



How much “real world” data is needed for clinical decision-making?

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A common procedure in degenerative lumbar instability is pedicle screw fixation in combination with cage lumbar interbody fusion (LIF). In 2009, the cortical bone trajectory (CBT) screw fixation as an alternative to traditional pedicle screw fixation was proposed [3]. The caudomedial entry point for CBT screws allows to limit dissection and paraspinal muscle retraction, thereby reducing the invasiveness of the approach and eventually improving outcome.

In the current issue of *Acta Neurochirurgica*, Silva et al. report their initial experience and learning curve with midline lumbar interbody fusion (MIDLIF), which in fact is posterior LIF in combination with CBT screw fixation, for the treatment of assumed segmental instability in degenerative disease of the lumbar spine [4].

Within 3 years, 30 patients were included. The majority of patients ($n = 20$) had degenerative spondylolisthesis. Twelve months after surgery, the clinical outcome parameters were significantly better than before surgery. The pre- and postoperatively obtained radiological sagittal balance parameters remained unchanged. The fusion rate, as confirmed by computerized tomography 1 year after surgery, was 96.7 %. The complication rate was 20% (mostly dural tears) and the re-operation rate 6.7%. The authors concluded that “MIDLIF can be considered as a promising alternative to more traditional ... techniques”.

Clinical trials testing new drugs, new devices, or surgical techniques are classified into four phases. Phase 4 trials are considered as confirmatory trials after completion of a successful phase 3 randomized controlled trial (RCT). Phase 4 trials

explore the external validity of the study, which is the reproducibility of the positive study findings outside of the setting of a study. These “real world” data finally decide whether a drug or device or technique gains broad acceptance or not. This means that not only RCTs are needed, but also “real world” data.

In spine surgery, we unfortunately face a substantial lack of RCTs and, as a consequence, phase 4 trials. What we do have are many retrospective and few non-randomized prospective studies, which, if well performed, also can provide the scientific community with the required “real world” data. The retrospective study of Silva et al. falls into that category as they wrote in the manuscript: “This series may represent the application of the MIDLIF technique to ‘real world’ population of patients needing lumbar fusion”.

However, the question raises how much “real world” data (and how many similar publications) we need to have before accepting or discarding a drug, device, or surgical technique. Since 2016, 14 studies with 466 patients and a meta-analysis [6] had been published comparing LIF and CBT screw fixation with LIF plus traditional pedicle screw fixation. In addition, several non-comparative case series with more than 30 patients became available in the last 3 years [1, 2, 5]. The results of these studies (despite being slightly different in terms of used outcome parameters and surgical techniques) were quite uniform: LIF with CBT screw fixation/MIDLIF significantly improves clinical outcome, has a high fusion rate, and can be performed with an acceptable rate of complications. Do we truly need to have the (smaller) study of Silva et al. for accepting that LIF plus CBT screw fixation is a viable alternative to LIF plus traditional pedicle screws? Probably not. Instead, the attempt should be made to take the next scientific steps. I am looking forward to long-term results, both clinically and radiologically, an RCT comparing LIF with CBT screw fixation with LIF and traditional pedicle screw fixation, and evaluation of the role of technical adjuncts such as robot or navigation assistance.

This article is part of the Topical Collection on *Spine degenerative*

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