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REVIEW ON FAILED BACK SURGERY SYNDROME

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Background:

Failed back surgery syndrome (FBSS) is a chronic pain condition that has considerable impact on the patient and health care system. Despite advances in surgical technology, the rates of failed back surgery have not declined. The factors contributing to the development of this entity may occur in the preoperative, intra operative and postoperative periods. Due to the severe pain and disability this syndrome may cause, more radical treatments have been utilized. Although FBSS is usually due to improper diagnosis and surgery, another important cause is peridural fibrosis. Recent trials have been published that evaluate the efficacy and cost-effectiveness of therapeutic modalities such as spinal cord stimulation for the management of patients with failed back surgery.

Review Summary:

This article will describe the epidemiology and etiology of FBSS. The importance of prevention will be emphasized. In those patients with established FBSS, a guide to interdisciplinary evaluation and management will be outlined. Special attention will focus on recent trials that have studied the efficacy of more invasive procedures such as spinal cord stimulation. Finally, a suggested management pathway is presented.

Conclusion:

FBSS is a challenging clinical entity with significant impact on the individual and society. To better prevent and manage this condition, knowledge of the factors contributing to its development is necessary. While research on FBSS has increased in recent years, perhaps the best strategy to reduce incidence and morbidity is to focus on prevention. More radical treatments for FBSS have now been extensively studied providing doctors with much needed evidence on their efficacy. Incorporating these results into our current knowledge provides a basis on which to construct an evidence-based guide on how best to manage patients who suffer from FBSS.

Keywords: Failed back surgery syndrome, spinal cord stimulation, therapeutic modalities and peridural fibrosis.

Introduction: “Failed back syndrome” is a term often used to describe patients who have undergone lumbar surgery, who have persistent pain syndromes. This is clearly not a diagnosis in itself but a term used to describe a large and diverse group of patients who have undergone a variety of lumbar surgeries, with unsatisfactory outcomes. Many investigators have attempted to discern a cause for these poor outcomes, in hope that it may be treated or prevented. Unfortunately, the causes, which include, among others, inappropriate patient selection for surgery, are so diverse as to preclude a single preventative or therapeutic solution.

Back surgery is an important treatment option yet a significant percentage have a poor outcome and may require either additional surgery, interdisciplinary treatment, or implantable devices to manage pain. Back pain is a widespread public health problem, affecting a staggering 80% of Americans at some point in their lives [1]. Each year, an estimated one out of every 14 people will seek medical care for back or neck pain, amounting to almost 14 million visits annually. Estimated annual costs for direct and indirect treatment range from \$20 billion to \$60 billion [2]. Back and/or neck pain is cited as the second most common reason for physician visits, and it is estimated that 25% of all work injuries in the U.S. are related to low back pain [3, 4]. Most back pain is acute or sub acute with 90% of patients recovering within three to four months. However, other estimates suggest less than 30% of patients are completely improved within 3-months of treatment [5]. These more chronic sufferers of back pain endure a cycle of pain that is detrimental to their physical and psychological health, lifestyle, and productivity. Chronic low back pain alone is responsible for the disability or partial disability of at least 7 million Americans. In terms of lost productivity, 93 million lost workdays per year are related to low back pain [6]. Diseases of the musculoskeletal system make up the 6th most common reason for hospitalization in the United States, with back surgery (laminectomy) accounting for the most common inpatient, musculoskeletal procedure [7]. Surgeons perform an estimated 300,000 to 400,000 back surgeries every year. Annually, neurosurgeons perform at least 100,000 operations for lumbar disc disease alone, and orthopedic surgeons perform a similar number [8]. It is estimated that between 20% and 40% of these operations are unsuccessful and result in FBSS [9].

Structure of the spine:

In order to understand why removal of a piece of bone from the arch of a vertebra relieves pain, it is helpful to have a brief description of the structure of the spinal column and the vertebrae themselves. The vertebral column usually

consists of 33 vertebrae: 24 presacral vertebrae (7 cervical, 12 thoracic, and 5 lumbar) followed by the sacrum (5 fused sacral vertebrae) and the coccyx (4 frequently fused coccygeal vertebrae). It is the vertebrae in the lumbar portion of the spine that are most likely to be affected by the disorders that cause back pain. The 24 vertebrae that are not fused are stacked vertically in an S-shaped column that extends from the tail-bone below the waist up to the back of the head. This column is held in alignment by ligaments, cartilage, and muscles. The bony arches of the laminae on each vertebra form a canal that contains and protects the spinal cord. The spinal cord extends from the base of the brain to the upper part of the lumbar spine, where it ends in a collection of nerve fibres known as the cauda equina. Other nerves branching out from the spinal cord pass through openings formed by adjoining vertebrae. These openings are known as foramina.

Between each vertebra is a disk that serves to cushion the vertebrae when a person bends, stretches, or twists the spinal column. The disks also keep the foramina between the vertebrae open so that the spinal nerves can pass through without being pinched or damaged. As people age, the intervertebral disks begin to lose moisture and break down, which reduces the size of the foramina between the vertebrae. In addition, bone spurs may form inside the vertebrae and cause the spinal canal itself to become narrower. Either of these processes can compress the spinal nerves, leading to pain, tingling sensations, or weakness in the lower back and legs. A lumbar laminectomy relieves pressure on the spinal nerves by removing the disk, piece of bone, tumour, or other structure that is causing the compression.

So why does the spine surgery fail ?

There are three reasons for that:

1. The diagnosis and patient selection was wrong.
2. The surgery created unwanted and iatrogenic changes in the spine.
3. The post operative care and rehabilitation efforts were poor.

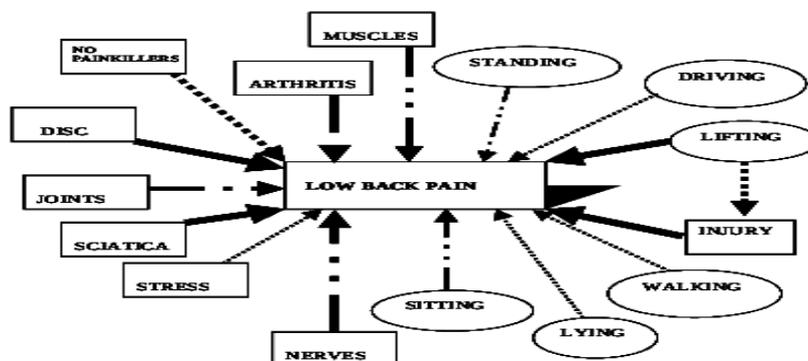
Specific symptoms and disorders that affect the lower back include [10]:

- **Sciatica:** Sciatica refers to sudden pain felt as radiating from the lower back through the buttocks and down the back of one leg. The pain, which may be experienced as weakness in the leg, a tingling feeling, or a "pins and needles" sensation, runs along the course of the sciatic nerve. Sciatica is a common symptom of a herniated disk.
- **Spinal stenosis:** Spinal stenosis is a disorder that results from the narrowing of the spinal canal surrounding the

spinal cord and eventually compressing the cord. It may result from hereditary factors, from the effects of aging, or from changes in the pattern of blood flow to the lower back. Spinal stenosis is sometimes difficult to diagnose because its early symptoms can be caused by a number of other conditions and because the patient usually has no history of back problems or recent injuries. Imaging studies may be necessary for accurate diagnosis.

- Cauda equina syndrome (CES):** Cauda equina syndrome is a rare disorder caused when a ruptured disk, bone fracture, or spinal stenosis put intense pressure on the cauda equina, the collection of spinal nerve roots at the lower end of the spinal cord. CES may be triggered by a fall, automobile accident, or penetrating gunshot injury. It is characterized by loss of sensation or altered sensation in the legs, buttocks, or feet; pain, numbness, or weakness in one or both legs; difficulty walking; or loss of control over bladder and bowel functions. *Cauda equina syndrome* is a medical emergency requiring immediate treatment. If the pressure on the nerves in the cauda equina is not relieved quickly, permanent paralysis and loss of bladder or bowel control may result.
- Herniated disk:** The disks between the vertebrae in the spine consist of a fibrous outer part called the annulus and a softer inner nucleus. A disk is said to herniate when the nucleus ruptures and is forced through the outer annulus into the spaces between the vertebrae. The material that is forced out may put pressure on the nerve roots or compress the spinal cord itself. In other cases, the chemicals leaking from the ruptured nucleus may irritate or inflame the spinal nerves. More than 80% of herniated disks affect the spinal nerves associated with the L5 vertebra or the first sacral vertebra.
- Osteoarthritis:** OA is a disorder in which the cartilage in the hips, knees, and other joints gradually breaks down, allowing the surfaces of the bones to rub directly against each other. In the spine, OA may result in thickening of the ligaments surrounding the spinal column. As the ligaments increase in size, they may begin to compress the spinal cord.

Composite Diagram:



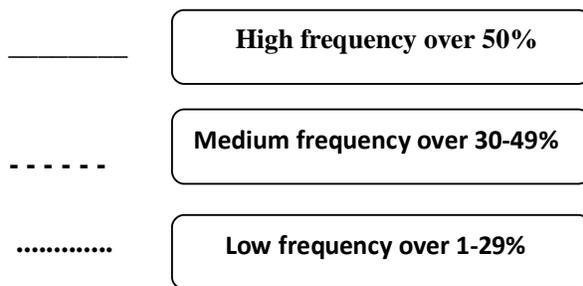


Figure-1: showing the factors with their frequencies causing low back pain.

Indications for Spinal Surgery:

Surgery represents an important treatment option for physicians in managing chronic back pain, especially conditions that are intractable to more conservative interventions. Except for emergency situations, surgery is only undertaken after attempting less invasive procedures. The most common conditions for which surgery is recommended are disc bulge, disc herniation, and disc disruption; spinal stenosis, spondylosis, spondylolisthesis, and failed back surgery syndrome.

Surgical Procedures:

The following are brief descriptions of common surgical procedures for back pain. A *laminectomy discectomy* is an operation on a herniated disc in which a small amount of bone is first removed from the lamina (the arched bony roof of the spinal canal). Afterwards, a decompression of the nerve root is completed by removing the disc tissue that is pressing on it. A *microdiscectomy* is similar to a discectomy except that it is done with the use of magnification such as an operating microscope that requires a smaller incision. Percutaneous disc removal involves removing the problem disc fragment through an endoscope (a small tube inserted through a tiny opening made into the back). A miniature video camera is attached to the tube and the disc fragments are cut away and removed by suction through the tube [11]. *Foraminotomy* is an operation that enlarges the bony hole through which the nerve root exits. Small pieces of bone over the nerve are removed through a small slit, allowing the surgeon to cut away the blockage and relieve the pressure on the nerve. *Spinal fusion* is a process in which the spinal disc between two or more vertebrae is removed and the adjacent vertebrae are joined together via bone grafts or metal devices/cages. Fusion occurs when the adjacent bones grow together to form a single bone. *Disc replacement* is a newer surgical option that is currently being explored by the U.S. Food and Drug Administration (FDA) and involves implantation of an artificial disc that reduces pain and improves ability to move [12].

Etiology of FBSS

Poor Selection for Surgery:

There are several paths to FBSS. The most common cause is poor selection for surgery. This means that the patient may have had a psychological profile or physical pathology that was contraindicated or not appropriate for the surgical intervention [12, 13]. Furthermore, if the patient is misdiagnosed, the surgery is obviously incorrect and damaging. The most common misdiagnosis in these cases is arthritis misdiagnosed as a lumbar disc disease. Often, improper selection and misdiagnosis follows from inadequate pre-operative evaluation and diagnostic work-up. A full diagnostic work-up should include a medical and psychological evaluation. The medical evaluation should include a comprehensive physical examination and history, imaging, and other relevant diagnostic procedures. Radiography, computed tomography (CT), magnetic resonance imaging (MRI), myelography, bone scanning, electromyography, discography, and various diagnostic injections are used to assist the physician in determining the diagnosis, location, and cause of the patient's pain [12].

Unnecessary Surgery:

Surgery that is unnecessary may also be the cause of FBSS. Unnecessary surgery not only fails to treat the problem appropriately, but may worsen the patient's condition. An unnecessary excision of the nucleus pulposus from a normal disc is likely to increase the risk of chronic back pain by creating instability and malalignment. Needless surgery places patients at unnecessary risk for injured nerve roots, torn dura or arachnoid, CSF leakage, and possible wound infection or haemorrhage later [14]. Moreover, most patients with lumbar disc disease and sciatica will respond successfully to nonoperative treatments. Three studies cited by Benzon in an early review article [15] demonstrate that treatments such as bed rest, intramuscular dexamethasone, and back support ultimately result in a large reduction in pain with no need for surgery in 68 to 82% of patients with herniated discs and/or nerve root irritation [16-18]. Doctors treated patients with herniated discs and radiculopathy with physical and pharmacologic therapy in multiple centers, and found that 90% of the patients showed significant symptom improvement and were able to return to work without surgery [18]. Other research has come to similar conclusions [14].

Improper or Inadequate Surgery:

The third most common cause of FBSS is improper or inadequate surgery. One example of improper surgery is disc excision performed at the wrong level. Differences exist among surgeons as to the amount and type of evidence

needed to make a determination about the level of the disc rupture. Some surgeons require imaging, while others may operate on the basis of clinical findings alone. Likewise, anatomical variation may create problems by making it difficult for the surgeon to accurately localize the surgical intervention, particularly if intraoperative radiography or exposure of the sacrum is not done. FBSS may also result from the presence of fragments of disc material that are not properly removed. The retained fragments may compress a nerve root, or scarring may develop around them, causing delayed onset of severe symptoms. Failure to identify a spinal tumor may also lead to improper surgery. This is especially possible when there is inadequate imaging or when the tumor is benign and asymptomatic. In other cases, surgery is inadequate to correct other bone abnormalities that exist in the area of the rupture. For example, the laminectomy may not be sufficiently wide to decompress a co-existent spinal stenosis [14].

Role of peridural fibrosis in FBBS:

Peridural fibrosis is a natural consequence of laminectomy [19, 20]. The extent of fibrosis depends primarily on the extent of the surgical procedure, and many surgeons believe that there is also a direct association between the extent of peridural fibrosis and the degree of hemostasis [21]. Thus, if a surgeon closes a bloody wound, a greater degree of fibrosis is likely to result. Peridural scarring, which is accurately visualized by magnetic resonance imaging, can bind and surround the dura and nerve roots [21]. Principles of neuromechanics can explain the role of peridural fibrosis in FBSS [22]. In all persons, bending the spine forward, backward, and sideways causes the dura to deform. Normal lifting of the limbs causes the nerve roots to move, and the spinal cord itself moves up and down with flexion-extension of the neck or back. These actions, which put traction on the nerve roots and dura, do not cause pain in a healthy individual. In a person with peridural scarring, however, in whom the dura and nerve roots are bound by the scarring, this binding could very well result in pain. Following laminectomy or discectomy, the patient's everyday activities, which put traction on the dura and nerve roots, may release phospholipase A2, leading ultimately to chronic inflammation at the site of the discectomy [23]. In those patients with peridural fibrosis, the dura and nerve roots bind at the site of inflammation, resulting in a greater perception of pain by the patient. This inflammatory component explains how scar tissue may lead to chronic pain. Because evidence suggests that chronic pain is seldom ameliorated by reoperation [21], inhibition of peridural fibrosis is essential. Thus Peridural Fibrosis is also one of the main reasons for FBSS.

Experimental approaches for limiting peridural fibrosis:

Over the years, many approaches to the prevention of peridural fibrosis have been investigated. In a systematic investigation of some of the more promising of these techniques, Yong-Hing *et al.* [20] performed laminectomy and partial facetectomy at the L6-7 level on 46 mongrel dogs. During surgery, epidural and perineural fat were removed with suction, the nerve roots and dura were gently traumatized, and the annulus fibrosus and neural arch were scarified with a curet. At the end of this procedure, one group of control animals received no treatment to prevent fibrosis, while dogs in six active treatment groups were treated with six types of preventive therapies. Animals were then sacrificed at 4, 8, or 12 weeks and their spines excised en bloc and decalcified. Transverse sections through the vertebral body, spinal cord, nerves, neural arch, and laminectomy were examined microscopically. Free fat grafts prevented nerve root fibrosis whether placed on the dura or around the nerve roots, although Gelfoam[®] impaired graft survival. Ligamentum nuchae, which has a content of 80% elastin and 20% collagen fibers, was equally effective as a barrier and space-filler, separating hematoma from the dura and nerve roots and thus inhibiting fibrosis.

In addition to their study of dogs, Yong-Hing *et al.* [20] also reported successful inhibition of fibrosis when free fat grafts were placed on the laminectomy defects of two patients undergoing lumbar discectomy. In two other patients, exploratory surgery after 1 year revealed that only half of the grafted fat had survived. Other investigators have reported more limited success with free fat grafts. Of a series of eight patients, for example, Benoist *et al.* [21] reported success in only one. No prospective trial has evaluated the use of fat in humans, but anecdotal reports indicate that free fat grafts, while not preventing the formation of scar, can inconsistently reduce adhesions and maintain a good anatomical plane between the dura and surrounding tissue [24].

Differential Diagnosis:

The cause of Failed Back Surgery Syndrome is in effect a list of differential diagnosis [25-33]. They are summarised below:

1. When the patient exhibit no improve after surgery.
 - a) Spondyloarthropathies
 - b) Neoplasm or Tumour
 - c) Psychological pain

- d) Sequestrated fragment missed
 - e) Far-out lateral stenosis syndrome
 - f) Infection
 - g) Wrong diagnosis or poor surgical technique
2. When there is temporary relief only after surgery.
- a) Scar/Fibrosis formation and Arachnoiditis
 - b) Reoccurrent disc herniation
 - c) Reflex Sympathetic Dystrophy
 - d) Surgical non union/Pseudoarthrosis
 - e) Instability
 - f) De-conditioning
 - g) Meningocele
 - h) Myofacial Pain Syndrome

Usual and Customary Examination:

1. Physical Examination: A careful history will assist the diagnostic process and may relieve important information such as whether there was decrease in pain after surgery or not. This information will shorten the list of diagnostic variables. It will also give important information regarding illness behaviour and possible secondary gain.

Physical examination should be thorough and directed to all contingent possibilities.

2. Diagnostic Imaging: It is further classified into 5 types

- a) **Pain Radiographs:** These are of value in the diagnosis of spondyloarthropathies, tumour, infection and instability [34-36]
- b) **Computer Assisted Tomography (CT):** CT is the imaging modality of choice for Failed Back Surgery Syndrome. It is useful in the diagnosis of spondyloarthropathies, tumour, infection, sequestrated fragment, far-outlateral recess syndrome, scar or fibrosis formation, reoccurrent disc herniation, stenosis, pseudoarthrosis, implant irritation, instability and menigocele [34-36].

- c) **CT with Contrast and Myelogram in isolation:** CT with contrast is the most sensitive test to detect arachnoiditis [34] and menigocele [35]. However myelogram on its owns is also an useful tool for imaging arachnoiditis [34].
- d) **Magnetic Resonance Imaging (MRI):** When available, Mri is suggested for those patients in whom the initial CT is equivocal in regard to post operative scar vs. reoccurrent disc herniation [35-37]. It is also indicated in patient whose fusion appears clinically unstable, Despite the absence of instability on plain radiographs and CT [36].
- e) **CT/Discography:** According to Jackson *et al.* CT/Discography has a high rate of accuracy and is recommended in selected patients with suspected lumbar disc herniation whose other tests are non diagnostic, especially in those with possible reoccurrent herniation. It is also considered the diagnostic imaging of choice for internal disc disruption [38-40].

Clinical and Laboratory Tests:

1. **Blood Test:** This may include a full blood examination, Erythrocyte Sedimentation Rate, serum urate, HLA B27, anti nuclear factor and alkaline phosphate. These tests may be useful for detecting rheumatoid arthritis, ankylosing spondylitis, gout neoplasm, infection and inflammation.
2. **EMG and Nerve Conduction Studies:** According to Saal the electodiagnostician is an important team member involved in management of Failed Back Surgery Syndrome [37]. Saal states that electrophysiologic tests are useful in stenosis, intraneural fibrosis (scar), occasionally instability and reoccurrent disc protrusion [37].

Goals of Treatment:

- a) Treat the cause where possible.
- b) Decrease pain and inflammation.
- c) Restore functions.

Conclusion:

Back surgery may be indicated for intractable spinal conditions including disc pathologies (bulge, herniation, or disruption), spinal stenosis, and spondyloisthesis. Due, in part, to improper screening of candidates, improper surgery selection or diagnosis and unnecessary or inadequate surgery. 20 to 40% of these surgeries may result in

failed back surgery syndrome. Treatment options for FBSS span the range from additional surgery, interdisciplinary pain treatment, mildly-invasive procedures, and ultimately implantable devices to manage pain.

As we conclude, a major thread in considering implantable devices is the initial use of conservative interdisciplinary care as a means of managing the pain. This is in keeping with the current biopsychosocial approach to spinal disorders [41, 42]. Failing to control the pain with conservative approaches, the next step is to conduct a pre-surgical psychological evaluation to determine the suitability of patients for such implantable devices [43].

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