NARRATIVE REVIEW

Operating room black box: GIMMICK or a patient safety tool?

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Abstract

The Operating Room Black Box (ORBB) is a relatively recent technology that provides a comprehensive solution for assessing technical and non-technical skills of the operating team. Originating from aviation, the ORBB enables real-time observation and continuous recording of intraoperative events allowing for an in-depth analysis of efficiency, safety, and adverse events. Its dual role as a teaching tool enhances transparency and patient safety in surgical training.

In comparison to traditional methods, like checklists that have limitations, the ORBB offers a holistic understanding of clinical and non-clinical performances that are responsible for intraoperative patient outcomes. It facilitates systematic observation without additional personnel, allowing for review of numerous surgical cases. This review highlights the potential benefits of the ORBB in enhancing patient safety, its role as a surgical training tool, and addresses barriers especially in resource-constrained settings. It signifies a transformative step towards global surgical practices, emphasizing transparency and improved surgical outcomes.

Keywords: Operating room, black box, surgical outcomes, patient safety

DOI: https://doi.org/10.47391/JPMA.AKU-9S-13

Introduction

The black box, though well known in aviation, is a relatively new concept in the medical field with its earliest use starting less than a decade ago. The Operating Room Black Box (ORBB) allows direct observation and continuous recording of the intraoperative technical as well as non-technical data; this allows a detailed analysis of efficiency, safety and adverse events.[1] It also acts as a teaching tool in surgical training as it may be used to provide feedback to trainees. Surgeons, thereby increasing transparency in the operating room and improving patient safety.[2]

The operating room (OR) has been identified as a venue for several adverse surgical outcomes, among which majority are preventable.[3,4] Over the years operating room checklists have been incorporated to improve patient safety.[5] However, the ORBB was introduced in the medical field to address the need for a holistic understanding of clinical and non-clinical performance in the operating room. The system allows retrieval of real-time audio and visual data of not only the procedure, and ongoing events inside the operating room. Subsequently, software-based algorithms and experts in the pertinent field analyse this data.[6]

The ORBB enables one to observe intraoperative performance in a systematic way. This eliminates the requirement of (without requiring)(omit) additional manpower and to have constantly and physically present in the operating room. It also allows the study of a high number of surgical cases, and provides the opportunity to learn and improve everyday practice.[7] This brings us to the aim of our study, which is to compile and review the current state of the ORBB technology, and its influence on surgical outcomes.

Search strategy and selection criteria

MEDLINE, Scopus and Google scholar were searched for peer-reviewed articles in the English language. Articles published between 2013 and 2023 were identified using the search feature, from 18 to 25th November, 2023. The following search terms were used 'operating room black box' AND 'surgical outcomes'. Additional studies were identified using the articles in the references and all the articles were critically reviewed. As this is a relatively newer concept, we present the results of these studies as a narrative review.

The utility of ORBB has been observed in several fields of surgery, radiology and anaesthesia.[8-11] However, this review focusses on the outcomes related to open and laparoscopic abdominal procedures.

Role in enhancing patient safety

Most surgical teams address intra-operative adverse

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events by analysing the self-reported data retrospectively, in morbidity and mortality meetings, patient charts, and incident reports. Unfortunately, the analysis of such events is biased due to low compliance, recall bias, and lack of details while in reporting adverse events. Furthermore, surgical teams often compensate for system and team errors, which prevent adverse outcomes, however, these near-miss errors are not disclosed or reported after the operation.[12]

In order to overcome this barrier and holistically evaluate the technical and non-technical factors that predict patient safety in the operating room, data should be collected continuously in the operating room and then analysed. Discussions should be done in an open non-judgmental manner to identify errors and learn from them, thereby preventing them in the future.[13] This has been demonstrated in a study by Molina G, et al. that hospitals with higher levels of safety attitude had better post-operative outcomes.[14]

A study by Jung et al. reported the under-reporting of Veress needle injuries when chart-review was compared to direct observation by the ORBB.11 Among the 131 cases included in the study, 12 (9%) Veress needle injuries were identified by direct observation compared to only 3 (2%) identified upon review of the patient chart. Liver and stomach injuries were reported by both methods, however, omental injuries were not reported in patient charts. Some of these non-reported injuries required up to 12% of extra operating time. There were a total of 47 Veress needle near misses (35% of cohort per year) which required rectification (majority of which were bleeding) and thereby added an average of 3 minutes or 4% of procedure time.

In another study conducted by Jung et al, there were 138 clinically significant intra-operative adverse events (2 episodes/case), among which 10 (7.2%) were of the highest severity, the most common one being bleeding, followed by mechanical injury and thermal injury, and spillage. Using the ORBB, Fecso et al. observed the relationships between intraoperative non-technical performance and technical events in bariatric surgery. Among a total of 63 cases, 828 errors were made, (median of 8, IQR 5-11). These were related to inadequate depth inappropriate, grasping force and poor orientation. Furthermore, a total of 222 events were recorded, with a median of (2 events per step) the most common being bleeding, followed by thermal injury.[15]

In a gynaecological study by Nensi et al. the ORBB captured intraoperative adverse events, errors and threats with at least one error being identified in 44% of the cases, bleeding being the most common during the ligation of the uterine arteries during laparoscopic hysterectomy. In all the instances error were corrected and resulted in no adverse outcomes. It is important to note, however, that the majority of these errors and events were not documented in the traditional operative record. This emphasizes the importance and use of the ORBB as a good teaching modality that can be used to improve technical skills, thereby improving patient outcomes.[16]

The Operating room environment, coordination between different teams and preparedness in stressful situations as a result of an adverse intraoperative event, influences surgical outcomes. The ORBB has revealed its ability to objectively assess these non-technical skills that play a major role in patient's safety.[3,17]

In the study by Rai et al. a total of 598 non-technical observations were recorded by the ORBB among various laparoscopic irological procedures. Among these majority of them (6 episodes/case) were positive in nature revealing good team dynamics, comprehensive communication, good leadership and high situation awareness.[17]

Jung J. et al similarly analysed distractions and errors in the operating room recorded by the ORBB. Auditory distractions occurred a median of 138 times (once every 40 seconds) per case. These included the opening of the operating room door, machine alarms, telephone calls and pagers. The OR door opened was opened once every two minutes or a median of 42 times per case. The cognitive distractions that were observed included time spent during a teaching activity (most common), absent or malfunctioning device, irrelevant conversations among team members, time spent managing another case, with at least 1 type of cognitive distraction occurring in 84 cases.[18]

Another study reported the OR door was opened on average of 33 times per hour. This is not only an auditory distraction but is associated with increased risk surgical site infections. Intraoperative errors were also noted with a total of 3435 errors identified (20 errors per case).[11]

The non-technical behaviour observed was positive in most of cases as reported in all the studies. However, when the difference in performance (between technical and non-technical) was compared, it was noted that the majority of surgeons and scrub nurses had a negative non-technical behaviour, before a rectification that had occurred after an event or error…Change this to… behaviour, prior to rectification..[5]

Surgical training tool

Not only does the ORBB serve as a potential tool to identify real-time events, and allow immediate interventions to improve patient outcomes, the data can be used by surgeons and trainees to retrospectively review their performance and identify errors. This provides a platform to assess the operating surgeon's expertise and can be used as a guide to prevent repetition of events/errors, thereby improving intra-operative patient safety.

Near-misses are defined as adverse events that have the potential to cause patient harm but did not result in it.[19] As noted in the studies above, these near misses are rarely recorded in the traditional intraoperative records, however, the ORBB in its' ability to capture all events, proves an impartial objective tool for monitoring. Not only that, non-technical events like distractions can also be recorded and reviewed as potential sources of delay and error that can affect patient outcomes.[11,21] Positive interactions may be highlighted and such events be used as examples to encourage and improve operating room team dynamics.

Barriers to the Operating Room Black Box

Confidentiality and Surgeon Fears

Medical data recording (MDR) offers the operating team the opportunity to review and learn from their performance and has demonstrated a reduction in errors; however, one of the biggest concerns is patient privacy and anonymity. Surgical procedures are often recorded for educational, research, and quality improvement purposes, nonetheless, concerns persist regarding the adequacy of implementation, data ownership, and potential medical negligence. Patient consent is crucial to effectively implement the ORBB, and in order to make it a norm, patients have to have active involvement in the development of this surgical safety research. Simultaneously, measures to ensure patient confidentiality must be ensured.[23]

In addition to the implementation of system-level or technological interventions, the improvement of surgical safety hinges on the culture within the operating room. Fundamental principles of quality improvement emphasize the importance of recognising, documenting, and sharing deficiencies in both technical and non-technical performance that contribute to adverse patient outcomes. Surgeons must feel empowered to openly discuss their own shortcomings in an environment that is safe, non-judgmental, and crucially, non-punitive. Despite societal shifts toward transparency and accountability, many surgeons remain hesitant to share experiences in the operating room that results in suboptimal patient outcomes.[24] Reasons for this reluctance include fear of legal repercussions and potential damage to professional reputations. Surgeons' express emotions such as shame, sadness, anxiety, and guilt as significant barriers to reporting surgical safety events.[25] Additionally, a lack of perceived personal benefit from reporting, contributes to the underutilisation of safety data. This information is beneficial in creating targeted quality improvement interventions that would reduce future patient harm through the improvement of operating room team performance.

Implementation of the ORBB in low middle income countries (LMIC)

Limited financial resources, infrastructure constraints and disparities in healthcare access present a great challenge in implementing the ORBB in LMICs. This is further complicated by the legal and ethical considerations related to patient consent, privacy, and data ownership. Transparency and protection of sensitive information is crucial with the implementation and use of the ORBB, especially in LMICs where regulatory frameworks are often not well defined and there is inequity in healthcare.

Nevertheless, the potential benefits are substantial, ranging from enhanced training opportunities for surgical teams, to the development of evidence-based best practices tailored to the local environment. The ORBB has the significant potential role in surgical training, by providing a detailed record of procedures. These devices offer a valuable resource for educating and mentoring surgical teams, particularly in regions where access to expert guidance is limited.

The real-time monitoring and retrospective analysis facilitated by ORBB not only contributes to improved patient safety (by identifying adverse events, near misses, and deviations from established protocols); but also provides the opportunity for real-time feedback and assistance between surgeons operating in remote areas and surgeon mentors in a different location. This would allow proactive intervention and the implementation of targeted interventions to mitigate risks in real-time thereby improving operative patient care and outcomes.

Conclusion

The Operating Room Black Box has recently emerged as a unique tool for intraoperative assessment of surgeries and patient outcomes, revolutionising the assessment of procedures and team dynamics. Despite hurdles in implementation, its role in enhancing patient safety and

serving as a valuable training tool is evident. Implementation of the ORBB in low- and middle-income countries will no doubt be a challenge, but overcoming these barriers may be worthwhile considering the potential for improved training and tailored practices. Lastly, it represents a much needed shift towards more transparent, efficient, non-judgmental and globally applicable surgical practice, thereby paving the way for a safer future in healthcare with improved intraoperative patient outcomes.

Acknowledgement: Dr. Fizzah Arif

Disclaimer: None.

Conflict of Interest: None.

Funding disclosure: None.

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