Failed back surgery syndrome: a suggested algorithm of care

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Abstract

Failed back surgery syndrome (FBSS) is a complex condition which can be very difficult to treat. In this article, we propose a pragmatic algorithm for the management of the syndrome. The management of this condition should include a comprehensive initial assessment to rule out treatable cause, pharmacological optimisation, psychological techniques and neuromodulation. There is good evidence to support early application of conventional spinal cord stimulation for FBSS patients suffering from predominant buttock and leg pain. Emerging techniques in neuromodulation such as high-frequency spinal cord stimulation, peripheral nerve field stimulation and dorsal root ganglion stimulation hold promise for the future, but long-term outcome regarding efficacy and safety is not yet established. Intrathecal drug delivery systems should also be considered in those who are unsuitable or unresponsive to neuromodulation and still warrant further treatment. However, the long-term outcome may not be as good as with other treatments mentioned above.

Keywords

Failed back surgery syndrome, treatment algorithm, pharmacotherapy, pain management programme, multidisciplinary team, neuromodulation, spinal cord stimulation, intrathecal pump

Introduction

Failed back surgery syndrome (FBSS) is a complex set of symptoms encountered after a patient has had surgery on the lumbar spine for disc-related pathology. The patient presents with recurrent and persistent pain, with or without a radiculopathy, following spinal surgery. Different definitions have been quoted^{1–3} and one of these has defined FBSS as ‘persistent recurrent pain, mainly in the region of the lower back and legs, even after technically, anatomically successful lumbosacral spine surgeries’.⁴ The epidemiology and extent of this condition varies worldwide. It is estimated to be anywhere between 10% and 40% following spinal surgery for disc-related pathologies.^{1,5,6} The overall extent of problem and economical impact is covered elsewhere in this issue.

Many patients find the term FBSS confusing and believe that their back, the surgeon or they themselves have failed in some way. This can have psychological consequences and affects progress. Time should be

taken to ask the patient what they understand to be the cause of their pain, and this can facilitate a discussion of what FBSS actually means in the particular scenario relevant to that patient.

Failed back surgery syndrome can be attributed to many causes as in Table 1.^{7,8}

Many of these patients would have a combination of nociceptive and neuropathic pain, and it is important to distinguish between these subtypes, as the treatment approach is different for each. Apart from

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Table 1. Reasons for persistent pain after discectomy.

- Recurrence of disc herniation/herniation at adjacent level
- Epidural fibrosis/scarring at site of spinal surgery
- Intraoperative trauma to nerve root(s)
- Operation at the wrong level
- Inadequate surgical treatment of spinal stenosis
- Multi-segmental spinal stenosis
- Pre-existing nerve damage as caused by initial disc herniation/sequestered disc fragment/cauda equina syndrome

Source: Fritsch E, Heisel J, Rupp S. The failed back surgery syndrome: Reasons, intraoperative findings, and long-term results: a report of 182 operative treatments. *Spine* 1996; 21(5): 626–633.

biological factors, there are often psychological and social factors at play that have an impact on the outcome of spinal surgery, and that is what makes this a complex condition easy to diagnose but difficult to treat. Further surgery is inappropriate and ineffective in many patients⁹ and a thorough assessment and pre-operative evaluation can avoid inappropriate surgery. Successful management of this condition requires management within the context of a multidisciplinary team as patients benefit from a range of treatment options including cognitive-behavioural, pharmacological (chemical neuromodulation), injections and (electrical) neuromodulation approaches.¹⁰

Background to proposed algorithm of care

In this article, we propose an algorithm of care (Figure 1) that provides a comprehensive management approach for this group of patients. We are aware that algorithms have previously been suggested to help manage this complex clinical entity,^{10–12} but we have endeavoured to make this algorithm more inclusive and patient centred. Patients' motivation, expectations and understanding of their condition should be taken into account when considering treatment options. The algorithm is driven by the perceived severity of pain, its location, accompanying physical disability and psychological distress, available local expertise in the pain service and availability of commissioned management options, as well as by patient choice. It is mandatory to exclude any curative treatment options (disc fragments, new disc herniation at another level, spinal instability or significant spinal stenosis), before considering the patient for pain relief or pain management options.

The algorithm has been simplified for the purpose of this article. In FBSS the range of presentation (pain, disability, psychological distress, expectation from

treatment) of patients varies remarkably. For simplicity, patients with FBSS have been divided into those with predominant neuropathic buttock pain and leg pain and those with predominant neuropathic back pain. However, in clinical practice many patients with FBSS have equally disabling neuropathic and nociceptive pain in the back and the lower limb. From the treatment perspective, FBSS management can be described as chemical or electrical neuromodulation and cognitive-behavioural rehabilitation. Chemical neuromodulation means treatment including pharmacological management by various routes including intrathecal drug delivery systems.

For appropriately selected patients with FBSS who have predominant neuropathic buttock and leg pain without major psychological issues, it is appropriate to consider neuromodulation ahead of a pain management programme therapy or related psychological techniques in line with current available evidence.^{13–15} The health technology appraisal by NICE published in 2008 regarding spinal cord stimulation (SCS)¹³ has been supportive of the cost-effectiveness of conventional SCS to manage FBSS patients in combination with a pain management programme if required. Unnecessary delays in offering this treatment may affect outcome, as the results of neuromodulation are better if applied early.¹⁶

If the major component of pain is persistent back pain with a predominantly neuropathic component, then emerging treatment modalities such as high-frequency SCS, dorsal root ganglion stimulation, peripheral nerve field stimulation or complex surgical paddle leads may offer better pain relief.^{15,17} However, these are emerging technologies and are currently undergoing further evaluation to confirm efficacy and safety.

Initial assessment

Initially, a comprehensive bio-psycho-social assessment is performed by the pain physician when the patient first presents with persistent symptoms following spinal surgery. This assessment should take into account pain severity and its impact on function and quality of life as well as dorsal column function and any associated deafferentation in the affected painful area. Time should be taken to provide a thorough assessment of these patients if they are to be managed effectively.

It is necessary to obtain the relevant records regarding previous treatments, including the details of spinal operations, from other departments or hospitals, as these details often provide important clues regarding management. Yellow flags should have ideally been identified before spinal surgery, since a correlation has been shown between the presence of yellow flags and

Figure 1. Failed back surgery syndrome: an algorithm of care.

the development of FBSS.^{18,19} Reassessment of yellow flags at this stage is to choose the correct treatment option. The assessment in a secondary care setting should include the use of validated pain assessment tools to assess pain severity, physical disability and psychological distress (Brief Pain Inventory, Oswestry Disability Index, Hospital Anxiety and Depression Scale, EQ-5D).

Imaging and spinal surgery in failed back surgery syndrome

An assumption should not be made that only psychological issues are the cause for the patient's persistent pain. Imaging should be used where it is thought appropriate to rule out the need for further surgery.²⁰ Magnetic resonance scanning has been found to be more sensitive in identifying causes such as postoperative discitis.²¹ Residual disc herniation needs to be differentiated from epidural scarring, as this has implications for further treatment options. New or recurrent lateral disc prolapse should be ruled out if the patient presents with a new onset of symptoms and signs of a radicular nature. Foraminal stenosis is one of the most common causes of persistent back pain following surgery.²² Surgical opinion should be sought, if not already obtained, especially if there is suspicion of a new or recurrent disc prolapse, or foraminal stenosis. However, a randomised controlled trial comparing repeat surgery with SCS suggested that repeat surgery has poorer results.²³ Ideally, the need for further surgery should be ruled out before the patient is referred to the pain physician.

Pharmacotherapy and spinal interventions in failed back surgery syndrome

If further surgery has been ruled out, then the analgesic regimen should be optimised. Although there are case reports published that report the effectiveness of gabapentin in postoperative epidural fibrosis after spinal surgery,²⁴ a large randomised controlled trial published recently failed to show efficacy of pregabalin in neuropathic pain associated with radiculopathy.²⁵ Overall the efficacy of gabapentinoids seems borderline at best for neuropathic pain, i.e. effect size is small and accompanied by side effects in many patients. Strong opioids for chronic pain are being re-evaluated because the side effects from the long-term use of strong opioids including immune suppression, endocrine suppression, reduced libido and an overall detrimental effect on the quality of life are becoming well known.^{26–28} There is concern that mortality may

be increased in patients with chronic pain who are using strong opioids in high dosages to control pain, though the exact contribution of opioids to increased mortality is not yet clear. Pharmacological treatment options are helpful only in a minority of patients with FBSS.^{29–31}

If local pathology contributing to the pain is suspected, spinal interventions such as transforaminal epidural steroid injection³² or facet joint denervation³³ should be considered. These treatment options may, in some cases, allow the patient to comply with on-going exercises, reduce medication use and avoid repeat surgery. Efficacy of interlaminar lumbar or caudal epidural steroid injections in FBSS is not as well established as for acute lumbar radicular pain.³⁴

Role of neuromodulation for failed back surgery syndrome

Details regarding suitable indications and mechanism of action of SCS are beyond the scope of this article. There are many suitable publications.^{35,36}

If the patient continues to have severe neuropathic buttock and leg pain, conventional SCS should be considered. In these patients, SCS plus conventional medical management has been found to be more effective than conventional medical management alone.³⁷ For patients with predominant neuropathic back pain, conventional SCS may help, but efficacy has not been as established as for radicular pain.³⁸

Neuromodulation should not be considered as a 'last-ditch' effort but should be offered early in the management plan. Neuromodulation has been shown to be less effective in older patients and those who have higher scores on the depression subscale D of the Minnesota Multiphasic Personality Inventory.³⁹ Neuromodulation may be unavailable locally, so referral to a neuromodulation centre should be made once it becomes clear that the patient has failed to respond to conventional locally available conservative treatments. Early referral and application of neuromodulation has been shown to increase its success in FBSS.¹⁶

Multidisciplinary team for failed back surgery syndrome management

A neuromodulation unit typically consists of a multidisciplinary team of trained professionals who can assess and manage these patients effectively, not only during the period before trial of SCS, but also during and following the permanent implant, and beyond, when complications or loss of efficacy may develop. Ideally this unit would also be able to offer a pain management

programme to suitable patients. Neuromodulation is a very significant commitment for the team delivering it, and also for the patient. The neuromodulation team should include pain physicians, psychologists, physiotherapists and neuromodulation nurses. Close collaboration with the spinal surgical team may be beneficial, especially to deal with hardware-related issues or neurological complications from neuromodulation.

Multidisciplinary team assessment and patient preparation for pain management programme and/or neuromodulation

Once a referral has been received by the neuromodulation centre, the patient is assessed initially by the pain physician, who will gauge the suitability of the patient for neuromodulation or the pain management programme (having already considered the role of further surgery, pharmacological and other simpler interventional treatment options). An important component of further assessment should be the early involvement of the multidisciplinary neuromodulation team⁴⁰ (MDT), who also have the skills to assess whether the patient should first be offered a pain management programme (PMP) or other treatment strategies (individual psychological counselling to prepare for PMP or neuromodulation). The patient should be educated regarding the various aspects of neuromodulation and PMP, and their expectations, understanding and motivation towards the treatment options should be gauged.

The team should include a psychologist trained in assessing patients in chronic pain, a chronic pain physiotherapist and a neuromodulation specialist nurse; their role, apart from patient assessment and education, is to liaise with members of the neuromodulation team and to be the first point of contact for the patient during the neuromodulation trial. The psychologist has an important role in the MDT, in helping to select and in optimising those who have the best chance of a successful outcome.⁴¹ Assessment of the patient is to educate about the implantation process. If significant psychological issues or behavioural issues are discovered, the patient may be deemed to be unsuitable for an implant at that time. The patient should be offered the PMP if they are motivated to develop techniques to improve self-management and coping mechanisms. A detailed description of the PMP is beyond the scope of this article. Not all patients are suitable for the PMP, and patients with unrealistic goals have been shown to have a poor outcome following PMP treatment.^{42–44} These patients can be very difficult to manage and should be managed by conservative means by close collaboration between GPs and pain clinics, using

containment strategies. Some patients can become suitable for PMP therapy with individual psychological and/or physiotherapy treatment sessions.

Pain management programme for failed back surgery syndrome

The PMP may be offered to patients who are unsuitable for SCS, to enable them to manage their pain, or to patients who would benefit from PMP prior to SCS, in order to optimise their outcome from neuromodulation. Following PMP, a small number of patients choose not to have SCS because they are satisfied with their ability to cope and manage symptoms. Patient education and support plays a vital role throughout this process and the patient should be encouraged to mobilise and should be supported in leading as normal a life as is possible.³⁸ Techniques such as mindfulness meditation have been shown by some authors to be effective in achieving this goal.⁴⁵

Neuromodulation for failed back surgery syndrome

Patients who do not need PMP, and are suitable for neuromodulation, should be prepared for a trial of conventional SCS, if the pain is predominantly neuropathic and localised to the buttock and leg. Trial before implantation is in line with the recommendation of current guidelines from NICE¹³ and the British Pain Society.¹⁴ Most of the units in the UK perform a trial prior to implantation. There are advantages and disadvantages to a trial of SCS before proceeding to permanent implant (including false negative or false positive trial), but these are beyond the scope of this article. The trial lead (Figure 2) should be left in place for a week to 10 days to assess whether or not SCS is beneficial for the patient (a successful trial results in pain reduction by more than 50% and increased function and quality of life). The trial lead is then removed, while the patient awaits implantation of the permanent lead and internal pulse generator (IPG). There is variation in practice, as some units will perform a trial for longer and complete the trial with connection of IPG, if the trial is successful. The insertion of an IPG and connection to the epidural electrode is usually performed by the pain physician, although some centres collaborate with spinal surgeons, who insert the permanent implant.

Several studies have shown SCS to be effective in treating the radicular pain after FBSS.^{9,16,46} A permanent implant (Figure 3) has been shown to be effective in more than 50% of the patients with radicular pain, with an improvement in pain, function and feeling of well-being.⁴⁶

Figure 2. Spinal cord stimulation octopolar trial lead in place at T10/11.

Figure 3. Spinal cord stimulator implant in situ.

Emerging neuromodulation technologies (undergoing evaluation by some pain units in UK)

High-frequency spinal cord stimulation: This technique has been shown to be of particular value in patients with FBSS with a predominant lower back

pain component.⁴⁷ A frequency of about 5000–10,000 Hz is used. A major advantage is that patients do not have to rely on the perception of paraesthesia in the affected area. There are no efficacy, cost-effectiveness or safety data from a randomised controlled trial or comparison with conventional SCS in relation to the long-term use of this technology.

Dorsal root ganglion stimulation: A specially designed lead is placed around the dorsal root ganglion, via the epidural space, and this produces pleasant paraesthesia in a dermatome or part of it. The major advantages seem to be that there is no change in perception of paraesthesia with posture, and it is possible to target dermatomes which would otherwise be difficult to target with conventional SCS (foot, groin etc.) without overspill of paraesthesia into other dermatomes. There are minimal long-term data regarding efficacy, safety and cost-effectiveness.^{48,49}

Peripheral nerve field stimulation: Specially designed leads have been approved for this use, especially for treating the neuropathic back pain component of FBSS. Use of this technique, in combination with conventional SCS or alone, has been published with impressive results in case series.⁵⁰ However, cost-effectiveness and long-term efficacy are not established.

Intrathecal drug delivery system for failed back surgery syndrome

Implanted intrathecal drug delivery systems (ITDDSs) have been used with benefit in patients with FBSS.^{51–54} Implantation usually follows a trial and a careful assessment of the trial results. However, it has not been established whether to trial a bolus of the drug or a continuous infusion of the drug and which drugs to use. There is considerable variation in the use of ITDDS by neuromodulation units. The management of patients on large doses of opioids before trial also varies (some wean off the opioids, some reduce the dose by half and some continue high-dose opioids during the trial process). A patient with an ITDDS requires long-term regular follow-up for regular pump refills, and to identify and solve potential problems which may arise in relation to efficacy, side effects related to drugs delivered through the pump and neurological or endocrine issues arising as a result of this treatment. A detailed description is beyond the scope of this article. These follow-up encounters could be in a secondary or tertiary care setting, with regular correspondence between the patient's GP and the neuromodulation team. The follow-up is not only to monitor the efficacy of the implant, but also to diagnose and treat complications.

Although there may be benefits from an ITDDS in some patients with FBSS, there is limited consensus

on long-term efficacy, safety and cost-effectiveness. Uptake of this mode of therapy is further hampered by limited advances in new drugs with better safety and efficacy profiles for intrathecal use. Intrathecal gabapentin did hold promise but further emerging data do not seem as favourable. Current hardware is robust but there is a need for more effective and safer drugs for intrathecal use.⁵⁵ Only intrathecal morphine, ziconotide and baclofen have approval from the US Food and Drug Administration for use in an intrathecal pump.⁵⁶ At present, there does not seem to be much enthusiasm regarding the use of intrathecal pumps for FBSS, but their use in palliative care is much more established, with efficacy and possibly increase in survival proven by a randomised controlled trial.⁵⁷

Aftercare of failed back surgery syndrome patients

These patients will need long-term support and on-going shared care between GPs and secondary or tertiary care pain units. Patients with SCS implants will need regular follow-up to adjust stimulation parameters, replace the IPG if required or replace other hardware. Patients with ITDDS will need regular follow-up to refill the pump, interrogate the pump to diagnose and manage pump-related issues, and identify and manage any neurological sequelae from the ITDDS. For these reasons close collaboration with spinal surgery and pain medicine is recommended. All patients should have outcome data collection. From a psychological and behavioural perspective, these patients need on-going support to help manage flare-ups in pain, new areas of pain- and tolerance-related issues and natural progression or deterioration in their condition. For many of the patients with FBSS who are not suitable for above management options, a containment strategy should be used in close collaboration with GPs to provide on-going assurance and support to the patient.

Conclusions

Failed back surgery syndrome is a complex entity that can cause considerable disability, distress to the patient and immense economic impact on the health-care system. Management of this condition requires a thorough assessment and early referral to a secondary or tertiary referral centre for further management. The above suggested algorithm should help in formulating an effective management plan for these patients within the context of a multidisciplinary team approach. Many patients can be significantly helped by the above approach, but many others will have to use, and rely on, self-management techniques. There

is a considerable revolution in the field of neuromodulation, and the number of patients who may benefit is likely to increase in the near future.

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2. **The following are true regarding FBSS:**
 - a) It is a misnomer.
 - b) It is a complex condition to diagnose but easy to treat.
 - c) It is a complex condition to diagnose and complex to treat.
 - d) It is a simple condition to diagnose but complex to treat.
 - e) It is a simple condition to diagnose and treat.
 3. **Most patients with a diagnosis of FBSS:**
 - a) are female with significant psychological distress.
 - b) need an MR scan of the spine.
 - c) have normal MRI scans (showing typical postoperative changes).
 - d) should have postoperative discitis ruled out by serial measurement of plasma C-reactive protein levels.
 - e) should have an MRI scan with gadolinium.
 4. **Spinal cord stimulation should be considered in:**
 - a) non-operated patients with a radiculopathy.
 - b) patients with FBSS after they have successfully completed the pain management programme.
 - c) patients with FBSS only after failure of all conventional methods of treatment.
 - d) a patient with FBSS, as it is effective in about 50% of patients with FBSS in relieving pain.
 - e) a patient with on-going severe pain, physical disability and psychological distress.
 5. **The following statements are true regarding the treatment of FBSS:**
 - a) Gabapentin or pregabalin is an effective pharmacological treatment as shown in a randomised controlled trial.
 - b) High-frequency spinal cord stimulation is effective for back pain as shown in a randomised controlled trial.
 - c) A combination of spinal cord stimulation and peripheral nerve field stimulation can be effective in relieving the symptoms in some patients.
 - d) Dorsal root ganglion stimulation is shown to be effective in a randomised controlled trial.
 - e) A psychological assessment of the patient is mandatory before a trial of neuromodulation.

Multiple-choice questions

1. **The following are the causes of failed back surgery syndrome (FBSS):**
 - a) Trauma
 - b) Recurrent disc prolapse
 - c) Postoperative adhesions
 - d) Anaesthetic technique
 - e) Severe anxiety and depression

Answers

1: b, c, e; 2: a, d; 3: b, c, e; 4: e; 5: b, c, d, e.