Simulation-based Training for Safety Incidents: Lessons from Analysis of Adverse Events in Robotic Surgical Systems

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Background: In minimally-invasive robotic surgery, the emphasis of simulation-based training has been on improving surgical skills to make surgeons comfortable with the prospect of working in a limited space and using scope for visualization, and master controls, pedals, and instruments for tissue handling and manipulation. However, there have been ongoing occurrences of safety-related incidents, with more than 23% of them resulting in either injuries and deaths, or procedure interruptions for troubleshooting system-related problems.

Methods: We develop new simulation-based training modules that can be integrated as part of the standard robotic surgery curriculums to prepare surgeons for handling safety incidents by exposing them to realistic safety-critical scenarios. We reviewed the adverse events experienced during robotic procedures, as reported to the U.S. Food and Drug Administration (FDA) during years 2000–2013. We determined common types of device and instrument malfunctions and inadequate operational practices used by surgical teams that led to complications, patient injuries, and deaths in a variety of surgical specialties. This analysis was used as a basis to develop representative system-related safety hazard scenarios and integrate them into the training modules of a robotic surgery curriculum.

Results: We identified five main system-related safety hazards based on analysis of adverse event reports: i) master control malfunctions (e.g. foot pedal not working), ii) robotic system malfunctions (e.g. unintended instrument operation), iii) console display malfunctions (e.g. 3D vision obstructed/lost), iv) instrument malfunctions (e.g. grasper not opened/closed), v) system errors (e.g. system freeze due to unrecoverable error). We integrated the hazard scenarios into the intermediate training modules within a standard robotic surgery curriculum, including ball placement, needle handling, basic electro-cautery, tissue retraction, and knot tying.

Conclusions: As robotic surgical systems continue to evolve with new technologies, development of advanced simulation environments and standards for training surgical teams for handling adverse events may reduce catastrophic patient impacts in the future.