

Vertebroplasty: about sense and nonsense of uncontrolled “controlled randomized prospective trials”

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On 6 August 2009, a paper has been published in the *New England Journal of Medicine*, which claims to prove that vertebroplasty is not effective [1]. This paper has drawn an attention worldwide, which is only rarely given to issues of musculoskeletal system medicine. The *New York Times* and almost all major international dailies have reported this work. Dr. Buchbinder, the Australian main author of the mentioned paper has been cited in the *New York Times* from 7 August 2009 with the strong sentence “that she would never undergo such an intervention”. This is like a religious confession, and I do not get rid of the suspicion that this confession was there before the study, and the presented work has now proven it.

It would be more interesting at this point to learn how the advocates against vertebroplasty would deal with the often extreme vertebral pain and possible progressive kyphosis if the patient does not want to be just knocked out by morphine medication and also has some demands of a reasonable quality of life.

The incidence of vertebral compression fractures per year is about 1.4 million people, and more than half of them are found in the US of whom only about one-third is treated [2]. With the increasing aging of the population, these figures will increase in spite of prophylaxis. The true prevalence of those fractures, however, is unknown because these fractures are differently defined and also assessed. The yearly direct medical costs for the treatment of those

fractures in the US are estimated to be between 12 and 18 billion US\$ for the year 2002 [2]. In the last 6 years, the number of the vertebroplasties in the US has doubled and is done in 4.3–8.9 patients per 1,000 people [2]. Even higher figures may apply for Europe. In spite of several studies, which have shown a positive effect of vertebroplasty [3, 4], there has never been done a blinded or a placebo controlled randomized study to prove this postulated effect in a clean scientific way [2]. However, this kind of studies is generally speaking difficult to achieve in surgical procedures and often reaches the limit of ethically acceptable studies.

Now, the paper has arrived, for which all interventionists with a commitment to evidence have waited for—however, big disappointment has spread out since this paper does not hold what it promised and what the publication in the highly prestigious *New England Journal of Medicine* would have made expect. A few quite essential questions arise about the validity of this paper, since the topic of it is of major practical significance.

This study is based on totally 78 patients who have been selected from a pool of potential 468 patients (!). 38 patients have been treated with a vertebroplasty, the others with a sham procedure including local anesthesia to the facet joints. This means that, in an average, 9.5 cases per center distributed over a time period of 54 months have been treated with a vertebroplasty, i.e. there were less than 0.73 vertebroplasties done per month and per center. If we consider only the 3 out of 4 centers, which contributed less than 10 cases or even only 5 cases for the study, then even less patients have been treated with vertebroplasty: 1 case every 2 years or even less—this can really not be considered as examples for expert centers. Only these little numbers distributed over a time interval of 54 months and 4 unequal centers are questionable in terms of methodology and make this study untrustworthy.

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There is an additional problem, which has been brought up by the authors who wrote themselves on page 565: “However, selection bias cannot be entirely ruled out, since 30% of potentially eligible patients declined to participate in the study.”

But it comes even better: the relevant inclusion criteria qualifying for this study is back pain for less than 12 months, the type of back pain, however, is not clearly defined. There are obviously different kinds of back pain, specifically back pain which goes along with a mechanical instability or pain under mechanical load. Consequently, there are quite different, pretty precise criteria for the indication of a vertebroplasty: besides the typical pain pattern, it needs to be taken in consideration mechanical criteria of increasing kyphosis of a vertebra or vertebral section and certain morphotypes of fractures. It is also well known that an increasing kyphosis due to serial fractures can finally increase the mortality because of pulmonary and abdominal dysfunctions. Nothing of that has been mentioned in this paper or has been taken in consideration. In addition, not all fractures can be put in the same pot. Specifically, fractures of one, two, or more vertebra cannot be considered as the same pathology. These are all elements, which influence themselves unfavorably (confounding factors). Furthermore, the authors claim that the executing radiologists (how many for how many cases where they?) followed a strict standardized protocol, however, whether this protocol really corresponds to what experienced vertebroplasty surgeons do, is nowhere written. From the amount of injected cement (2.8 ± 1.2 ml), it can easily be concluded that the authors have done in principle two placebo operations, and compared them with each other (an insufficient vertebroplasty compared to a facet bloc with local anesthesia in the control group) and therefore the insignificant differences in terms of pain relief and disability in both groups can be easily explained. Three months postoperatively, the pain score for the vertebroplasty group was only 2.6, for the control group 1.9, respectively, improved, what is fundamentally different from all what has been published until today in several studies [3, 4]. In addition, the follow-up of 1 year is short to catch consequences of osteoporotic compression fractures with increasing kyphosis, which finally may lead to death.

This study is based on the above analysis, and is not in a position to provide a new insight in to the relevance of vertebroplasty in the treatment of osteoporotic vertebral compression fractures, but contributes to a further irritation, by not helping at all the patients to make an informed

decision, or the doctors and insurances to make evidence-based decisions. Although this study has been initiated by serious and legitimated scientific questions, it remains finally an artificial construct of desk writers, who are far away from the clinical reality. Such studies are of no use for the patients, or for the treating doctors. It would have been much more reasonable to go at least one step down in the “evidence pyramid” and to initiate a big prospective national observational study in form of a registry, which pictures the reality of the medical routine, and which includes relevant outcome parameters. Such registries can even be organized in an international network, and can therefore establish generally valid benchmarks. However, those registries should be under the mandate of the professional societies, which are also in a position to make an audit of the data in different institutions, which are included in those registries. This would certainly contribute to an as big as possible transparency for the doctors and patients. In this way, a big number of cases can be collected, and therefore even with the different subgroups, statistically significant conclusions can be made and contribute to set treatment standards and guidelines [5]. Such a procedure would certainly help the health services of different countries in a better way than artificial studies with not adequate methodology, objectively wrong questions, and treatment indications through questionably qualified specialists in a small group of patients of unequal multi-center groups during a far too long time period.

Sometimes, we cannot get rid of the impression that prestigious scientific journals occasionally tend to sell an ideology rather than to serve with objective science the sick human beings.

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