Background

• For many medical devices the evidence of efficacy and safety is limited compared to pharmaceuticals\(^1\)
• Typical high quality evidence generation through randomized controlled trials is often not feasible for medical devices\(^2\)
• This can be overcome by real-world data collected during device use
• Here we evaluate the lessons learned from data collection during procedural sedation in major hospitals

Methods

• As part of a quality improvement initiative (QII) hospitals collected data on current practice and also after introduction of capnography
• The world SIVA tool\(^3\) was used to define adverse events and interventions of interest
• Simple tools were developed to capture:
  • ASA risk
  • Sedative used
  • Depth of sedation
  • Escalation of care
  • Patient death
  • Identified adverse events
  • Interventions applied
• Proof-of-principle used an offline Excel tool that was later developed into an iPad app (Fig.1)

Results

• Four sites have completed and 5 are currently undertaking a QII using the developed tools (Fig.2)
• User reception to and uptake of the data collection tools was positive
• Three sites have been analyzed in full
• To date, data on over 5,000 patients has been collected; far larger than any published clinical study
• The uptake of capnography decreased the cumulative incidence of adverse events by at least 20% at each analyzed site
• Overall, a 41.9% reduction was observed (Fig.3), suggesting a positive effect on the awareness on respiratory compromise
• The reduction is in line with published literature\(^4\)

Lessons learned

• Success was dependent on the cooperation and buy-in of the medical staff
• Therefore, designing the tools simple and easy-to-use was of paramount importance

Conclusion

• Digital technology may lower the barrier for real-world data collection
• For medical devices, real-world data collection may:
  • Increase their evidence base
  • Help hospitals to understand the incremental benefits provided by new health

Excel tool Project evolution Mobile app with site-specific options

Fig.1 Workflow and evolution of data collection. All online data transfers are encrypted

Fig.2 Countries in which hospitals engaged in collaborative quality improvement initiatives (QII). Red: Completion of the QII (Belgium, Canada, France, Spain); Blue: Ongoing QII (England, Norway, Sweden, Turkey); Orange: Planned QII (France, Italy, South Africa, United Arab Emirates)

Fig.3 Primary outcome data from all fully analyzed sites (Belgium, Canada, Spain)

References

1. Tarricone R et al.: Health Econ. 2017 Feb;26(1):5-12


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