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EDITORIAL

Levels of scientific evidence ☆

Niveles de comprobación científica

Recently *RECOT*, like the majority of current scientific journals, has brought in so-called “niveles de evidencia” (evidence levels), an inappropriate interpretation from the English of what should be better translated as “niveles de comprobación científica” (levels of scientific verification). This is a concept that was created with what was called “Evidence Based Medicine”, that is, proof-based medical practice, or in the words of one of its leaders, David Sackett, “conscious, explicit and wise use of the best, most up-to-date knowledge when taking decisions in caring for patients.”^{1,2}

With respect to publications, the aim of this initiative is to categorise articles according to their ability to respond to scientific questions with certainty, so that the possible readers can significantly increase their confidence in the effectiveness of the medical and surgical procedures commonly used in daily practice, that is, evidence that the results obtained are due to the treatment used and not to other causes.

To the question “Which article provides the greatest level of scientific evidence?” we should reply, those where research is conducted assigning the participants a given treatment at random, with a double blind design – one in which researchers and patients do not know the treatment really applied to each participant – in which there is a “control” group where another alternative treatment is applied and, lastly, a placebo group. Thus, according to its goodness, the work of this type of randomized and controlled clinical trials, as previously described, will be at the top of the pyramid, with the highest level of scientific evidence; meanwhile, expert opinions (whose value is more questionable) will be at the bottom.

During the last decade, with this paradigm as a standard, the most powerful journals in the scientific field have progressively tended to ask the authors about the strength of their article in terms of this type of classification. The aim is to offer readers a tool to allow them establish a level of confidence that is worthy of that which is written. Overall,

editorial lines tend to publish work with the highest level of evidence (prospective, randomized and controlled) and, on the other hand, reject those that have less (such as clinical series with no controls, etc.).

However, some facts have very recently shaken these solid foundations. The publication of an article in a journal as well known as the *New England Journal of Medicine* about a prospective, randomized and controlled clinical trial on the best treatment for anterior cruciate ligament reconstruction (ACL) became a major trigger.³ This article compared early ligament reconstruction surgery (during the first 10 weeks) to deferred surgery, and only if required, in a young and active population. The results were assessed 2 years after the lesion through the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire and showed a surprising result; there was no difference between those who had been operated on and those who had not and only 39% of those who did not receive surgery immediately required it at a later stage. The authors concluded that “2 years later, immediate reconstruction did not produce a better result according to the patient’s perception.” An even more amazing second conclusion was that “more than 50% of ACL reconstructions could have been avoided without adversely affecting the results.”

These surprising conclusions, extracted from a well done study with a high level of scientific “evidence,” which seemed to contradict the current commonly accepted concepts for action when faced with an ACL lesion, deserved a comment by the editors of the publication itself⁴ and a clear reply from other publications.⁵ A close look at the article showed that although its concept, method and results were correct, several limitations such as the use of the KOOS scale (which after 2 years of follow-up does not appear to reflect long-term knee function, nor the risks of future instability) or the ability of patients to take up previous activities that included pivoting the knee had not been taken into account. Other long-term consequences for the non-operated knees such as meniscus lesions, with a higher meniscectomy rate in the non-operated group, were not taken into account either. Therefore, the authors’ conclusions and inferences were less than adequate, given that from the same results we could also conclude that “non-immediate reconstruction of the

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ligament led to worse knee function after 2 years, with greater risk of meniscectomy, and a consequently greater potential of future arthritic degeneration in the conservatively treated knee.”⁵

This story in the editorial world is not the only one. A few years ago, another article also published in a well known journal suggested – not only from its title but also its contents – the demonstration of an idea that was floating around the minds of many surgeons: what was the point of performing arthroscopic surgery on a degenerative knee? The study dealt with a group of military veterans with arthritic knees who were randomly split into 3 groups, alternately assigning them to arthroscopic debridement, arthroscopic lavage or placebo surgery.⁶ The results were astounding; the best group after 2 years was the placebo group. In that case, the conclusion had been correctly extracted from the results. However, the methodology was full of limitations: in the patient selection, in procedures being performed by just one surgeon, in mishandled treatment assignments and so on. This was why the conclusions were, once again, more than questionable.

Therefore, all this new scientific methodology available to the reader undoubtedly contributes to quantify the scientific strength of the publications and what it really provides to scientific knowledge. However, their systematic application does not exclude the critical view of possible readers to carefully judge what is on offer, extract their conclusions and finally choose what they feel is best for their daily practice. Meanwhile, we authors, reviewers and editors will

continue our vigilance to improve the presentation of the information to be published, without a doubt using the levels of scientific evidence, highlighting the limitations of the studies that could influence the results obtained and trying to avoid errors in the interpretation of data, on the other hand, correctly extracted.

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