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Dogmata versus Evidence in Operative Sports Medicine – We Must Actively Regain Control of Practice

Dogmen versus Evidenz in der operativen Sportmedizin – Wir müssen das Heft des Handelns wieder aktiv in die Hand nehmen

EDITORIAL

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"the time will soon come when just general comments on the success of this or that operation will no longer suffice, but every doctor will be called a charlatan if he can't express his experience in numbers."

Even though this audacious statement by Surgery Professor Theodor Billroth stems from the 19th century and the abstract demand for scientific evidence of our daily working is nothing new these days, it appears more current than ever in these times in which headlines on "unnecessary operations" rule the media. Yes, it could even be expanded by adding that those who cannot provide any measurable results for their surgical procedures may even fall through the cost-payers' screen with their surgical performance and thus no longer be paid adequately for their work.

As an example, and for the first time, arthroscopy in gonarthrosis was stricken last year from the catalog of surgical services reimbursed by the state health insurances (1) and we don't need to be visionaries to see that other operative procedures will be evaluated by similar standards in the near future and subjected to the same tests.

Interestingly, very different intentions from various areas become apparent which make this theme especially relevant. Among these are:

- the public, often subjective perception which has developed a critical stance to surgery and its necessity in the boulevard press – but in professional journalism as well,
- the viewpoint of the reimburser, that initially sees only a cost-intensive treatment which possibly does not correspond with the principle of economic viability and
- the viewpoint of the licensing authorities, which especially in medication use (which is becoming more and more relevant in many therapies with a biological background) in addition to safety increasingly set the efficacy of a procedure in the center of the evaluation.

All these various aspects underline the increasing relevance and also the explosiveness of the topic.

The actions appear logical in the current example of arthroscopy in gonarthrosis – its efficacy is hotly debated even in professional circles. In the treatment of symptomatic meniscus lesions, for example, the dogma of the necessity of surgical treatment and the scientific evidence collide so hard that the attention will be great if strict scientific criteria with respect to an efficacy test should be applied. Other surgical procedures, too, such as the treatment of rotator cuff ruptures, treatment of cruciate ligament or Achilles tendon ruptures would have to face similar demands.

Lamentable, however, is that doctors and performers can still only react to what different areas throw at them. The possibility of acting proactively for the clinical necessity would have existed for years; the demands for evidence-based data are not new but have been formulated many times (5).

In individual areas this has been done, even if not thanks to an intrinsic motivation of doctors and operators. Meanwhile, for example, there is a large number of prospective-randomized studies for the manageable area of surgical treatment of damaged cartilage with cell-based procedures (2, 7, 8). The background are new regulatory demands from the authorities, which demand licensing of the cell-based products used here, which in turn is associated with proof of efficacy by corresponding high-quality studies. These data will certainly be useful when a test of economic viability is made.

Unfortunately, it must be mentioned that proactive participation in drawing up the regulations for evaluating clinical evidence was passed by. Today, the prospective-randomized study is thus the gold standard and only possibility to achieve Level 1 evidence for the efficacy of a procedure. This is, however, certainly not generally valid and is hotly debated (9, 10). Many queries, especially in sports medicine, such the influence of gender or body weight, cannot be answered in such a study form. Nonetheless, in the evaluation of procedures these days, for example in the procedures of efficacy and economic viability by the INEK (Institut für das Entgeltsystem im Krankenhaus; Institute for the reimbursement system in the hospital) it is considered the only study form suitable for the investigation and the term the "best available evidence", which is highly valued in many sports-orthopedic-operative procedures, recedes to the background and is ignored.

The example of meniscus surgery makes this especially clear. In the past, some studies with prospective-randomized study design were published (with an overview in a Review in the Deutschen Ärzteblatt (6)), none of which could show superiority compared to a control group with non-surgical approach. These have considerable methodical weaknesses and the basic question is justified whether these studies are able to demonstrate an equivalence of operation and a non-operative control group at all. A critical examination of study-methodical ›

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aspects going beyond the simple categorization is missing, as is the willingness to include other data in the evaluation of the procedure.

Of course, the reproach that no better studies of one's own can be shown, is absolutely justified. It is imperative to counteract this with one's own studies. However, a basis and acceptance must be created, especially in the operative sector, that the evaluation of the procedure not be founded solely and exclusively on prospective-randomized studies. The trend toward offsetting this with instruments such as registry research and generating one's own data from care reality is absolutely to be applauded. In the vanguard here are the Scandinavian countries, in which for many years now not only the known Endoprosthesis Registery, but a number of other Registries, such as on treatment of crucial ligament injuries have been established (3). For this reason the development of the KnorpelRegister DGOU (Cartilage Registry)(4) and the German-language Arthroscopy Registry (DART), which will be initiated in the Fall of 2017, are definitely of great importance. A strong and proactive engagement for the recognition of such data is compelling and necessary, since from a clinical point of view, these instruments of clinical research contribute to improvement of the database.

We, doctors and scientists together, must regain control of the activities. It is our responsibility to become active. The gaps in the clinical-scientific evidence must be closed and we are called upon to define the methods and studies so precisely that the definition emphasizes arguably what corresponds to many years of clinical experience and what we stand for. Pointing out the weakness of other studies should soon be no longer necessary. We can prove what we believe, but also refute that of which we have been convinced thus far only with the help of these collected data. Billroth's demand for measurability of our results is today, nearly 150 years later, more important than ever.

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