given the strong relationship between sleep and pain, it is evident that poor sleep, and in particular multi-nocturnal waking, makes pain worse. Moreover, chronic pain populations commonly experience poor sleep and that chronic pain in turn can disrupt sleep. The message is clear: people with chronic pain would benefit from better sleep. This provides an exciting and potentially impactful avenue of exploration for developing health interventions that form part of multi-modal approaches to pain management. Sleep need no longer be a secondary factor to take note of or a symptom of pain disruption, but front and centre in pain research.

Funding

This study was supported by the NIHR Biomedical Research Centre at University Hospitals Bristol NHS Foundation Trust and the University of Bristol. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health and Social Care.

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Being mindful of mindfulness: part 1: the role of Vipassana in the history and evolution of modern mindfulness techniques

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Vipassana meditation was the basic meditation technique followed by Siddharth Gautama to achieve the state by which he was also better known as Buddha, the enlightened one.¹ Buddha then taught this meditation to others for 45 years before his death. The great Buddhist scholar T. W. Rhys Davids possibly coined the term of 'Mindfulness' more than a century back to describe a perfect awareness as taught in *Vipassana* meditation technique in Eastern traditions.²

A few centuries after Buddha passed away, the technique of *Vipassana* became adulterated due to various modifications in the teaching practices by later teachers. There are various traditions which have emerged after the pure form of *Vipassana* was completely lost from its homeland, India. The modifications to the *Vipassana* have continued until recently, giving rise to quite a few techniques of meditation based on *Vipassana*. However, the Buddha's meditation reached the West through various gurus and scholars on Buddhist studies such as Sangharakshita and Dr Jon Kabat-Zinn.

Dr Jon Kabat-Zinn,³ the pioneer of the Western mindfulness meditation technique, developed his mindfulness-based stress reduction (MBSR) programme based on ancient *Vipassana*. In fact, it is said that the idea to develop the MBSR programme came to his mind while practising meditation. MBSR practices are not strictly *Vipassana* but a combination of techniques such as imagination, breathing exercises and body movements mixed with the 'staying aware' part from the original teachings. MBSR is the most investigated way of mindfulness in modern medicine. There is now good evidence for this approach in various medical, psychological and chronic pain conditions.

Sangharakshita learnt Buddhism and meditation practices for 20 years from the 1940s to the 1960s. He served in the British Indian Army in India and Sri Lanka in the 1940s. He then gave up everything and wandered in search of knowledge and peace in the Indian subcontinent. On his return from India he founded the Friends of the Western Buddhist Order (FWBO, now known as the Triratna Buddhist Community) in 1967. FWBO teaches

mindfulness-based approaches (MBAs) to help participants with stress and psychological disorders. FWBO mindfulness techniques are a combination of different methods of concentration and movements with element of 'being aware'.⁴

Modern mindfulness taught in the West involves a combination of specific movements with awareness, imaginations and visualisations and observation of body sensations – both natural and created. The majority of them also involve mindfulness of abstract thoughts, actual or imaginary colours and sounds.

The word *Vipassana* in the Pali language means to experience, as it is without any reaction towards the experience. Pali was the spoken language of Northern India during the time of Buddha. (The word *Vi-* in a specific way, *passana-* to experience as it is). Interestingly, Buddha was not the first person to invent this technique. The oldest Indian texts known as *Vedas* (4000 B.C.) have mentioned *Vipassana*. *Rigveda* is the oldest of the *Vedas* and has many references about *Vipassana*.⁵

Many intellectuals have called Buddha the greatest psychologist who ever existed on earth and his teachings as the best written material on human psychology.^{6,7} His teachings, discourses and explanations were collected in three big volumes called the *Tripithaka* (three basketfuls of books). A great Indian King, *Ashoka*, who united India around 200 B.C., was instrumental in spreading the knowledge of the *Tripithaka* and practice of *Vipassana* to the neighbouring countries. One of the neighbouring countries, *Suvarnabhumi*, now known as Myanmar (Burma) maintained the practice and theory together through a chain of teachers through the generations.⁸ The latest teachers in this chain were The Venerable Ledi Sayadaw (1846–1923), Saya Thetgyi (1873–1945) and Sayagyi U Ba Khin (1899–1971). Sayagyi U Ba Khin was a renowned *Vipassana* teacher and the first to teach Westerners in English. It was under his leadership that the International Meditation Centre opened in Yangon in 1952 and started teaching *Vipassana* to the general population.

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Vipassana was reintroduced to India and to the world by S. N. Goenka (1924–2013). He was an industrialist of Indian heritage who was born and lived in Myanmar. S. N. Goenka was instrumental in establishing the first *Vipassana* centre in India, the Vipassana International Academy (VIA), at *Dhammagiri*, Igatpuri in 1970s. *Dhammagiri* revealed *Vipassana* to the whole world. The *Vipassana* meditation centre in Herefordshire in England is known as *Dhamma Dipa*. In 2016, *Dhamma Dipa* celebrated its 25th anniversary. It offers short (10 days) and long courses (up to 60 days). It is one of many centres around the world dedicated exclusively to the teaching of Vipassana meditation.

What is Vipassana?

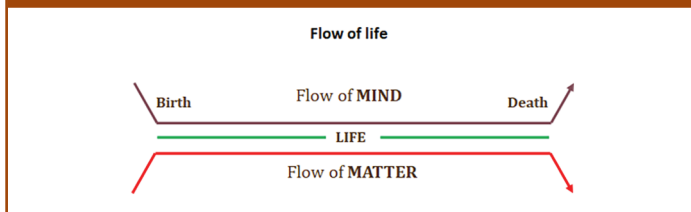
According to the Eastern teachings, any form of life is only possible through the union of matter with the mental flow. This union is called *yoga*, which in fact has no connection with the *yoga* exercises we practise in modern days. The ancient

meditation gurus including the Buddha advocated working at the level where mind unites with body (*yoga*) to achieve the state of balance (equanimity) and realise truth pertaining to self.⁹ The process of this self-realisation ultimately leads to experience of the truth related to existence of life and the truth beyond mind and matter, the state termed as liberation or enlightenment.

Buddha in his discourse *Mahasatipatthana sutta* attributes the misery and suffering to mental reactions.⁸ These reactions could be in response to internal or external stimuli. It is impossible even for monks to isolate themselves from all the worldly stimulations. The internal body stimuli in the form of various biochemical processes, thoughts, feelings and ideas are present all the time with the individual.

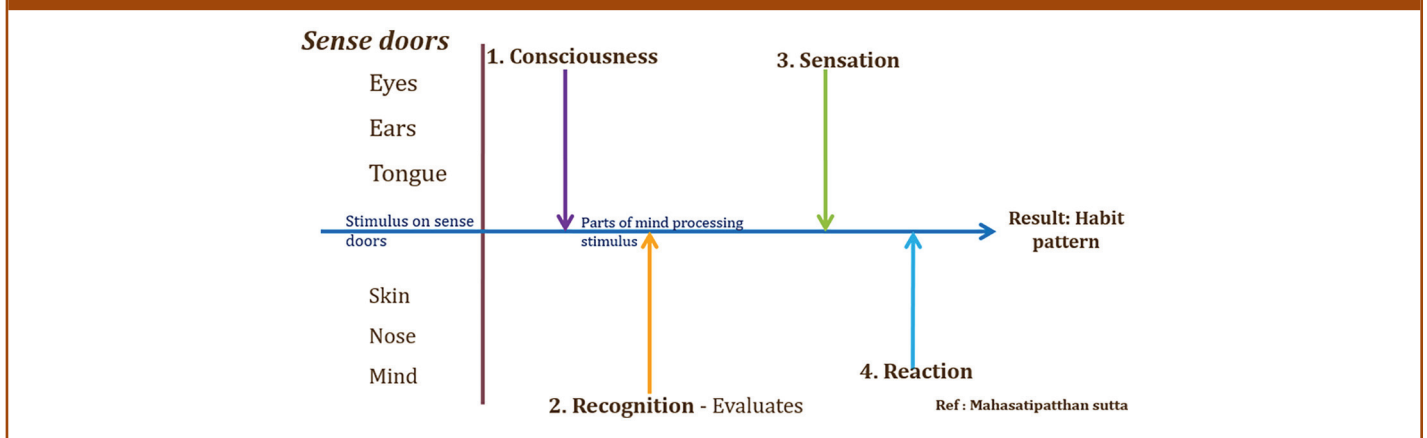
According to the teachings of Buddha, the mind consists of four different parts.¹⁰ The first part of the mind detects any stimulus arising in relation to body (consciousness). The second part recognises the stimulus and gives judgement (recognition). The third part of the mind creates sensations all over the body in response to the judgement made by the second part. The sensations produced could be pleasant or unpleasant based on this judgement. The fourth part of the mind is responsible for producing reaction to these sensations. The pleasant sensations will cause reaction of craving, whereas unpleasant ones will cause aversion. These reactions result in development of 'habit patterns' of the mind. These habit patterns were described as 'defilements' in ancient Pali literature. The intensity, frequency and duration of mental reactions will decide the patterns of the defilements. The stronger mental reactions will produce deeper defilements which will cause more distress and suffering.

Figure 1. Flow of life



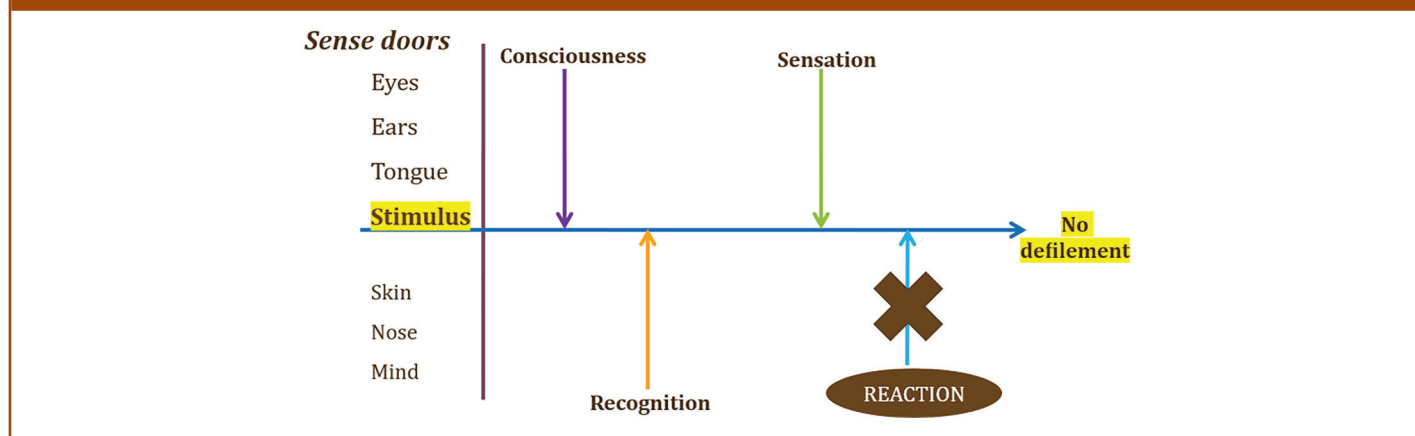
Life exists if the flow of the mind is in union with the matter. At birth, mental flow unites the matter and at death, they separate.

Figure 2. Processing of a stimulus by mind



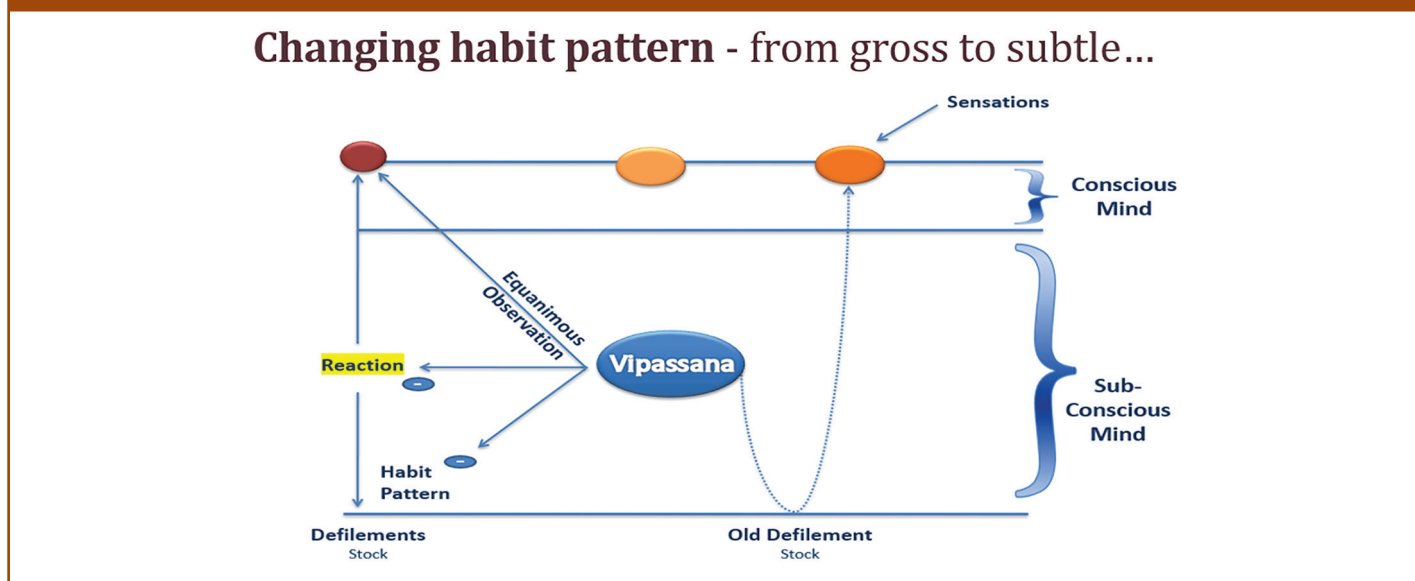
Any stimulus arising at any of the six sense doors ultimately produces sensations in the body. Every stimulus must face four different parts of the mind: consciousness, recognising, sensation forming and reacting parts of the mind.

Figure 3. Stopping mental reactions (Equanimity)



All four processes take place simultaneously. Every stimulus will produce sensations. The only part of the mind which we can control is 'giving reaction' to stimulus. When one learns to stop reactions, one stays equanimous.

Figure 4. Mechanism of *Vipassana*: No new defilements, getting rid of old ones



The three coloured oval shapes represent body sensations. The mind is in constant touch with the sensations and keeps reacting 24/7. The reactions of the mind produce habit patterns (defilements). When one learns 'not to' react to these sensations there are no further defilements produced. With continued practice pre-existing defilements pop-up on the surface of the mind and equanimous observation gets rid of them, making one feel peaceful and stress free.

According to Pali canon – सब्बे धम्ममा वेदना समोसरणं (*sabbe dhamma vedana samosaranang*) – every mental phenomenon is always accompanied by corresponding sensations on the body.¹¹ The sensations will come and go. The subject or meditator ideally

just observes these natural body sensations objectively inside the body 'as they are' with no mental reaction towards them. There is no imagination, no visualisation, no verbalisation, no artificial creation of sensations and there are no rituals.

Being mindful of mindfulness: part 1: the role of Vipassana in the history and evolution of modern mindfulness techniques

Vipassana meditation is nothing but observation of the natural truth of the mind and body at the level where the two interact with each other.

Of the four parts of mind, we are only able to control the fourth part which controls the reactions in response to the sensations. The other three parts, that is, consciousness, recognition and sensation forming parts are not under our conscious (effortful) control. These parts will work naturally and will lead to generation of sensations in response to every stimulus received through six sense doors.

To be able to observe the body sensations without being judgemental (a so-called 'equanimous mind') achieves a very important goal. This stops the mind from supporting habit formation. There are no more defilements produced through mental reactions. The mind which stays equanimous in the presence of a stimulus is the most peaceful and relaxed mind. This mental training helps the meditator to stay balanced in the presence of both pleasant or unpleasant life events such as disease, pain, stress or psychological distress.

As the *Vipassana* meditator progresses on the path, deep-seated defilements raise their heads.¹² Each such defilement produces sensations in the body while meditating. This is a well-known phenomenon in psychology. When patients with significant unresolved psychological trauma are being treated, they may present with a lot of emotional turmoil. This is thought to be nothing but the old defilements from the deep subconscious mind surfacing when one undergoes certain therapies. These may present as very uncomfortable bodily sensations. If the meditator continues simply to observe these sensations objectively, they naturally fade away. This process is explained in the accompanying diagram. This is how *Vipassana* helps the practitioner to get rid of reactionary habits and instead makes one feel happy and peaceful.

With continued practice, one can clear the whole stock of defilements. *खिन्नं पुराणं नवं नथी संभवं (khinang puranang, navan natthi sambhavang)* – old defilements are eradicated and new ones are not generated.¹² This is the stage of enlightenment, the Buddhahood. Practically, for a common man, *Vipassana* helps to achieve peace, happiness and harmony – both inside and outside.

In summary, *Vipassana* is an art of equanimous observation of our own natural truth. Every physical or mental process in our body presents in the form of body sensations constantly arising and passing away. Observing these sensations with objectivity trains the mind on one hand and gets rid of reacting habits on the other hand. *Vipassana* meditation as described in ancient texts consists of a three-stage meditative practice. The first stage begins with the concentration of the mind through observation of a natural unmodified breath. This breath meditation was called as *anapanasati*.¹³ After experience of *anapanasati*, the meditator learns to observe the natural body sensations with a balanced mind (*Vipassana*). This is the basis of every mindfulness meditation technique being practised today. The third stage involves practicing *Metta* (compassion/ loving kindness) meditation. Details of the free *Vipassana* courses in the United Kingdom can be found on – www.dipa.dhamma.org.

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Treatment of discogenic back pain and sciatica in daily practice: report of 100 sequential cases of interventional spinal pain treatment with DISC-FX

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Introduction

Back pain due to internal disruption of the intervertebral disc may be common, with estimates between 26% and 42%.^{1–3} In a series of consecutive cases referred specifically for further diagnostic assessment at two American specialist centres,¹ 39% were positive to provocation discography. Higher prevalence estimates of discogenic pain may therefore reflect a degree of selection in referral and may not reflect the prevalence of discogenic pain in more general practice. Discogenic pain may result from a variety of potentially overlapping pathologies affecting both the annulus and nucleus^{4–11} and including increased stress in the posterior annulus.¹²

To date, attempts to treat discogenic pain by addressing the annulus with radiofrequency (RF) heat denervation by the intradiscal electrothermal annuloplasty (IDET)^{13,14} or biacuplasty^{13,15} techniques have yielded variable results. Percutaneous decompression of the nucleus by coblation nucleoplasty is now approved in the UK by the National Institute for Clinical and Healthcare Excellence (NICE) for the treatment of back pain and of sciatica due to contained disc protrusion. It has been evaluated as a stand-alone technology (single technology appraisal)¹⁶ and as part of a comprehensive pathway of back pain management.¹⁷ These approvals validate the concept of discogenic pain and the possibility of treatment at least by removal of small volumes of disc nucleus.¹⁸ It may, however, be logical to target both annular and nuclear pain generators to obtain optimal results.

DISC-FX™ (Elliquence, NY) is a day case fluoroscopically controlled, three-step technique using a single 3mm access

cannula (see Figure 1). Step 1 allows disc nucleus decompression by mechanical nucleotomy employing fine pituitary graspers. Step 2 uses a specially designed steerable 'Trigger-Flex' RF catheter deploying a specialised waveform for RF ablation of the nucleus analogous to coblation but utilising higher frequency RF energy at 1.7 MHz (designated 'Turbo' mode). In the third step, the RF generator is adjusted to produce RF heating (designated 'Hemo' bipolar mode) and the Trigger-Flex catheter is then steered along the inner surface of the posterior annulus to denervate and modulate fissures.¹⁹ It is also referred to as microtubular decompression and nucleotomy or mini-micro discectomy.²⁰

This approach therefore aims to produce a definitive adjustment of pain-generating pathological disc tissue as a treatment principle for back pain. Favourable longer term outcomes have been reported with this technique, in up to 71 cases^{20,21} in Europe and Asia.

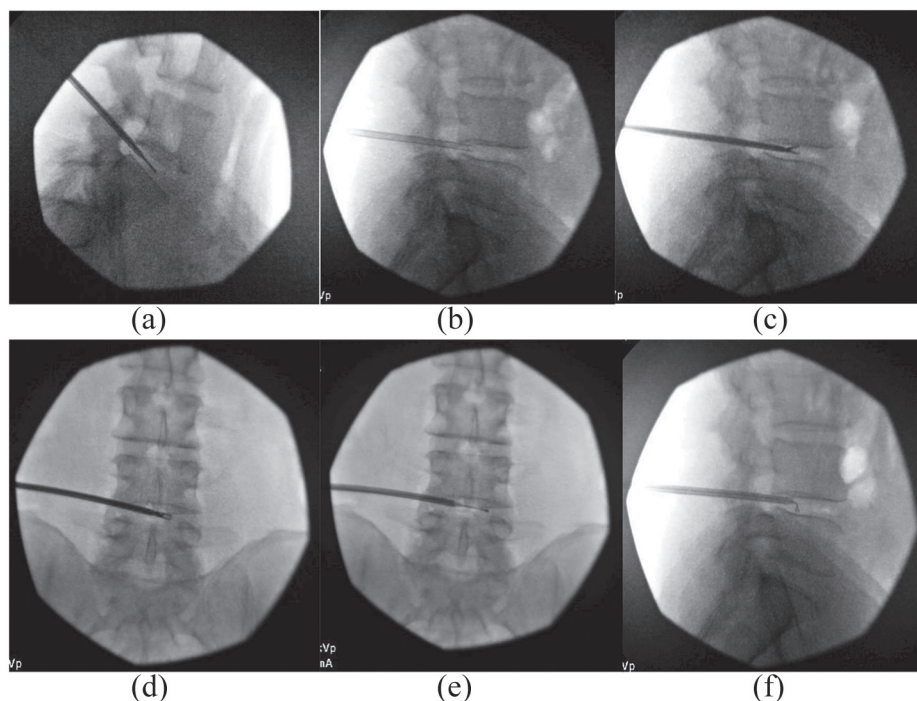
We report here the results of the diagnosis and treatment of discogenic pain by DISC-FX in 100 sequential, prospective cases of back pain and/or sciatica. Results reported here add to the available data on this treatment. These results may suggest that the treatment of spinal disc-related pain should be included in routine clinical interventional pathways.

Methods

Patient selection

Patients referred by general practitioner for spinal pain were seen by a single clinician (A.H.) at a small private clinic (Kings Hill Medical Centre, West Malling, Kent: KHMC) and then a

Figure 1. Steps in the DISC-FX treatment of L4/5. (a) Lateral view of introducer and guidewire in position across annulus into nucleus. (b) Lateral view of working channel in position to commence decompression (c) Lateral view of deployment of nucleotomy forceps. (d) PA view of nucleotomy forceps confirming central position in nucleus. (e) PA view of steerable 'Trigger-Flex' RF catheter deployed across central nucleus for ablation in 'Turbo' mode. (f) Lateral view of 'Trigger-Flex' catheter positioned across posterior annulus for heat denervation in 'Hemo' mode.



larger private hospital (KIMS Hospital, Maidstone, Kent). Approval for data collection was given by KHMC Medical Advisory Committee. Patients were both insured and self-funding; six National Health Service (NHS) cases were also included. Cases reported were treated between October 2011 and April 2017. The cases reported here are those who progressed to DISC-FX treatment under the progressive interventional pathway described below. Selection for DISC-FX treatment was informed but not restricted by recommended clinical and radiographic selection/exclusion criteria for DISC-FX, which include 50% retained disc height and moderate protrusion only. On this basis, the first 100 sequential cases in which DISC-FX was deployed are reported. These cases were drawn from a group of 114 patients. A further 14 patients who provided no or uninterpretable data were excluded. Data were collected in routine consultation and at the time of procedures. In consultation, patients completed pro forma result sheets prior to meeting with A.H. Data entry was independent of the clinician.

Treatment pathway

Treatment of peripheral pain generators

Potential discogenic pain generators were assessed clinically on the basis of history, examination, radiology and magnetic resonance imaging (MRI) scanning. Therefore, when necessary other possible pain generators were treated first, for example, peripheral multiple muscle trigger points and nerve root pain were treated by epidural or related injections, and medial branch pain and sacroiliac joint pain were treated by injection or RF denervation. Techniques were deployed according to Spine Intervention Society (SIS) technical standards,¹³ and best evidence or clinical practice was followed.

Discography

Only where prior techniques failed to resolve the patient's pain syndrome and where history, physical signs and or imaging suggested that axial pain may have discal origin, as assessed by A.H., pain provocation discography to SIS standards was undertaken including manometric measurement using the

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Arthrocare Disc Stimulation System in most cases. Discs were selected on the basis of clinical and radiographic suspicion and a control disc was included. The provenance of discography has been fully discussed previously.²²

Disc selection

Discography positive discs were treated by DISC-FX, either at the time of discography or as a second step. Ideal criteria for DISC-FX include 50% retained disc height and no or moderate, contained disc protrusion.¹⁹ However, in this series, strict disc morphological selection criteria were not applied and positive discs were treated if accessible and judged relevant. Up to four discs were treated in the same session. Occasional cases were encountered where multiple positive disc levels were diagnosed at discography but one of these was not accessible for DISC-FX, for example, being too narrow or the disc margin occluded by osteophytes. In this situation, DISC-FX was carried out at accessible levels and a palliative such as pulse RF at the non-accessible levels.^{23,24}

Disc-FX

Standard DISC-FX technique was employed.¹⁹ Briefly, the patient is placed prone, skin prepared and draped. Light continuous sedation and local anaesthetic is used for comfort and safety. Under continuous fluoroscopic imaging, a 16-g introducer needle is passed to and beyond the anterior face of the subjacent superior articular process into the target disc (Figure 1(a)). A skin-stab incision is made with a size 11 scalpel and sequentially, a guidewire, dilator and working channel and annulotomy catheter are deployed, the 3 mm diameter working channel left in position visualised across the depth of the annulus in anteroposterior (AP) view (roughly the diameter of the facet mass) and in the posterior third of the disc diameter in lateral projection (Figure 1(b)). The three-step procedure is then progressed with nucleotomy to remove approximately 1 cc of nucleus by pituitary forceps (Figure 1(c) and (d)) and then bipolar RF nucleus ablation by steerable 'Trigger-Flex' catheter using six passes in 'turbo' mode (Figure 1(e)). Finally, the Trigger-Flex is deployed across the posterior annulus in lateral than AP screening control (Figure 1(f)) and 'hemo bipolar' RF heating mode at up to 80°C deployed using three passes of 6 seconds in the upper, middle and lower portions of the annulus. This is intended to denervate the internal aspect of the annulus, to seal fissures and to contract the annulus. Up to 30% reduction in cadaveric annulus and concomitant 9% improvement in volume of epidural space have been noted (Elliquence, data on file). Intravenous antibiotics are given (cefuroxime 1.5 g or gentamicin 320 mg or ceftriaxone 2 g) and the disc irrigated during the procedure via an infusion port in the Trigger-Flex

catheter with 20 mL bupivacaine 0.25% containing 10 mg/mL cefuroxime (or equivalent) and dexamethasone 10 mg per disc to reduce post-procedure pain. Patients were discharged on day of treatment and recovered at home on reduced activity for 1 to 4 weeks. First follow-up in clinic was at week 4.

Outcome measures

Measures taken were area of pain on a 100-square body mannequin grid, visual analogue scale (VAS) average back and right or left leg pain, worst pain at any site, Oswestry Disability Index (DI), post-treatment VAS, global improvement (GI) and Likert-type scale. Measures were collected as part of routine practice from first consultation, before each procedure, including the day of DISC-FX, during follow-up and at discharge. Forms were filled in by patients in the waiting room, or on the ward for procedures. Results were abstracted and entered onto an Excel database by research nurse (C.O.) and student assistant (M.H.). Statistical analysis was by AcaStat Software. Patients were assisted where needed but not formally supervised or placed under duress to fill these in and hence at times some parts would be omitted. N numbers for individual data sets reported here therefore vary.

Follow-up

As this is an as-observed clinical practice report, there was therefore no opportunity to schedule long-term follow-up solely for the purpose of data collection. Patients were reviewed at week 4 post-procedure and monthly till mutually agreed discharge either following treatment success or failure. Usually, short follow-up therefore represents rapid, clinically adequate improvement. In this context, average follow-up was 4 months and median 3 months. Twenty-six patients were discharged at 1 month, 36 by 2 months and 52 by 3 months while 25 took longer than 6 months to conclude and the longest was 13 months. Patients were invited to return if problems recurred, and those who had failed treatment were referred on as appropriate or returned to family practitioners.

Results

Complications

No procedure complications or cases of discitis occurred. One patient was admitted to hospital overnight for pain control. Ten patients were referred onwards for surgical consideration post treatment, including five who experienced a re-protrusion and one with protrusion at a new level. Four patients have re-presented late, after initial successful discharge, for further management within the 6-year span of this report.

Table 1. Initial and final VAS for average and worst back and leg pain, area of pain, Oswestry DI, percentage global improvement (GI) and Wilcoxon Z scores for 100 sequential cases treated by a pragmatic sequential interventional strategy including percutaneous disc decompression by DISC-FX.

Variable	Mean		Percentage improvement	Wilcoxon (z)	p < value
	Initial	Final			
Average back pain	58.2	29.3	49.6	6.485	<0.0001
Worst back pain	74.7	39.9	46.6	6.254	<0.0001
Average leg pain	36.9	13.8	62.7	5.454	<0.0001
Worst leg pain	41.2	20.0	51.5	4.119	<0.0001
Area	11.3	5.2	52.8	6.479	<0.0001
Oswestry (pre/post)	40.1	27.1	32.5	5.235	<0.0001
Average % global improvement			57.4		

Patients and demographics

One hundred patients, 53 women and 47 men of average age 43.7 and 44.8 years, respectively (range 17–78), were treated. There were no gender differences in respect to variables studied (data not shown). With regard to number of discs, there were 39, 52, 8 and 1 instances of 1-, 2-, 3- and 4-level treatments (total 171 discs). While there were trends, there was no statistical relationship between age, duration of symptoms, number of discs treated, and patient's %GI achieved (data not shown). In clinical categories, 38 cases were back pain, 40 back and leg, 5 sciatica, 10 described as complex and 7 non-assigned. Patient %GIs were numerically similar in each group at 58.9%, 55.9%, 60.8% and 63.5%, respectively. Mean total duration of pain was 58.5 months, continuous pain 22.4 months. The maximum duration of spinal problems was 45 years and 19 had spinal pain for over 10 years.

VAS back and leg pain, area of pain, Oswestry DI and %GI

Mean initial and final VAS scores for average daily back and/or leg pain, worst experienced back or leg pain, area of pain, Oswestry DI and perceived global improvement (%GI) are shown in Table 1. All reduced in a statistically significant fashion and with numerical results at and above the conventional 50% clinically important pain relief level, and the average %GI reported by all patients was 57.4%.

Likert-type scale and quartiles of response

Categorical responses on a 5-point Likert-type scale (N=89) were as follows: Much worse 0 (0%), Worse 5 (5.6%), Same 22 (24.7%), Better 30 (33.7%) and Much Better 32 (36.0%). Accordingly, 69.7% of patients rated themselves Better or

Much Better. The %GIs consistent with each response were 0.2%, 15.2%, 64.7% and 86.8%, respectively. Percent GI responses were then divided for illustrative purposes into four quartiles to examine the spread and degree of benefit and to determine the proportion of patients achieving over 50% improvement as follows (N=97): 0%–24%, 23 (23.7%); 25%–49%, 8 (8.2%); 50%–74%, 24 (24.7%); and 75%–100%, 42 (43.3%). Accordingly, 66 (68%) patients crossed a notional 50% response hurdle and the average %GI achieved in each of these quartiles were 5.2%, 37.4%, 61.1% and 87.7% and for those over 50% was 77.7% (see Figure 2).

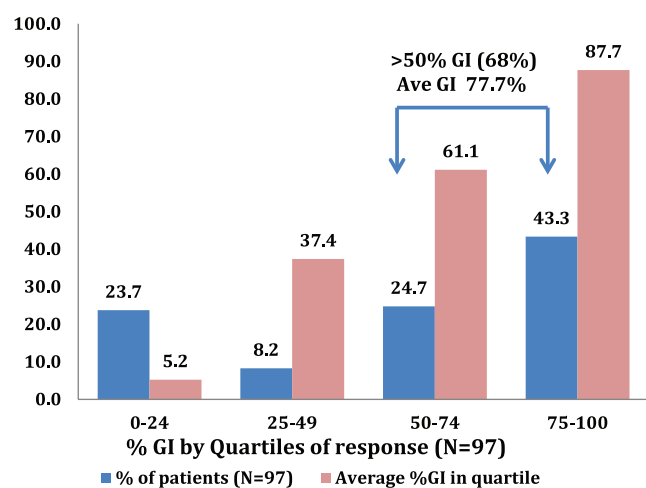
Exploration of interventional pathway

Patients were treated on a pragmatic pathway with interventions to reduce superficial pain generators prior to discography and DISC-FX. We therefore examined the relative contributions of the interventions delivered prior to DISC-FX. Thirty-seven patients had discography and DISC-FX only and no other procedure. Twenty-six had a procedure before DISC-FX, 16 after and 21 both pre and post. A total of 141 additional procedures were used throughout the study.

Among the patients who had procedures pre-DISC-FX, there exists the possibility that the prior interventions were responsible for the benefits seen. Forty-seven patients had procedures pre-DISC-FX (including those who also had procedures after) and 40 have available data, though some data sets are poorly completed (worst leg pain).

Changes seen from initial to pre-DISC-FX scores among those with prior procedures are 17.1%, –11.9%, 31.5%, –6.5%, –6.6% and 0.1% for area, average leg pain, worst leg pain, average back pain, worst back pain and Oswestry, respectively, whereas the same data in the step from pre-DISC-FX to final in the same group were 55.9%, 58.7%,

Figure 2. Percent global improvement (GI) divided into quartiles of response among 97 patients. Of these, 0–24%, 23 (23.7%); 25–49, 8 (8.2%); 50–74, 24 (24.7%); and 75–100, 42 (43.3%). Average % GI among 68% of patients achieving over 50% GI was 77.7% and for 43.5% of patients achieving over 75%, average GI was 87.7%.



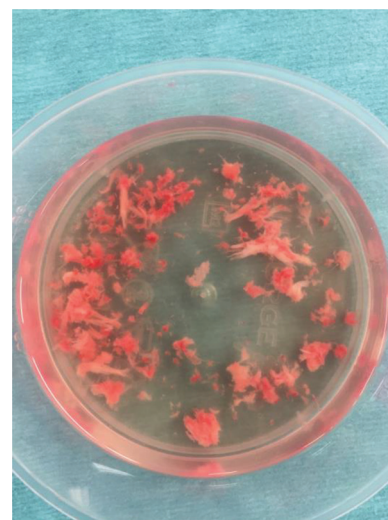
70.8%, 48.7%, 45.9%, 34.3% and 57.4% GI. Among those with procedures post-DISC-FX, the benefits from pre-DISC-FX treatment to final were almost exactly the same at 58.7%, 46.2%, 72.2%, 50.7%, 45.7%, 31.8% and 55.9% GI, respectively.

Discussion

Patients with contained disc protrusion which is thought to be causing back pain and/or sciatica do not have easily available surgical options²⁵ while fusion and disc replacement surgery is not recommended for back pain in current UK guidance.¹⁷ UK national guidance, however, does recommend disc decompression by coblation for back pain and sciatica when considered as an individual technology,¹⁶ and its use as an intervention in back pain and sciatica as part of a strategy in which RF denervation of facet joint in low back pain is the principle recommendation.¹⁷ However, since dominant facet pain may represent a minority of cases, certainly in younger back pain sufferers,¹ there remains significant unmet clinical need where a discogenic source is thought to be the principal pain generator.

The DISC-FX technique is a 'mini-micro discectomy' which employs mechanical and RF nucleotomy and annulus modulation. The RF component is analogous to nucleoplasty

Figure 3. Inflamed, pathological disc nucleus removed during the nucleotomy step of DISC-FX treatment.



decompression treatment which uses proprietary coblation RF technology. In DISC-FX, however, a higher frequency of 1.7 MHz¹⁹ is used, which is also modifiable in two modes to create tissue lesions at low temperature (Turbo) and also heat-based RF modulation (Hemo) of the posterior annulus, thus addressing both the major domains of disc pathology. In many cases, volumes of pathological, presumably inflammatory nucleus material are removed (Figure 3). Whereas there are European clinical data showing successful outcomes over 2 to 4 years,^{20,26} and Asian data,²¹ there are no equivalent UK data. Moreover, there are no data illustrating the likely utility of discal treatment in everyday use where patients are not specifically selected as optimal responders. We therefore report open label, prospective results of a stepwise pragmatic strategy of interventional care including DISC-FX in 100 sequential patients with chronic or persisting back pain which had failed conservative care.

In the author's experience, patients with discogenic back pain of the sort reported here usually give a characteristic history of episodic pain and spasm, often with compensatory scoliosis frequently described as 'I put my back out'. In those who progress, such episodes become more severe, frequent, long-lasting and ultimately continuous with exacerbation spontaneously or by trivial provocation, and the patient has to 'walk on egg shells' to avoid these. Consistent with this history, in this series the average overall duration of pain history was 58.5 months and the duration of the continuous phase was 22.4 months. The longest history of pain seen here was

45 years and 19 patients had pain of over 10 years' duration emphasising that chronic pain of this type is not untreatable if the correct diagnosis is made.

While other authors emphasise that patients usually have a single pain generating pathology and combinations of facet and disc pain occurred in only 5%, in one series,²⁷ in the cases reported here A.H. was struck by the apparent complexity and variability of symptoms and signs and therefore potential multiple clinical diagnoses at presentation among patients who ultimately respond maximally to discal treatment. This may be explained by central sensitisation,²⁸ essentially, that in the presence of a significant competing pain generator the sensitivity of clinical testing, and hence false positive tests, may rise while specificity falls. Consistent with this concept, Bogduk¹³ advise that 'it would seem pertinent and wise to clear patients of zygapophyseal joint pain and possibly sacroiliac joint pain before undertaking disc stimulation'. This principle has been extended in this study to include all potential pain generators where these seemed clinically indicated including central pain amplification, muscle trigger points and neural tension as well as apparent facet and SIJ pain.

However, since clinical signs, for example of facet pain, do not correlate with objective testing by Medial Branch Block,²⁹ it is not possible to know prospectively whether a physical sign on examination is true or false positive. We speculate this phenomenon may affect pain blocks and provocations also. We have therefore, in general, used the least invasive techniques for the preliminary steps to avoid unnecessary overtreatment, for example, facet or SIJ injection rather than medial or lateral branch RF.

We understand these procedures may offer temporary relief of pain but argue that is sufficient for this purpose. True pain generators can be treated definitively subsequently if symptoms persist. Where patients respond fully to these treatments, management stops but continues with disc management if pain persists. The intention in so doing is to remove peripheral pain sources and leave the disc as the most likely persisting pain generator, thus optimising sensitivity and specificity for the more invasive disc testing and subsequent treatment.

Under this strategy, 37 patients progressed to disc management directly, while the remainder had treatments before or after DISC-FX in addition. The numerical improvements in measured parameters achieved by pre-DISC-FX procedures were minimal, while almost the total benefit was seen in the step from DISC-FX to final. Improvements seen were almost identical when comparing those who had prior with those having subsequent interventions, suggesting the interventions other than DISC_FX were not material. This may also imply that most of the apparent signs of alternate sources of pain were indeed false positive. This argument, however, is circular, since under the

pathway, patients responding adequately to other treatments did not progress to discal therapy.

While we have not documented the details, all patients had failed prior conservative therapy and many had received extensive and sometimes prolonged prior treatment without resolution of the ongoing problem, and 19 patients reported spinal problems for over 10 years. However, despite such previous failure, by utilising available palliative injection and definitive RF techniques, and by recognising the central role of disc pain in those whose problems are not resolved by those techniques, it appears here that a good proportion of patients can be relieved of the majority of symptoms, with 19 patients reporting over 90% improvement. Responses to Disc-FX treatment are likely to be long-lasting, with reported 4 year results appearing stable.²⁰

The results obtained here are not as emphatic as some, with those reported internationally with reductions from VAS 7.6–8.6 to 1.6–2.6 sustained over 1 to 3 years³⁰ This may reflect less exclusive case selection and the everyday treatment as opposed to clinical trial setting. With regard to complications, in this series, six patients experienced re-protrusion events (one at a non-treated level) and a further four have returned with further disc problems to date, treatments having commenced in 2011, similar to reports from structured follow-up.²⁰

The radiographic diagnosis of lumbar disc pain is complex. MR scanning is necessary but not sufficient since the relation between pain and radiology appearances is poor,³¹ though features such as a High Intensity Zone (HIZ) may be a reliable clue.^{5,32} In this study, we estimate that 53% of patients would be wrongly assigned to treatment on the basis of MRI findings alone, and we therefore propose that systematic pain provocation discography to SIS standards should be considered as a preliminary to disc treatment. However, Hellinger²⁰ used discography only to establish annulus competency and the technique remains contentious; for example, the author has experienced two cases of discitis in over 20 years' clinical practice, none in this series. Thirty-nine 1-level, 52 2-level, 8 3-level and 1 4-level cases were recognised and treated (total 171 discs). Multiple-level disc treatment would be difficult to achieve by other means.

Limitations

This is an observational study with numerous limitations. These include the potentially restricted patient profile in UK private practice which may not be widely representative, single practitioner management, short follow-up, unblinded/clinician-led data collection, lack of control population and potential uncontrolled confounding variables. In this series, no long-term follow-up was carried out but patients were invited to return if problems recurred. The presumption of long-term benefit

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therefore depends on the fact that few (four) patients did re-present in this time frame. We accept this is a significant limitation in drawing conclusions about the long-term efficacy of the procedure, though structured long-term follow-up shows benefits are stable over 4 years.²⁰ Should these results be confirmed in controlled studies as part of an appropriate pathway, the magnitude and stability of responses seen would be of considerable potential significance to a common group of back pain patients. Finally, cost-utility is not addressed here, nor are return to work data, but again such data may not be generalisable from a mainly insurance-based patient group. However, early surgical discectomy may be cost-effective at a threshold of €40,000 per QALY.³³ Since in the UK percutaneous decompression and injection treatments are substantially less expensive, it is possible it would prove cost-effective in routine use.

Conclusion

Percutaneous decompression and annulus modulation by DISC-FX is the major contributor to initial positive outcomes in an interventional pathway of management of chronic discogenic spinal pain in a sequential prospective analysis. Further, formal study appears warranted.

Acknowledgements

A.H. would like to acknowledge Mrs Michelle Burgess for assistance in records management and secretarial services.

Conflict of Interest

A.H. has received support for conference expenses in one instance from Elliquence, NY.

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The stratification of pain management programmes: a solution to the supply–demand issue?

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Introduction

Pain Management Programmes (PMPs) are recommended by a variety of best practice guidelines for the management of persistent pain in the United Kingdom^{1,2} (SIGN, 2013). Consisting of a blend of patient education, physical exercises and principles from psychological therapies such as cognitive behavioural therapy (CBT), the broad aim of this intervention is to improve patient functioning so that attendees can better cope with their pain.³

Recent meta-analyses of PMPs indicate small-to-medium treatment effects in domains such as pain intensity, coping and disability,⁴ which persist up to a year after treatment completion in some,⁵ but not all trials.⁶ Qualitative evidence corroborates the value of these programmes, with patients describing improvements to their pain management skill set, shifts in their relationship with their pain, reduced reliance on medication, and increased engagement in movement and physical exercise as a result of attending a PMP.⁷

McGhie and Grady⁸ highlight that the already high prevalence of chronic pain in the United Kingdom, combined with an ageing population living for longer with long-term health conditions, means that the demand on pain management

services is great and will become even greater in the near future. Drawing on data that suggest significant structural and staffing issues in pain management services, they conclude that ‘... pain management services are understaffed and poorly resourced to manage this problem’ (p. 160).

The efficient and effective use of limited resources is one of the driving principles of contemporary healthcare in the United Kingdom.⁹ In an attempt to realise this principle in practice, ‘stepped’ or ‘stratified’ model of service provision has been adopted. ‘Stepped care’ refers to a tiered model of care whereby low-cost, low-intensity interventions are offered at a high volume. Patients are offered low-intensity interventions and are ‘stepped up’ if lower intensity interventions prove ineffective.¹⁰ ‘Stratified care’ similarly adopts a tiered approach, although in contrast to stepped care models, where patients are matched to a level of intervention commensurate with the severity of their clinical needs.¹¹

In the treatment of depression, meta-analyses of randomised trials involving the stepped care model have produced negligible treatment effects ($d=0.07$), whereas trials adopting a stratified approach have produced notably larger ($d=0.41$) improvements for patients.¹² The stratified model has also

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proven to be more effective than stepped care in the medical treatment of migraine.¹³ In the treatment of chronic lower back pain, stratified physiotherapy treatment pathways have produced superior outcomes (e.g. in domains such as disability, emotional functioning and pain intensity) in contrast to non-stratified care, as well as reduced absenteeism, lower treatment costs and an additional 0.039 quality-adjusted life years.¹⁴

The British Pain Society advises that the intensity of PMPs may need to be differentiated in accordance with the level of need. For example, they suggest that brief psychologically informed pain management interventions may be beneficial if delivered early on in a patient's journey, but severely distressed and disabled patients require high-intensity interventions.¹⁴ A review of 10 randomised controlled trials (RCTs) revealed that intensive interventions produced significant gains in the areas of pain intensity and level of functioning, but less intensive interventions did not.¹⁵ Conversely, the meta-analysis reported above by Du et al.⁵ conducted subgroup analyses, whereby trials examining intensive treatments were directly compared with trials examining less-intensive treatments. Surprisingly, effect sizes for measures of disability were comparable between treatment intensities, and for pain intensity scores, effect sizes were actually larger for the shorter interventions. It should be noted, however, that this effect size estimate had a very wide confidence interval (CI), spanning small, medium and large effect sizes using Cohen's nomenclature.¹⁶ The precision of this claim is therefore limited.

One possible explanation for these discrepancies is the effects of treatment intensity were compared between, but not within trials. Trials typically featured a treatment arm and a control arm, but not multiple treatment arms that varied in intensity level. Put another way, there is no way of telling if patients with mild needs benefit from less intensive treatments, and patients with severe needs benefit from more intensive treatments, because all participants within a trial typically receive the same-level treatment. This opens up the possibility of 'over-treating' some patients and 'under-treating' others.

There is a need to expand the pain management literature to examine the effects of stratifying patients to a level of PMP that is consistent with the severity of their needs. In addition, direct comparisons between higher and lower intensity PMPs are required. The current report provides results from a service evaluation of stratified PMPs in the North East of England, whereby the effectiveness of both higher and lower intensity programmes were considered.

Method

The project reported here is a service evaluation of routinely collected treatment outcomes for PMPs delivered by the

Department of Clinical Health Psychology, North Tees and Hartlepool NHS Foundation Trust, UK.

Design

The project was a routine service evaluation comparing treatment outcomes over time. There was no randomisation as the project was not a research study. Evaluation was done pre- and post-treatment of either brief or standard intensity PMP.

Procedure

The Department of Clinical Health Psychology offers two main group-based pain management interventions, as summarised below.

Brief pain management psychoeducation group (PMP-B).

The PMP-B is a brief psychoeducational intervention delivered by two Assistant Psychologists, under the supervision of a qualified Clinical Psychologist. The programme is delivered over six 3-hour sessions (18 hours in total) and is intended for patients with mild-to-moderate difficulties. The content of the PMP-B is informed by the biopsychosocial model of pain management and basic principles of CBT.

Standard PMP (PMP-1). The PMP-1 is a multidisciplinary intervention featuring input from a Clinical Psychologist, physiotherapist, pain management specialist nurse and medical consultant. The programme is delivered weekly over nine 3-hour sessions (27 hours in total) and is intended for patients with moderate-to-severe difficulties. The content of the PMP-1 is informed by biopsychosocial models of pain, CBT, and acceptance and commitment therapy (ACT).

A third, intensive PMP (twelve 3-hour sessions) is also provided for patients with complex and severe needs. However, this group is in its infancy and there is insufficient data to consider this group in the current evaluation.

All patients referred for a PMP are assessed for suitability via a 50-minute triage assessment conducted by a qualified or Assistant Psychologist. The intensity of intervention offered was decided using a combination of clinical information (e.g. intensity of mood difficulties, number of problem areas and level of functioning) and patient preference (e.g. preference for brief intervention due to other commitments such as work or childcare).

Participants

Outcome data from 77 participants completing one of the PMPs between April 2016 and April 2017 were evaluated. The 6-week intervention was completed by 43 participants and the 9-week intervention was completed by 34 participants. The

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programmes adopted wide inclusion criteria and as such were attended by patients with a variety of chronic pain problems including musculoskeletal pain, neuropathic pain, migraine and fibromyalgia-related pain. Exclusion criteria for both interventions were as follows: not consenting to attend a PMP; unwillingness to engage in group work; active suicide risk; comorbid and severe mental health problems that precluded engagement in a group intervention; inability to communicate in spoken and written English (translations services were available if required); severe cognitive problems that would preclude engagement in the intervention; and serious substance misuse problems that would interfere with group engagement.

Ethical approval

The project was a service evaluation of routinely collected treatment outcomes, with the aim of judging current care. The evaluation was not considered research as it (a) did not involve changes to routine care; (b) did not involve any form of randomisation; and (c) aimed to evaluate the service in question as opposed to investigating a research hypothesis. While formal ethical approval was not required for the project, it was, however, reviewed and approved by the Research and Development Department of North Tees and Hartlepool NHS Foundation Trust. No individual patient data are reported.

Measures

Both interventions have the aim of improving ability to accept and cope with pain in order to live a good quality and rich life. These aims are measured using two brief questionnaires.

The Warwick–Edinburgh Mental Well-being Survey. The Warwick–Edinburgh Mental Well-being Survey (WEMWBS) is a 14-item scale designed to measure mental well-being. Respondents are required to rate each item on a five-point Likert-type scale. Higher scores indicate higher levels of mental well-being. The WEMWBS has demonstrated a single factor structure and has been shown to have good internal and test–retest reliability.¹⁷ This measure has also been used previously in chronic pain populations for the purposes of evaluation of PMPs.¹⁸

The Chronic Pain Acceptance Questionnaire. The Chronic Pain Acceptance Questionnaire (CPAQ) is a measure of psychological pain acceptance. From an ACT perspective, the term ‘acceptance’ refers to a willingness to experience pain and shift one’s attention from unsuccessful efforts to control it, to a focus on living a rich and valued life despite the presence of pain.¹⁹ The CPAQ was initially developed by Geiser¹⁹ and was later refined by McCracken et al.²⁰ The most recent validated version

known as CPAQ-8 demonstrates that levels of pain acceptance are associated with reduced depression, anxiety, pain severity, interference of pain on daily life and frequency of pain-related medical visits.²¹

Analyses

A within-between mixed analysis of variance (ANOVA) was performed on the outcome data using R. The outcome data were normally distributed, and sphericity was assumed. Tukey pairwise comparisons were conducted in the event of a significant interaction effect.

The WEMWBS data were subject to further analysis using the Reliable Change Index (RCI) and clinically significant change (CSC) analysis. The RCI indicates whether an observed improvement in response to an intervention is ‘real’ or simply a result of measurement error. Calculation of CSC indicated whether an observed improvement is likely to be meaningful to the patient. Criterion C, which provides an estimation of whether a patient has moved from a ‘clinical’ distribution of scores to a ‘non-clinical’ distribution of scores, was adopted for the analysis.²² For the RCI, an alpha coefficient of 0.91¹⁷ was adopted. For the CSC analysis, population norms from Ng Fat et al.²³ were adopted.

Results

Positive psychological well-being (WEMWBS)

WEMWBS scores were analysed using a 2 (treatment group) × 2 (time: pre-treatment and post-treatment) mixed-model ANOVA. No significant main effect of group was found ($F(1, 75) = 0.09, p = 0.76$). A significant main effect of time was observed ($F(1, 75) = 80.4, p < 0.001$), with a large effect size ($d = 0.84$). Mean WEMWBS scores were significantly higher at the end of a PMP (43.69, $SD = 8.04$), compared to pre-treatment baseline (36.92, $SD = 8.14$).

A significant group × time interaction effect was also observed ($F(1, 75) = 11.52, p = 0.001$). Exploration of this interaction (Tukey contrasts) revealed significant (and large) differences between pre- and post-treatment time points for the PMP-1 ($p < 0.001, d = 1.31$), but not the PMP-B (Figure 1).

Pain acceptance (CPAQ)

CPAQ scores were analysed using a 2 (treatment group) × 2 (time: pre-treatment and post-treatment) mixed-model ANOVA. A significant main effect of group emerged ($F(1, 75) = 5.06, p = 0.03$) with a small-to-medium effect size ($d = 0.45$). Participants attending a 9-week programme had a lower mean CPAQ score (17.59, $SD = 7.47$) than participants attending a 6-week programme (20.83, $SD = 6.91$).

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Figure 1. Pre/post–well-being (WEMWBS) scores for 6- and 9-week pain management programmes (bars indicate 95% confidence interval).

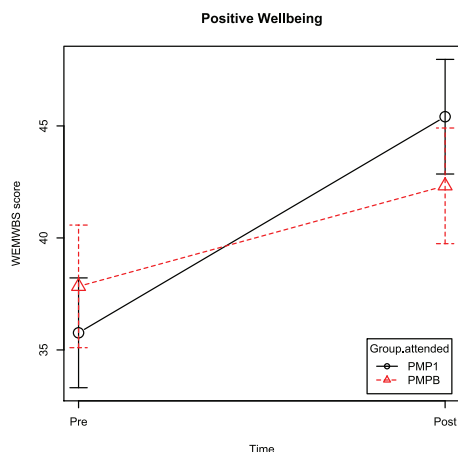
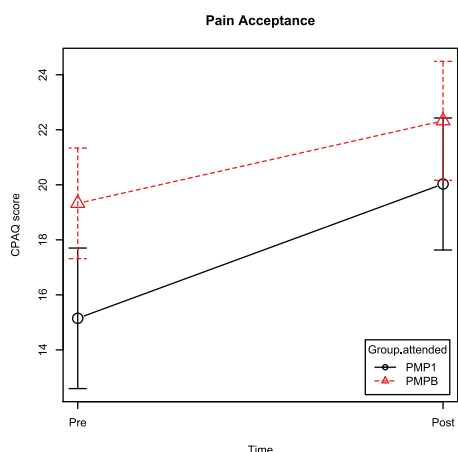


Figure 2. Pre/post–pain acceptance (CPAQ) scores for 6- and 9-week pain management programmes (bars indicate 95% confidence interval).



A significant main effect of time was also observed ($F(1, 75)=32.84, p<0.001$), with an observed effect size in the medium range ($d=0.54$). Mean CPAQ scores upon completion of a PMP were higher ($21.31, SD=7.01, 95\% \text{ CI } (19.74, 22.88)$) than at the start of a programme ($17.48, SD=7.2, 95\% \text{ CI } (15.87, 19.09)$). No significant group \times time interaction emerged ($F(1, 75)=1.95, p=0.17$) (Figure 2).

Clinically significant and reliable change

The number of patients exhibiting clinically significant and reliable changes in positive well-being is summarised in Tables 1 and 2. Note that these analyses were not conducted on pain acceptance data as due to the requirement for normative scores for this form of analysis.

Table 1 indicates that a small number (8/43) of patients attending the brief PMP exhibited CSC that was not due to measurement error. The majority of patients attending a brief PMP (19/43) exhibited no change.

Table 2 highlights that just under half of patients attending a 9-week PMP (15/34) exhibited both reliable change and CSC. A further seven displayed reliable improvement although this was not categorised as clinically significant using the adopted criteria.

Discussion

The aim of this article was to examine if a stratified system of PMPs achieves their intended aims, that is, to improve positive well-being and increase psychological acceptance of persistent pain.

Regarding the first treatment aim, positive psychological well-being, the observed interaction between time and intervention, suggests that large treatment effects can be achieved in PMPs. These gains are only seen in the more comprehensive, 9-week programme.

Examination of indices of clinically significant and reliable changes corroborates this observation – the 9-week programme produced more instances of clinically significant and reliable changes than the brief intervention. It is of note that the cut-off point for CSC was derived from normative data from a sample of *healthy adults*, who are not in chronic pain. Expecting patients to obtain well-being scores that are commensurate with a non-pain population may be considered a high benchmark and thus an overly conservative analysis. Developing norms for such measures within a chronic pain sample that have achieved successful outcomes (and can therefore be considered to be managing their pain effectively) may provide a more appropriate benchmark for indices of clinical change. To the authors' knowledge, however, such data do not exist at present.

Regarding the second treatment aim, psychological pain acceptance, the observed main effect of time indicates that attending one of the PMPs produced statistically significant improvements in this domain, with a medium effect size. Of note, the significant main effect of group indicates that average level of pain acceptance was lower in participants attending a PMP-1 in comparison to those attending a PMP-B. This finding is perhaps unsurprising given that the 9-week group is

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Table 1. Reliable and clinically significant changes in WEMWBS score for PMP-B patients.

Clinically significant change	Reliable change		
	Deterioration	Improvement	No change
Not significant	1	5	19
Okay at baseline ^a	1	0	7
Significant change	0	8	2

WEMWBS: The Warwick–Edinburgh Mental Well-being Survey; PMP: Pain Management Programme.

^aParticipants who scored in the non-clinical range at the start of treatment.

Table 2. Reliable and clinically significant changes in WEMWBS score for PMP-1 patients.

Clinically significant change	Reliable change		
	Deterioration	Improvement	No change
Not significant	0	7	7
Okay at baseline ^a	0	0	4
Significant change	0	15	1

WEMWBS: The Warwick–Edinburgh Mental Well-being Survey; PMP: Pain Management Programme.

^aParticipants who scored in the non-clinical range at the start of treatment.

intended for patients with more intense or complicated needs, lower levels of pain acceptance being one such example. What this finding does suggest is that pain acceptance may be a useful measure for stratifying level of need in the context of a matched care model of pain management.

Taken together, the findings suggest that the standard-intensity PMPs within the service were effective in achieving their intended aims. The picture is less clear regarding the low-intensity intervention, given that improvements in psychological well-being were not observed in this group.

There are a number of interpretations of this result available. For example, it is possible that a brief intervention represents an inadequate ‘dosage’ for a population with long-term pain management problems. Indeed, evidence from a meta-analysis of 9 studies (11 comparisons) of RCTs of CBT for health anxiety indicated that treatment effect sizes increased as a function of treatment length.²⁴

Alternatively, it is possible that there are elements of the standard programme that are crucial to treatment success which a brief programme does not include. For example, the standard groups are facilitated in a multidisciplinary format, with contributions from Clinical Psychologists, physiotherapists,

specialist nurses and medical consultants. In contrast, the brief format group is delivered in a unidisciplinary format by two Assistant Psychologists under the supervision of a qualified Clinical Psychologist.

Multimodal delivery may be essential for treatment effectiveness. Multimodal care has been found to produce superior outcomes to unimodal treatments in persistent lower back pain^{15,25} and mixed pain presentations.²⁶ It should be noted that where brief (but still multidisciplinary) interventions have been evaluated, these significant treatment gains are not observed.¹⁵ This suggests that while unimodal delivery may play an important role in the effectiveness of PMPs, treatment duration may be a more prominent determinant.

The importance of collaborative working between pain management professionals is highlighted by Gatchel et al.,²⁶ who contend that working in an *interdisciplinary* format is essential for effective pain management interventions due to the unique benefits this way of working offers, including improved communication between staff, better coordination of service, and a more coherent and engrained treatment philosophy. This is not to be conflated with *multidisciplinary* pain management, which Gatchel et al.²⁷ define as a way of

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working whereby professionals ‘pursue treatments with separate goals that do not take into account the contributions of other disciplines’ (p. 120). Lack of communication and coordination between pain management professionals has been identified as a source of high dissatisfaction, and a barrier to effective pain management services, according to qualitative interviews of participants accessing pain management services in the United Kingdom.²⁸

The findings obtained from the current service evaluation provide promising evidence that when delivered at an appropriate ‘dose’ and format, PMPs within the service offer an effective intervention for improving well-being and psychological pain acceptance. The evaluation is faced with some limitations that restrict firm conclusions being drawn in all instances however. Due to resource limitations, follow-up data were not collected, meaning that conclusions cannot be drawn about whether the treatment gains observed persisted after completion of the programme. It is also of note that the range of outcome measures administered to attendees was limited to two core self-report questionnaires. While this has the advantage of limiting testing burden, it also means that other non-measured treatment effects may have gone unnoticed. In the service of improving quality of care and better benchmarking, The British Pain Society, in collaboration with the Faculty of Pain Medicine of the Royal College of Anaesthetists, has recently compiled a shortlist of key pain management outcome measures² that will be considered and adopted in future interventions within the service.

Completer analysis was adopted for this evaluation, meaning that the observed effects may be skewed. Those who did not complete the programme may respond differently to those who did. In future, exploration of the characteristics of non-completers would shed light on how better to meet the needs of this group of patients. Finally, since this was a service evaluation of routine practice, no randomisation to treatment group occurred. Given that the two interventions were designed for different levels of need, the lack of effect in the PMP-B group, and presence of effect in the PMP-1 group, may be accounted for by regression to the mean. While beyond the modest scope of an evaluation of routine care, there is an apparent need for RCTs examining the efficacy of stratified PMPs. This would ensure that, at baseline, patients are matched between the groups in terms of severity of needs.

Effective, multimodal pain management interventions are in high demand, but there are challenges to meeting this demand in the United Kingdom. Stratified care offers a possible mechanism by which to ensure that the available resources are used with fairness and equity. Whether this model is feasible or clinically effective has yet to be reliably and consistently established. The data from the current evaluation present some evidence that PMPs within the service can be stratified, but this

conclusion is equivocal at present. Level of psychological pain acceptance differed as a function of intervention level, suggesting that pain acceptance could be used to identify patients who would benefit from particular levels of treatment intensity. However, a stratified system of care is only as effective as the interventions contained within it. The current data suggest that the brief format programme may not confer the treatment gains of more intensive groups. It is imperative to ascertain whether this is a matter of dosage, treatment format or otherwise.

Acknowledgements

We extend our thanks to Dr Raymond Chadwick, Clinical Psychologist, for the insightful and supportive comments offered in the preparation of this article.

Conflict of Interest

The authors have read the declaration of interest guidance and have no interests to declare. This service evaluation was conducted as part of routine service activity and received no funding.

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Results of an audit of ‘real-world’ patient-reported outcomes following a therapeutic trial of Sativex® for persistent non-cancer pain within a Jersey pain centre, local guideline adherent, self-selecting patient cohort

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Introduction

Persistent non-cancer pain (PNCP) is a long-term and often disabling condition with a high prevalence across Europe (20%).¹ PNCP is associated with high personal and societal costs. The prevalence is increasing in Western countries and conservative estimates would put the rising prevalence at approximately 5% per decade. It is estimated that 14 million people live with persistent pain in England alone.² Estimates within older age groups are even higher, with up to 62% of those aged 75 years and above reporting chronic pain symptoms.³ In 2011, 31% of men and 37% of women in the United Kingdom reported persistent pain.² Of these, 25% (one in four – 3.5 million) said that their pain had kept them from usual activities (including work) on at least 14 days in the previous 3 months.² Within the population served by the Jersey Pain Centre, up to 37% of working-age adults have reported a pain problem and 16% of those rated this as moderately or severely impacting on their day-to-day activities (23,700 and 10,250, respectively).⁴

As the prevalence and impact of PNCP increases, so does public demand for more effective medical treatments. Social and political pressure groups have been increasingly keen to see medicinal cannabis made available for the treatment of PNCP.⁵ Studies of the use of cannabinoids for both acute and persistent pain primarily relate to synthetic derivatives of tetrahydrocannabinol (THC) and/or cannabidiol (CBD), with a smaller proportion of studies looking at whole-plant cannabis extracts.⁶ The quality and reproducibility of results from studies looking at cannabis for pain management have been variable.⁷ Evidence of efficacy as well as safety is still sparse or conflicting in relation to pain treatment, and repetitive calls have been made by researchers for more well-controlled clinical trials to evaluate any potential role of the drug for this patient cohort.⁶

Jersey is a crown dependency of Great Britain; it has its own political and legal machinery and own Government. In 2017, the

Minister for Health & Social Services made medicinal cannabis (in particular Sativex®) available for public prescription by Secondary Care Specialist Consultants, including Pain Specialist Consultants. The drug has not been licensed for use in pain management; so, this permission was for ‘off-label’ use. To manage the predicted increase in demand from patients for a clinical trial, a clinical audit pathway and local protocol and guideline were developed by the Jersey Pain Lead and adopted within the clinic.

Methods

Patients referred to the Pain Clinic between January 2018 and November 2018 who expressly requested the potential to try Sativex were reviewed and assessed by one of the Pain Clinic Consultants.

Inclusion criteria are aged 18 years and above, diagnosed with a PNCP condition and who was asked to try Sativex.

Exclusion criteria are history of medication misuse, history of recreational drug use, significant psychiatric co-morbidity, current complex polypharmacy for pain and unwilling to engage with assessment pathway (as per Figure 1).

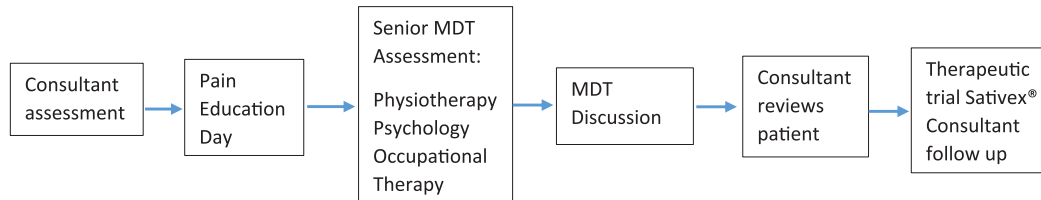
Measures Pain

Pain was assessed using the Brief Pain Inventory (Short Form; BPI-SF), which evaluates subjective reporting of pain intensity (BPI-I-SF) and pain interference in functioning (BPI-Int-SF). As well as the aggregate score for interference, this measure was also subcategorised into three domains (physical functioning, emotional functioning and sleep),⁸ and the results for the subcategories were also analysed.

Emotional functioning

The Beck Depression Inventory (BDI) is recommended as a core outcome measure of emotional functioning in chronic pain

Figure 1. Pathway.



clinical trials.⁸ The short-form Beck Depression Inventory for Primary Care (BDI-PC) is the preferred version for pain settings as 'In participants with concomitant physical illness the BDI's reliance on physical symptoms such as fatigue may artificially inflate scores due to symptoms of the illness, rather than of depression'.⁹ In an effort to deal with this concern, Beck and colleagues developed the BDI-PC, a short screening scale consisting of seven items from the BDI-II considered to be independent of physical function. Unlike the standard BDI, the BDI-PC produces only a binary outcome of not depressed or depressed for patients above a cut-off score of 4.¹⁰

Pain self-efficacy

Patient self-efficacy has been shown to be an important determinant of prognosis. It can also mediate the impact of pain on areas of functioning and participation and reduce negative consequences of symptoms. We therefore also measured patients' pain self-efficacy using the Pain Self-Efficacy Questionnaire (PSEQ). The questionnaire asks respondents how confident they are that they can still do things *despite* pain.

Outcome data were collected at the start of trial and initially after 1 month. Data were analysed using PSPP. Pre and post scores on the relevant measures were evaluated using paired samples t-tests for the 1-month data (Figure 2).

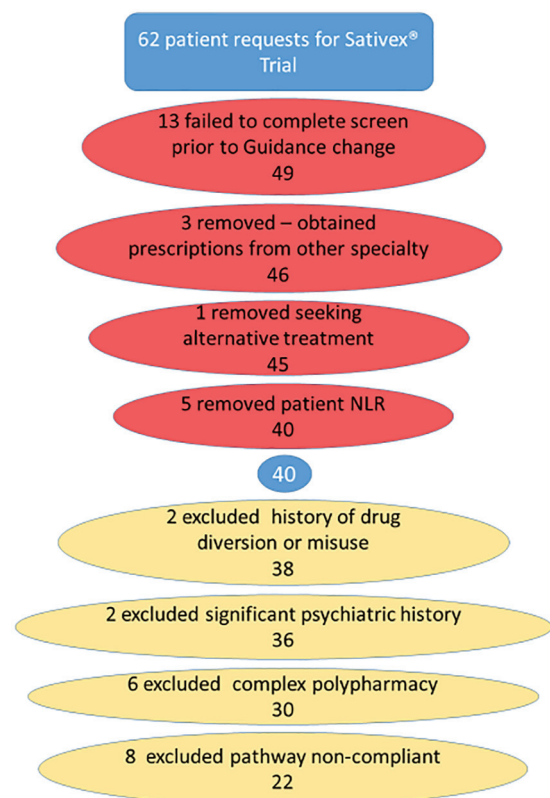
Results

Population

In all, 62 patients initially requested to be considered for a therapeutic trial of Sativex for their persistent pain. Of these, 22 were not included as either they changed their minds, received treatment outside of the trial or failed to complete the trial screening pathway prior to the publication of updated guidance from both the Royal College of Anaesthetists (Pain Specialists) and the Royal College of Physicians, which did not recommend cannabinoid treatments for persistent pain outside of properly controlled clinical trials. The total cohort included 29 men and 33 women.

Of the 40 patients who commenced the pathway, 18 were excluded as per exclusion criteria. There was a significantly larger proportion of males excluded than females (2:1).

Figure 2. Outcome of patients requesting Sativex.



Subjects who subsequently completed the pathway and were included in the drug trial were more likely to be female (7:4). Of the trial subjects, 77% were of working age, with only 5 subjects above retirement age.

Population demographics

Outcome scores were only provided by subjects included in the trial. Prior to the commencement of Sativex, the trial group reported a mean pain intensity of 26.4 (standard deviation (SD)

Table 1. Popular demographics.

Inclusion subjects n=22		Exclusion subjects n=18		Total numbers requesting n=62	
Age	Mean = 54.8 years; SD = 13.3 years	Age	Mean = 52.3 years; SD = 15.3 years	Age	Mean = 53.2 years; SD = 14.6 years
Gender	M 8; F 14	Gender	M 12; F 6	Gender	M 29; F 33
Pain intensity (BPI-I-SF)	Mean 26.4; SD 5.7				
Pain interference (BPI-Int-SF)	Mean 48.4; SD 12.5				
Pain self-efficacy (PSEQ)	Mean 24.5; SD 10.5				
Emotional Depression Inventory (BDI-PC)	Mean 5.9; SD 3.5				

BPI-I-SF: Brief Pain Inventory (Short Form); PSEQ: Pain Self-Efficacy Questionnaire; BDIPC: Beck Depression Inventory for Primary Care.

5.7), moderate pain. They reported moderate to high levels of interference in functioning due to pain (mean 48.4, SD 12.5). They reported low self-efficacy (mean 24.5, SD 10.5), with only 2 out of the 22 subjects rating their self-efficacy above 40, which is the prognostic cut-off for maintaining physical function and work despite pain. The average BDI score for the group was 5.9 (SD 3.5), with 68% of patients reaching cut-off for clinical depression (15:22).

Two subjects dropped out of the trial within the first week due to adverse reactions to Sativex and did not complete the 1 month f/u data (Table 1).

Outcome scores group-related differences

For all measures including the subgroup analysis of the BPI, differences were statistically significant at the 0.01 level, with the exception of the BDI which fell just short at the 0.03 level.

However, for pain intensity, the statistical shift was considerably lower than the 30% (13.32%) expected by the IMMPACT (2008) guidelines threshold for clinically significant change. For pain interference, the average change scores also do not meet the 30% improvement threshold (25%).

We performed subgroup analysis of the three domains of the BPI-Int-SF (physical functioning, sleep and emotional functioning).⁸ For the physical functioning subgroup, there was only a 24% reduction in scores on average. Within the sleep subgroup, there was an average improvement in scores of 38%. Similarly, within the emotional functioning subgroup, there was an average group improvement of 34%.

Results for the PSEQ pre to post 1 month Sativex trial were statistically significant and again represented a change only just short of a 30% threshold (29%). Mean scores post intervention (31.71), however, remained well below the positive prognostic cut-off of 40+.¹¹

Results for the BDI-PC did not meet statistically significant cut-off at the 0.01 level, but did make the less stringent 0.05 level ($p=0.03$). This change does not meet the Steer et al¹⁰

cut-off point of a reduction from above 4 to below 4 (for clinical to non-clinical depression range) (Table 2).

Outcomes for individual patients

Of the 22 patients who started the drug trial, 11 (50%) stopped the medication. Two subjects stopped in the first week due to unacceptable side effects, but did not complete their follow-up questionnaires. Of these, one reported significant confusion and one reported a worsening of their respiratory illness. Two patients experienced significantly negative effects on mood; one experiencing psychosis and one doubling their BDI Depression score. One patient reported crashing their car due to disorientation. One patient experienced mouth pain and tooth loss which they attributed to the medication. A further two patients chose not to continue with the drug as they found it ineffective. One patient was removed for failure to comply with the trial requirements but also reported a significant increase in pain (70%) which took them from a moderate to severe level of pain. One patient was advised not to continue due to other health issues and no change on impact scores. A final patient withdrew themselves for personal reasons, but also did not report any clinically significant benefits on any of the measures from the trial of the medication.

Cohort remaining on Sativex at 1 month

Of the remaining 11 patients who continued with the drug due to subjective ratings of global improvement, only four recorded a clinically significant change in pain scores. The same four also achieved clinically significant changes in pain interference scores. However, one of them also experienced a clinically significant negative impact on their mood (BDI-PC); despite this they wanted to continue with the medication. In total, 6 subjects reported clinically significant changes in pain interference and 4 recorded clinically significant improvements in mood as measured by the BDI-PC. None of the 11 reported clinical improvements in self-efficacy.

Table 2. Outcome scores group-related differences.

Measure used	Pre trial		1 month follow-up		Measure of differences	
	M	SD	M	SD	t	p
BPI-I-SF	25.90	5.67	22.45	6.37	2.72	0.01
BPI-Int-SF	47.40	12.77	35.65	17.77	4.68	0.00
BPI-Int – physical	19.78	6.22	15.06	8.63	3.73	0.00
BPI-Int – sleep	8.00	1.85	5.00	2.54	4.83	0.00
BPI-Int – emotional	19.72	7.49	13.06	8.27	5.39	0.00
PSEQ	25.68	10.78	31.37	11.48	-3.18	0.01
BDI-PC	5.85	3.65	4.80	4.20	2.30	0.03

BPI-I-SF: Brief Pain Inventory (Short Form); PSEQ: Pain Self-Efficacy Questionnaire; BDIPC: Beck Depression Inventory for Primary Care.

Table 3. Costs associated with the trial

Intervention	Numbers receiving	Unit cost	Total cost
Consultant assessment	62	£81.00	£5,022
MDT screen	22	£144	£3,168
Follow-up medical assessment	22 × 2	£41.50	£1,782
One month prescription of Sativex	22	£400	£8,800
Further 11-month prescription costs for Sativex	11	£400	£4,400
Total estimated ^a annual cost to clinic	£67,172		

^aFurther discussion on included and not included costs is given in the following.

Costs associated with the trial

Costs for the trial were estimated from staff annual salaries as well as the cost of the drug. The costs of both the initial consultation with a medic plus the required follow-up appointments are reported. The cost of the MDT screen was also added for those who progressed through the pathway (this involved three 1 hour assessments with each of the MDT professions: Occupational Therapy, Psychology and Physiotherapy). This is not the total cost as some patients attended some appointments and not others, so for simplicity only the costs of those who completed the screen were included. Initial costs of the 22 subjects receiving 1 month supply of the medication were added, and then subsequently, the cost of a further 11 months of the drug were calculated for the remaining 11 patients who have remained on the medication after the first month review (Table 3).

prescribing of Sativex by Pain Consultants for PNCP, despite the fact that the medication was not licensed for Pain. The protocol and audit therefore had to be conducted with a pragmatic approach to ensure minimal disruption to clinical delivery and to provide a framework for evaluation and safety. Data on subjects who did not proceed to the medical trial but who had initially requested the medication are not complete. This limits our ability to fully understand this cohort. This was due to practical administration of information within the clinic as well as the need to manage the increased clinical burden this placed on the clinic. Similarly, the follow-up data for the two patients who started the drug trial, but who withdrew within the first week due to adverse reactions to the drug, were not recorded. The aggregated group means are therefore potentially artificially inflated as the negative experiences of these two subjects were not captured.

Discussion

General

There was no additional funding or support provided to the Pain Team in advance of the political decision to allow

Gender

The gender distribution of patients self-selecting for a trial of Sativex for pain was different to our general persistent pain patient population, with an increased representation of males.

Results of an audit of 'real-world' patient-reported outcomes following a therapeutic trial of Sativex®

In relation to new patients, there is usually 65%–70% female ratio compared to males. For the total study cohort, this changed to a 53:47 ratio females to males. A higher proportion of males were excluded from the trial due to non-compliance or exclusion criteria, twice the amount of female subjects. It is acknowledged in the literature that it is more difficult to engage males with behavioural and non-medical management strategies for persistent pain. This is a significant problem for Pain Centres, as this is a cornerstone of internationally recognised treatment for the condition. It would be useful to work with male patients to determine barriers and facilitators to engaging with the multidisciplinary work of a pain team, as current attitudes and behaviours may have negatively disadvantaged this group.

Work status

Nearly 80% of the trial subjects were of working age. Limitations of resourcing have meant that it has not been possible to look at the impact of the medicine trial on the social outcome of work status. Recommendations have been made about determining wider outcomes from medication trials than just symptom reduction;¹² particularly if symptom reduction may come at the cost of broader participation and functioning losses, as has been seen within Opiate prescribing. Capturing the impact of novel analgesic agents on these broader outcomes would be useful in future trials.

Depression

A total of 68% of the subjects in the trial were classified as having clinical depression by the BDI-PC, which is slightly higher than our general clinical population of 61%. Co-morbid or even dominant depression presents a further level of complexity when considering patient selection for medication. To further elucidate the specific interactions between the symptom presentations and the medication trial, it would have been useful to be able to further analyse the clinically depressed cohort separately. Due to the low numbers associated with the current trial, this was not feasible. Given the present results, however, this would be a recommendation for work going forward.

Impact on pain

A key finding of the trial was the low impact the medication had on pain severity reporting; only 13.3% average reduction for the trial cohort. Of the 40 subjects who were suitable for the trial, 18 did not meet the inclusion criteria and 11 stopped the medication due to significant side effects or lack of efficacy. Of the 11 remaining subjects, only 4 reported a clinically significant drop in pain intensity or 1:10, and for one of these, the pain reduction was associated with a worsening of reported mood,

as measured by the BDI-PC. Conversely, six subjects reported harm from the medication trial, and for some, these harms were considerable, such as an episode of psychosis and crashing a car.

Risk versus benefit

Much is made of the prevalence of cannabis use in the 'general population' and those who potentially use cannabis-based products for medicinal purposes, including pain relief. This is used to support a perspective that the drug is relatively safe. The majority of these reports are taken from population survey-related data with limited data on clinical populations and in particular data on novel exposure to cannabinoids for pain treatment. Prior use of cannabis-based products was not explicitly recorded for the study population, although anecdotally some of the subjects did report that they had used cannabis plant products for pain. Based on conflicting reports of tolerability and efficacy reported within community samples versus pain clinic population samples, it is not possible for pain prescribing clinicians to give accurate assurances on potential benefit and risks, which is a legal requirement for prescribers. The current trial data do not add to the evidence base for tolerability or efficacy. The cost of identifying the 1:10 patients who may benefit without potential harm is significant, and this is a major issue within healthcare services with diminishing budgets per head of patient populations.

Pain interference

In relation to interference from pain, six of the subjects who remained on the medication reported a clinically significant reduction on the BPI-Int measure. From the subgroup analysis, it would appear that this is most likely related to improvements in sleep and reported emotional functioning (relationships with others, enjoyment of life and mood); however, these data are not available at the individual patient level. Two of these subjects reported these reductions despite no clinically meaningful change in pain. Again, this highlights the importance of understanding and elucidating from research trials what is most bothersome and what most contributes to the distress as well as intensity of pain production for individuals.

Psychological affect and sleep

The sleep and emotional functioning data fit with other systematic trial data that suggest that cannabinoids may not impact on aspects of pain production or functioning but that they influence a sense of improvement by their secondary effects on sleep and psychological affect.

It is important to recognise that this audit actually looked at emotional functioning and mood twice: once with the

Results of an audit of 'real-world' patient-reported outcomes following a therapeutic trial of Sativex®

subgroup analysis of the BPI-Int and also with a tool that supports brief evaluation of clinical depression. There was not a clinically significant impact on reported symptoms of depression only emotional functioning, the psychological affect element. Again, just changing the affective relationship to difficulty without altering functioning should be recommended cautiously. Without an ability to understand how the drug changed participation and functioning, we have to be cautious that any positive results seen only reflect this aspect of change.

However, it is widely understood that improvement of sleep alone can be extremely valuable to long-term health outcomes, and as such, this should be a specific area of future inquiry.

Costs

The costs for the trial were estimates only. These have not included all of the audit costs, the additional administrative costs or the entire clinical costs, as tracking these for all who did not comply with the audit protocol was considered too onerous for the purposes of this audit. The costs of ongoing medical reviews were not added as the exact number that will be required for those remaining on the drug is not yet known. The cost of ongoing other medical and non-medical interventions that some of the patients continue to receive in addition to their Sativex prescription was also not calculated. None of the subjects within the audit receive Sativex as their only intervention for PNCP. Therefore, the total figures are very conservative estimates of the cost of the drug in relation to the overall Pain Management costs for the individual patients. Extrapolating the costs of the 1 in 10 subjects who reported benefit from the medication to the entire clinic population would add a conservative £670,000 to the clinical costs of treatment. Future studies could further explore the specific costs of one subject experiencing a clinically significant improvement in pain so that other clinics could extrapolate the data to their own population needs.

The challenge for the clinician

Pain has likely been under-recognised and under-treated by healthcare practitioners in the past. Commissions on healthcare standards have sought to address this,¹³ as have international governing bodies.¹² However, in our race to redress this imbalance, the false notion that pain medication alone can render a patient 100% pain free has led to unrealistic patient expectations. This has also resulted in the health care provider's fear of being labelled as uncaring or a poor doctor and has altered prescribing habits and in part explains some of the tragic consequences of the opioid 'epidemic'. Given the trial results, particularly those of significant adverse responses,

clinician caution is not only justified but essential, in particular as the decision to widen access to the drug was not made by the mechanisms of drug trials, evaluations and guideline issuing authorities that would normally give some assurances. This was not driven by a sudden change in evidence, but rather was motivated by social and political pressure. Significant weight was given to The Barnes Report⁵ in making this decision.

The evidence base for treating PNCP supports a biopsychosocial approach rather than the 'medical model'. Concentrating on medications alone undermines the psychosocial approach. However, it is recognised that patients are entitled to informed choice, as long as the clinician feels the chance of benefit outweighs the risks and that the patient has the correct information. Informed consent is required prior to any treatment. Medical treatments for chronic pain are more effective if combined with other management strategies. Pain Management Programmes, for example, have a better evidence base of benefit than Sativex. As the above protocol illustrates, there is significant difficulty in getting patients to potentially want what they may need. Political and social pressure as well as exaggerated and imbalanced views on drug efficacy do not help this situation.

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Peripheral neuromodulation – part 3: peripheral nerve stimulation in other regions including autonomic nerves

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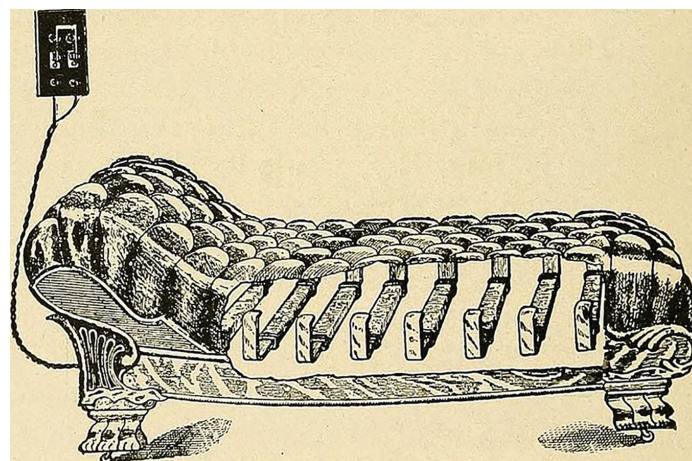
This is part 3 of a three-part article on the history, current practice and future directions of peripheral neuromodulation. We continue to discuss the applications of peripheral nerve stimulation (PNS) in different parts of the body.

Sacral stimulation

Sacral neuromodulation (SN) was first used in 1998, and it proved to be an effective treatment for chronic dysfunction of the diaphragm, pelvis, intestines and urinary system.¹ The devices are implanted surgically, typically at the S3 level, and the electrodes stimulate the sacral plexus with impulses. This stimulation enables the patients to experience that their urinary bladder is full, creating the need to void it more spontaneously and completely. The devices for SN have been used by patients with chronic urinary retention, defecation disorders, intestinal dysfunction and chronic pain.^{2,3}

Nerve stimulation in visceral pain

Chronic visceral pain is treated with a blockade of the coeliac and lumbar sympathetic plexuses, but the benefits of this treatment are usually short-term and may cause serious complications, especially with repeated treatment or injection of neurolytic drugs.⁴ The electrodes for electrical stimulation are percutaneously placed in the proximity of the coeliac plexus or near the sympathetic trunk in the lumbar area under imaging. During the procedure, a test stimulation enables a precise placement of the stimulation field in the target area. To date, the stimulation of the coeliac plexus has been used in patients with pain due to pancreatitis, and the stimulation of the lumbar sympathetic trunk has been used in patients with pain associated with chronic hematuria (loin hematuria syndrome). Stimulation has achieved pain reduction of 80%–90%, a reduced need for prescribed medications and a significant functional improvement. Reports indicated that the stimulation

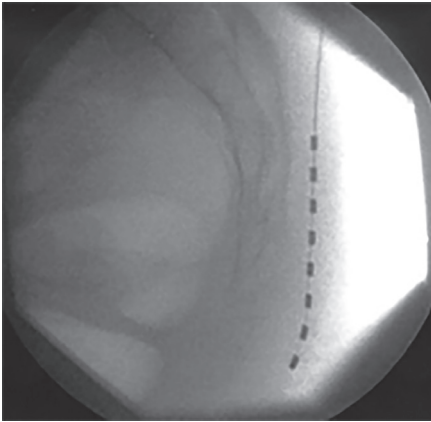


Credit: Homer Clark Bennett.⁸⁶

of the coeliac plexus or the lumbar sympathetic trunk can be used as an alternative to spinal cord stimulation (SCS).^{5–7} Neuromodulation procedures used in patients with visceral pain were described comprehensively in 2015 in a book edited by Kapural.⁷

Vagal nerve stimulation

Vagal nerve stimulation (VNS) has been used to treat drug-resistant epilepsy since 1988, when the first implantation was made.^{8,9} From a clinical perspective, VNS requires an open surgical procedure. A systematic review of the literature showed that VNS can reduce the number of epileptic seizures by 50%.^{10,11} Among patients with epilepsy who underwent VNS, 6%–27% ceased having epileptic seizures.⁸ VNS was also used to treat patients with depression, but it is not clear how VNS works in this condition.^{12,13} In animal models, the stimulation of the vagus nerve changes neurotransmission in the brain, including the transmission in the adrenergic and



Coccyx neurostimulation for severe coccygeal pain.

Source: T.G. copyright, with permission.

serotonergic systems.¹⁴

Non-invasive vagal nerve stimulation (nVNS) in the cervical region or the auricular nerve is a relatively well-documented treatment for patients with headache or epilepsy.^{15–17} External (non-invasive) stimulation of the vagus nerve (ExVNS) or the auricular branch of

the vagus nerve is a promising alternative to surgery for obese patients.¹⁸ Preliminary studies show that stimulation of the vagus nerve and bariatric surgery have a similar effectiveness in treating obesity and are in further trial.¹⁸ The indications for stimulation of the vagus nerve are systematically modified, and VNS is now being assessed for the treatment of atrial fibrillation and asthma.^{19,20} The newly formed Society for the Stimulation of the Vagus Nerve is a dynamic forum for the exchange of experience concerning this important method of peripheral neuromodulation.

Gastric electrical stimulation

Gastric electrical stimulation (GES) is used to treat drug-resistant gastroparesis. The devices that stimulate the stomach are implanted surgically. Usually, several electrodes are placed in the muscle layer of the stomach. The Enterra (Medtronic, Minneapolis, USA) is the most commonly used device for GES; it uses high-frequency and low-energy stimulation.²¹

Other devices for GES, such as sequential GES or low-frequency and high-energy GES, are being assessed in clinical trials. The evidence supporting GES as a treatment for drug-resistant gastroparesis is limited. However, in many reports, GES considerably improved quality of life and reduced some symptoms of gastroparesis, for example, nausea and vomiting.²²

Subcutaneous stimulation, peripheral nerve field stimulation and peripheral target stimulation

Many patients experience pain that cannot be related to a specific nerve, nerve plexus or dermatome. In such cases, SCS or PNS does not provide sufficient coverage with paresthesia. In 2000, Goroszeniuk^{23,24} used a new peripheral approach to treating pain in such patients. This treatment was based on the initial experience with the stimulation of the ulnar nerve with low-frequency (2 Hz)

electric current applied via mono-electrodes. The treatment relieved pain for 11 weeks. Because of these encouraging outcomes, low-frequency stimulation of target subcutaneous sites was then used.^{23–25} Later, similar results were published by O'Keeffe et al.²⁶ This treatment was termed peripheral target stimulation (PTS), and it was further extended to peripheral nerve field stimulation (PNFS). This treatment (PTS/PNFS) was first used in three patients with severe neuropathic pain in the chest due to costochondritis, postoperative damage to the intercostal nerves and postoperative parasternal pain. In all three patients, neurostimulation decreased the pain experience by 85%–90%.²⁵

Stimulation of the pain centre may reduce pain in the entire painful area, including the areas that are not directly targeted by the stimulation. It is important to place stimulation electrodes in the 'epicentre' of pain,^{23,25} which can be determined with needle stimulation of the peripheral nerve or with an external nerve mapping device. Then, low-frequency (2–10 Hz) stimulation of varying amplitudes is used. In PTS/PNFS, after the 'epicentre' of pain is found, the stimulation electrode is inserted with one of the following tools: a cannula (Abbocath 14G),²⁷ a Tuohy needle (14G) or Coude Stim.²⁸ To improve the technique of inserting stimulation electrodes subcutaneously, a modification was proposed that takes into account the distance from the skin surface to the target site.²⁹

In a large group of 111 patients with lower back pain, neck pain and post-herpetic neuralgia, Sator-Katzenschlager et al.³⁰ showed that PTS/PNFS reduced the pain scores by more than 50%, engendering a reduction in medications. Among 100 patients with diverse pain in the face, trunk, abdomen and pelvis, Verrills et al.³¹ proved that PTS/PNFS reduced both the pain (by 4.2 points on an 11-point pain scale) and analgesic drug use (by 72%).

Over the last decade, PNFS/PTS has been used in many indications,^{32,33} including stimulation within the chest,²⁵ abdominal wall,³⁴ lumbosacral region^{35–38} and knee³⁹ and for the treatment of shoulder pain.⁴⁰

PNFS/PTS in cardiac pain

SCS is considered as an effective treatment for drug-resistant angina pectoris. Its effects are similar to those of coronary artery bypass grafting, but SCS causes fewer complications and is used in patients who cannot undergo coronary artery bypass grafting.^{41,42}

At St Thomas' Hospital in London, subcutaneous PNFS of the chest wall was shown to be effective in patients with angina pectoris.^{43,44} Because relatively few patients have undergone PNFS/PTS for angina-related pain to date, we still do not know the place of this approach, even though the initial observations indicate that this treatment is effective.^{43–45}

Combination of PNS and SCS

PNS and SCS can be used at the same time, and the combination of both treatments offers the maximum coverage of the pain area. For example, this combination can be used to treat axial lower back pain. It is difficult to cover the entire pain area in patients with axial lower back pain by SCS alone and adding peripheral electrodes to SCS can enlarge the treated area. Mironer et al. used the term ‘spinal-peripheral neurostimulation’ to describe the combined use of PNS and SCS. One study compared the effects of either SCS or PNS alone with a combination of these two treatments in patients with axial lower back pain. The combination these treatments was more effective than either SCS or PNS alone for covering the lower back with effective paresthesia.⁴⁶ Navarro described the combined use of peripheral subcutaneous electrodes and SCS for the treatment of axial lower back pain as ‘triangular stimulation’. In a retrospective study involving 40 patients, this ‘triangular stimulation’ improved the pain index and reduced the doses of analgesic medications.⁴⁷

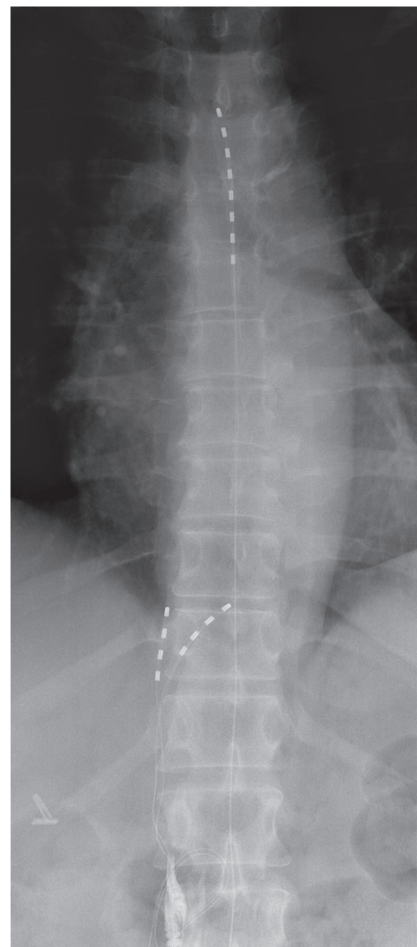
The combination of peripheral techniques and SCS has also been used to treat abdominal pain and drug-resistant angina pectoris.^{44,45,48} In nine patients with pain after ineffective spinal surgery and axial lumbar pain, adding stimulation with subcutaneous lumbar electrodes to SCS effectively enlarged the treated pain area, because the SCS alone covered the limb pain but not the back pain. This combined treatment reduced pain to a greater extent than SCS by itself. The pain index decreased by about 50%, and the doses of analgesic medications decreased by 70%.⁴⁹

Minimally invasive stimulation

Minimally invasive stimulation is performed with needles or stimulation catheters, and is used for both diagnosis and treatment. The equipment needed for minimally invasive stimulation consists of two components: a stimulation generator and a disposable needle or stimulation catheter. In the case of PRF (pulsed radiofrequency) and PENS (percutaneous electrical nerve stimulation), the generator is expensive because it contains complex software and electronics. However, the simple stimulators for regional anaesthesia can be used instead as an inexpensive alternative.

In the 1970s, Rutkowski published several papers on percutaneous stimulation, which he performed with self-designed stimulators, with impressive outcomes. He also observed that the peripheral stimulation improved hypertension, an observation that was subsequently confirmed.^{50,51}

Ghonomie et al. carried out peripheral stimulation by introducing several stimulation needles into the subcutaneous tissue or muscles relevant to the pain area. These investigators analysed the outcomes of that treatment in a series of randomised trials.^{52–54} The reduction in pain was greater in the treated patients than in the control groups. These studies were,



Combined SCS and coeliac plexus stimulation for severe benign pancreatic pain.

Source: T.G. copyright, with permission.

however, not blinded, and the follow-up periods were short, lasting only a few weeks. The technique was named percutaneous electrical nerve stimulation (PENS). The results of the study by Raphael et al.⁵⁵ have supported the initial PENS reports.

Direct stimulation (DS), introduced in 2000, is short (5–10 minutes) and of low frequency (2–10 Hz). DS is based on the same principles as the regional anaesthesia of the peripheral nerves and nerve plexuses.⁵⁶ Unlike PENS, the target of DS is the nerve itself or the epicentre of pain, and the treatment is carried out with a single needle. This technique proved to be particularly effective in the treatment of patients with neuropathic pain, which encouraged further development of non-invasive methods and different techniques of target field stimulation that are now available.^{24,25,57–59} DS has become a popular treatment, and it is sometimes referred to as subcutaneous electrical nerve stimulation (SENS).²⁶ This simple

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Brachial Plexus ExStim.
Source: T.G. copyright, with permission.



ExStim self-administration for a case of severe neuropathic leg pain post external fixation.
Source: T.G. copyright, with permission.

The stimulation sessions can be repeated at regular intervals as a long-term treatment, depending on the indication, outcome of initial treatment and local guidelines. The recent Food and Drug Administration (FDA) approval for the SPRINT PNS system (SPR Therapeutics, Cleveland, OH, USA) is excellent news for many patients who would benefit from the peripheral percutaneous temporary stimulation (PPTS).⁶⁰

Percutaneous tibial nerve stimulation is a simple treatment used in patients with incontinence due to bladder hyperactivity. The effectiveness of percutaneous tibial nerve stimulation has been confirmed in a systematic review.^{61,62} The treatment involves a weekly percutaneous stimulation of the posterior tibial nerve. The needle is inserted posteriorly into the medial malleolus by a person trained in this technique. Long-term studies confirmed the 3-year effectiveness of percutaneous stimulation of the posterior tibial nerve, and the treatment can be repeated for an indefinite period.⁶³

Non-invasive stimulation (neuromodulation)

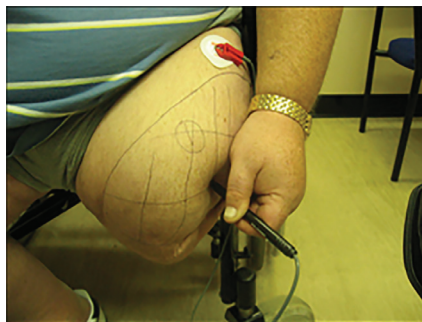
Modern non-invasive neuromodulation dates back to the beginning of SCS. Shealy et al.,⁶⁴ who first used dorsal column stimulation (DCS) in 1967, created the first modern device for

method can be used routinely for diagnosis and can be part of long-term treatment.

Minimally invasive stimulation targets individual nerves or plexuses, and it can be used in patients with chronic pain or with pain that does not correspond to the usual distribution of dermatomes. In these patients, PTS/PNFS can be used. These treatments involve an insertion of a needle or catheter into the epicentre of the pain area. The stimulation, which is usually low frequency, is given for 5 minutes in PRF, 5–10 minutes in DS, 20–30 minutes in PENS and up to 8 weeks in the case of trial stimulation with a stimulation catheter.



ExStim self-administration for neuropathic pain in the region of the peroneal nerves.
Source: T.G. copyright, with permission.



ExStim self-administration for stump/neuroma pain.
Source: T.G. copyright, with permission.

transcutaneous electrical nerve stimulation (TENS) when he tested SCS transmitters.^{65,66} Currently, TENS is used commonly to treat patients with most pain syndromes. Although we have a vast experience with TENS, and there are many reports on its use, the effectiveness of this treatment is often compared to that of placebo.^{67–69}

External stimulation (ExStim) in the treatment of patients with chronic pain, mainly neuropathic pain, is a stimulation involving low-frequency pulses, in which a stimulation pen is used to locate the relevant nerves. ExStim, as a non-invasive technique,

has created new treatment possibilities because it is effective and simple.^{24,57–59}

Initial reports showed that patients with chronic neuropathic pain who did not benefit from TENS did improve with ExStim. In more than 90% of patients, ExStim significantly reduced the pain threshold. In contrast, TENS either did not reduce the pain threshold or reduced it only slightly.^{24,57,59} Importantly, ExStim can be used by patients themselves when the initial stimulation improves the pain. Lowering the pain threshold by more than 50% for 6–8 hours is sufficient to qualify the patient for self-stimulation.⁵⁸ Current evidence on the effectiveness of ExStim comes from case reports,^{24,57–59,70–73} but randomised control trials (RCTs) are underway (C Perruchoud, personal communication, 2018; K Van Tilburg, personal communication, 2018). ExStim is used for the stimulation of individual nerves and nerve plexuses, but it can also be used for target and field stimulation in patients with chronic pain, or to achieve functional improvement.

Transcutaneous supraorbital nerve stimulation (tsNS) is promising, and it may prove to be an effective treatment for patients with migraine.^{15,74} Preliminary reports on the effects of

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transcutaneous occipital nerve stimulation (tONS) are also encouraging.¹⁵ Transcranial direct current stimulation (tDCS) is used to manage central pain in patients after a stroke and in patients with visceral pain or phantom pain; in these patients, tDCS is often used as an adjunctive treatment.⁷⁵

Transcutaneous posterior tibial nerve stimulation (tPTNS) is another method of transcutaneous stimulation that can be used to treat patients with urinary incontinence or with diseases of the anus. This method is currently being clinically evaluated.⁷⁶

Transcranial magnetic stimulation (TMS), since the first clinical trials conducted by Barker in 1985, has been used by more and more investigators to treat patients with schizophrenia and other similar conditions. The development of technology used for TMS and the miniaturisation of the equipment will improve outcomes in the treated patients.^{77,78}

External stimulation, in its many varieties, is a fast-developing form of peripheral stimulation. Non-pharmacologic treatment of pain and other diseases will open a new chapter in medicine, particularly because these treatments are used to manage more and more diseases, not just in pain. Some of the new indications for external stimulation have come from basic sciences. Rheumatic, cardiologic and psychiatric diseases, as well as migraine, are among the new indications for external stimulation.

Future

In addition to the current indications, such as pain,^{79–84} PNS is being used in many new ways, such as in the treatment of heart diseases, asthma, arthritis, gastrointestinal diseases and many immunological disorders.⁸⁵ The use of such PNS has increased because it is relatively simple and demonstrates functional improvement.^{74–76} Smaller and specially designed devices will increase the effectiveness of treatment in many indications. The increased use of non-invasive techniques and stimulation of targeted subcutaneous areas will expand the availability of PNS for doctors and patients. Patients will be able to use their portable devices in a similar way as in TENS. It is necessary to base the growing practice of PNS on good data from clinical trials. Only then will PNS become an evidence-based treatment option.

Summary

PNS is a rapidly growing area of neuromodulation, with many new indications, including the treatment of chronic pain and functional disorders. The terminology of PNS is still developing due to its constant expansion and the development of new techniques. Since 1999, when the first percutaneous lead was used for PNS, many new non-surgical treatments have appeared, which target different body sites. Often, it is a less

expensive alternative to the implantable treatment, and it can be used outside of specialised centres. Due to the technological advances, PNS is now safer and more efficient, leading to improved outcomes.

Acknowledgements

The authors would like to acknowledge that this work is based on their previous publication: Goroszeniuk T, and Król A. Peripheral neuromodulation: an update. *Ból* 2017; 18(1): 15–27. (The official journal of Polish Pain Society). T.G. is a developer of ExStim.

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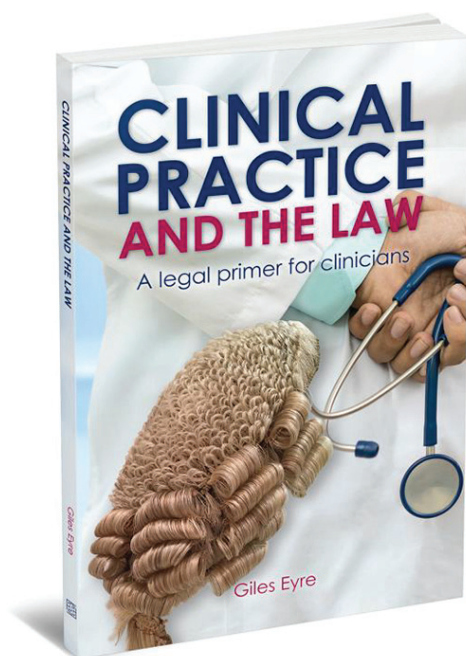
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Book review



***Clinical Practice and the Law: A Legal Primer for Clinicians*, edited by Giles Eyre; London: Professional Solutions Publications, 2018, 160 pp., ISBN-10: 0956934129, ISBN-13: 9780956934123.**

Reviewed by Dr Laura Munglani *BM BCh MRCP*

In the current litigious climate and following recent high-profile cases involving the Law, the GMC and junior doctors. I asked two doctors at the start of their careers to review this book to assess whether it succeeds in its purpose which aims to inform and so forewarn health care professionals, and of course to be forewarned is to be forearmed.

–Ed.

This book succinctly sets out the governing principles by which the law interacts with medicine on a daily basis. Everyone, from medical students to consultants, will find it of use.

At 132 pages long, the book focuses on the key areas of clinical and legal practice that cause clinicians the most concern. The chapter on ‘A lawyer’s mind’ provides real insight into how a

lawyer approaches medical facts and evidence – something that is not taught in medical school.

Medicine has benefitted from borrowing ideas and strategies from other industries, such as patient safety and the aviation industry. Using the more logical legal framework of considering evidence in a stepwise approach described and explained by Giles Eyre will aid in medical diagnosis. It helps clinicians think like lawyers, in a more logical fashion, and may lead not only to more correct diagnoses at the time but also to understanding the thinking behind a clinical case should it be medicolegally re-examined later on.

Inquests/coroners’ courts are words that strike fear into junior doctors’ hearts, and in recent years, as clinical practice comes under greater scrutiny, more junior doctors are being called to give evidence in coroners’ courts. Clinicians may now find themselves working in a litigious environment, with the role of criminal law increasingly finding its way into medicine and having repercussions on how all doctors practise. An example of this is the tragic case of Jack Adcock and Dr Bawa-Garba. General Medical Council (GMC) and other governing bodies are increasingly scrutinising individuals’ clinical practice and documentation. Note writing and the language we use in clinical records is something else that is not taught in medical school, but such notes are vital and can be scrutinised when things go wrong, or when there is an inquest. The book not only explains clearly the importance of written records and the accurate use of language but also contains many tips as to how this may be done effectively and quickly.

An understanding of how cases are looked at ‘from the other side’, and demystifying the process when things go wrong, is very helpful.

As a junior doctor, I found Giles Eyre’s introductory book on the law from a clinical perspective an invaluable adjunct to my clinical practice. This book should be read by everyone who wishes to further their career in medicine.

Reviewed by Dr Nathan Riddell *BM BCh*

A clinician’s first noticeable experience of medical law often, unfortunately, comes at the hands of a complaint, a witness statement or a disciplinary issue leading to trepidation and fear surrounding the subject. However, our day-to-day jobs and actions are often unknowingly based in medical law such as

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consenting patients for procedures, communicating decisions with patients, assessing capacity or ensuring confidentiality for patient interactions. Retired barrister Giles Eyre successfully aims to share his wisdom gained over many years conducting and advising on medicolegal cases in order to provide clinicians with a thorough grounding in all the aspects of law that a clinician is likely to face throughout their career.

The first chapter clearly defines the terms of engagement, taking the reader through evidence, proof and the court system. Eyre spends time explaining how a lawyer's mind works and uses this as an undercurrent for the subsequent chapters to signpost the importance of documentation, communication, confidentiality and consent. I found this viewpoint particularly enlightening in the author's elucidation of how a lawyer is likely to interpret the decisions made by clinicians with and without documented explanation of the reasoning behind them. Much as we would ensure that we appropriately note when a patient is able to weigh up their options to interpret their capacity, too often this process is inadequately documented, when instead it is the clinician doing the deliberation. This leads to potential difficulties for a defence lawyer in the event of complaints or serious incidents.

While topics such as confidentiality and consent are taught in medical school, the focus is often on the ethical implications rather than the medicolegal. Through chapters on communication, consent, capacity and confidentiality, Eyre gives the reader a comprehensive education in how the law relates to these topics encountered by clinicians daily. His explanations from the perspective of how a lawyer interprets our actions give the reader a more complete insight into both how we can act in the interests of improving patient care through a knowledge of the law and how we ensure that we comply with what is expected of us from a medicolegal standpoint.

Very few, if any, clinicians pursue a career in medicine in order to interact with lawyers. Often, this is the antithesis of what we hope our roles involve as doctors. However, at some point in a clinician's career, they are likely to be asked to provide a witness statement – not necessarily because of any wrongdoing, but rather as the clinician who provided care to a

patient who is themselves, or by cause of injury, then subject to investigation. It is, undoubtedly, a daunting and unsettling task, but provided the information written is of sufficient detail and quality, written in the correct way, it often mitigates the need for the clinician to give evidence in person. The author provides excellent instruction on the form and content expected by the courts and, on a personal level, having this book would have made the experience of writing my first witness statements for patients seen in the emergency department significantly less daunting.

Although I believe it would be almost impossible to find any clinician (junior or senior) who could not relate to at least a couple of the topics covered throughout the book, this book did feel more aimed at junior clinicians, given its concise and efficient coverage of the basics of medical law. I, therefore, found the chapter on acting as an expert witness came surprisingly early in the book (although I do understand that it follows 'preparing a witness statement') as I felt it interrupted the continuity of the junior doctor's otherwise excellent education in the law they are likely to encounter. The chapter itself is, nonetheless, a useful primer and provides aspirational reading for those interested or involved in this more advanced area of medicolegal work. In future editions of the book, I feel this chapter would perhaps be a nice addition at the end of the book – a 'further reading' point – rather than in the midst of the meaty topics for a junior clinician such as evidence, proof, consent, communication, capacity, confidentiality and documentation.

Overall 'Clinical practice and the law' proves to be a valuable resource for any clinician in providing a concise guide to the majority of interactions a doctor is likely to have with the law. It is clearly set out and excellently punctuated with summarising messages for the reader, relevant real-life examples and references from Good Medical Practice and other General Medical Council literature. I would recommend this to any medical student or junior doctor, as well as those more senior looking to revise their knowledge of medical law, and would not be surprised to find this in a medical school core reading list over the years to come. I have already recommended it to a number of colleagues.

