



Medical Statistics, Critical Thinking, New Technology in Treating Spine Pain; and the Role of Open Access Journals

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DOI: 10.31080/ASOR.2022.05.0537

Received: June 27, 2022

Published: July 26, 2022

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Barak Obama, the 44th President of the United States said, 'Change is never easy, but is always possible' [1]. Closer to home, Mahatma Gandhi said, 'An error does not become truth by reason of multiplied propagation, nor does truth become error because nobody sees it. Truth stands, even if there be no public support. It is self-sustained' [2].

I began by these quotes, because they represent how we change the 'prior art' in the treating of our patients in the hope of achieving a better clinical outcome. How do we know that we are improving our patients? For those who were medically trained in the last 40 years, they were probably taught that EBM: Evidence Based Medicine; and Medical Statistics [3]; provided guidance for treatments.

Many times when I meet young, newly qualified (super) Specialists who are very talented in their technical clinical disciplines; I am amazed with their mastery of the current literature; and their technical skill in the very delicate surgical procedures recommended for patients who require intervention. What is often quoted are the statistics of survival and the complication rates of a particular procedure. Is this of value to our patients? Does a patient understand what a five percent (5.0%) risk of an unexpected outcome is? It is a 100% (all or none) event for the individual. Does clinical outcome change with time? Is the accepted two years follow up of a surgical procedure representative of true clinical outcome?

We are always reminded that what is important is the patient, and no one else but the patient. Critical thinking [4] is how we should assess the outcome of technical procedures for each individual. Each patient is unique; with their own expectations of treatment, their own experience of the disease process, their own understanding of what their treatment entails and their own hopes

for their recovery. No two patients are alike; they are not statistics or numbers, and only by evaluation of an individual's requirements, will we get the best outcomes for our patients. This is where critical thinking, and sometimes observation; comes to play. In an extreme response to protagonists of statistics and EBM, Smith and Pell published an article where there were no randomised controlled trials in the use of a parachute in preventing injury when jumping from a height [5]. The point of the paper was that observation may be sufficient in certain situations; implying that wearing a parachute when jumping off an aircraft 1000 feet in the air is important for survival. There was no need for a control group in this study.

More relevant, would be trying to compare data from tools which are poor discriminators of an outcome, such as pain, a major symptom of spine diseases. One such example is the evaluation of treatment modalities for discogenic pain [6]. One glance at the results show that there is no difference between the modalities used for the pain intervention (Table 1). My own thinking is that using VAS and ODI are not sufficient enough a discriminator of clinical satisfaction. The question that arises, if the tools are not sufficiently discriminatory (analogy of 2 PD in sensation); is how can we apply statistics?

How do we assess New Technology for spine procedures? The tools for measuring clinical outcomes in spine pain; namely VAS, ODI and any other scoring systems; may not be able to tell the difference in outcome between modalities My own feeling is we must use critical evaluation based on a balance of the patients' expectations, the possible occurrence of an undesired outcome, and the clinicians own experience on treating such conditions. This requires a big dose of prudent Critical Thinking. Clinical Assessment should take precedence over radiological data as radiological outcome is

Physiotherapy	IDET	Mechanical Decompression (Stryker DeKompressor)	RF ablation - (Arthrocare Nucleoplasty)	RF ablation - Endoscopic assisted (Ellman)	RF ablation and Nucleus augmentation
70 patients 60 completed	55 patients 45 completed	165 patients 124 completed	166 patients 138 completed	136 patients 119 completed	22 patients 17 completed
Mean follow up 24.33 mo	Mean Follow up 28.5 mo	Mean Follow up 24.33 mo	Mean Follow up 24.87 mo	Mean Follow up 24.87 mo	Mean Follow up 24.65 mo
24-month evaluation	24 months evaluation	24-month evaluation	24-month evaluation	24-month evaluation	24 months evaluation
VAS 8.5 to 4.0 (p < 0.0001)	VAS 8.3 to 3.2 (p < 0.0001)	VAS 8.3 to 3.2 (p < 0.0001)	VAS 7.4 to 4.0 (p < 0.0001)	VAS 7.3 to 4.0 (p < 0.001)	VAS 8.5 to 3.0 (p0.0001)
ODI 25.1 to 11.0 (p < 0.0001)	ODI 25.2 to 10.2 (p < 0.0001)	ODI 25.1 to 10.0 (p < 0.0001)	ODI 21.8 to 9.8 (p < 0.0001)	ODI 22.7 to 10.2 (p < 0.001)	ODI 25.1 to 10.2 (p < 0.0001)

Table 1: The comparison of treatment in different modalities from a single surgeons series on treating disc origin spine pain. No statistical difference in the outcome of all modalities used in this clinical presentation. The reason for this could be poor discrimination of the tools used in the clinical outcome measures used (VAS and ODI). How does one make the best decision in this situation?

of no value for a patient who still has pain despite an improved imaging.

An example of this would be spinal fusion for degenerative lumbar spine stenosis. The prior art of instrumented fusion has been hailed as the ‘Gold Standard’ for treatment for this clinical entity [7]. However a more recent Cochrane review evaluating fusion for spinal stenosis suggests that fusion does not add any extra benefit; and instrumented fusion increases the risk for peri operative morbidity and mortality [8,9]. The possible adverse outcomes that give an unsatisfactory outcome are among others; adjacent segment disease, metalosis, and issues related to destroyed anatomy and scar formation, and problems related to implant removal [10].

The newer non fusion modalities available to treat degenerative lumbar spine stenosis, such as inter laminar spacers (ILS) somehow are not covered extensively in the medical literature (subscription journals), despite being available for at least a decade. One available study on inter spinous process distraction (IPD) has concluded that while there is improvement in claudication symptoms, it has not proven to be cost effective [11]. It is clear that more high-quality studies in the field are required. But on observational data alone, enough information is available for a clear clinical decision to be made (Table 2) [12].

Implant	n	VAS start	VAS 1 year	VAS 2 years	Complications
Intraspine	102	6.5	2.1	3.0	Redo 4
Rocker	93	6.8	2.3	2.9	Redo 0
Coflex	48	7.0	2.5	3.3	Redo 3

Table 2: Observational outcomes of 3 different types of ILS; and their revision rates at 2 years. The observational data may be sufficient to inform the patient what the expected outcome would be like.

The open access journals, by definition mean that no subscription is required to access the published information. They may have a wider audience who do not require cost involvement in procuring the information (such as subscriptions). These journals are subject to the same peer review; but may be earlier to publish data; and may be also more free in accepting studies for publication. For new information that needs to be publicised to a wider audience; the open access journal is the way forward.

In the absence of this high-quality EBM studies with high powered statistics; critical thinking and good observational data may provide a suitable solution. The absence of EBM does not mean the absence of benefit for our patients.

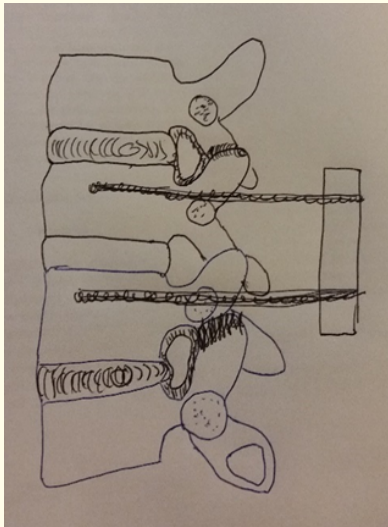


Figure 1a: The Adjacent segment disease after a spinal fusion. The middle segment is protected from movement; causing the resultant forces on the upper and lower segments to bear an additional 50% of the forces acting on it; resulting in 150% forces acting on each of the upper and lower segments. Only powerfully built patients may withstand 150% forces on the disc by having strong back muscles to load share the forces acting on them. This can possibly lead to failure of the adjacent segments, also called Adjacent Segment Disease (ASD) or Junctional Disease.

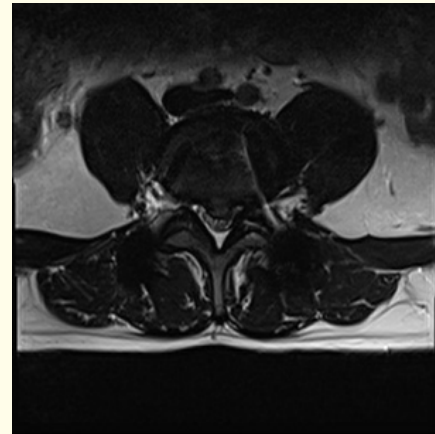


Figure 1c: The same patient with the cross sectional view at L 4/5. Note the large central intervertebral disc herniation.

The rationale for Functional Non-Fusion Interlaminar and Inter-spinous implants: Distracting the posterior ligaments without fusion.

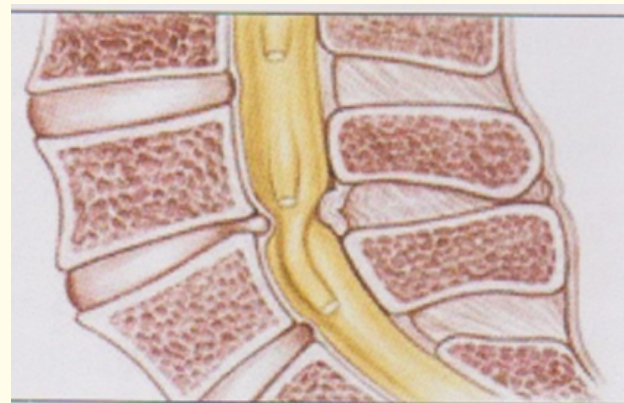


Figure 2A: The pathology of lumbar stenosis: a posterior compression with or without an anterior compression. The result is a narrowing of the spinal canal and a reduction of the intervertebral foramen space, causing compression of the neural elements in the canal and compression of the nerve roots in the foramen. Presents clinically as claudication distance and leg pain.

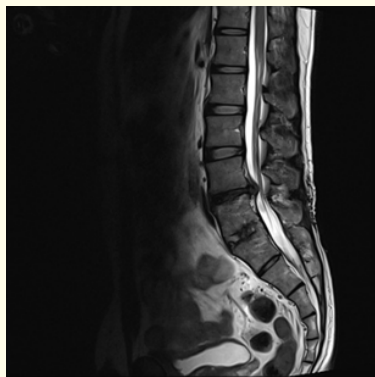


Figure 1b: A clinically apparent intervertebral disc herniation at L4/5 segment; post fusion L5/S1.

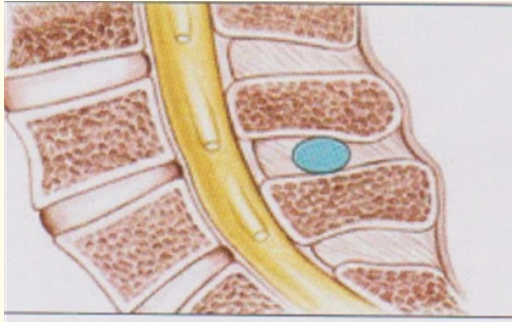


Figure 2B: The solution with a non-fusion instrument. The principle is a posterior distracting force allowing the increasing of the spinal canal space and opening up of the intervertebral foramen space; allowing more cross-sectional area in the canal for the neural elements and increase space for the nerve root in the foramen. The clinical outcome expected is increase in walking distance and reduction in leg pain.

Definitions

- **Medical Statistics:** It is the science of summarizing, collecting, presenting and interpreting data in medical practice, and using them to estimate the magnitude of associations and test hypotheses. It has a central role in medical investigations. It not only provides a way of organizing information on a wider and more formal basis than relying on the exchange of anecdotes and personal experience, but also takes into account the intrinsic variation inherent in most biological processes.
- **Critical Thinking:** The process of analysing information in order to make a logical decision about the extent to which you believe something to be true or false.

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