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# "Evidence of Overuse of Medical Services Around the World" By Brownlee et al., Lancet, 2017: Does This Apply to Transforaminal Lumbar Interbody Fusions (TLIF)?

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Editorial

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## INTRODUCTION

In 2017, Brownlee *et al.* published a paper in Lancet entitled: "Evidence for overuse of medical services around the world." In this article they discussed the overdiagnosis of "disease," the overuse of medical devices, and resultant unnecessary treatments being performed in medicine/surgery. Here we reviewed Brownlee's key points, and offer direct parallels to the present overuse of transforaminal lumbar interbody fusion (TLIF) to treat degenerative lumbar disc disease and stenosis with/without degenerative spondylolisthesis.

#### Over Diagnosis, Overuse, and Overmedicalization of Medical Devices/Services

#### Overdiagnosis

Brownlee described overdiagnosis as the "...diagnostic labeling of abnormalities or symptoms that are indolent, nonprogressive or regressive, and that if left untreated or treated later will not cause significant distress or shorten the person's life."<sup>[2]</sup> They further discussed overdiagnosis as including "...the provision of medical services that are more likely to cause harm than good..."<sup>[2]</sup>

#### Overuse

Brownlee *et al.* (2017) defined: "...overuse in the form of aggressive treatment of clinically insignificant findings."<sup>[2]</sup> In the US, they estimated overuse occurs in 6-8% of all cases, while in Medicare patients, the frequency was 29%.<sup>[2]</sup> Ausman provided yet another definition of overuse (personal communication, James I. Ausman, M.D.): "Overuse is the use of a tool or management of a problem unnecessarily."

Through a personal communication, Dr. Koo Van OverBeeke made the following comments regarding the overuse of spine instrumentation. He stated "We all know this is a money driven overuse. In the Netherlands the use of spinal instrumentation is restricted by rules from the insurance companies. Patients are not allowed to pay more by themselves; we do not have private practices for these surgeries. In other countries, such rules are known. Spinal instrumentation is

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much more common. Is it really necessary? It is something that we always wanted to know, but we are afraid to ask." He also stated: "Because of the enormous rise of medical costs in the Netherlands, the ministry of health asked for a survey in order to see what is useful in the daily practice of all doctors working in Dutch hospitals. The preliminary result was that 50% of medical care was not proven to be of any effect compared with no medical treatment. Of course, medical treatment should be tailored to any individual patient, which means that a medical treatment can be useful for one patient and not for the other".

#### **Overmedicalization**

Overmedicalization, according to Brownlee et al. consisted of: "...disease or abnormality...leading to populations previously considered "normal" or health being labeled diseased."<sup>[2]</sup> For example, degenerative findings as attributed to the normal aging process in the spine should not necessarily be considered "disease" warranting any intervention; e.g. epidural injections, and surgery. Promoting such treatment options in the absence of significant "pathology" would, therefore, fall under their definition of overmedicalization. Further, Brownlee et al. described providing such services as those "... that are unnecessary in any way and for any reason..." for which there was no "... evidence or consensus-based guidelines...."[2]

#### Application of Browlnee et al. Overuse, Overdiagnosis, and **Overmedicalization As It Could Be Applied to TLIF** (Transforaminal Lumbar Interbody Fusion)

Certainly, overuse, overdiagnosis, and overmedicalization would apply to many of the transforaminal lumbar interbody fusions (TLIF) vs. decompression alone performed to treat lumbar disc disease, stenosis, with/without degenerative spondylolisthesis (DS). In 2018, Epstein reviewed the outcomes/complications of performing laminectomy alone for patients with 2-3 level (58 patients; stenosis/disc disease) and 4-6 level lumbar disease (79-disc disease/ stenosis/26 DS).<sup>[4]</sup> Postoperatively, patients experienced: no new neurological deficits, no infections, no a djacen subsequent publications" they found "originally unpublished segment disease (ASD), no readmissions, 1 reoperation (seroma; in-house postoperative day 7), and 4 (2.9%) cerebrospinal fluid fi st ulas.<sup>[4]</sup> The se re su lts we re than those complications cited in the literature associated with TLIF/MI TLIF that ranged from 7.7% to 23.0%. For example, for TLIF/MI TLIF, the following complication rates were reported; wound infections (8.3% vs. 0% for laminectomies alone), durotomies (6.1% vs. 2.9%), permanent neurological deficits (9.7% vs. 0%), new sensory deficits (20.2% vs. 0%), and reoperation rates (1.6-6% 0.7%). The following additional complications were unique to TLIF/MI TLIF; 2.3% instrumentation failure, 1.26-2.4% cage migration, 0.8% cage extrusions, and 1.6% misplaced

screws (1.6%), for an additional total complication rate of 7.1% not observed for laminectomy alone.

#### SPORT Trial Documented Efficacy of Laminectomy (With or Without Fusion) For Lumbar Degenerative Spondylolisthesis (DS)

Abdu et al. in their 2018 randomized controlled Spine Patient Outcomes Research Trial (SPORT) evaluated the 8-year outcomes for patients from 13 centers treated for DS utilizing "decompressive laminectomy (with or without fusion) versus standard nonoperative care."[1] They found that DS treated surgically resulted in better 8-year outcomes vs. those managed non surgically. However, outcomes for all fusion groups were comparable; laminectomy with noninstrumented PLF (posterolateral fusion), instrumented PLF, and 360 instrumented fusions (e.g. including TLIF).<sup>[1]</sup> Not only should spinal surgeons reassess whether they are overdiagnosing and overmedicalizing DS, but they should also recognize and reemphasize the efficacy of laminectomy without fusion to avoid overusing medical devices.

#### Failure of Industry-Supported Studies to Report **Complications of TLIF/MI TLIF**

In 2011, the Carraggee et al. article "A Critical Review of Recombinant Human Bone Morphogenetic Protein-2 Trials in Spinal Surgery" reviewed the results of 13 Medtronicfunded studies in which they found skewed results favoring the product rhBMP-2.<sup>[3]</sup> They noted: "In the original peer review, industry-sponsored publications describing the use of rhBMP-2 in spinal fusion, particularly TLIF, adverse events ...were either not reported at all, or not reported to be associated with rhBMP-2 use."[3] In the 13 industry-sponsored rhBMP-2 publications, analyzing 80 patients receiving rhBMP-2 (e.g. in prospective controlled studies) they found: "No rhBMP-2-associated adverse events (0%)." Furthermore, the study designs were found to be heavily biased in favor of surgical RhBMP-2 use. Reviewing "FDA documents and adverse events and internal inconsistencies." The result was the discovery of a previously unreported 10%-50% be tradence of adverse events when using rhBMP-2 use in spine fusion (i.e. especially TLIF/MI TLIF), while a 40% risk of complications (e.g. including life-threatening events) occurred in patients undergoing anterior cervical fusion with rhBMP-2.

### **CONCLUSION**

As so aptly described by Brownlee et al. (2017), today's practice of spine surgery, particularly as it concerns TLIF/ MI TLIF, is overshadowed by the overdiagnosis, overuse, and performance of unnecessary operations.<sup>[2]</sup>

#### Disclaimer

The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Journal or its management.

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