

Symptomatic adult spinal deformity: implications for treatment and research

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It has been noticed that scoliosis affects up to 35% of the population over 60 (1), and it's frequently associated with a reduced quality of life (2). The most important factors predicting the clinical impact of scoliosis during adulthood are the severity of the curve on the frontal plane and the sagittal profile of the spine (2). The Cobb angle is meant to measure the curve severity in the frontal plane and can predict the risk of progression of the deformity, which is negligible for curves below 30° Cobb, and very high for curves over 50° Cobb (3). The severity of the curve in the frontal plane is also correlated with respiratory restrictive syndrome when the Cobb angle exceeds 70° in thoracic curves (3). The sagittal balance and its impairment are associated with back pain and disability; thus, its evaluation has become more relevant for both the conservative and the surgical approach. Lumbar scoliosis is particularly relevant for its significant correlation with back pain (4). There are two main common etiologies for this pattern, degenerative scoliosis and idiopathic. Degenerative curves, also called “*de novo*” scoliosis, derive from pathological changes at the level of the facet joints and discs in the lumbar spine (5). Usually they are not very large but frequently very painful and rapidly progressive. The other type is an idiopathic scoliosis appeared during growth that start its progression in adulthood, usually depending on the size of the curve as previously stated (5). There is a further type of adult scoliosis called metabolic, which is less frequent (5).

The most common treatment for scoliosis patients

with chronic low back pain, according to current practice, is the surgical one. This has the aim to both preventing progression and improving pain and quality of life. Unfortunately, surgery in such patients is associated with a relevant number of complications, so that it cannot be considered appropriate for every patients, especially those with certain comorbidities (6). Moreover, some patients don't want to be operated. These issues should give more relevance to the conservative treatment, but unfortunately so far there is scant literature about. Recently, some papers reported some promising results in effectively reducing pain, increasing the quality of life and preventing or sometimes even stopping the progression with bracing and/or exercises (7-10).

In this scenario, the paper “*Operative versus nonoperative treatment for adult symptomatic lumbar scoliosis*” by Kelly *et al.* is very interesting, trying to give a further insight in the problem (11). This study presents a mixed design, with a randomized and an observational arm. In both arms, conservative treatment was compared to surgery. The general conclusions were driven from the observational arm, since in the randomized one the rate of crossover was dramatically high (64%): this led to similar results for both the approaches in the intent to treat analysis (ITT). For the observational arm, the success of surgery in improving pain and reducing disability was clearly higher than for the conservative approach as supported by the as treated analysis.

We think that this study raises a number of interesting

points that should be discussed in the scientific community. The authors tried to apply the best possible design, which is the randomized control trial, but its results were not really informative for the high crossover rate. The ITT is considered more conservative in such cases, and this could be an advantage in case some efficacy is equally demonstrated, but it also underestimates the side effects, and this is a significant shortcoming. In case no effect is demonstrated this can be a relevant bias (12). We think it's thus evident that the RCT design cannot be applied to the comparison of surgery and conservative treatment at least in this specific field of spine care. When patients have to face big issues like a painful scoliosis, and/or very invasive treatments like fusion for scoliosis, they want to choose their treatment. Some of them want to be operated in case the conservative treatment is not effective, others are scared of surgery and decide to avoid it. A good observational study with an elaborated statistical analysis could be much more informative in this field. The level of evidence would be considered inferior, but is it really like that? A recent Cochrane review which compared the results of RCTs and observational studies, found that in most of the cases, they were consistent (13). RCTs evaluate the efficacy of an intervention or a treatment under ideal conditions while observational studies measure the effectiveness of an intervention which are the results in real world scenario. This is much more similar to the condition in which clinicians work in everyday life, being thus more attractive for practical interpretation. Other studies reported that well-designed observational studies compared to RCTs on the same topic have similar results without any overestimate of the magnitude of the effect size (14,15). So, why shouldn't we accept the idea that RCTs are not the best design for this task? It becomes necessary to rethink whether those scientific evidence levels are similarly applicable to surgical works and to nonsurgical trials, when considering the various limitations of surgical trials (16).

The conservative treatment approach proposed in the study was not really standardized and well described. This is a very common problem in the spinal literature. Many papers, mainly made in surgical settings, lack a good conservative treatment protocol. We think that for papers like these, experts of the conservative treatment should be involved, being these Physical and Rehabilitation Medicine and other conservative physicians, together with physiotherapist working in the field of scoliosis. The conservative treatment protocol applied in this study doesn't rely on the Guidelines on the conservative treatment

currently available. This could also have happened because the patient recruitment started before their publication, and the body of evidence available at that time was much less informative. Current guidelines are more informative, with the indication of application of specific exercises for scoliosis (17). This is based on the publication of some relevant papers in the field (7,8). Also for bracing there is now some evidence, both in terms of improvement of pain and in terms of preventing the progression (9,10).

In the study there was no distinction between degenerative and idiopathic scoliosis. We know that the progression rate of the two is different, and also the association with pain (18). Degenerative scoliosis is more challenging for the conservative treatment and focusing on this would have been more informative.

Another important point related to the placebo effect, that always sums above the biological one. The more invasive is the treatment, the greater is the placebo effect (19). In light of these considerations, also results of invasive versus non-invasive treatments should be regarded with some caution. The placebo effect should be quantified somehow, and also the expected results in terms of superiority of the invasive treatment should really be high. It is true that in the end, in real life, what count is the final result, but if most of the effect comes from the placebo, we should also perhaps rethink about the expenses and risks for the patients (19). This issue is obviously general and not only of this study.

Finally, the side effects and complications of the two treatments should be considered. The main side effects for the conservative treatment were associated with the use of NSAIDS, which are not so effective in this pathology due to the mechanical origin of pain. On the other side, the rate of side effects was really high, up to 35% in the surgical group. Surgical complications are a big challenge in adult patients with scoliosis, so we cannot consider surgery as the best option for a problem that can affect QoL but is not life threatening. We strongly believe that surgery can be a good option for very selected and motivated patients, but we need more data about the advantages of surgery over the conservative treatment, and hopefully a further improvement of the surgical approach. On the other side, we need an appropriate conservative approach to be studied, based on the current guidelines and evidence and managed by experts in the field.

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Footnote

Conflicts of Interest: Dr. Stefano Negrini holds ISICO stocks. The other authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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