Risks and benefits of regional anesthesia in the perioperative setting

Valorization addendum

RELEVANCE

In this thesis we analyzed and investigated various risks and benefits of regional anesthesia and included not only the different type of surgery and high-risk patient populations in a context of chronic post-surgical pain and acute pain but also the characteristics and use of new anesthetic devices.

Not only the high number of operating room procedures (15,6 million in the United States of America annually[1]) but also the recent increase in the number of procedures, (from 1,1 to 1,4 million procedures in the Netherlands[2]) makes evaluation of optimal peri-operative care including anesthesia of utmost importance.

We furthermore discuss difficulties (risks) and comparison of the mode of anesthesia and relation to peri-operative mortality and morbidity. At present, recommendations for use of a specific mode of anesthesia but also for the use of specific anesthetic devices are commonly based on small-scale studies. Whereas anesthesia in general closely facilitates and directs the surgery in the operating theatre it needs no further comment that the outcome small-scale studies may have huge clinical impact. As clearly pointed out in this thesis, due to the relative low number of accidents related to anesthesia in general, large scale multicenter studies are needed to allow the demonstration of increased safety of newly developed anesthetic procedures.

As discussed before (see Chapter 2) a comparison of the risks and benefits of regional versus general anesthetics only is a manifestation of a limited approach and underestimates the potential benefits of combined regional and general anesthesia techniques in high-risk populations. The combined use of regional and general anesthesia might considerably improve the development of post-operative pain management programs for specific types of surgery like abdominal surgery and major oncological breast surgery.

To develop and improve peri-operative anesthetic techniques (regional anesthesia) a detailed knowledge of the human anatomy is essential. Therefore feasibility testing and teaching[3] of regional anesthesia techniques in the anatomy laboratory is highly recommendable.

To further implement a successful comprehensive perioperative pathway, anesthesia devices that are meant to relief pain should optimally do their job. Clearly, the proper functioning of catheters might be affected by the material characteristics. In this context it is surprising to see that until recently no systematic investigations are required for CE approval even for high-risk anesthetic devices. It is therefore that we were among the first investigators in the field of Anesthetics to carefully test anesthetic devices based on the use of a scientific study protocol. Our approach, as we think, will set the tone and might be directive in future use and implementation of new anesthetic devices in the clinic.

TARGET GROUPS

Patients

Patients and patients' associations are the most important target groups. Patients should receive the best (anesthetic) care as possible that is preferentially based on scientific evidence. The use of carefully tested and certified anesthetic devices significantly improves the quality and safety of Anesthesia.

Clinicians

It is obvious that the Anesthetists needs to be extremely careful before implementing or generalizing newly developed anesthetic procedures because the scientific evidence often is limited as the observations are based on small scale studies. Also the safety of new anesthetic devices needs carefully be evaluated before implementing into the standard anesthetic procedures. Here future CE-approval, required for implementation into the clinic, needs to be strictly based on scientific evidence.

The results and observations as reported in this thesis furthermore demonstrate that the Anesthetist needs not to completely rely on the anatomical textbooks before development and/or application of new or revived anesthetic techniques like the thoracic paravertebral block (see Chapter 5). As anatomical textbooks are basically using schematic reproductions of human anatomy our study shows that detailed anatomical post-mortem studies are absolutely required before application of a new or revived anesthetic technique.

Health care policy makers and Stakeholders

The increasing demand for optimally monitored anesthetic care and anesthetic techniques will further increase the health care costs in general. Cost-benefit analysis will form a significant part of study design and conduct in the near future. The

recommendations with respect to the acceptance of alternative study designs should contribute to a cost effective way of monitoring quality of care.

Furthermore results from this thesis clearly show the urgent need for international standardization of regulations and procedures to assure constant quality of newly developed high tech industrial products.

Our findings support stakeholders in their efforts to contribute to a transparent and safe device development programs.

Activities, Innovation and Implementation

Identification of risks and benefits of various anesthetic techniques and devices is essential in the continuous process of improvement of anesthesia in general. Requirements for systematic investigations may lead to further standardization and certification of anesthetic devices. Furthermore results from this thesis may contribute to enhanced interest and insight into the immense problem of chronic post-surgical pain (CPSP). Accurate prevention and treatment of CPSP will be necessary to increase quality of life after surgery.

REFERENCES

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