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PAIN NEWS

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THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

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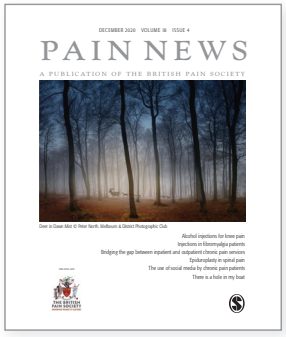

The Editor welcomes contributions including letters, short clinical reports and news of interest to members.

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In this issue

Jenny Nicholas

Pain News
2020, Vol 18(4) 184

It's hard to believe that we're in December already, and what a year 2020 has turned out to be.

Having spent the last issue of *Pain News* looking very much at COVID-19 and how the pandemic is affecting pain services and patient care, this issue moves away from the unfolding COVID-19 story as once again we look at pain management/ medicine in its wider sphere, as well as bringing you some pieces of lighter relief through artwork.

But first, it is with great pleasure that we acknowledge the achievements of some our esteemed colleagues as we congratulate Professor Amanda Williams, Dr Tim Johnson and Dr Paul Wilkinson on their recent well-deserved awards. Congratulations to you all!

Here's a little peak at just some of the content we have in store for you this time . . .

- Liz Colquhoun's article looks at 'Bridging the Gap: Formation of a Transitional Pain Clinic in NHS Tayside' describing a pilot study of rapid access appointments to allow the timely review of patients following discharge.
- A service evaluation by Tom Bendinger and Joel Perfitt presents the outcomes of 'Alcohol ablation of the genicular nerves for knee pain secondary to osteoarthritis – case series'. We also have a second article by Tom and Joel in this issue on 'Significance of ACR Fibromyalgia questionnaire positive diagnosis and predictive value of ACR Fibromyalgia questionnaire in patient selection process for epidural injection for treatment of lumbar radicular pain – observational prospective study'.
- Pradeep Desai and Rafik Sedra share with us a retrospective study on 'One day caudal epiduroplasty using normal saline for failed back surgery syndrome and spinal stenosis'.
- 'Social media – a way to ease the pain?' by Emma Shaw and Rajesh Menon looks to answer the question 'is the internet, community support groups or social media currently being utilised for pain education and support by our chronic pain patients?'

We do hope that you enjoy this issue of *Pain News*, and we are always glad to hear your feedback!

From the President

President's message

Arun Bhaskar

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

Pain News
2020, Vol 18(4) 185–186

SAGE

Dear Friends
I trust this finds you well.

The leaves on the trees had been displaying the splendour of the autumnal colours over the past few days only to be blown away in the recent storm and rains, a preamble to the winter. This winter unlike past years brings in more challenges with the 'second' peak of COVID-19 bringing in increasing number of cases and related fatalities. At the time of writing this message, we are midway into the second national lockdown. Even though the R numbers are reducing, there is a still a sense of uncertainty about easing the restrictions in the coming months. In addition, it has been suggested that those of us who are active in the clinical field may be redeployed for COVID duties if the number of active cases admitted into the hospital is overwhelming existing arrangements. This would negatively impact on the delivery of pain services which had already been adversely affected in summer with increasing waiting lists and lead to further setbacks to the recovery plans to reinstate pain clinics back to their full capacity.

It was with a heavy heart we had to move the 2020 ASM and several other planned meetings and educational events. In my previous communication, I had mentioned that we would aim to conduct a meeting towards the end of the year as a networking event. However, in view of the state of affairs with the second national lockdown, we have decided to have it as a virtual meeting on Zoom during the first week of December. It would be an opportunity to thank all of you for your dedication and selfless hard work for supporting the response to the pandemic as well as update you on some of the developments we had during the year.

We are in the process of setting up a virtual educational platform that could impart knowledge and training for not only BPS members and other multidisciplinary colleagues involved in pain management but also other specialities and healthcare professionals in the primary care as well as patient groups. The aim is to have a platform that could be used for future engagements as it seems that a lot of future meetings and workshops would have an online version to engage with more people. I am also taking this opportunity to inform you that the ASM2021 will be held in spring and will be a virtual meeting. The Scientific Programme Committee has already met and will be keeping you updated soon with the details.

The Annual General Meeting which is traditionally held during the ASM had to be held as a virtual meeting on 29 September 2020 as per the statute of the Society. Three main decisions were taken on the day. First, Dr Ashish Gulve was formally appointed as the Hon Treasurer of the Society for a period of 3 years. He had stepped in at short notice as Hon. Interim Treasurer and worked tirelessly to stabilise our extremely challenging financial situation. He was unanimously elected by the Council, and double congratulations are in order as he has also just started his 2-year term as the President of the Neuromodulation Society of United Kingdom and Ireland. On behalf of everyone, I thank him for his hard work and support and wish him all success in these roles; I am sure this would also open a new chapter in collaborative working between the two societies. The membership fee structure has been a point of discussion for the past few years and I thank the work done by Ashish, the Council members and the Secretariat to present this at the AGM and get it approved. Finally, we had to have a Special Resolution amend Article 58.1 of our Memorandum & Articles to incorporate virtual media options for future general meetings in light of the recent experiences with the global pandemic. On a positive note, I am hoping that we would get better representations by the membership at future meetings. The Special Resolution was passed unanimously by 75% of the members present and voting in person or by proxy.

Article 58.1 will now read as follows:

No business shall be transacted at any General Meeting of the Society unless a quorum is present at the time when the meeting proceeds to business. Fifty persons being Ordinary Members or Honorary Members or 10% of the

Ordinary Members (whichever is the lesser), being persons present in person or by proxy (which shall exclude members of Council) entitled to vote upon the business to be transacted, shall be a quorum at any General Meeting.

Notwithstanding any other provision of these Articles, any General Meeting (and any associated poll or ballot) may be held by suitable electronic means, agreed by the Council, by which a participant attending the General Meeting is able to communicate with all the other participants. In respect of any reference in these Articles to attendance at a General Meeting (or any associated poll or ballot) 'present' or 'present in person' includes being present by suitable electronic means as aforesaid.

At the time of writing, it is a bit early to say whether we will be able to get together with family and friends during the festive season at the end of the year after the hardships over the past few months. Let us hope that decisions are made in such a way that we can spend time with our families and loved ones, but also without compromising the progress made in reducing the spread of the virus and herald in a safer 2021. I wish you all a Merry Christmas and a very Happy New Year and look forward to meeting you soon.

Citation for Professor Amanda Williams

Professor Chris Eccleston

Pain News
2020, Vol 18(4) 187

Professor Amanda Williams is a star of pain science, internationally respected and admired. She continues to make a major contribution in science, clinical practice and policy initiatives in pain, as she has done for the last 30 years. This year, the IASP recognised this achievement by bestowing the award of an honorary life membership for making '*outstanding contributions in pain-related fields to advance the mission of the IASP*'.

Amanda is perhaps best known for her work developing cognitive behavioural therapy for chronic pain, and managing the evidence base for treatments. She is a Cochrane editor and the psychology field editor for the IASP flagship journal PAIN.

Perhaps, less well known is her contribution to combating torture and helping its victims both clinically and politically. She also is a world-leading scholar in evolutionary science, providing a rare expertise in comparative evolutionary psychology and pain. If that was not enough, outside of work, she is also a championship free-diver, accomplished musician and a generous friend to the many trainees she has nurtured into their own lifetime of practice.

Honorary membership citation for Dr Timothy William Johnson

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

Pain News
2020, Vol 18(4) 188–189

SAGE

R Krishnamoorthy

Council Member, BPS

It is my greatest pleasure to present the citation for the highest award from the British Pain Society (BPS), the Honorary Membership to Dr Timothy William Johnson. He has made outstanding contributions to the development of pain medicine both in the UK and Africa, phenomenal work on medical education in Salford, patient care at the Manchester and Salford Pain Centre, publications, British Pain Society and in the medico-legal field.

Tim graduated from King's College Hospital, London and had his higher training in Anaesthesia from South West deanery. He obtained his FRCA in 1984 and FFPMRCA in 2007. The other qualifications are M.Ed. in surgical education, certification in hypnotherapy and Diploma in Obstetrics and Gynaecology. Tim spent some time as a general practitioner in New Zealand (1988–1999) and as a fellow in pain management at the University of Washington, Seattle, USA.

Tim has been a consultant in pain management and anaesthesia, Hope Hospital, Salford, since 1993. After his association with legends in pain medicine Dr Christopher Spanswick and Professor Chris Main, Tim helped establish the multidisciplinary team approach to pain management. We all know the Salford Pain Centre is still one of the centres of excellence in chronic pain management, providing all round care from spinal cord stimulation to in-house pain management programmes.

He was the clinical director of the Manchester and Salford Pain Centre for 5 years from 2004. He was the director of post-graduate medical education at Salford Royal Hospital Trust for about 10 years from 2002.

Tim was considered as the most successful DME of the time and his input on modernising medical careers was immeasurable. Tim contributed his time and experience to Edge Hill University and NW deanery as associate tutor. Academic advisor, OSCE examiner, communication skills tutor and trust lead for simulation and training were his other contributions in the field of education. He has served as a performance assessor for the GMC.

Tim says his greatest achievement was working with the Zambia Anaesthetic Development Project (ZADP 2010–2018) when he established, trained and developed a cohort of anaesthetists to provide safe pain management. This training helped the local hospitals to apply for funding from the government, as it was the government policy to support only the Zambian anaesthetists to benefit from this fund. Tim has been a regular visitor to the University of Zambia and his lectures and training have transformed the care and pain management in Zambia to a new level. Thanks to this wonderful project which he considers the top achievement of his life.

Tim is highly regarded in the medico-legal field. He has written more than a thousand medico-legal reports over a period of 25 years but has not been called to court in the last 10 years, which speaks of his expert witness skills and diligence in preparing the reports. He has contributed to articles and books in pain management and clinical negligence.

Tim was not remaining idle before becoming a full-time pain management consultant. His clinical interest while being an anesthetist was on post-operative cognitive dysfunction. He was one of the investigators of ISPOCD 1 study (International Study on Postoperative Cognitive Dysfunction) and published articles on POCD in the elderly, middle-aged patients and conducted RCTs on the impact of regional versus general anaesthesia on cognitive dysfunction.

Tim's contributions to research, education, innovation and publications in pain medicine covers a wide range of topics

like anaesthetists and chronic pain relief, an inexpensive self-assembly pressure algometer, outcomes in chronic pain, patient-controlled analgesia, thoracic epidural catheter placement and pig thoracic epidural course. He invented a radio-opaque dummy for X-ray-guided injections that helped trainees to gain confidence in spinal techniques before attempting them in patients.

Tim continued his passion for pain medicine when he was elected to the council of BPS in 2013 and served for two terms until 2018. Tim's input and ideas on pain management programmes directory, acute pain SIG, philosophy and ethics SIG helped achieve significant milestones of these SIGs and strengthened the multidisciplinary fabric of the BPS. He helped steer BPS on many guidelines and response to national guidelines including the NICE guideline on back pain management and cannabis-based medicinal products. His focus was always centred on safe patient care and involved the multidisciplinary approach in the treatment of pain.

Tim is a great teacher, trainer, friend, philosopher and guide. I learned the art of pain medicine from him especially from the quite late evening pain clinics, which he used to conduct in the Salford and Manchester Pain Centre. I have seen patients who used to come with more than half a dozen pain medications, with high pain scores, leaving the consulting room after an or two, happy to wean off most of the pain relief medications with pain reduction by 50% instantaneously. That is's is Tim's magical power of pain-relief.

This is what some of his colleagues say about him – 'Tim is known for his brilliant analytical mind and his creativity. He is highly regarded by his patients as he is compassionate and caring'.

'Like many of us from the NW, Tim was involved in shaping my professional career right from my first days as an anaesthetic SHO to an advanced pain trainee with quiet advice and words of wisdom that continued into my days as a consultant and also as a chair of many pain academic groups. Subsequently I had the honour of serving alongside him as a council member and his counsel was always a source of support and inspiration. A tall man with a taller stature, this honour is very well deserved'.

Honorary membership citation for Dr Paul Wilkinson

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

Pain News
2020, Vol 18(4) 190

SAGE

John Hughes

It is with great pleasure that I read this citation as the British Pain Society (BPS) bestows honorary membership to Dr Paul Wilkinson. This is only bestowed on those who have made an outstanding contribution to the advancement of the objectives of the Society.

In the case of Paul, this is certainly true as many of you will be aware, but it goes much further than the confines of this Society and continues to leave his mark on the advancement of pain management in its broadest sense.

The first time I really met Paul was at the 9th International Association for the Study of Pain (IASP) World Congress in Vienna in 1999. It was apparent then that he had a passion and, along with his experience as a general practitioner (GP), a breadth of understanding regarding pain. This encompassed the biopsychosocial model of pain and holistic interactions with the patient to achieve successful outcomes.

I would like to highlight a few of the areas he has influenced and apologise for any I miss.

Education

Paul has always had an educational interest which he has developed and used to excellent effect. This is exemplified with his membership of the IASP Education Programmes Working Group and previously as chair of the IASP Global Year for Excellence in Pain Education in 2018. This is clearly a feather in Paul's cap and also to the BPS for having a senior member of its team involved in this way.

Pain management programmes

Pain management programmes (PMPs) are another area that Paul has always championed both clinically in his local area and nationally. He continues to foster the ongoing development, understanding and integration of pain management programmes into clinical practice based on the growing evidence and research base.

Standards and guidance

Paul has increasingly become involved with standards and has developed a significant focus not only on standards but also on their impact on guidance and eventual benefit to patients. This is exemplified in his role as Chair of the Professional Standards Committee of the FPM and the degree of output that he and his team have successfully produced. A significant amount of that work crosses professional boundaries and often is linked with the BPS as seen by a wide variety of coproduced or badged documents. This is testament to his ability to work in not only a multidisciplinary manner but also across organisations. It demonstrates his tact and also focus on the task in hand.

Medicolegal

Paul has a national and international involvement and reputation in the medicolegal area. He is active in the IASP Special Interest Groups (SIG) regarding legal and ethical issues in pain, going back to at least 2010. His medicolegal skills allow him to not only see but also articulate the counterarguments, which is invaluable to all his roles. I have seen the results of this to excellent effect, ultimately to the benefit of our patients.

Paul has held a number of positions within the BPS, initially being elected in 2015 and becoming vice president in 2016–2018. He has fully engaged in those roles and deservedly built a broad base of support from all parts of the multidisciplinary team.

Paul continues to influence the world of pain management and further the objectives of this society. It gives me great pleasure to ask you all to congratulate Dr Paul Wilkinson for his commitment to pain management and well-deserved honorary membership of the BPS.

Article

Bridging the gap: formation of a transitional pain clinic in NHS Tayside

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

Pain News
2020, Vol 18(4) 191–194

SAGE

Liz Colquhoun *Senior Pain Specialist Nurse and Independent Prescriber; NHS Tayside Pain Service, Ninewells Hospital, Dundee*

Introduction

Inpatient Pain Services have traditionally been involved in the perioperative management of patients at risk of, or who have been identified as having, problematic pain. Campaigns by professional bodies during the 1990s aimed to incorporate pain as the fifth vital sign.[1]

The deleterious consequences of uncontrolled acute pain have become more fully understood and recognised as a significant post-operative complication. Effects on a wide range of physiological systems such as cardiovascular (coronary ischaemia, myocardial infarction), respiratory (hypoventilation, respiratory infections), gastrointestinal (ileus and nausea and vomiting) and renal (urinary retention, oliguria) have been well documented as have effects on prolonged wound healing times and negative psychological consequences.[2] These factors not only affect patient health, recovery and satisfaction but also contribute to the economic burden of healthcare.

Evidence has also shown that inadequate post-operative pain management may be a causative factor in the progression to chronic persistent pain. Repetitive nociception may cause complex biochemical and structural changes leading to central and peripheral sensitisation.[3,4] The prevalence of chronic post-surgical pain causing functional interference is approximated at 10% following all surgical procedures, leading to a significant public health concern.[5]

As result of research into the effective management of acute post-operative and post-trauma pain as well as the possible progression to chronic persistent pain, guidance and standards have been set for the provision of post-operative pain management with the aim of attenuating these issues.[6,7] Evidence-based pathways, including balanced multimodal analgesia, appropriate adjuvant therapies and regional techniques, have been developed for the management of acute post-operative or post-traumatic pain.[8–10] In conjunction, developments in surgical techniques and pathways have reduced length of inpatient stay and allowed patients to be discharged earlier in their post-operative recovery period. Although there are many benefits to these advances, the result is that analgesic plans are difficult to evaluate and adjust and early signs of persistent pain, often neuropathic in nature, are not identified.

A further important role of inpatient pain services is the management of patients admitted with an acute exacerbation of their chronic pain condition. Once screening investigations are complete, these patients are usually deemed fit for discharge once pain is under control. The nature and persistence of chronic pain makes this an unrealistic expectation. The long-term management of pain has been described as 'fighting a war not a battle'.[11] Expectations of a quick fix may lead to dose escalations, unhelpful investigations and interventions and patient frustration and anxiety, thus exacerbating their acute presentation.[12]

Capacity and flow within busy hospitals can lead to patients being discharged with an increased level of opioid analgesia or the worry that a pain management plan is not in place. The author has witnessed that early discharge of both post-operative patients and of patients with an acute exacerbation of chronic pain has influenced the level and choice of analgesia that patients may be discharged with. Patients may be discharged on newly started anti-neuropathic medications that require titration to reach a therapeutic level.[8] Patients may also be discharged on strong opioids which require regular review to ensure compliance, concordance, continuing requirement and appropriate reduction in line with the recommendations set out by the Faculty of Pain Medicine within their Opioids Aware website.[13] Overprescribing of opioids in the post-operative setting has been purported to potentially contribute to the current opioid 'epidemic' currently witnessed in North America.[14] Responsible prescribing, patient risk assessment and timely review are therefore paramount in the prevention of this phenomenon within the United Kingdom.[15,16]

Traditionally, referral from primary to secondary care services may take a number of months to facilitate and process. Contemporary developments have proposed a more transitional pain clinic model.[5] While working as part of a dynamic nurse-led inpatient pain team, the author of this article

Figure 1. Referrals to pilot project

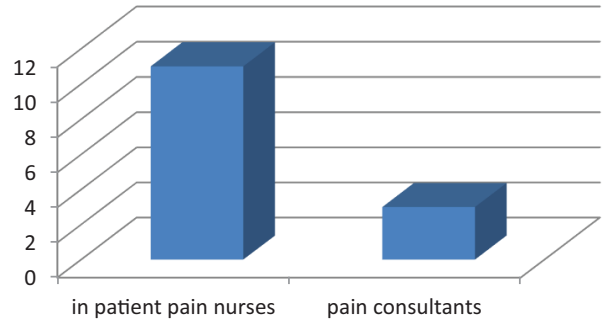
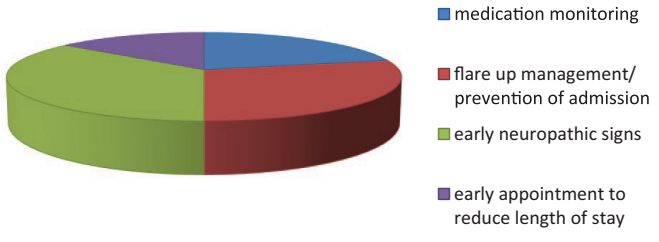


Figure 2. Primary reason for referral



became frustrated with the traditional division between inpatient and outpatient pain service delivery. Patients were often discharged, following significant and prolonged input from the inpatient pain service, with no routine pain follow-up. This often led to a delay in referral to outpatient services for ongoing management. During this delay patients experienced problematic pain, upwards titration of medications, reduced function and resulting psycho socioeconomic factors. Depression and low mood are common while relationships can become strained. Patients may have prolonged periods away from work, causing financial hardship and economic strain on employers.[17] Issues of governance were also reflected upon. Specialist nurses within the Inpatient Pain Team are non-medical prescribers and often initiate pharmaceutical treatment plans for patients. Following discharge, these plans cannot be reviewed, evaluated and adjusted by the prescriber in line with prescribing standards due to the patient no longer being an inpatient within the hospital.[18]

Pilot study

Managerial integration of the pain specialist nursing team and adjustments in roles within the team allowed the pilot of a rapid access appointment. One appointment each week was reserved within a senior specialist nurse clinic to allow the timely review of patients following discharge. Rather than being referred through primary care providers, often leading to delays in access, patients were referred directly following inpatient input by all members of the multidisciplinary Pain Service, although the Pain Nurses were the highest referrers (Figure 1).

Reasons for referral for rapid review were often multifactorial. However, for ease of analysis, the primary reason for referral was selected (Figure 2).

Some patients only received one appointment while others required further follow-up (Figure 3). Two had more prolonged input from the Pain Service; one due to the complexity of her case (MDT involvement and liaison with surgical team) and one due to an ongoing prescription of Ketamine.

There were a number of non-attendances and a total of seven appointments were lost this way. Examples of non-attendees include a female patient who had frequent admissions with abdominal pain, who attended her first appointment but subsequently did not attend a further two appointments due to a significant mental health crisis. Another female patient with a variety of pain complaints attended her first appointment and then failed to attend three subsequent review appointments. This patient has a long history of non-engagement with outpatient services and a history of repeated admissions. During the pilot period, she had 4 inpatient admissions, 4 emergency room (ER) attendances and 34 out-of-hours attendances.

One male patient was referred for post-discharge monitoring following a prolonged hospital admission as a result of a road traffic collision. He was discharged from hospital on high-dose opioids and displayed early neuropathic signs but failed to attend on two occasions. Concerns were communicated to his general practitioner following his first non-attendance. The patient attended ER between the two scheduled appointments with opioid toxicity due to erratic use of prescribed medications.

Results

The provision of early access outpatient pain service review provided appropriate governance and concordance and compliance with analgesic prescribing. The titration and monitoring of anti-neuropathic medications was supported and the reduction of post-operative opioid prescriptions encouraged. As a result, prolonged or escalating doses of opioids were largely avoided.

Figure 3. Number of appointments required per patient

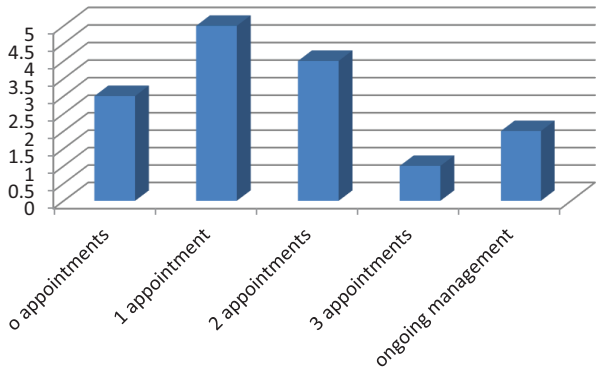
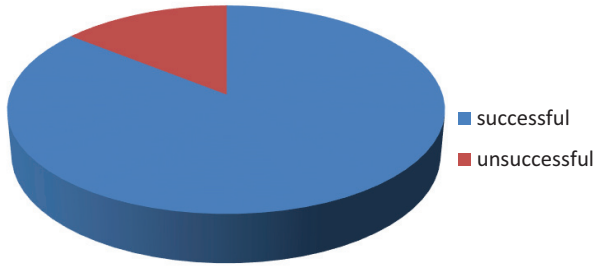


Figure 4. Reflection of success



Input also focused on early self-management support. A wide range of written, online and face-to-face pain education was provided. Patients were encouraged to continue with appropriate activity function goals tackling the concept of fear avoidance.[19] The effect of the stress response on both sleep and pain were also discussed. Patients were assisted to adopt helpful strategies such as relaxation, mindfulness and good sleep hygiene to address this. A greater understanding of the science of pain was felt to be helpful by patients.

The success or failure of this pilot was difficult to measure empirically. The author subjectively divided patient contacts into those that had been 'successful' dependent on the reason for referral. For example, if the reason for referral was to monitor the reduction of opioids post discharge, and this was achieved with patient satisfaction, this was deemed to be a successful contact. The breakdown of successful (86%) and non-successful (14%) contacts is reflected in Figure 4.

The most successful interactions have been the post-discharge 'check-up' patients. Early follow-up allows rapid reaction to early neuropathic signs and symptoms, preventing the progression of chronicity. Communication from the integrated team pre-discharge has also allowed identification of early distress (e.g. early post-traumatic stress disorder (PTSD)-type symptoms) and early signposting to appropriate support, for example, 'Beating the Blues', 'SilverCloud'. Even if patients fail to attend outpatient appointments following a difficult admission, medication use can be checked remotely and any concerns communicated to Primary Care. This communication ensures appropriate governance is maintained, which is particularly important with respect to the prescription of controlled drugs by the inpatient nursing service Non-Medical Prescribers prior to discharge.

The least successful interactions were with those patients who had been admitted with a flare-up of chronic pain. Some had been previously known to outpatient services and previously disengaged, while some had never been referred. These patients present with highly complex pain presentations alongside high levels of anxiety and distress, psychiatric co-morbidity, significant polypharmacy including opioids and no identifiable management plan. We observed that those patients who had not engaged in the past were unlikely to engage on this occasion unless there had been a significant change in their presentation. The provision of a rapid access appointment and outpatient support did not seem to be beneficial to these patients and was not reflected in reduced hospital admissions due to crisis.

Conclusion and future development

This small pilot informed our rapid access development going forward. Experience through the pilot project has led to the formation of more robust criteria for referral, outlining reason for review and communicating expectations. Where possible, the senior specialist nurse running the rapid access clinic will review the patient with inpatient colleagues prior to discharge to begin the therapeutic relationship. Improving criteria for referral has resulted in a fall in non-attendance.

In conjunction, the team as a whole has begun parallel work to look at increasing engagement of those who do not attend outpatient review following an admission due to acute exacerbation of chronic pain. This group have features in common with patients who are repeatedly re-referred to the outpatient service from primary care. Work is underway looking at readiness to engage using change behaviour methodology.

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Article

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SAGE

Alcohol ablation of the genicular nerves for knee pain secondary to osteoarthritis: case series

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Abstract

Ablation of the genicular nerves has recently become a novel treatment modality for patients with chronic knee pain due to osteoarthritis. The procedure, initially described using radiofrequency ablation, has been reported to show clinical improvements in knee pain. The technique of chemical ablation of nerves has been practiced in pain medicine for decades, and its potential benefits include low cost, short procedure time and lower periprocedural pain when compared to radiofrequency ablation. This service evaluation presents outcomes of alcohol ablation of the genicular nerves for 10 patients with knee pain secondary to osteoarthritis. Pre-procedural median pain score was assessed on a numerical rating scale (NRS). NRS improved from 7.5/10 to 4.0/10 after alcohol ablation at four months follow up, p=0.0219. Median Oxford Knee Score improved from 13.5/48 to 19.5/48 after alcohol neurolysis, p=0.0153, mostly due to improvement of pain severity component of OKS. Alcohol ablation did not cause any adverse events in the observed group. Alcohol neurolysis of genicular nerves appears to be a safe and beneficial treatment option for chronic knee pain.

Background

Chronic knee pain is a common symptom associated with advancing age and osteoarthritis, with a lifetime prevalence of approximately 45%.[1] The most common cause of moderate to severe knee pain is osteoarthritis. Treatment options for the management of painful knee osteoarthritis include conservative management (analgesics and physiotherapy), intra-articular injections and arthroplasty surgery. Total knee arthroplasty (TKA) is considered the gold standard treatment for severe end-stage symptomatic knee osteoarthritis. Patients who fail to respond to conservative measures often proceed to surgery. Outcomes from TKA are generally good; however, approximately 20% of patients continue to have significant pain and disability following surgery not accounted for by surgical complications such as infection or loosening.[2]

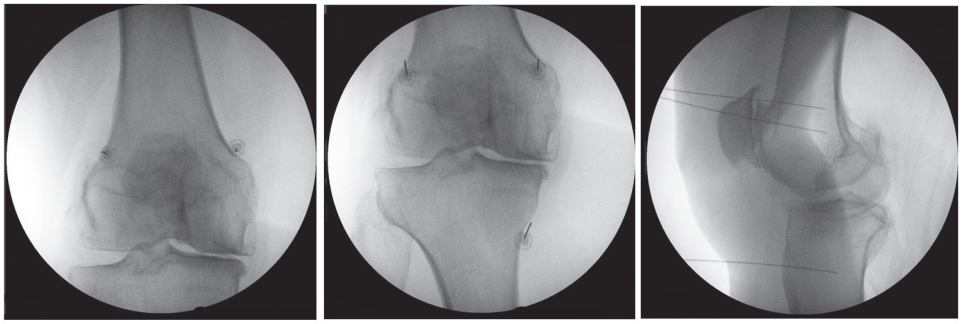
Radiofrequency (RF) ablation of the genicular nerves is a novel technique described in 2011 in a randomised controlled trial by Choi et al.[3] This study described the use of RF ablation of the superior-medial, superior-lateral and inferior-medial genicular nerves to reduce knee pain. This treatment option is now widely practised and has been described using standard monopolar or bipolar RF, pulsed RF, as well as cooled RF. All the various techniques described have achieved beneficial outcomes with low complication rates.[4,5] Moreover, the image guidance of these procedures continues to evolve, from fluoroscopy to combine ultrasound scan (USS) and X-ray, or USS only, each with their own advantages.

In order for the RF ablation to be effective, there must be precise correlation of the targeted peripheral nerve and the site of the overlapping RF lesion produced in order to produce a neuroablative lesion. Accurate placement of RF cannula relies on reliable and consistent neural anatomy in relation to landmarks, and the use of image guidance. Genicular nerve RF may be technically challenging as these nerves do not have such a reliable position in relation to bony landmarks as compared to medial branches of dorsal rami at lumbar level. The use of ultrasound imaging can, however, facilitate localisation of nerves but this may be clinician and patient dependent.

Genicular nerve ablation employing alcohol neurolysis has been described.[6] Even small volumes of injectate have the potential to spread over a larger area than a thermal RF lesion. This technique may therefore overcome problems associated with RF lesioning, but with the potential risk of inadvertent spread of neurolytic agent.

This service evaluation of routine clinical practice presents pain severity improvement, functional outcomes assessed using the Oxford Knee Score (OKS) and safety profile of chemical ablation of the superior-medial, superior-lateral and inferior-medial genicular nerves using alcohol.

Figure 1. (a) AP view confirming position of needles in close proximity to superior medial and lateral genicular nerves (with kind permission of patient/author). (b) AP view confirming position of needles in close proximity to inferior medial genicular nerves (with kind permission of patient/author). (c) Lateral view confirming position of needles in relation to femur (with kind permission of patient/author)



Methods

This service evaluation of routine clinical practice has been performed in tertiary pain clinic in the United Kingdom. Patients with knee pain due to osteoarthritis were referred to the pain clinic by orthopaedic surgeons when surgical treatment was impossible. Those patients with moderate to severe anterio-medial knee pain secondary to osteoarthritis who were not appropriate for TKA due to weight, comorbidities or patient's preference were eligible for the procedure.

Patients who fulfilled the eligibility criteria and consented for the procedure were investigated according to our usual practice by performing a diagnostic genicular block with local anaesthetic only. A 22G Quinke spinal needle was positioned under ultrasound guidance with its tip located adjacent to the superior-lateral, superior-medial and inferior-medial genicular nerves. Needle position was confirmed using fluoroscopy in anteroposterior (AP) and lateral view (Figure 1). One millilitre of 0.5% levobupivacaine was injected to each site around the nerves (total 3 mL of 0.5% levobupivacaine) under direct ultrasound visualisation. Diagnostic block was considered positive if patient reported ⩾70% pain severity reduction from 30 minutes to 4 hours post procedure. Those patients in which the diagnostic block was positive were listed for therapeutic genicular nerve ablation.

Chemical genicular ablation with alcohol was offered to patients in whom there were absolute or relative contraindications to RF. This included anti-coagulated patients (risk of bleeding), very slim patients (risk of skin burning), patients with pacemakers or patients with relative contraindications to remifentanil sedation (required during RF ablation). There was no randomisation to treatment groups and the decision of treatment modality was dependent on the physician.

Safety assessment was performed using analysis of complications reported to the clinical team during the period of observation, up to 4 months post-procedure.

Prior to the therapeutic procedure, all patients self-completed baseline screening which included Numeric Rating Pain Scale (NRS) (0 = no pain, 10 = worst pain) to assess pain severity and the OKS questionnaire to establish baseline pain and function. The OKS was chosen due to its well-established role in assessing outcomes following therapeutic procedures for knee pain including TKA.[7] We used the OKS according to the 2007 guidance.[8] The OKS assesses both pain severity (OKS-P) and functional performance (OKS-F). The self-assessment questionnaire comprises 12 stems, each one scoring from 0 (worst outcome) to 4 (best outcome). Maximal outcome of 48/48 indicates the highest level of function and no pain.

Chemical ablation of the genicular nerves was performed using absolute alcohol in the following way. After subcutaneous local anaesthetic infiltration with 1 mL of 1% lidocaine at each site, 22G Quinke spinal needles were positioned under ultrasound guidance with the needle tips located in the region of the superio-lateral, superio-medial and inferio-medial genicular nerves. Needle position was confirmed using fluoroscopy in AP and lateral views. After needle tip position had been confirmed, 1 mL of 1% lidocaine was injected to each site around the nerves under direct ultrasound visualisation after needle aspiration to exclude intravascular placement. After 2 minutes, a further 1.5 mL of absolute alcohol was injected in the same position under direct ultrasound visualisation in the same way as before. The procedure was performed without sedation.

Outcome of the procedure was assessed 4 months post-procedure using NRS and OKS to allow comparison with pre-procedure pain severity and functional impairment. Any

Figure 2. Boxplot presents the change of NRS score by 3.5 points (from median 7.5/10 to 4/10) after alcohol ablation to genicular nerves of knee at 4-month follow-up

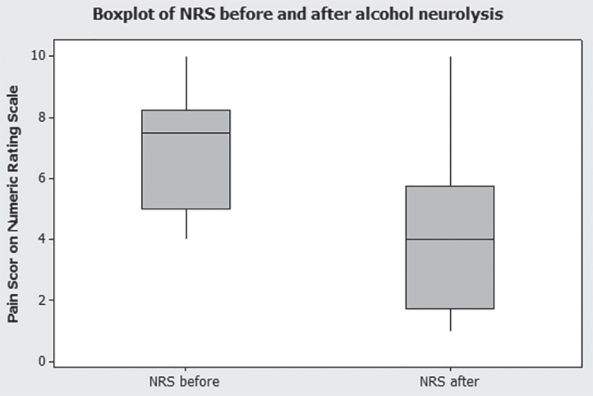
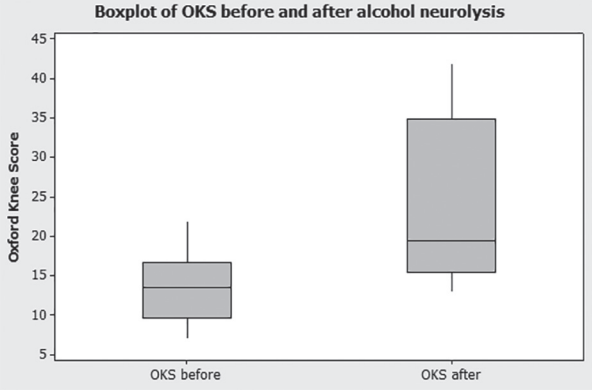


Figure 3. Boxplot presents improvement of OKS from median of 13.5/48 to 19.5/48 after alcohol ablation to genicular nerves of knee at 4-month follow-up



complications of the procedure reported either at 4-month follow-up or at any other time were recorded.

Statistical analysis concerned with comparison of ordinal data of OKS was represented as median 95% confidence interval (CI; lower–upper CI) analysed with Mann–Whitney test.

Results

A total of 10 patients reported a positive diagnostic block outcome and fulfilled the criteria for alcohol ablation between June 2018 and November 2018. Mean age was 68. Female-to-male ratio was 50:50. One out of 10 patients underwent previous total knee replacement. Pre-procedure median pain score assessed on NRS was 7.5/10 and reduced to 4.0/10 after alcohol ablation at 4-month follow-up, $p=0.0219$ (Figure 2).

Pre-procedure median outcome of OKS was 13.5/48 (11–20, lower–upper interval) versus after alcohol neurolysis 19.5/48 (17–33), $p=0.0153$, Figure 3. Median OKS-F before alcohol neurolysis was 6.5/20 (5.5–8) and improved slightly to 8.0/20 (6–13), $p=0.11$. OKS-P improve from 7/28 (6.5–11.5) before alcohol neurolysis to 11.5/28 (10.5–20) after neurolysis, $p=0.006$.

There were no major side effects or complications observed in cohort of patients. There was no motor weakness or deafferentation pain in observed period. Four patients experienced mild pain during the injection of alcohol which resolved after a few minutes.

Discussion

Chemical ablation of the genicular nerves using the well-established technique of alcohol neurolysis as described in this case series is a variant of the RF ablation technique describe by Choi et al. Questions remain regarding the potential limitations of genicular RF, including the number of genicular nerves involved in the transmission of knee pain, variable location of particular genicular nerves, and close proximity of vascular structures and perineal motor nerve.[9]

Despite multiple studies, there is no agreed standard technique for genicular ablation, and many variations have been described.[5,10] Chemical ablation of the genicular nerves has been described in case reports as an alternative to thermal or cooled RF.[6] There are several potential advantages to this technique. The procedure does not require a RF pulse generator and consumables and is therefore less expensive to perform. It has the potential to be quicker as no time is required for the RF lesion to be created, and it can be performed using smaller gauge needles which may cause less procedural pain and other complications. An additional potential therapeutic advantage is the ability of the injected neurolytic agent to cover a larger anatomical area than a conventional RF lesion, which may be more likely to create a neuroleptic lesion, depending on the position of the RF cannula. If a similar volume of injectate is used in the diagnostic block and the therapeutic chemical ablation, then the nerves blocked and therefore the therapeutic effect may be expected to be similar between the two procedures.

In these cases, our technique involved chemical ablation of the superior medial, lateral and inferior medial genicular nerves, those targeted by Choi et al in 2011.[3] We positioned the needles under USS guidance, allowing visualisation of the needle and target, and observation of local anaesthetic/neurolytic agent spread. Needle position was further verified with AP and lateral X-ray allowing secondary position check,

and a reference to compare diagnostic and therapeutic needle position. The use of ultrasound guidance may also improve the safety profile of the procedure and rule out intravascular injection by allowing real-time observation of the spread of injectate.

In these cases, improvement of pain severity score and OKS was less than in some studies, but this could be due to pre-procedure patient characteristics.[10] Those patients were not eligible for TKR due to surgical and patient factors and were referred for pain management only. An initial OKS which is very low indicates severe pain and impairment in function and therefore likely more severe disease. Greatly impaired function, as measured using OKS, may not only indicate severe knee pathology but also be multifactorial and concern other comorbidities apart from the knee joint itself. In our case series, there was statistically significant improvement in OKS-P but not OKS-F. We hypothesise that while pain reduction is achievable by genicular ablation, as reported in other studies, improvement in functional performance is more challenging. This may be due to factors such as comorbidity, deconditioning and coexisting pain limiting improvement in function. Nevertheless, the chemical ablation was the last remaining treatment option, which those patients had not already exploited, with the alternative being to learn more coping strategies via pain management programmes.

RF ablation was previously performed for patients after TKR; therefore, we tried chemical ablation. However, the outcome was poor and the patient pain severity level did not improve at all.

Chemical ablation is done with significantly smaller needles and took less time in our centre. None of the patients required sedation or additional manpower to perform the procedure.

Our practical experience of genicular nerve ablation with alcohol during this case series has shown us that there are several advantages with this procedure compared to conventional RF ablation. Time taken for this procedure is less in our experience than with RF. However, these data were not specifically collected and statistical analysis is therefore not possible. Chemical ablation also has fewer relative/absolute contraindications as it can be easily done for patients with neurostimulators or pacemakers without risk of equipment damage, or deactivation of these devices. As the procedure requires smaller gauge needles than RF, ongoing anticoagulation does not seem to be problematic and none of the patients in our case series experienced any bruising or bleeding complications.

Conclusion

Chemical ablation of the genicular nerves using alcohol is likely to be a safe procedure providing significant pain reduction 4 months post procedure in patients with moderate to severe knee pain secondary to osteoarthritis. This procedure has several potential advantages over conventional RF techniques. Further studies are required to assess this procedure in a larger patient cohort and to establish duration of analgesic effect and to compare to other techniques.

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Article

Photography Showcase

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SAGE

Newborough Storm© Keith Truman

'Newborough Storm' was shot on Newborough Beach in Anglesey in November 2018 as a storm approached across the Menai Straits from Snowdonia.

'Deer in Dawn Mist' (Front Cover) was taken early one morning in April 2019 at Hertfordshire wood. The mist soon lifted as the sun rose.

The photos 'Newborough Storm' and 'Deer in Dawn Mist' were shot by Keith Truman and Peter North, respectively, and both photos achieved the accolade of being commended at the prestigious Landscape Photographer of the Year Competition 2020.

In addition to being good friends and both living in North Herts, Keith and Pete are chemists who worked in Research and Development for a major drug company before retiring. As a retirement hobby, they have both became more serious about their photography and are members of Melbourn & District Photographic Club which meets in South Cambridgeshire, a club which prides itself on the informal and friendly exchange of information and expertise between the club members (http://melbournphotoclub.com).

Article

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SAGE

Significance of ACR Fibromyalgia questionnaire in positive diagnosis and predictive value of ACR Fibromyalgia questionnaire in patient selection process for epidural injection for treatment of lumbar radicular pain: an observational prospective study

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Abstract

Lumbar radiculopathy is a common condition which can result in significant pain and disability. Lumbar radicular pain is frequently treated with epidural steroid injections but despite long experience with those injections, there is still a lack of reliable predictors of successful treatment to assist in patient selection. Fibromyalgia is prevalent in patients attending pain clinic and has been identified as a predictor of outcome for some orthopaedic procedures such as arthroplasty. Fibromyalgia has not previously been investigated as a predictor for epidural steroid injections for radicular pain.

We designed an observational, prospective single centre study. The aim was to investigate whether the American College of Rheumatology (ACR) Fibromyalgia diagnostic questionnaire has any predictive value for outcomes following epidural type steroid injections (interlaminar and transforaminal injections) for radicular pain.

77 patients were recruited to the study and received therapeutic injections between Nov/2017 and Dec/2019 Patients were divided into two groups based on the defined primary outcome - ≥50% pain reduction at 3 month follow-up. The primary outcome was achieved in 26 patients (group A), and not achieved in 51 patients (group B). Median value of Widespread Pain Index (WPI) in group A was 5 vs. 4 in group B, p=0.447. Median value of Symptom Severity score (SS) was 7 in group A vs. 6 in group B, p=0.201. Of the 26 patients in group A, 9 (30%) fulfilled the ACR diagnostic criteria, while 17 patients did not. Of the 51 patients in group B, 15 (28.3%) fulfilled the ACR diagnostic criteria, while 36 did not (p=0.83). Analysis of fibromyalgia symptom severity (`fibromyalgianess')– the polysymptomatic distress scale (PSD=WPI + SS)– showed that median in group A was 11 vs. 10 in B, p=0.325.

Neither diagnosis of fibromyalgia using the ACR diagnostic criteria, or any components of the criteria, showed any significant difference between groups A and B. We therefore conclude fibromyalgia phenotype has no predictive value for the outcome of epidural type injections for radicular pain assessed at three months post procedure.

Background

Lumbar radicular pain is a common condition presenting either as the primary symptom or co-existing with lower back pain. Treatment options for the management of lumbar radicular pain include invasive and noninvasive strategies. Conservative treatment options include patient education, exercise, manual therapies and psychological therapy. Pharmacological treatments include conventional analgesics and anti-neuropathic pain medications. Invasive management includes epidural steroid injections and surgical interventions.[1] Invasive management options such as epidural injections and surgery are costly to provide and involve some risk of complications. It is desirable to identify reliable predictors of successful treatment outcome to provide these treatments to those patients most likely to benefit.

Table 1. Types of diagnostic blocks and frequency of positive responses.

Type of block	Group A (positive outcome) N=26	Group B (negative negative) N=51	P (with Yates correction)
Lumbar nerve root injection/transforaminal epidural	20	42	0.79
Lumbar interlaminar epidural	4	7	0.88
Lumbar caudal epidural	2	2	0.87

The beneficial outcome of interventional procedures for chronic pain relies not only on the medical indication for, and technical execution of, the procedure but also on other psychosocial factors. Studies investigating predictors of successful invasive treatment of lumbar radicular pain, including spinal cord stimulation, reveal a lack of consensus on reliable predictive factors.[2,3]

Fibromyalgia is a common diagnosis among patients attending pain clinic, including those presenting with focal symptoms such as radicular pain alongside widespread pain.[4] If patients who exhibit fibromyalgia phenotype or central sensitisation syndrome present with specific focal pain presentation such as radicular pain, interventional treatment may be indicated. There is some evidence that a diagnosis of fibromyalgia may negatively predict the outcome of surgical treatments for pain such as arthroplasty.[5] We aimed to investigate this hypothesis to determine whether fibromyalgia phenotype is a predictor of outcome following epidural-type steroid injections (interlaminar, transforaminal and caudal) for lumbar radicular pain.

Methods

We designed a single-centre prospective observational research study to investigate the predictive value of fibromyalgia phenotype in patients undergoing interventional procedures for chronic pain in a tertiary pain clinic in the United Kingdom. Ethical approval was granted (IRAS project ID: 231514). The observation period extended from November 2017 to January 2019. Inclusion criteria were all English-speaking chronic pain patients listed for therapeutic procedures for chronic pain. This article analyses those patients receiving epidural steroid injections (interlaminar, transforaminal and caudal) as a treatment for radicular pain. Exclusion criteria were no consent or withdrawal of consent, and incomplete data available (incomplete American College of Rheumatology (ACR) fibromyalgia criteria or outcome data not obtained).

Patients were listed for epidural injection after being assessed by the physician responsible for their care. The decision to perform therapeutic injection was according to usual practice, consisting of comprehensive and individualised biopsychosocial assessment, history, examination and investigation results including spinal imaging, where appropriate. Routine screening was also available as part of our usual pain assessment, including Brief Pain Inventory (short form), Pain Self-Efficacy Questionnaire, 7-item Generalised Anxiety Disorder (GAD-7), 9-item Patient Health Questionnaire (PHQ-9) and EuroQol 5-dimension (EQ-5D). Once patients were selected for and consented to the procedure, all consecutive patients were approached by the research team to be included in the study and to provide written consent. Consented patients were asked to self-complete the 2010 ACR fibromyalgia diagnostic criteria prior to the procedure. Pain physicians responsible for the patient's care were blinded to the outcome of the fibromyalgia screening questionnaire.

Results from the self-completed ACR fibromyalgia diagnostic criteria were collated and analysed. Scores for each patient in the domains of Symptom Severity score (SSS) and Widespread Pain Index (WPI) were calculated. For each patient, it was determined whether they crossed the diagnostic threshold of WPI ⩾7 and SSS ⩾5 or WPI 3–6 and SSS ⩾9.6. If they crossed this threshold, then they were defined as 'fibromyalgia ACR positive'.

Figure 1. Box plot presents Widespread Pain Index for both groups, which do not differ statistically significantly between them.

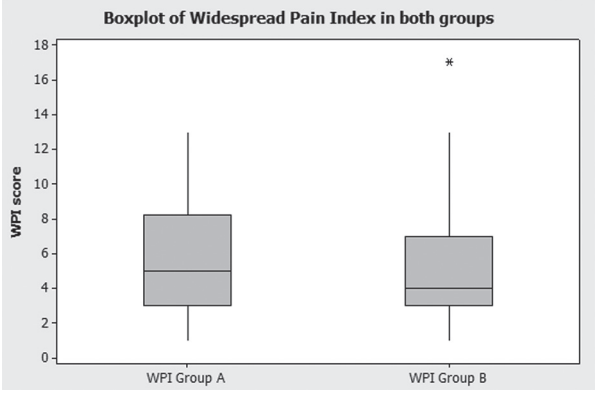


Figure 2. Box plot presents Symptom Severity score for both groups, which do not differ statistically significantly between them.

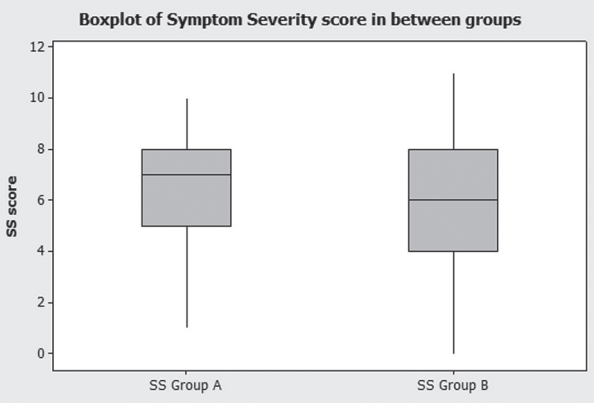
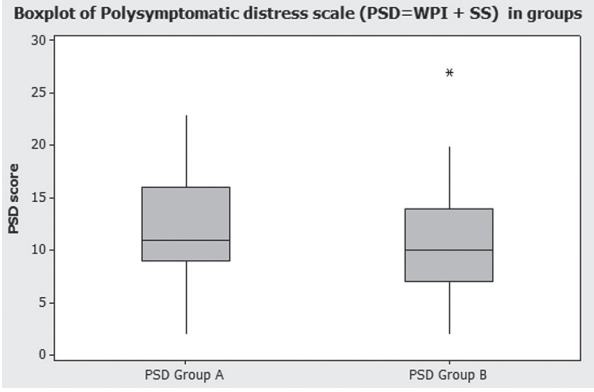


Figure 3. Box plot presents polysymptomatic distress scale – fibromyalgianess for both groups, which do not differ statistically significantly between them.



All epidural injections were performed using non-particulate steroids (dexamethasone) and local anaesthetic – bupivacaine 0.25% as the injectate. Results from therapeutic epidural injections were assessed by 3-month telephone follow-up by a blinded research team member. The outcome of the procedure was defined as positive if the patient reported a greater than 50% reduction in radicular pain. Based on this primary outcome, the cohort was divided into two groups: group A, patients who achieved >50% reduction in radicular pain, and group B, patients who failed to achieve the primary outcome.

Statistical analysis between groups A and B was conducted as follows: continuous variables with normal distribution are presented as mean ± SD, and the comparison of means for such data (age of patients) was performed by *t*-test (normal distribution confirmed with Kolmogorov–Smirnov test). Categorical data are described as percentages and compared with the χ^2 test. Ordinal variables, WPI and SSS, are presented as median and analysed with the Mann–Whitney test. Further statistical analysis for parameters that achieved statistical difference in investigated subgroups aimed to use receiver operating characteristic (ROC) analysis and logistic regression to find predictors.

Results

Seventy-seven patients who had received epidural injection were recruited for the study between November 2017 and January 2019. Patients were divided into two groups based on the defined primary outcome, >50% pain improvement at 3-month follow-up. In all, 26 patients had a positive response (group A) and 51 patients had a negative outcome of injection (group B). Sixteen females were included to group A versus 27 to group B, p=0.47. The mean age of group A was 60.1 ± 13.5 versus 55.7 ± 14.1 in group B, p=0.176. Table 1 shows the types of therapeutic injection performed in both groups, which do not differ significantly.

The median value of WPI in group A was 5 versus 4 in group B, p=0.447 (Figure 1). The median value of SSS was 7 in group A versus 6 in group B, p=0.201 (Figure 2). As none of the measured variables differed significantly between subgroups, further analysis of WPI or SSS would not show any predictive value for therapeutic spinal injections for radicular pain.

Analysis of fibromyalgia symptom severity ('fibromyalgianess') – the polysymptomatic distress scale (PSD=WPI+SSS) – showed that the median was 11 in group A versus 10 in group B, p=0.325 (Figure 3).

Of the 26 patients in group A, 9 (30%) fulfilled the ACR diagnostic criteria. Of the 51 patients in group B, 15 (28.3%) fulfilled the ACR diagnostic criteria. There was no statistically significant difference between the two groups (p=0.83). Therefore, in this data set, the presence of ACR questionnaire for positive diagnosis of fibromyalgia does not have any predictive value.

Discussion

This study did not find any correlation between fibromyalgia-positive phenotype or fibromyalgia symptom severity and the outcome of epidural injection at 3 months in patients selected for injections by experienced pain physicians. The fibromyalgia questionnaire or any of its components did not have any predictive value for outcome of epidural-type injections when measured 3 months after procedure.

As far as we are aware, there is no other study investigating this topic. One similar study by Brummett et al. evaluated diagnostic medial branch blocks for chronic lower back pain. That study showed that patients with fibromyalgia exhibited differences in longitudinal response patterns. These patients presented a slower initial response with prolonged analgesic response beyond the expected duration of the local anaesthetic, which may suggest a false-positive outcome. There was, however, no difference in numbers of positive or negative responders between fibromyalgia-positive and fibromyalgia-negative patients.[6]

Other studies concerning steroid injections carried out for carpal tunnel syndrome or epicondylitis showed that patients with fibromyalgia were less likely to benefit when assessed at 2 weeks and 3 months after injection.[7,8]

In a study of outcomes of surgery for internal derangement of temporomandibular joint, which is a common chronic pain condition with multifactorial background, results from 28 patients at 5 months did not correlate with an existing diagnosis of fibromyalgia. This cohort of patients is likely to be closer to a chronic pain clinic population than most patients with large joint osteoarthritis.[9]

Orthopaedic studies that investigated the correlation between Fibromyalgia Severity Score (PSD) and surgical outcomes showed a correlation between higher PSD and negative outcome, but this was not confirmed in the analysis of WPI or SSS as a predictor of outcome. An observational study of 464 patients published in 2015 showed that higher scores on the 2010 ACR fibromyalgia diagnostic criteria were associated with less improvement in pain following hip or knee arthroplasty. They found a 17.8% increase in failure to meet the threshold for 50% improvement in pain 6 months after surgery for each 1-point increase in 'Fibromyalgia Severity Score', which is the combined PSD – Fibromyalgia Severity Score taking the total score from both WPI and SSS and as a total out of 31 points.[5]

Our own findings are in support of the literature, suggesting a lack of evidence for worse outcomes after procedures for chronic pain in patients with fibromyalgia phenotype. This is important as the majority of published evidence mostly from surgical specialties is contrary to this.

There are several limitations to our study, which we acknowledge, and we appreciate that they can contribute to bias. Prevalence of fibromyalgia phenotype is less common in our study in comparison with the literature – 22%. This may be related to the design of our study, which observed standard practice of a tertiary clinic and did not interfere with it, aiming to present realistic outcomes. Patients were referred for spinal injection after initial referral triage and multimodal assessment by experienced physicians. There may be pre-inclusion bias in our study based on the assessment of patients, those with chronic widespread pain (common in fibromyalgia) being perhaps less likely to be selected for interventional procedures.

All injections were performed by experienced practitioners, but there was a lack of strict protocol regarding the technique or doses of steroid and local anaesthetic. There was also no protocol for selecting patients for these injections, other than clinical judgement and usual practice within our clinic. We deliberately designed our study to observe our usual clinical practice and as such make it valid for real clinical practice. If the study protocol differed from usual practice, this would make the results less valid in real clinical conditions and raise ethical considerations for the study.

The use of 3-month follow-up is open to question. There is no widely recognised 'correct' time point at which to measure outcomes. We believe that 3 months is an appropriate duration of effect to be clinically significant for the patient and practical for the study design.

Conclusion

Neither fibromyalgia symptom severity ('fibromyalgianess') – the PDS – nor the presence of ACR Fibromyalgia questionnaire positive phenotype had any predictive value for the outcome of spinal epidural injections for radicular pain. None of the component part of the ACR Fibromyalgia questionnaire, WPI or SSS, has any predictive value either. Multifactorial expert clinical judgement should not be affected by the presence of fibromyalgia when selecting patients likely to benefit from epidural injections to treat radicular pain. Our study has certain limitations as described above, and therefore further studies are needed on this topic.

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Article

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SAGE

Does the diagnosis of complex regional pain syndrome have any clinical utility and does it have the potential to cause more harm than good?

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The Madness of Fear. La locura del miedo.
Francisco Goya Date: 1819 – 1823 Style: Romanticism.[1]

Francisco Goya was a talented Spanish painter and printmaker, and is considered one of the last of the Old Masters of painting, as well as the first of the moderns. Between the years of 1792 and 1793, Goya suffered from a mysterious illness, which made him deaf, and affected his mental behaviour. Some current medical scientists believe that his deafness was a result of the lead in which he used in his paints, whereas others believe it may have been some sort of viral encephalitis. Either way, its effect on Goya cannot be understated. After his illness, he became withdrawn and introspective, and began painting a series of disturbing paintings on the walls of his house in Quinta del Sordo.[2]

Introduction

It is not the intention of the author of this article to challenge the existence of a well-documented but rare phenomenon characterised by painful sensory symptoms with concurrent sudomotor and vasomotor abnormalities that can follow tissue injury (traumatic or iatrogenic) which goes by the name of complex regional pain syndrome (CRPS). The author has seen, diagnosed and treated the condition, as well as witnessed the potentially catastrophic consequences that can accompany this phenomenon.

The aim of this article is to reflect upon the diagnosis of CRPS, its clinical utility, the implications of the diagnosis and whether the criteria upon which the diagnosis is based might be biased towards presentations that are influenced by factors that are known to lead to reports of chronic symptoms characterised by disproportionate pain and accompanying disability.

I will argue in what follows that it is likely, on balance, that a sizable proportion of those historically and currently diagnosed with CRPS probably do not have the condition and this is a function of the nature of the current diagnostic criteria and how they actually perform in clinical (and other) settings.

A contemporary view

The focus of much of the research and the treatment of CRPS has been based upon potential biomedical mechanisms that have been thought to be important in the aetiology and maintenance of the various features of the condition.

Some authors have been optimistic about the status of our understanding of the biological basis for and the treatment of CRPS,[3] but a pragmatic review of the evidence base supporting any one treatment or combination of treatments shows that our understanding remains poor.[4,5] Many studies are flawed by design and so the reality is that there is no therapeutic modality that can be confidently offered with any certainty to our patients.

As a consequence, most treatments are trialled after consideration of the risks (usually low) and the evidence suggests that the clinical course of the disease takes its usual unpredictable course irrespective of what treatment is offered and applied.

We as clinicians have all been impressed by the apparent efficacy of a particular treatment in one case only to be disenchanted by its apparent inconsequential impact upon another.

Despite a considerable body of research on the subject of CRPS over the last decade, this position is relatively unchanged, and this is not through a lack of effort on behalf of the scientific community or an unawareness in the clinical community of the importance of early treatment and robust support of the patient; encouraging a return to normal functioning of the affected limb. As it transpires, there appear to be no predictive factors for the outcome of any one therapy or the clinical course for a presentation of CRPS.

In the light of the growing sophistication of research methodologies and the apparent absence of any new leads towards unravelling the clinical Gordian Knot that CRPS appears to represent, perhaps a different paradigm needs to be adopted rather than a re-working of hypotheses that were first proposed just short of a century ago?

Biomedical mechanisms

Perusal of the literature that has been published over the last decade or so reveals that while there remains a thirst to elucidate the mechanisms that underpin the abnormal inflammatory,[6,7] neurological[8,9] and immune[10,11] responses thought to be important in mediating an abnormal response to injury, the biomedical mechanisms responsible for the phenomena remain elusive, and causation (the relationship between the triggering event and the clinical phenomena) even more so.

A recent review has highlighted a relatively new realm of investigation that, while invaluable in the steady march towards scientific enlightenment, has, within the context of CRPS, acted to emphasise the heterogenic nature of patients' response to trauma at a cellular level and the cross-over of populations considered to have developed CRPS and those that did not. The authors concluded that specific biomarkers for the phenomena at the centre of this discussion have not been identified and probably never will be.[12]

So, it seems unlikely that there is something, as yet unidentified, that differentiates those who have CRPS from those who do not; or is it possible that the CRPS population itself (as it is currently defined) is just too heterogeneous for a link to be identified?

Supporting the latter is the observation that despite the array of therapeutic options that have been made available over time, treatments directed towards postulated biomedical mechanisms that are thought to underly the clinical presentation of CRPS have failed to stand up to the scrutiny of the controlled trial and it is now only within the context of a research project that patients are considered for anything other than physical and psychological therapies and trials of anti-neuropathic medications endorsed by National Institute for Health and Care Excellence (NICE).

There is evidence indicating that electrical neuromodulation might prove effective in the management of the painful symptoms of CRPS.[13,14] Whether this modality modifies the disease process remains unclear; mechanisms of this might include immunomodulation and/or effects of improved function of the affected limb.

The mechanisms that drive neuropathic pain at a neural level are already quite well understood and it should be no surprise that an effective therapeutic tool in the management of neuropathic pain syndromes has the potential to provide benefit in those presenting with CRPS.

The diagnosis of CRPS

Despite efforts to refine the diagnostic criteria for CRPS the absence of reliable objective tests means that the validation of the criteria for diagnosis still has at its centre a circular argument (as highlighted by Borchers and Gershwin[15] in their 2014 review) that the criteria are used to both identify the specific patient group and also distinguish it from other patient groups.

The same review details the staggering array of clinical presentations that might all fulfil the diagnostic criteria, but which can also be explained by other conditions; the authors of the review reiterated the earlier opinion of others.[16]

Earlier work suggesting that subtypes might be identified and allow more focused therapies highlighted the heterogeneity of the clinical phenomena that fall within the criteria for a possible diagnosis of CRPS.[17]

However, the relative lack of understanding of the pathophysiological mechanisms that were recognised at the time of the publication is no nearer to being clarified, despite the amount of work directed towards the subject. The condition(s) remain stubbornly resistant to therapies and no one pattern of presentation is any more predictive of response to treatment now than was the case in 2002.

It therefore remains a consequence of the lack of understanding of the pathophysiological mechanisms of this phenomenon that the diagnosis of CRPS continues to be based upon observed, vague clinical criteria which have to be interpreted by clinicians with often poor consensus between themselves. Thus, the diagnostic criteria are practice based

and not evidence based; this reflects our ongoing lack of understanding of the conditions but is a matter that is perhaps oft overlooked in the out-patient clinic context.

Differentiating CRPS from other chronically painful conditions

In their later review Borchers and Gershwin[18] again highlighted the spectrum of conditions that bear similarities to CRPS sufficient to fulfil the criteria if applied, ranging from the more mundane (a normal response to trauma or surgery (or both)) through to the predictable effects of immobilisation and on to neural injury or entrapment.

A surprising proportion of patients report significantly intrusive symptoms, often with neuropathic qualities, months after surgery or trauma, and this has been a subject of interest for decades.

As Katz and Seltzer stated in their erudite review of post-surgical pain, all chronic pain was, at some stage, acute pain.[19] While the transition from acute to chronic pain is well recognised, consideration of the evidence of the range of factors thought to influence the transition reveals that psychosocial factors are, in fact, central to that transition.

It is also well established that persistent pain (and consequently disability) following trauma is influenced more by psychosocial factors than injury-related factors.[20,21]

The recent evidence in Birklein's review reveals that the current biomarkers after trauma are not disease specific and, in all likelihood, there is a broad spectrum of responses within the population. Therefore, it remains unclear what mechanisms, at a cellular level, lead to the chronic picture seen in CRPS in particular but also in the wider context of chronically painful conditions more generally.

The evidence leans towards the main driver promoting chronic pain to be beyond tissue-trauma mediated factors and furthermore knowing what we do about the central mechanisms of chronic pain[22] is it any surprise that specific biomarkers for a chronically painful condition such as CRPS (or indeed therapies directed towards putative biomedical mechanisms of CRPS) have not proved particularly useful avenues at a research or clinical level?

We accept that physical impairment as a consequence of biomedical causes needs to be distinguished from impairment secondary to psychological, social and behavioural factors, which can all contribute to the overall disability in a particular case.

This is no less important in the context of considering a diagnosis of CRPS; behavioural changes, such as immobilisation, can lead to changes in physical appearance that are also said to be diagnostic of CRPS. There is the risk, therefore, that the diagnosis of CRPS might be confounded by the impact of behavioural changes such as immobility on the affected limb's appearance.

When appraising a presentation of reported disproportionate pain there are likely, on balance, to be a broad range of factors that need to be considered. Restricting attention to the injury-/surgery-related biomedical factors, a practice that reflects the well-worn paradigm of Western medicine, fails to recognise other factors that are likely, on balance, to have a role.

The Royal College of Physicians Guidelines for diagnosis, referral and management of CRPS[23] and the myriad published review articles on CRPS point to the lack of evidence of psychological or psychosocial factors having a role in the aetiology of the condition. The same position is fairly persistent throughout literature on the subject of CRPS.

Few of us have the time or inclination to study the literature upon which such claims are based in great detail, but the citation rate of certain papers that support this position is remarkably high.

Appraisal of the 2011 Beerthuizen et al.[24] study might give some insight into the issues that this current article is attempting to address. This study is cited in the current and previous Royal College of Physicians publications referred to above (and many others).

In this study structured interviews were undertaken at the time of cast removal following limb trauma (T1) and 3 months later (T2) in 596 post trauma patients. At these two time points CRPS was diagnosed in 7% of patients.

Some of those 42 individuals who met the criteria might actually represent a population who have developed CRPS, but the high incidence, on balance, probably also reflects capture of individuals who were undergoing a completely normal response to trauma and immobilisation.

In other words, is it actually possible to diagnose CRPS in a limb that has been traumatised and immobilised, at the time of cast removal?

At the second time point in the study when individuals were assessed for the possible development of CRPS (T2), this assessment was undertaken by telephone. The Life Events Inventory and Symptom Checklist-90 (SCL-90) was used to measure psychological factors in the whole study population.

Can any valuable inference on the role of psychological factors in the rehabilitation of this population of 42 be gleaned given the likelihood that less than half of them actually have CRPS, according to internationally accepted incidence of CRPS?

The study did reveal a relationship between somatisation and CRPS (as established by the study group) but when items in the Symptom Checklist-90 that were considered to be confounding factors (somatisation, agoraphobia, insomnia and insufficiency) were removed from analysis, any relationship was lost.

It might well be true that a genuine presentation of CRPS is independent of pre-morbid psychological problems, somatisation or malingering, but one unfortunate consequence of the current diagnostic criteria might be that all three (pre-morbid psychological problems, somatisation or malingering) have the potential to create a presentation that has the necessary hallmarks to fulfil the criteria and generate a diagnosis of CRPS.

In light of our current understanding of chronic pain, it is reasonable to accept the likelihood of psychosocial factors to have a potential role in a presentation with the hallmarks of CRPS (as it is currently diagnosed). Furthermore, the literature focusing on the hypothesis that there is no relationship between pre-morbid psychological problems and the development of CRPS is limited and in my opinion does not provide a robust argument.

The majority of cases that are labelled CRPS segue on to spontaneous resolution.[25] It is natural to ask whether these individuals have a different condition to those that become chronic?

There is no relationship in CRPS between the extent of injury and chronicity of the condition or an identified biological marker that separates those that go on to develop chronically disabling symptoms and signs from those that recover spontaneously.

Is it not possible that psychological factors might account for this lack of correlation in the current population of those diagnosed with CRPS? It is accepted that in the chronic pain population as a whole, there is the potential for a significant psychosocial contribution. It is likely therefore that such factors are also potentially active in patients with CRPS who present to tertiary referral centres with limbs with a markedly abnormal appearance and concomitant reports of disproportionate pain and disability.

As has been discussed, a unique biomedical identifier for CRPS has not been, and apparently may never be, isolated; however, at the time of diagnosis of CRPS it is likely that biomedical mechanisms will be placed at the centre of the patients' presentation (despite a striking dearth of information on how or why it develops). In addition, the diagnosis depends heavily upon self-reported (by definition) symptoms.

The reasons for under or disuse of a limb are likely to be multifactorial but whatever the mechanism, those behavioural changes have the potential to alter the appearance and cortical processing of the afferent information entering the central nervous system from the affected limb.[26,27]

The confounding effects of diagnosing CRPS and the risk of medicalisation of limb pain and dysfunction

Once the label of CRPS is documented in the patient's clinical records, future focus (of both the treating physicians and therapists, as well as the patient) is upon CRPS, the ostensible implications of such a diagnosis, and the apparent intractable nature of the condition.

A setting has therefore been created in which, despite a profound lack of understanding of aetiology and biomedical mechanisms, provision of a diagnosis potentially stymies any further consideration of the actual cause of the clinical presentation and has the potential to influence both clinical and patient attitude towards the chronic pain reported and, alarmingly, influence their treatment pathway.

The diagnosis of CRPS therefore has the potential to create a unique situation, and there are few, if any, other correlates of this situation in clinical medicine. Once established, a diagnosis of CRPS is difficult to repudiate, not because of the infallible and robust nature of the diagnostic criteria, but rather because they are so non-specific.

It would seem, therefore, that defaulting to the diagnosis of CRPS (using the current criteria) which if we remind ourselves, are based upon highly non-specific diagnostic criteria, might well risk the 'medicalisation' of limb pain and dysfunction.[28]

The situation enters a whole realm of irrationality when the diagnosis of CRPS-NOS (not otherwise specified) is made, a diagnostic subtype for those who do not actually fulfil the criteria for the diagnosis at the time of assessment but did at some stage in their clinical course.

Documentation of the diagnosis in the clinical record (often with little or no attention to the exact findings on clinical examination) can lead to perpetuation of the terminology in the hospital and general physician (GP) records without proper assessment in the future and should an absence of signs be noted later then a diagnosis of CRPS-NOS can be relied upon.

The symptom-based criteria for the diagnosis of CRPS are, by definition, self-reported. A proportion of the clinical signs is also under the control of the sufferer and can be recreated by those with the motivation to do so. The busy orthopaedic outpatient clinic is the place for neither a detailed appraisal of all of the potential influences that might be at play at the time of assessment of a case of disproportionate pain nor for a

detailed review of all of the clinical records (even if they were to be made available).

In addition, identification of the psychological diatheses that have the potential to influence an individual's response to trauma is almost impossible without appraisal of all clinical records (primary care, private, psychiatric).

CRPS and litigation

Dissecting away the potential effects that involvement in litigation might have upon an individual's reported pain and disabilities requires considerable time and access to a full complement of records, both clinical and non-clinical. Even then it represents a considerable challenge.

Having had the opportunity to objectively explore large numbers of extensive records of individuals with the diagnosis of CRPS (including CRPS-NOS) in the medico-legal context, the author is of the opinion that once the diagnosis is made in the clinical context it appears not uncommon for all efforts to explore further potential differential diagnoses to cease.

The legal ramifications of this and the diagnosis of CRPS are such that the tenacity with which both Claimant and legal team hold on to the diagnosis has the potential to distort the nature of the case and therefore the therapeutic pathway that is offered to the Claimant by the legal team and indeed the Court. It can also hinder identification of the true nature of the Claimant's condition.

Within the context of litigation in particular (in which loss of amenity consequent to disability that is in response to chronically pain symptoms might be compensated) but also in the clinical context, the potential role of manipulation, malingering or psychogenic disorder must not be dismissed and indeed need to be considered. In reality, however, these factors are rarely contemplated.

Summary

Medical diagnosis is the process of determining which disease or condition best explains a patient's symptoms and signs. It directs (evidence-based) therapies and can have the added benefit of facilitating research into a particular condition by providing research teams with a select cohort of individuals. Diagnostic criteria for any one specific clinical condition should act to limit the heterogeneity of the population of patients with that condition.

The current criteria used for the diagnosis of CRPS appear to have had the opposite effect, and clinical research in particular might actually have been encumbered by the very nature of the criteria used to create the current CRPS population.

The current criteria for the diagnosis of CRPS do not provide sufficient focus to exclude conditions that have predominant psychosocial influences. The diagnosis has the potential to influence patient responses to their condition, confound clinical judgement and has significant, negative implications in the medico-legal context.

It is the author's opinion that the current criteria risk capturing too many patients who do not have CRPS. Marcus Cicero is quoted as saying '*I criticise by creation not by finding fault*'.

How this situation is taken forward will be determined by a number of factors, but it is the author's hope that by adding to the undeniable groundswell of opinion challenging the status quo[29] a point will be reached when a new, fresh approach towards diagnosing CRPS will be attempted. Those who work within the chronic pain arena are best placed to make this change; the broad and complex issues that can lead to reporting of high levels of chronic pain and disproportionate disability lie squarely within the chronic pain arena and we represent the group that should be taking on the task of redefining the group of patients who actually have CRPS.

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SAGE

One-day caudal epiduroplasty using normal saline for failed back surgery syndrome and spinal stenosis: a retrospective study

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Background

Chronic back and leg pain is triggered from various structures in the spine. The pain generators can be intervertebral discs, nerve roots, dura, facet joints, ligaments, fascia and muscles as tissues capable of transmitting pain in the low back and lower extremity.[1,2] The aetiology and pathophysiology of low back pain (LBP) and radicular pain has been comprehensively discussed in literature such as vascular compromise, inflammation, biochemical influences, postlumbar laminectomy syndrome, spinal stenosis and disc herniation or compression.[3] The painful symptoms in 'failed back surgery syndrome' (FBSS) following surgical spinal procedures can occur in up to 40% of patients.[4] Among postlumbar laminectomy syndrome patients, epidural fibrosis is seen in approximately 60% of the patients with recurring symptoms along with instability.[5] Epidural fibrosis may also develop without surgical intervention, secondary to annular tear, hematoma and infection.[4,5]

There are two systematic reviews showing that in patients with previous back surgery, fluoroscopically guided epidural (caudal/lumbar, translaminar or transforaminal) steroid injection will spread to reach the level of pathology in only 26% of cases. The inability to reach and effectively spread to the affected nerve roots is considered to be due to the surrounding adhesions.[6]

The hypothesis of this study was that the targeted epidural medication delivery near the desired nerve root after adhesiolysis may result in better pain relief using normal saline as a 1-day protocol.

Objectives

The goal of this study was to look for improvement in pain scores, level of function improvement and quality of life change using the Global Pain Assessment scoring system explained by John T Farrar.[7] In our study, we compare the outcomes where we used normal saline for epiduroplasty as 1-day procedure versus 3-day protocol where hypertonic saline was used.

Methodology

In this case study, we present 32 patients who underwent caudal epiduroplasty, 29 patients with a diagnosis of FBSS and 3 cases with spinal canal stenosis. The study was carried out over 32 months between January 2017 and September 2019. We used the Global Assessment of Pain which includes the quality of pain control, quality of life change and functional improvement following epiduroplasty. The Global Pain Assessment is used, as suggested by John T Farrar, as it can combine multiple important outcomes, it allows patients to integrate factors and it answers important clinical questions. The scale is explained as change expressed in the following terms: much worse, worse, a little worse, no change, a little better, better and much better.

Patients were consented and received an information leaflet prior to the procedure. All patients were discussed in multidisciplinary team meetings with spinal surgeons, radiologists and physiotherapists. The ones considered suitable for psychology input had received one to one psychology support.

Inclusion and exclusion criteria

Inclusion criteria – Patients aged between 18 and 85 years, with a history of chronic LBP and/or lower extremity pain of at least 6 months who have shown an absence of facet joint pain by controlled comparative local anaesthetic blocks or facet joint injections. They had also failed to respond to other

conservative treatment including fluoroscopically guided epidural injections.

Exclusion criteria – Large contained or sequestered herniation, cauda equina syndrome, compressive radiculopathy, drug addiction and uncontrolled major psychiatric disorders, local and global infections, coagulopathy and patients who are suitable for spinal surgery.

Demographics

Thirty-two patients were included in this study, 20 females and 12 males, aged between 37 and 86 years.

Procedure

All patients were given sedation by an anaesthetist and had appropriate monitoring throughout the procedure. They received one dose of antibiotic at the beginning of sedation.

A 16-G RK needle (Epimed International) was introduced into the caudal epidural space guided by fluoroscopy. Once the needle placement was confirmed to be in the epidural space, an epidurogram was obtained, utilising the contrast, Omnipaque 300. Then, a RACZ-STF catheter was advanced via the caudal epidural space to appropriate target level, and spread of contrast viewed for filling defects. The RACZ catheter was advanced to the areas where the suspected adhesions were to be targeted at the filling defect areas.

Normal saline of 2–5 mL was pushed through the catheter each time at levels of adhesions to about 20–25 mL total, followed by hyaluronidase 1,500 I.U. diluted to 5 mL with normal saline. Contrast was injected again to check improved spread afterwards, identified by nerve root filling as well as ventral and lateral epidural filling. If it appeared that the catheter was not advancing despite several gentle pushing, no force was applied. Also if a kink appeared at the catheter tip, the catheter was withdrawn and a fresh one was inserted. In addition, the absence of subdural, subarachnoid and intravascular uptake of contrast was confirmed. Then, triamcinolone 80 mg (after preservative was aspirated and discarded) diluted with 5 mL of normal saline was injected into the target area. Total volume of contrast Omnipaque 300 used was between 15 and 20 mL. All patients were transferred to recovery in the supine position.

Postoperatively appropriate analgesia was prescribed for pain control in recovery. Most patients in this study were discharged home on the same day without any complications, apart from two patients who had significant pain immediately following the procedure, which was managed by appropriate analgesia. One patient stayed overnight for analgesia management.

Results

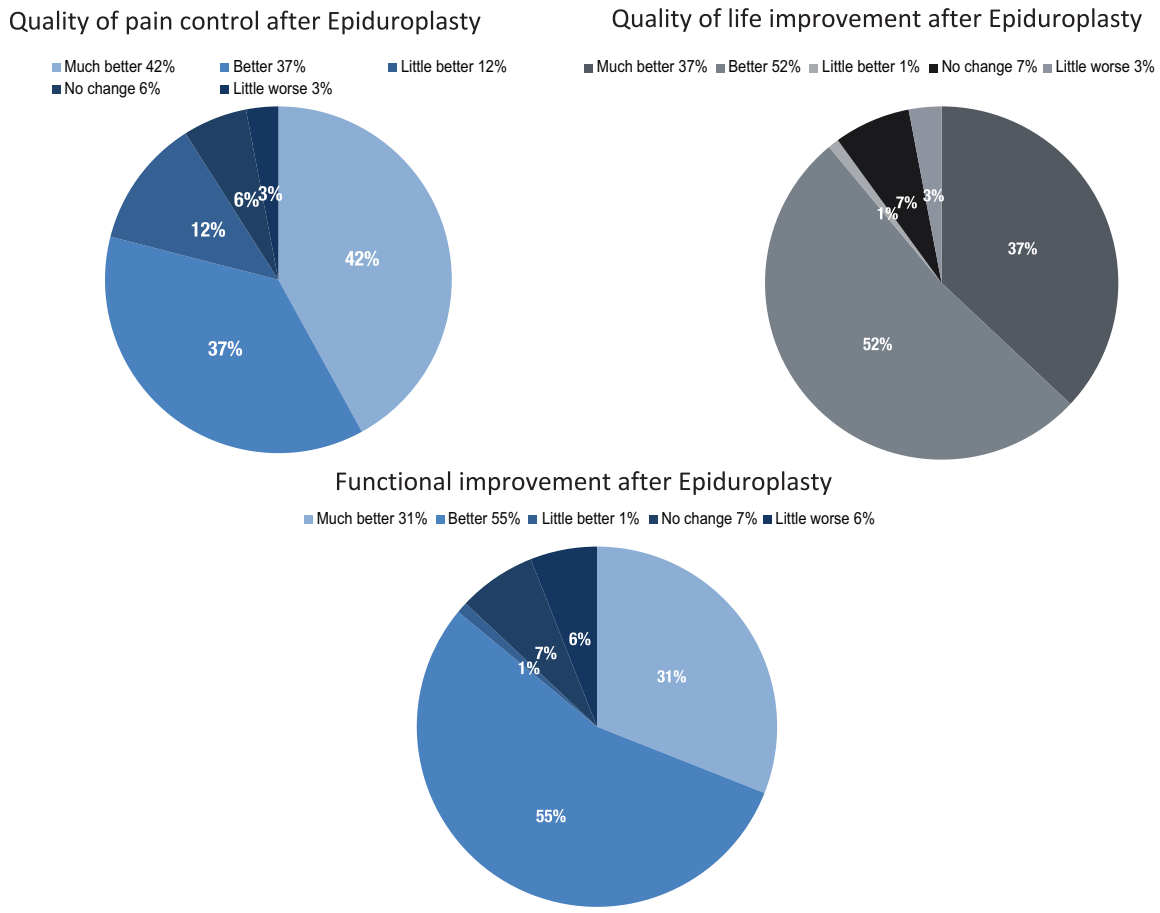
Our study shows that the duration of range of pain control is between 1 month and a maximum of 48 months. Seven patients had repeat injections. The average interval for repeat injections was 5.16 months (minimum 3 months and maximum 9 months). Quality of pain control as reported by patients was as follows: 42% felt themselves to be much better, 37% better, 12% a little better, 6% no change and 3% a little worse. Quality of life improvement as reported by patients was as follows: 52% reported as better, 37% much better, 1% a little better, 7% no change and 3% a little worse. In Figure 1, improvement of function was described by patients as 55% better, 31% much better, 1% a little better, 7% showed no change and 6% were a little worse.

Discussion

FBSS is a poorly defined, heterogeneous disorder with surgical and non-surgical pathologies when patients fail to improve after back surgery.[6] Adhesions surrounding nerve roots may interfere with their nutrition and blood supply and are likely contributors to radicular pain. Impairment of blood flow to the neural structures is probably the final common pathway leading to abnormalities in nerve conduction and pain generation.[4]

It is postulated that epiduroplasty may allow room for the restoration of blood supply and nerve root nutrition, resulting in improvement of nerve dysfunction and pain relief.[2] In our study, we used 1-day protocol versus the standard 3-day RACZ procedure. This avoids the potential for introducing infection due to longer siting of catheter in caudal epidural space and repeated injections.[8] In addition to a longer hospital stay, increased risk of hospital-acquired infections, deep venous thrombosis and more demand on precious hospital resources. In our study, we used normal saline instead of hypertonic saline used in the standard RACZ procedure. This is to avoid potential complications of hypertonic saline such as severe pain during injection, paresthesia and chemical arachnoiditis. There is also a lack of readily available hypertonic saline.[9,10–12] Normal saline is readily available and has no significant risks. Racz et al.[13] reported the percentage of patients who had pain relief for 1–4 weeks as 83%, while 49% had relief for 3 months, 43% for 6 months and 49% for 1 year. Manchikanti et al.[11] reported results for 1-day procedure adhesiolysis using hypertonic saline as 72% of patients showing an improvement in pain scores (a reduction of more than 50%) at 3, 6 and 12 months. Manchikanti et al. reported results of 1-day procedure adhesiolysis using normal saline after 3, 6 and 12 months as 64%, 60% and 60% of patients consecutively having a reduction in pain by >50%, respectively.[2] Epiduroplasty using normal saline, as 1-day procedure, shows encouraging results

Figure 1. Quality of pain control, quality of life improvement and functional improvement after epiduroplasty.



in improvement of pain scores (between 1 and 48 months), quality of life and function. In our study, the main postoperative complication was temporary worsening of pain immediately after the procedure, which was managed with appropriate analgesia. From our small retrospective study, we can conclude that epiduroplasty using normal saline rather than hypertonic saline can achieve acceptable pain relief.

Conclusion

Epidural adhesiolysis is used to treat chronic LBP by eliminating fibrous tissues from the epidural space. There is fairly good evidence that it is a safe and effective intervention in relieving low back and leg pain. It is recommended to be used not as initial treatment but after simple procedures have failed. Our results show that 1-day protocol of epiduroplasty using normal saline, hyaluronidase and triamcinolone is an effective treatment for chronic low back and leg pain (especially for FBSS) that has failed to respond to other measures.

Limitations of the study

It is a retrospective, non-randomised, non-blinded small study.

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Article

Group and save sampling in percutaneous spinal cord stimulator surgery: a review into current practice

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EXPERTISE WHERE IT MATTERS

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SAGE

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Introduction

Spinal cord stimulation surgery (SCSS) is offered to patients with chronic intractable neuropathic pain lasting 6 months or more.[1]

As part of the preoperative work up for SCSS, it is common practice for patients to undergo multiple Group & Save (G&S) blood tests despite a very low risk of the patient subsequently requiring a blood transfusion.[2,3] The National Institute for Health and Care Excellence (NICE)[4] guidelines on preoperative testing for elective surgery states that the need for G&S testing is dependent on the likelihood and severity of blood loss. Therefore, as a procedure with a low risk of significant blood loss and transfusion, a single G&S test may be more appropriate.

The aim of this study was to assess if single G&S testing in those undergoing percutaneous SCSS is safe, cost effective and supported by the literature.

Methods

A retrospective review of patients who underwent first-stage percutaneous SCSS at one centre over a 3-year period was carried out. The primary and secondary outcome measures were transfusion rate and surgical blood loss, respectively.

Alongside a review of the current literature, a cost analysis of single G&S testing was performed.

Results

Over the 3-year period, 100 patients underwent percutaneous SCSS. In total, 51 of these patients had implants inserted for the first time and 49 underwent revision implants. No patients received a blood transfusion in the post-operative period.

Hb was checked in 97% of patients preoperatively compared to 73% post-operatively. The average Hb loss was 10 g/dL. There was no significant difference in average blood loss between those undergoing SCSS for the first time and those undergoing revision surgery (9 g/dL (139 – 130 g/dL) vs 10 g/dL (137 – 127 g/dL), $p = 0.1$).

Scrutiny of patient records identified 58 patients with one or more risk factors for increased risk of bleeding. No significant difference in average Hb loss between those with 0(42), 1(42), 2(12) or 3(4) risk factors was observed ($p = 0.364$).

Discussion

Current NICE guidelines for preoperative testing enable clinicians to avoid unnecessary investigations. These guidelines are based on risk of surgery (low, intermediate, major or complex) and patient ASA (American Society of Anesthesiologists) grade.[5] However, these guidelines do not include G&S testing and patients regularly undergo multiple tests prior to elective surgery without bleeding risk considered.

The risk of adverse bleeding associated with SCSS is low, occurring in 1.9 per 1,000 patients.[3] Lower still is the risk of needing a transfusion (0.3 per 1,000).[6]

While the transfusion risk is low, there are patient factors that increase both the risk and severity of bleeding. In spinal surgery, preoperative anaemia, tumour surgery and pulmonary disease are associated with increased transfusion rate.[7] Hypertension, abnormal liver or renal function, history of stroke or bleeding tendency, age over 65 and excess alcohol use are all associated with greater bleeding risk in general.[8]

Anticoagulation, antiplatelet and non-steroidal anti-inflammatory drug (NSAID) treatments are also associated with increased bleeding risk.[2,9] However, the risk associated with NSAID use may be negated through discontinuation in the preoperative period.[2]

If a transfusion is required in a patient who has had a single G&S test, a further sample would need to be

processed prior to fully cross-matched blood being available. In the event of an emergency transfusion, group O negative (GrO–) blood can be ordered and received in the same time taken to release matched blood (≤5 minutes).[10,11] Reducing G&S testing preoperatively has been associated with a minimal increase in reliance on GrO– blood transfusions.[12]

Cost analysis

Upon review, 57% of those who underwent SCSS were eligible for single G&S testing. This represents a reduction in cost from £4,552 to £1,958 for G&S testing alone.

These savings represent the cost of the G&S test alone and do not consider the cost of outpatient appointments or the issue of the large environmental footprint left by laboratory tests which produce a considerable amount of toxic waste.[13]

Conclusion

The risk of requiring a transfusion from spinal cord stimulator surgery is low. In those with low bleeding risk, single G&S testing safeguards from unnecessary tests and holds significant cost-saving potential. Current guidance on preoperative testing do not cover G&S sampling and further work towards setting national guidelines for low-risk elective procedures could hold substantial economic potential and a reduction in the burden to patients.

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Article

Social media – a way to ease the pain?

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

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SAGE

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Social Media Icons. Public Domain.[1]

Background

Social media is an ever-expanding force with popular sites such as Facebook boasting over 2.4 billion monthly active users. These figures are continuing to grow as the availability and use of mobile devices is expanding worldwide.[2] Despite its increasing popularity, social media has been hovering under a cloud of negativity with fears of addiction, bullying, propagating of misinformation and the growing world of 'influencers' promoting their own health suggestions, often at personal gain.[3] However, hiding in this dark world there are hundreds of support and education opportunities on the Internet for those who know where to look.

Chronic pain presents a significant challenge to healthcare professionals with patients often suffering functional disability and reporting reduced quality of life. Although pharmacological interventions may help some, it is accepted that medication only benefits a percentage of patients. There is a movement within chronic pain (e.g. through multi-disciplinary pain management programmes) to educate patients on self-managing in the long-term and addressing coping strategies to improve quality of life, even where pain remains.[4]

Aim and method

Given the health economic burden of chronic pain and the increasing popularity of the Internet and social media, we ask the question – Is this resource being utilised by our patients? The aim of this study was to determine whether the Internet, community support groups or social media were currently being utilised for pain education and support by our chronic pain patients.

Over the course of 1 month at Calderdale Royal Hospital, we surveyed 100 patients attending chronic pain clinic with a simple four question survey addressing their current utilisation of the Internet and its offerings:

1. *Are you aware of any pain education websites for patients?*
2. *Are you aware of any support groups in the community for pain?*
3. *Do you use social media?*
4. *Are you a member of any social media pain groups?*

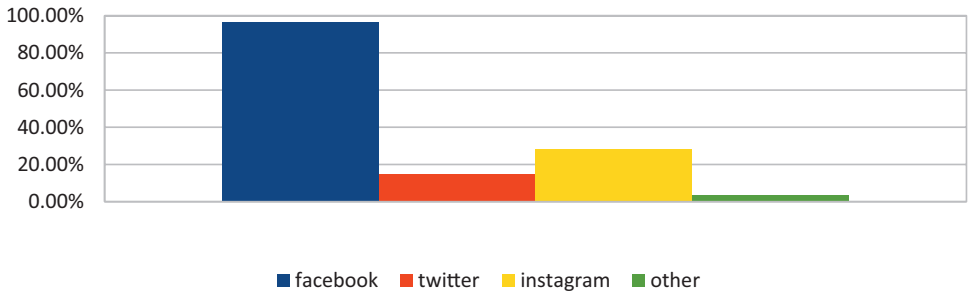
We encouraged participants to add comments on each question, which has helped us to gain a better insight into patient practice.

Results

It was notable that the majority of participants disclosed using Internet search engines such as Google to hunt for answers and advice regarding their pain. However, only 11% of respondents were already aware of pain education websites available to them. A key theme emerged, and this was the use of National Health Service (NHS) websites as the most popular bank of information, being quoted as the most trustworthy source of medical information.

A total of 10% of patients surveyed were aware of community support groups. Interestingly, despite only a small percentage of patients being involved in community support groups (10 from the 100 participants), eight different support groups were cited.

A total of 60% of participants reported using social media. By far the most popular form of social media quoted by participants was Facebook (96.67% membership of the social media users). Following Facebook was Instagram (28.33% membership of the social media users) and then Twitter (15%



membership of social media users). Of note 'other' social media used was quoted by participants as 'WhatsApp', which is classed as a social media application, but it has been traditionally used as a messaging service and not as a platform for public review.

Despite 60% of participants disclosing to social media use, only 2% of those reported being a member of a social media pain group. Of note those 2% report being a member of the same social media pain group – Fibromyalgia Awareness group on the social media network Facebook.

Limitations

Patients invited to participate were limited to a single centre over a 1-month period. In order to gain a better insight into how the chronic pain population as a whole are using the Internet and social media, it would be beneficial to roll this survey out over several sites. Another potential drawback to the survey was that individuals were asked to complete the survey at their appointment and therefore may have forgotten details of websites/support groups, and so on.

Discussion

Analysis of the survey has suggested that patients are looking for information regarding their condition, pursuing the Internet in search of answers with the vast majority unaware of websites to turn to or support groups to engage with. With almost every patient surveyed being a member of Facebook, could this be utilised as a method of both disseminating information and offering support? Educators are already taking to social media such as Twitter to spread information and links to resources; it seems we need to both expand upon this and inform our patients of its existence.[5]

The NHS faces ongoing pressure with outpatient clinics in high demand. Given the nature of chronic pain, these patients often require support and follow-up for several years. By collaborating and networking online patients may be able to find some of the answers they need here, relieving some of the burden on busy clinics. Looking forward, social media can be used as both a place for medical professionals to engage with communities, helping to dispel misinformation, and a place to signpost individuals to peer-led support and resources.

If we are to take advantage of the worldwide web, we need to consider where we are signposting patients – Are we going to invest in new websites and new forums or utilise those already in existence? And how reliable are those out there today – If medical professionals find it difficult to find reliable websites, do patients stand a chance? Our study noted that patients were already utilising the NHS website to research their medical condition which claims to be 'objective and trustworthy' and provide 'accurate and clearly presented content'. This content is reviewed at least every 3 years.[6]

Other websites which patients mentioned using in our survey included http://painconcern.org.uk/, a charity-run website which professes its mission is to 'help, support and inform those who live with pain' and states its publications are 'normally written by expert authors or created from interviews with experts'.[7] Also cited was https://healthunlocked.com/: this runs in a slightly different fashion as a social network for health, whereby patients share experiences and discuss their conditions. They quote 69% of users reporting that they have visited their doctor less since using HealthUnlocked.[8]

Despite such reassuring statements, healthcare professionals might still find it uncomfortable to signpost patients to such websites without the full knowledge of what lies within them, including how frequently information is reviewed and updated and to what standard. How can we be confident we are giving patients the National Institute for Health and Care Excellence (NICE)-approved, evidence-based, multi-centre trialled guidance which is drilled into physicians since medical school?

There are some tools already in use which may help guide both practitioners and patients when accessing online resources. For example, MedlinePlus Guide to Healthy Web Surfing offers a brief, user-friendly guide to evaluating the

quality of health information on websites.[9] Another approach already adopted by many institutions such as Great Ormond Street Hospital, Royal United Hospitals Bath and Gloucestershire Hospitals has been to produce a local information leaflet on how to find good-quality health information on the Internet and in some instances listing examples of recommended websites.[10–12]

In summary, it seems patients are taking to the web for answers and support and for mutual gain (improved patient satisfaction, possibly improved quality of life as well as potential for reducing the burden on outpatient facilities), and we will be called upon to advise and assist. Although we may feel more comfortable quoting the NHS websites for reliability, there are hundreds of other resources out there and perhaps taking the time to research those relevant to our own clinical fields will give us confidence to utilise these through face-to-face advice or through local targeted information leaflets.

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Article

There's a hole in my boat

Suzanne Kidd

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

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SAGE

Inspired by my Dad who strongly disputes the analogy of us 'all being in the same boat'. This has been used a lot at the start of the Covid19 pandemic. It made me think that actually we are all in our individual boats but we are all sailing on the same sea.

I'm not a health professional. I live with multiple chronic illnesses with my main issues being hypermobile Ehlers Danlos Syndrome (hEDS) and Postural Orthostatic Tachycardia Syndrome (PoTS). I wrote this piece for my immediate family to explain what I feel it's like to live with chronic illness. I hope it helps to give some sort of understanding for people with and without chronic illness.

Your boat is your life circumstances. What you are born into will determine the size, power, condition and stability of your boat: whether you are born into poverty or riches, good or poor health, your social standing, war or peace, where you live, your personality, your family relationships or anything that may be used to discriminate against you. You cannot control any of these factors, they are decided before you are even born. Your boat can change as time goes on as your life circumstances change, for worse or better. We are, however, sailing on the same sea throughout our lives.

I am going to focus on how chronic illness can affect you, as this is my experience.

Chronic illness, physical or mental, is like having a hole in your boat. It takes effort to keep afloat scooping out the water. This is the effort it takes to manage your condition: diet, exercise, medication, sleep, planning ahead, supplements, treatment, physio, adaptations, medical appointments, psychological support, mindfulness, holistic therapies, relaxation and many more things.

Sometimes you will want a quick fix and attempt a rough patch job on the hole but this will not last and the hole will open up again, leading to disappointment and frustration. This can cause you to struggle more in your boat. Other times you might want to ignore the hole and pretend it isn't there; this may work temporarily but in time you will be overwhelmed by the amount of water that has come up through the hole. There will also be times when you have had enough of the effort used to scoop out the water and will be frustrated that not everyone else has to deal with such a hole. Frustration will cause your boat to rock and make the waters around you more difficult to sail through. Learning how to accept and manage the hole long term in a sustainable way can help you to keep moving forward more calmly. In time you may become expert at doing this and people watching from afar will see you floating by, unaware of the effort it is taking. Only those you allow close to you will see – and even then, they may not fully understand.

If a storm is approaching, big or small, extra effort is required on top to keep you afloat. A storm might be small and be something that may only affect you, such as a change of routine, missing a meal, forgetting medication, lack of sleep or a flare-up of symptoms. It can be something that is out of your control and would not cause a problem for someone without a hole in their boat. The bigger the storm, the more of a problem. It can be anything from catching a virus up to a major change in life, world events, grief and loss. These would cause problems for anyone, regardless of the size or state of your boat, but having a hole in your boat puts you at a disadvantage. Storms can sometimes be seen approaching if you know the signs to look for or they can sometimes catch you completely off guard; both situations can be challenging.

Even doing things you enjoy by yourself and with others can cause the waters around your boat to become choppy. Anxiety

and worry before the event can make it difficult to manage the hole. It could be anything from meeting friends or family to attending a wedding or a holiday. The longer the event goes on the choppier, the water will be when you get out on the other side. Sometimes it can lead to a storm to sail through, which it will take time for you to recover from. A careful decision will need to be made as to whether you can manage it at all. Some things are so challenging that you won't be able to even attempt them, and this can change from one day to the next. It can be frustrating to see people from afar who appear to be enjoying themselves and doing things you would like to do if you were able. This frustration can lead to choppy waters too. If there isn't a hole in your boat, you may not understand or even be aware of how difficult that struggle can be.

As time passes, your condition may improve. This can be like partially patching up the hole; it is easier to sail along but you are aware that the hole is always there and may open again at any point. Your condition may worsen or another health issue arise and another hole may open up in your boat, and it will take all your resolve and experience to deal with it. Storms and new holes may stop you in your tracks and you cannot sail forward with others. It can be very disheartening to put in so much effort and not be moving anywhere. Storms do pass but it will take time to assess the damage caused to your boat and try to move forward again. You may think you have gone backwards, but this isn't the case. The lessons learned from the storm will keep you moving, even if it is in a different direction.

Sometimes you may be so stuck in a storm and struggle to manage the holes that you will need help from another person in their boat and you can be supported and towed along. You may need to ask to be towed or someone may notice that you are struggling and offer help. However, some people may not have anyone sailing near them and no one to ask for help.

You may have struggled for a long period of your life without understanding where exactly the water is coming from that fills up your boat; you just know that you are struggling and have a hole somewhere. You may have been told by professionals or well-meaning people that there isn't really a problem and you just need to get on with scooping the water out. When you eventually discover where the hole is in your boat it can be a huge relief, and the understanding of why you have struggled to stay afloat for most of your life can be overwhelming. You can now learn the best ways to manage the hole rather than struggle blindly. You may also need to come to terms with the fact that it will always be there and this is where using techniques such as mindfulness and acceptance can start to be gently explored.

Using techniques such as mindfulness to help you manage stress can keep you moving, even when you don't realise it. Only time will show you how when you look back. Any personal growth, learning and lessons learned can keep you moving, no matter how slow. Any struggle of acceptance you have with the hole in your boat can cause extra worry, anger, frustration and stress and this will affect how your boat sails, no matter how calm the sea. You are in control of sailing your boat and this will cause your boat to rock and become unsteady, taking on more water. It may sometimes take a while for you to realise that you are causing your boat to struggle even more, but recognising this can be huge. Learning how to use mindful skills such as being present, acceptance and being non-judgemental can help to settle the boat. These can take time to learn but they will help you to move forwards again.

Sometimes the hole in your boat is visible. This can give others an idea that sailing along is not that easy for you, but they will not completely understand the struggle that goes into scooping out the water. You may be treated differently or patronised because of this. If the hole in your boat is hidden it can confuse others as to why you may struggle to keep up with them, especially those whom you do not see so frequently, and from afar they may think that your boat actually looks in good condition, not knowing how hard it can be to keep going. It can also cause hurtful remarks from others and even strangers, who may demand to see proof of the hole. They may even suggest that the hole is your fault, you're not trying hard enough, or they may offer advice that is completely useless. Both of these situations can lead to further struggle and might create a storm for you to get through.

Having people around you who believe and accept your struggle and treat you with compassion and respect can be incredibly helpful and make you feel less alone. A strong support network of family, friends and medical professionals is the most helpful, but not everyone is lucky enough to receive such support. To be believed and supported can be a huge relief and can help calm the feelings of having to prove yourself to everyone. You do not have to prove yourself to anyone, it is not your responsibility how others may act or think. This is out of your control, and trying to control it can make the boat unsteady and the waters choppy around you.

It is important to look after yourself; if people you are close to have their own struggles to deal with it can impact you. The ripples that will come from the struggle in their boat will cause your boat to rock and become unsteady. The closer you are to the person the more their struggle will rock you, and you can end up taking on extra water. You may get so caught up with dealing with the extra water that you forget to keep on top of managing your hole. It is important that you pull away to calmer waters to give yourself chance to rid your boat of the extra water before you can carry on again.

Chronic illness can affect any boat. You may be sailing in anything from a large yacht to a small rickety rowing boat – any boat can have a hole. This is where your life situation can give you an advantage or disadvantage in dealing with the hole. You may be able to afford the latest medical treatments and private healthcare or you may struggle to get by, relying on welfare and charity. You may have a good support network around you or you may be completely alone. You may be someone who copes well in a crisis or you might find it too much to cope with.

Having a hole in your boat can give you a deep understanding of how difficult sailing can be. You may be able to spot when others are struggling in their boats before people without a hole in their boat would notice. Sometimes you may come across somebody who has the same hole in their boat and it can be reassuring to compare how you manage it. Your knowledge can sometimes be more valuable than professional opinions to someone who has recently discovered the hole in their own boat.

The lessons you have learned and the skills you have can also be helpful to somebody without a hole in their boat. Everyone will have to sail through storms. Every storm can help you to appreciate when the water is calm. We are all in our different boats, depending on our life situation; every life is unique. Your boat may change as you sail along, your life situation will change, be it money, health, relationships or loss, but it will still have the bones of the boat from when you were born. You may be sailing along with others and this will change, some others will join you, some will drift away and back again, and others will be lost. If you are kind to yourself and others, it can help you sail along more smoothly.

Written by Sue Kidd 5 May 2020

Book review

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

Pain News
2020, Vol 18(4) 222–223

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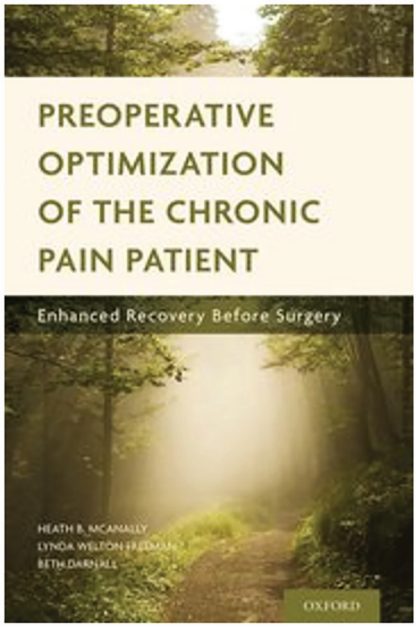

***Preoperative Optimization of the Chronic Pain Patient: Enhanced Recovery Before Surgery*, edited by HB McAnally, LW Freeman, B Darnall; New York: Oxford University Press, 2019, ISBN: *9780190920142*.**

Reviewed by Dr Alice Gerth, *Anaesthetics SpR, Cambridge University Hospital*

In this book, McAnally and co explore the impact chronic pain has on surgical outcomes. They develop the economic case for implementation of a chronic pain enhanced recovery programme and describe their own experience of implementing such a programme at Stanford Hospital.

This book is useful for anaesthetists and surgeons at all stages of training. It convincingly lays out the burden of chronic pain both economically and more holistically to patient outcomes. It brings the anaesthetic sub-specialty of chronic pain into the forefront of day-to-day anaesthesia and explores many of the challenges chronic pain patients present. It both lays out the challenge and provides holistic suggestions for how these patients can be optimised. It goes beyond pain to explore other important factors affecting outcome including smoking cessation, nutrition and exercise, all of which carry a greater disease burden in the chronic pain population.

Initially, the book lays out the need for specialist chronic pain perioperative management, and then it looks at the tools required, before applying these to specific areas. It concludes with a summary and exploration of obstacles to providing such a programme. Throughout the book there are practical suggestions for implementation often linked to the programme they introduced in Stanford Hospital.

In the argument for a perioperative chronic pain programme, it looks at the effects of chronic pain on length of stay and outcomes. The authors show that increased lengths of stay, worse outcomes and ongoing health needs of these patients outweigh the costs of a chronic pain programme. They also show that disproportionate numbers of patients attending for ambulatory surgery have chronic opiate use and chronic pain compared to the general population. Not only do those presenting with chronic pain do less well but they also make up a large proportion of our elective surgery cases.

The authors then take time to provide a tool kit that will be applied in later chapters. They explore the factors that impact patient motivation and habits from a psychological perspective. This includes chapters on understanding motivation, habit forming and pain catastrophising. Each chapter explores how the chronic pain understanding can be adapted to the surgical setting and explores methods that could be used in the perioperative period to improve patient pain perceptions, including education sessions, cognitive behavioural therapy and online learning.

Having looked at the psychological involvement in pain it then moves on to related topics of sleep, physical activity, nutrition and smoking cessation. They demonstrate how the tools developed in the chapters on motivation and habits can help encourage patients to improve their sleep, exercise and nutrition. Finally, it ends by looking at weaning opiates before bringing the book to a close with a summary of the preceding chapters and a discussion of the general obstacles to preoperative optimisation (the surgeon, the institution, the patient).

Overall, the book is an interesting read and directly clinically applicable. The book assumes minimal prior knowledge of the themes discussed, while going into a level of detail that will be

Book review

of interest to someone working in the relevant field. This means that it is readable by a range of health professionals. However, unless you have a specific interest in developing a perioperative chronic pain management programme, some parts of the book will be of more interest than others. The authors root their discussion in daily clinical practice helping to give the theory context; however, this means at times it feels more useful to someone working in the American health care system and delves into a level of detail that is beyond the need of most general anaesthetists.

The authors write in a manner that is accessible (without being too simplistic) to a variety of health professionals. This book will appeal to psychologists, anaesthetists, surgeons and nurses. For a trainee, the book is helpful both in the context of chronic pain training and in perioperative general anaesthesia.

In summary, I'd particularly recommend this book to anaesthetists with an interest in perioperative medicine, chronic pain and acute pain. It will also be of interest to other allied health professionals working in pain management. As a book it challenges the reader to take a more holistic view of pain and to see the possibility for improving patient outcomes. It also emphasises the need for a more focused approach to optimising these patients prior to surgery and makes a strong economic argument for the provision of a chronic pain perioperative service.

End piece

Howard Hodgkin

THE BRITISH PAIN SOCIETY
EXPERTISE WHERE IT MATTERS

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SAGE

ICE Howard Hodgkin 2008. By Kind Permission of the Estate[i]

Sir Gordon Howard Eliot Hodgkin CH C BE (6 August 1932–9 March 2017) was a British painter and printmaker. His work is most often associated with abstraction.

Gordon Howard Eliot Hodgkin was born on 6 August 1932 in Hammersmith, London, the son of Eliot Hodgkin (1905–1973), a manager for the chemical company ICI and a noted amateur horticulturist, and his wife Katherine, a botanical illustrator. During the Second World War, Eliot Hodgkin was an RAF officer, rising to Wing Commander, and was assistant to Sefton Delmer in running his black propaganda campaign against Nazi Germany.

His maternal grandfather Gordon Hewart, 1st Viscount Hewart was a journalist, lawyer, MP and Lord Chief Justice, and the scientist Thomas Hodgkin was his great-great-grandfather's older brother. Hodgkin was a cousin of the English still life painter Eliot Hodgkin (1905–1987).

During the Second World War, Hodgkin was evacuated with his mother and sister to the United States, where they lived on Long Island, New York. On returning, he was educated at Eton College and then at Bryanston School in Dorset. He had decided on a career in art in early childhood and ran away from school to pursue this.

He studied at the Camberwell Art School. In 1981, Hodgkin had collaborated with the Rambert Dance Company's Resident Choreographer, Richard Alston, for his abstract work 1981 for the production of Night Music and later for the production of Pulcinella in 1987.

In 1984, Hodgkin represented Britain at the Venice Biennale; in 1985, he won the Turner Prize; and in 1992, he was knighted.

A major exhibition of his work was mounted at Tate Britain, London, in 2006. Also in 2006, *The Independent* declared him one of the 100 most influential gay people in Britain, as his work has helped many people express their emotions to others.[ii]

Notes

i. https://howard-hodgkin.com/
ii. http://en.wikipedia.org/wiki/Howard_Hodgkin

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Refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentation: tablets containing either 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg or 300 mg pregabalin per tablet.

Indications: Treatment of peripheral and central neuropathic pain in adults. Treatment of epilepsy, as adjunctive therapy in adults with partial seizures with or without secondary generalisation. Treatment of Generalised Anxiety Disorder (GAD) in adults.

Dosage and administration: *Adults:* 150 to 600 mg per day, in either two or three divided doses, taken orally with or without food. Treatment can be started at a dose of 150 mg per day and increased based on individual patient response and tolerability. *Neuropathic pain:* Dose may be increased to 300mg/day after an interval of 3 to 7 days, and if needed, to a maximum dose of 600mg/day after an additional 7-day interval. *Epilepsy:* Dose may be increased to 300mg/day after 1 week. The maximum dose of 600mg/day may be achieved after an additional week. *Generalised anxiety disorder:* Dose may be increased to 300mg/day after 1 week. Following an additional week the dose may be increased to 450mg/day. The maximum dose of 600mg/day may be achieved after an additional week. The need for treatment should be reassessed regularly. Treatment should be discontinued gradually over a minimum of one week. *Renal impairment/Haemodialysis:* dosage adjustment necessary; see SmPC. *Hepatic impairment:* No dosage adjustment required. *Elderly:* Dosage adjustment required if decreased renal function. *Paediatric population:* Safety and efficacy in children below the age of 12 years and in adolescents (12-17 years of age) have not been established.

Contraindications: Hypersensitivity to pregabalin or any of the excipients.

Warnings and precautions: There have been reports of hypersensitivity; discontinue immediately if symptoms of angioedema. Some diabetic patients who gain weight may need to adjust hypoglycaemic medication. Occurrence of dizziness and somnolence could increase accidental injury (fall) in elderly patients. Advise patients to exercise caution since loss of consciousness, confusion and mental impairment have been reported. Visual adverse reactions have been reported, including loss of vision, visual blurring or other changes of visual acuity, and visual field changes. Discontinuation may result in resolution or improvement of visual symptoms. Renal failure has been reported which, in some cases, showed reversibility on discontinuation. There is insufficient data for withdrawal of concomitant antiepileptic medication, once seizure control with adjunctive pregabalin has been reached. Withdrawal symptoms suggestive of physical dependence have been observed in some patients after discontinuation of short and long-term treatment; see Side effects. The patient should be informed about this at the start of the treatment. Convulsions, including status epilepticus and grand mal convulsions, may occur during use or shortly after discontinuation. Data suggest that incidence and severity of withdrawal symptoms after long-term treatment may be dose-related. Congestive heart failure has been seen, which may be resolved on discontinuation. Use with caution in elderly cardiovascular compromised patients. There is a possible increased risk of suicidal ideation and behaviour; patients should be monitored for signs and appropriate treatment considered. Advise patients and their caregivers to seek medical advice should signs of suicidal ideation or behaviour emerge. Events related to reduced lower gastrointestinal tract function (e.g. intestinal obstruction, paralytic ileus, constipation) have been reported when co-administered with medications having potential to produce constipation. Consider measures to prevent constipation when used in combination with opioids. Cases of misuse, abuse and dependence have been reported. Exercise caution in patients with a history of substance abuse and monitor for symptoms of pregabalin misuse, abuse or dependence. Cases of encephalopathy have been reported, mostly in patients with underlying conditions that may precipitate it. The incidence of adverse reactions, especially somnolence, is increased in patients treated with pregabalin for central neuropathic pain due to spinal cord injury; possibly due to additive effect from concomitant medications.

Interactions: Pregabalin is unlikely to produce, or be subject to, pharmacokinetic interactions; see SmPC. There are reports of respiratory failure and coma when taken with other central nervous system (CNS) depressants. Pregabalin appears to be additive in the impairment of cognitive and gross motor function caused by oxycodone and may potentiate the effects of ethanol and lorazepam.

Fertility, pregnancy and lactation: *Pregnancy:* Pregabalin should not be used during pregnancy unless benefit to the mother clearly outweighs risk to the foetus. Effective contraception must be used in women of childbearing potential. *Breast-feeding:* Pregabalin is excreted into human milk and the effect on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue pregabalin therapy. *Fertility:* No clinical data on the effects on female fertility. A clinical trial to assess effect on sperm motility showed no effect. Reproductive and developmental effects have been seen in rat studies but clinical relevance is unknown.

Effects on ability to drive and use machines: May affect ability to drive, use machines and engage in other potentially hazardous activities.

Side effects (see SmPC for full list): Very common (≥ 1/10) - dizziness, somnolence, headache; Common (≥ 1/100 to <1/10) - nasopharyngitis, appetite increased, euphoric mood, confusion, irritability, disorientation, insomnia, libido decreased, ataxia, coordination abnormal, tremor, dysarthria, amnesia, memory impairment, disturbance in attention, paraesthesia, hypoaesthesia, sedation, balance disorder, lethargy, vision blurred, diplopia, vertigo, vomiting, nausea, constipation, diarrhoea, flatulence, abdominal distension, dry mouth, muscle cramp, arthralgia, back pain, pain in limb, cervical spasm, erectile dysfunction, oedema peripheral, oedema, gait abnormal, fall, feeling drunk, feeling abnormal, fatigue, and weight increased; Uncommon (≥ 1/1,000 to <1/100) – neutropenia, hypersensitivity, hallucination, panic attack, restlessness, agitation, depression, syncope, stupor, myoclonus, loss of consciousness, psychomotor hyperactivity, dyskinesia, dizziness postural, intention tremor, nystagmus, cognitive disorder, mental impairment, speech disorder, hyporeflexia, hyperaesthesia, peripheral vision loss, visual disturbance, eye swelling, visual field defect, visual acuity reduced, tachycardia, atrioventricular block first degree, sinus bradycardia, congestive heart failure, dyspnoea; Rare (≥ 1/10,000 to <1/1,000) - angioedema, allergic reaction, convulsions, vision loss, keratitis, QT prolongation, sinus tachycardia, sinus arrhythmia, pulmonary oedema, ascites, pancreatitis, jaundice, Stevens Johnson syndrome, rhabdomyolysis, renal failure, oliguria, urinary retention; Very rare (<1/10,000) - hepatic failure, hepatitis. After discontinuation of short and long-term treatment withdrawal symptoms have been observed in some patients: insomnia, headache, nausea, anxiety, diarrhoea, flu syndrome, convulsions, nervousness, depression, pain, hyperhidrosis and dizziness. Data suggest that incidence and severity of withdrawal symptoms after long-term treatment may be dose-related.

Legal category: POM.

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