Ivo Schauwecker

Challenges of Clinical Research in the Surgical Field – How to Generate Clinical Evidence?

Introduction:

Compared to clinical research on medicinal products or low risk medical devices (i.e. not implanted), performing clinical research with implantable medical devices adds methodological complications. Two major aspects are 1) the involvement of a surgeon and other medical staff in applying the treatment and/or device and 2) limitations of clinical investigation designs which do not provide the highest level of scientific evidence.

Examples:

One of the biggest challenges in generating clinical evidence with implantable devices – and in the surgical field in general - is to quantify the influence of surgical skills and operation management in the theater as well as in aftercare. Whereas some of these aspects may be controlled with rigid standardization of protocols and close monitoring, other aspects are almost beyond the control of researchers. One approach may be to perform investigations on the impact of education taken by surgeons and other medical personnel involved in the surgery on clinical outcomes.

One other obvious limitation in clinical research methodology is the virtual impossibility of masking, or even double-masking, treatments. Another shortcoming is the necessity of extended follow-up periods to gain evidence on long term safety and performance of implanted devices. These challenges can be addressed in several ways. For example, by applying appropriate statistical concepts or employing carefully designed and closely monitored clinical investigations to partly compensate for the lower level of scientific evidence. Carefully choosing the right objectives and measures are among the other approaches which may also assist in combatting limitations.

Conclusions:

Clinical data providing evidence of highest standards have assumed a new importance in supporting stricter regulatory requirements in the medical device field. Simply "copy-pasting" wholesale from concepts which were not specifically developed for implantable medicinal products is not sufficient and may even lead to wrong conclusions being drawn. There is a pressing need for further development of robust concepts and approaches in order to generate best clinical evidence in the surgical field.