Review

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Failed back surgery syndrome – definition, epidemiology and demographics

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Abstract
Failed back surgery syndrome is an unhelpful term that hides the true issues concerning the mechanism of pain and subsequent therapies that patients with chronic radicular neuropathic pain are exposed to. Patients with chronic radicular neuropathic pain who have had previous spinal surgery are numerous and comparable in prevalence and incidence to other pain associated diseases such as rheumatoid arthritis but with higher annual costs. Better recognition of this patient group with the effective recognition and multi-disciplinary care aimed at achieving best patient and societal outcomes is required.

Keywords
Spinal cord stimulation, failed back surgery syndrome, chronic neuropathic pain demographics, epidemiology, cost effectiveness

Introduction

Failed back surgery syndrome (FBSS) has been defined as follows:

> Surgical end-stage after one or several operative interventions on the lumbar neuroaxis, indicated to relieve lower back pain, radicular pain or the combination of both without positive effect.[1]

The term, first coined by Follet and Dirks, highlighted the awareness that back surgery and repeat back surgery were not always the solution to back and leg pain. Until that time eminent surgeons would explain that the previous surgeon had performed surgery at the wrong level to relieve symptoms, or that the type of surgery had not been adequate. When the eminent surgeon's efforts failed, it was because of disease progression or psychological factors that were poorly understood.[2,3]

At that time, pain clinics were becoming more commonplace. Important new concepts started and continued to gain traction. First, the increasing understanding that neuropathic pain exists and that the mechanisms are an explanation for chronic long-term pain. Second, following on from gate control theory, that the perception of pain is modulated at multiple levels within the sensory system, sometimes enhancing or inhibiting pain perception. Third, that those cognitive, affective and behavioural features of pain are often explanations of the disability as much as or more than abnormal sensory-related pain.

Definitions of failed back surgery syndrome

Definitions are important and I need to spend some time unpacking these to fully explain my thinking. The simple version is as follows:

> Persistent or recurrent pain in the back/neck or limbs despite surgery or treatment thought likely to relieve pain.

This tells us that, in this group of patients, previous surgery designed to relieve pain must have occurred

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and the pain has gone on unaltered or has recurred in presumably the same manner as before.

Neuromodulation therapies, in particular spinal cord stimulation, have been used to treat the pain of FBSS. One randomised controlled trial, the PROCESS study published in 2007, looked at the effects of adding spinal cord stimulation to usual care in comparison with usual care alone in 100 patients with FBSS. The definition used in the PROCESS study was as follows:[4]

> Chronic radicular pain that has recurred or persists in the same distribution despite anatomically satisfactory previous spinal surgery. (Leveque)[5]

This tried to concentrate more on the possible mechanism of pain, that is neuropathic pain and its distribution (i.e. pain in the leg more than the back), and tried to satisfy the 'eminent surgeon' that all were agreed that previous surgeries had been performed correctly. Importantly, it was about recurrence or persistence of the original pain.

The International Association for the Study of Pain (IASP) definition is as follows:

> Lumbar (cervical) pain of unknown origin either persisting despite surgical intervention or appearing after surgical intervention for spinal (origin) pain originally in the same topographical distribution.[6]

The definition goes on to say that 'this diagnosis has been formulated as an entity distinct from lumbar spinal pain of unknown origin to accommodate beliefs that the failed attempt at surgical therapy complicates the patient's condition pathologically, psychologically, or both'. This suggests that the clinical status of this group of patients is now different from the original status as a result of acquiring complications, both in pathology and in the psychological domains.

This may be true as patients have had to undergo painful procedures with long recuperation and rehabilitation periods, accompanied by the toll that poor outcome and complexity of long-term pain can take.

In my view, whether or not they have been operated on, many patients with chronic radicular pain share many features, and it is not helpful to subdivide these patients on the basis of whether there has been prior surgery. We have ended up using this term simply because, historically, the treatment of radicular pain with or without back pain had become a surgically based specialty.

Perhaps another definition might be as follows:

> Chronic back and leg pain that persists or recurs despite application of the back surgery clinical pathway.

If you ask most spinal surgeons these days they will tell you that the best outcomes are achieved in patients with radicular pain syndrome who have a history, clinical examination and significant findings on magnetic resonance imaging that are together indicative of a surgical target. However, some will fail to understand the significance of neuropathic findings on history and clinical examination. In the presence of a large disc herniation it is difficult for them not to recommend surgery. This would be acceptable as long as the expectation of a lack of full sensory recovery and the likelihood of up to 40% of pain recurrence was explained and partly expected.

In a secondary care pain management clinic it is common to find patients with chronic radicular pain who have no evidence of sufficient surgical target for 'decompression' and have not had previous spinal surgery, or have widespread spinal disease or significant co-morbidity. It is hoped that these patients will not be offered surgery and so will have failed the surgical algorithm of care. Sadly, we know that this is not a consensus view and, throughout the UK and overseas, patients such as these are operated on.

Although it has become established in the spinal surgical and pain medicine literature, FBSS is a poor term for the following reasons:

- It implies previous surgery.
- It implies that the surgeon, surgery or algorithm of care has failed.
- It tells us little about pain mechanism or patient impact.
- It implies that patients are different simply because they have not improved with surgery.

However, we do know that repeat surgery is less likely to succeed than primary surgery[7,8] and that the prevalence of FBSS increases with incidence rates of spinal surgery.[9]

Epidemiology of failed back surgery syndrome

Patients with FBSS might include those who

- are at the end of the surgical algorithm of care;
- would achieve better or similar outcomes if they were treated non-surgically; and
- have been excluded from surgery but are medically contraindicated, or the outcome from surgery is known to be poor.

The last two points make the epidemiology difficult to ascertain, but we can deduce the epidemiology of the first point.

The incidence of lumbar spine surgery in the UK is 5 in every 10,000 people.[10]

Failure rates of spinal surgery are quoted in the } literature as ranging between 10% and 40%.[2,3] Conservatively, we might assume a failure rate of 20%.

If we assume the UK population to be 60 million, then the number of new FBSS patients each year is 6000: that is 10 in every 100,000 (ranging from 5 to 20 per 100,000 depending upon the frequency of spinal surgery failure accepted).

FBSS patients have a long-term condition, as I will discuss later, so the prevalence of this condition is surprising. The prevalence in the UK of neuropathic back and leg pain is 5800 per 100,000 of the population.[5] Thus, 405,115 people in England and Wales suffer from neuropathic back and leg pain, many of whom would fulfil the broad definition for patients with FBSS.[11,12]

Prevalence and incidence rates for FBSS are about the same as for rheumatoid arthritis, and about 10 times more than for complex regional pain syndrome (CRPS), 10 times less than for fibromyalgia and 100 times less than for osteoarthritis.[12]

FBSS represents a significant healthcare problem from these numbers alone; let us now consider the impact of FBSS on individuals, families, work, carers, healthcare and other societal costs.

Demographics of failed back surgery syndrome

Spinal cord stimulation has been established as a cost-effective treatment for patients with neuropathic back and leg pain.[13–16] Part of the evidence for this is from the PROCESS study[4]. This study, across 12 centres, recruited 100 patients with FBSS who satisfied the inclusion and exclusion criteria. Patients must have had recurring or persistent leg pain, greater than back pain, despite one or more anatomically successful back surgeries for the same original pain. This gave an opportunity to look more carefully at this 100-patient cohort and their demographics prior to randomisation. It gave some interesting insights into this group of patients.[12]

Half of the patients had undergone more than one spinal surgery. They had endured a mean (SD) of 4.7 years (4.7 years) since their last surgery. Eighty-seven per cent of patients had tried four or more types of drug or non-drug treatments (e.g. physical rehabilitation, antidepressants, anticonvulsants, transcutaneous electrical nerve stimulation, acupuncture, pain-relieving nerve injections or psychological interventions). By the time of randomisation 62% of the patients were taking opioids, 38% antidepressants and 38% anticonvulsants, with only a few patients continuing with non-drug treatments. This was reflective of usual non-surgical care for FBSS from 2004 to 2007; patients tend to reject therapies that are not helpful or give adverse side-effects.

In the same paper on demographics of FBSS, a literature search was carried out to look at four other chronic pain conditions and, wherever possible, to populate the demographic dataset to allow comparison of the FBSS cohort with CRPS types 1 and 2 (CRPS), rheumatoid arthritis, osteoarthritis and fibromyalgia. This was done by a structured literature search of PubMed until the beginning of 2008. A single reviewer extracted data from studies, providing that the study had been published in the last 10 years, and identified whether these data contained relevant demographic information for one or more of the four chronic pain conditions, unlimited by age or gender. A second reviewer verified this information.

The epidemiology of these four conditions and FBSS has been presented above. Only half of the patients with FBSS in the PROCESS study were female whereas the majority of patients with CRPS, rheumatoid arthritis, osteoarthritis and fibromyalgia were female. The average age of FBSS was 50 years similar to the patients with CRPS, RA, OA and FMS. However 78% of FBSS were on work disability, which was more than twice the rate for CRPS and FMS patients and half as much more again for RA patients.

The health-related quality of life (HRQoL) outcomes found in the PROCESS study were surprising. These were measured using the EQ5D and the SF-36. The EQ5D is advantageous in that it is directly correlated to QALYs (quality-adjusted life years), but each measurement helps to validate the other. The mean EQ5D result for FBSS was 0.16, where 0 equates to HRQoL of death and 1 to that of perfect health. Comparison with other pain populations (CRPS, rheumatoid arthritis, osteoarthritis, fibromyalgia) showed FBSS patients in the PROCESS study to be more severely affected, with EQ5D scores of 0.42–0.47, 0.43–0.47, 0.35 and 0.33, respectively. The SF-36 measures showed all FBSS domains to be markedly lower than all domains of SF-36 for CRPS, rheumatoid arthritis and osteoarthritis, but comparable with fibromyalgia.

The average annual cost of medication was calculated from the FBSS data and compared with that of the other four pain conditions. Treating a patient with FBSS cost €1802 per annum compared with between €183 and €1261 per annum for the other conditions (based upon 2006 prices).

Discussion points

FBSS is a relatively common condition, similar to rheumatoid arthritis in incidence and prevalence. Patients suffering neuropathic pain secondary to FBSS appear to experience greater reported levels of pain, lower HRQoL and decreased function than those suffering from other common chronic pain conditions such as CRPS, rheumatoid arthritis, osteoarthritis and fibromyalgia. The burden on society is also greater for FBSS, as exemplified by the increased work disability rate and higher annual medication costs.

Why are there so few demographic data on this important and significant group of patients?

FBSS, as discussed above, is an artificial construct and not a disease entity in itself. The name implies that patients are distinct from other patients with neuropathic back and leg pain simply because they have been treated by a surgeon. These patients have remained hidden from epidemiological scrutiny; they are prisoners of a surgical algorithm of care. A variety of disciplines, each with its own treatment concepts, has inherited these patients. These include neurological and orthopaedic spinal surgery, physiotherapy, pain medicine, rheumatology, neurology, primary care and psychiatry. Surprisingly little communication among them takes place.

The diagnosis of FBSS can be delayed by spinal surgeons who continue to believe that more surgery will solve the problem, or by pain physicians working through an array of drug and non-drug interventions, or primary caregivers continuing the re-referral cycle of despair.[2,9,10] In the PROCESS study the patients waited for 4.7 years before randomisation.

There are several steps needed to be able to offer these patients more effective care.

First, a consensus on the population in question is required. The epidemiology suggests that this is a significant size of population with significant impact of disease and is worthy of greater understanding.

Second, it must be understood that these complex patients have complex multidisciplinary needs and for them to be successfully treated we must draw them away from a single specialty modality of care. Recent work by the British Pain Society with the Department of Health and the Map of Medicine, if adopted, may have a useful role here.[17]

Third, it should be recognised that effective treatment exists for many patients in this group and that to delay treatment is neither moral nor a cost-effective use of scarce resources. Cost-effective treatments for long-term conditions does not mean selecting the cheapest start-up cost option, which may have a modest benefit and a high long-term failure rate. A technology appraisal guidance by the National Institute for Health and Clinical Excellence[15] has shown that spinal cord stimulation for refractory neuropathic pain (such as FBSS) is the treatment of choice in selected patients.[13–16] With an incremental cost-effectiveness ratio now calculated as £5624 for FBSS, it is cheaper than introducing inhaler technology for asthma.[18]

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References

1. Follet K and Dirks B. Etiology and evaluation of the failed back surgery syndrome. *Neurosurg Q* 1993; 3: 40–59.
2. North RB, Kidd DH, Zahurak M, et al. Spinal cord stimulation for chronic, intractable pain: experience over two decades. *Neurosurgery* 1993; 32: 384–394.
3. Wilkinson HA. *The Failed Back Syndrome: Etiology and Therapy*. Philadelphia: Harper & Row, 1991.
4. Kumar K, Taylor RS, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007; 132: 179–188.
5. Leveque JC, Villavicencio AT, Rubin L, Bulsara K,, Gorecki JP. Spinal cord stimulation for failed back surgery syndrome. *Neuromodulation* 2001; 4: 1–9.
6. Lumbar spinal or radicular pain after failed spinal surgery. Page 179 Classification of Chronic Pain IASP second edition. 1994 Merskey H., Bogduk N.
7. Ragab A and Deshazo RD. Management of back pain in patients with previous back surgery. *Am J Med* 2008; 121: 272–278.
8. North RB, Kidd DH, Farrokhi F, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial. *Neurosurgery* 2005; 56: 98–106.
9. Cherkin D, Deyo R, Loeser J, Bush T and Waddell G. An international comparison of back surgery rates. *Spine* 1994; 19: 1201–1206.
10. Taylor RS. Epidemiology of refractory neuropathic pain. *Pain Practice* 2006; 61: 22–26.
11. Eldabe S, Thomson S and Baranidharan G. Variation in spinal cord commissioning: What does the Hospital Episode Statistics database tell us? *Pain News* 2012; 10: 94–96.
12. Thomson S and Jacques L. Demographic characteristics of patients with severe neuropathic pain secondary to failed back surgery syndrome. *Pain Pract* 2009; 9: 206–214.
13. North RB, Kidd DH, Farrohki F and Piantoadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomised, controlled trial. *Neurosurgery* 2005; 56: 98–107.
14. Kumar K, Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomised controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery* 2008; 63: 762–770.
15. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE technology appraisal guidance 159. *London: NICE*. Available at: http://publications.nice.org.uk/spinal-cord-stimulation-for-chronic-pain-of-neuropathic-or-ischaemic-origin-ta159 (2008, accessed 24 February 2013).
16. Simpson E, Duenas A., Holmes M, et al. Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation. *Health Technol Assess* 2009; 13(17):
17. Map of Medicine. Initial assessment and early management of pain; Spinal pain. Available at: http://www.mapofmedicine.com/ (accessed 13 March 2013).
18. Taylor R, Ryan J, O'Donnell R, Eldabe S, Kumar K and North R. The cost effectiveness of spinal cord stimulation in the treatment of failed back surgery syndrome. *Clin J Pain* 2010; 26: 463–469.

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