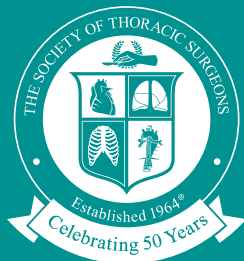


50th Annual Meeting

Orlando, Florida
January 25-29, 2014

ABSTRACT BOOK



**The Society
of Thoracic
Surgeons**

6:30 AM – 5:00 PM

Convention Center Entrance

Registration: STS 50th Annual Meeting

9:00 AM – 4:30 PM

Palms Ballroom Foyer

Scientific Posters Open

9:00 AM – 4:30 PM

Cypress Ballroom

Exhibits Open

7:00 AM – 10:45 AM

Crystal Ballroom G-Q

General Session I

Moderators: Douglas E. Wood, Seattle, WA, and Keith S. Naunheim, St Louis, MO

COMMERCIAL RELATIONSHIPS D. E. Wood: Research Grant, Spiration, Inc; Consultant/Advisory Board, Spiration, Inc

Unless otherwise noted in this program or by the speakers, speakers have no relevant financial relationships to disclose and will be presenting information only on devices, products, or drugs that are FDA-approved for the purposes they are discussing.

Unless noted with an asterisk (*), presenting authors are listed first on each abstract.

The physician competencies addressed in this session are patient care, medical knowledge, and professionalism. These physician competencies will be addressed through a series of individual lectures and focused discussion on key points of presentations.

7:00 AM

Crystal Ballroom G-Q

Opening Remarks

7:15 AM

Crystal Ballroom G-Q

J. Maxwell Chamberlain Paper for Adult Cardiac Surgery

Safety Implications of Robotic Surgery: Analysis of Recalls and Adverse Event Reports of da Vinci Surgical Systems

H. Alemzadeh², R. K. Iyer², *J. Raman¹

¹Rush University Medical Center, Chicago, IL, ²University of Illinois, Urbana-Champaign

Discussant: W. Randolph Chirwood Jr, Greenville, NC

Purpose: We review device-related recalls and safety issues with the da Vinci robot.

Methods: The number, types, and causes of robot malfunctions that led to patient complications and safety hazards were analyzed. Data included recalls and adverse events reported to the US FDA between January 2000 and December 2012, from two public FDA databases.

Results: 4,798 adverse events (involving 4,807 device uses) were reported to the FDA, involving 85 deaths, 414 patient injuries, and 3,402 device malfunctions. We calculated estimated rates of adverse events and injury/death events per year for 2004-2012. The number of safety-critical (injury or death) reports increased from 13.3 per 100,000 procedures in 2004 to 50 per 100,000 in 2012. Comparable accidents in a safety-critical industry, such as aviation, stayed constant over 1992-2011, ranging 0.01-1.81 per 100,000 flight departures. 147 cases (6.5%) were related to cardiothoracic procedures. 74.1% (63/85) of deaths were reported after the procedure and 18% (15/85) during the procedure. In 545 cases (11.3%), a part of the device or burnt/broken pieces of instruments fell into the patient's body, with 12.2% in cardiothoracic surgeries. In 499 cases (10.4%), a system error code was experienced and the robot was transferred to a recoverable or non-recoverable safety state. A high-level control structure of the robot was developed based on the adverse events and used to analyze accidents and characterize safety hazards of system. This study helps identify missing and existing safety controls that were inadequate in mitigating patient injury. Insights on improving the design of future systems were developed.

Conclusions: The da Vinci robot continues to have adverse events and complications, despite increased numbers of procedures. Adoption and use of standard engineering safety mechanisms with this technology may reduce adverse events.

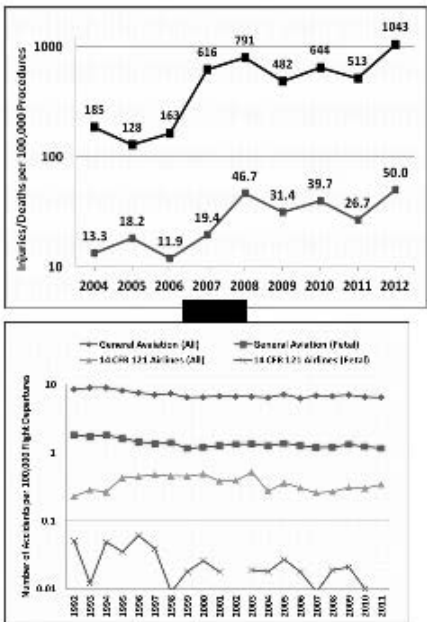


Figure 1 – Comparison of accident rates in robotic surgery and aviation industry:
(a) Total number of adverse events and injury/death events per 100,000 procedures per year
(b) Total number of accidents and fatalities in different aviation classes per 100,000 flight departures per year