RESEARCH LETTER

Morbidity and Mortality Associated With Robotic Head and Neck Surgery: An Inquiry of the Food and Drug Administration Manufacturer and User Facility Device Experience Database

Transoral robotic surgery (TORS) using the da Vinci Surgical System (Intuitive Surgical) was first approved for use in otolaryngology by the Food and Drug Administration (FDA) in 2009. With increased adoption of this technology, the head and neck surgical community should continue to evaluate its safety and efficacy.

The FDA Manufacturer and User Facility Device Experience (MAUDE) database is a publicly available national database that allows the anonymous reporting of adverse events (AEs). Since December 13, 1984, the FDA has required device manufacturers to report any device malfunctions, serious injuries, or deaths associated with medical device use by means of this database.1 We review reported data in MAUDE and describe the morbidity and mortality associated with the robotic head and neck surgery.

Methods | The MAUDE database was queried from January 1, 2009, to August 31, 2015. Death, injuries, and AEs associated with use of the da Vinci Surgical System were identified by querying by manufacturer, “Intuitive Surgical.” All reports reflecting use in head and neck surgery were identified on the basis of the description, including tonsillectomy, base of tongue resection, and thyroidectomy. Duplicate entries were identified and removed. Limitations include the lack of patient-specific clinical information and the fact that all data were self-reported. However, mandated reporting by device manufacturers may minimize the underreporting of mortality in this database.

Results | There were 14 deaths and 11 injuries associated with use of the surgical robot for head and neck surgery (Table). Only 1 event (radial nerve injury) occurred during a robotic-assisted thyroidectomy, and the remaining events were all associated with TORS. The majority of the deaths (12 [86%]) and injuries (8 [73%]) occurred in the first 3 years after FDA approval of the TORS system (2009 to 2012) (Figure).

Most of the deaths (11 [79%]) were associated with postoperative bleeding, and 1 death (7%) was associated with aspiration. In all cases of death, it was concluded that the device worked as intended and there was no malfunction. The most common injury was trauma to the lip and oral cavity, thermal and/or mechanical, which occurred in 6 patients. Postoperative bleeding was a reported injury without mortality in 2 cases and was controlled with reoperation in both cases.

Table. Morbidity and Mortality Associated With Use of the da Vinci Surgical System in Otolaryngologic Procedures, 2009 to 2015

<table>
<thead>
<tr>
<th>Etiology</th>
<th>Events, No. (%)</th>
<th>Events, No. Intraoperative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>11 (79)</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (14)</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Aspiration</td>
<td>1 (7)</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>14</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Injury</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burns and traumaa</td>
<td>6 (55)</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Bleeding</td>
<td>2 (18)</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Otherb</td>
<td>3 (27)</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>9</td>
<td>2</td>
</tr>
</tbody>
</table>

a Includes injury to the lips, tongue, and tonsil.
b Includes radial nerve injury due to patient positioning, visualization of 2 intraoral lesions, and 1 case in which the spatula tip melted but no burns were sustained.

Figure. Temporal Trends in Reported Morbidity and Mortality Associated With Use of the da Vinci Surgical System in Otolaryngologic Procedures, 2009 to 2015

A Morbidity

B Morbidity

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Discussion | The MAUDE database demonstrates low rates of mortality associated with robotic surgery. From 2009 to 2011, there were an estimated 2528 TORS procedures performed. Thus, these MAUDE data indicate a mortality rate of 0.3% (8 of 2528) after transoral robotic surgery and a surgical morbidity rate of 0.08% (2 of 2528). Previously, it has been shown that the mortality after TORS is 0.3%. However, MAUDE does not consistently capture other commonly reported complications: hemorrhage (3.1%), tooth injury (1.4%), dehydration requiring readmission (1.3%), and aspiration pneumonia (1.1%). Reporting of surgical margins is an important quality benchmark in head and neck oncologic surgery; however, no data on margins are recorded in MAUDE. The most common major complications after robotic thyroidectomy include recurrent laryngeal nerve injury (0.5%) and tracheal injury (0.3%).

Knowledge of a typical surgical practice suggests that the current MAUDE database is not capturing the normal expected proportions of surgical AEs because typically the number of non-fatal AEs exceeds the number of deaths in the perioperative period, whereas in this report, deaths exceed the other AEs. Our results suggest that deaths are being adequately reported to the FDA, but other complications may be underreported.

These data suggest that the current MAUDE tracking system may adequately capture mortality due to surgery and perhaps intraoperative morbidity, but to capture more longitudinal outcomes of surgical quality, other solutions should be considered. One option is a robotic head and neck surgery registry administered or supported by one of our academic surgical organizations.

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Author Contributions: Both authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Both authors.

Acquisition, analysis, or interpretation of data: Both authors.

Drafting of the manuscript: Both authors.

Critical revision of the manuscript for important intellectual content: Both authors.

Statistical analysis: Both authors.

Obtained funding: Holsinger.

Study supervision: Holsinger.

Conflict of Interest Disclosures: None reported.

Additional Information: The Medical Device Reporting regulation (21 CFR 803) requires that manufacturers, importers, and “device user facilities” report device-related adverse events and deaths possibly related to a medical device. A user facility is not required to report a device malfunction but can voluntarily advise the FDA of potential complications or adverse events using the “MedWatch” Form FDA 3500 under the Safety Information and Adverse Event Reporting Program. 1


COMMENT & RESPONSE

Ethical Considerations When Counseling Patients With Thyroid Cancer About Surgery vs Observation

To the Editor | In a recent Viewpoint, Stack and Angelos 1 remind physicians about ethical obligations to outline risks, benefits, and alternatives of all treatment options to patients. Discussing the option of observation for papillary microcarcinoma (PMC), the authors assert that “this approach is not the standard of care in the United States.” However, if considered, should only be offered under an institutional review board-approved research protocol or if patients sign a “surveillance contract.”

On behalf of the multidisciplinary thyroid cancer team at Memorial Sloan Kettering Cancer Center (MSKCC) (a letter dated November 24, 2015, was signed on behalf of all attending physicians of the MSKCC Disease Management Team for Thyroid Cancer [https://www.msckc.org/cancer-care/types/thyroid], including senior leadership in surgery [Dr Ashok Shaha and Dr Jatin Shah] and in endocrinology [Dr James Fagin]), we write to express our concerns about these opinions. While we certainly agree that physicians must comprehensively educate patients about the fullest possible set of treatment options for thyroid cancer, we dispute the misguided assertion that anything short of immediate biopsy and resection of subcentimeter suspicious thyroid nodules is outside the “standard of care.” This extreme position disregards the public health ramifications of aggressive therapy for indolent PMCs, present in 5% to 30% of the adult population, very few of which ever cause clinically significant disease. 2

In fact, the 2015 American Thyroid Association (ATA) clinical practice guidelines recommend observation rather than immediate fine-needle aspiration (FNA) and surgery for most intrathyroidal, subcentimeter, sonographically suspicious thyroid nodules (most of which are presumed to be thyroid cancers). For biopsy-proven cancers, “an active surveillance management approach” can be “considered as an alternative to immediate surgery” in patients with very low-risk tumors, at high surgical risk, with relatively short lifespans, or concurrent medical issues taking priority. 3,4 The decades-long experience of our Japanese colleagues confirms excellent clinical outcomes with an observational management approach for PMC. 4 For years, MSKCC has offered active surveillance as an alternative to immediate surgery in properly selected patients with PMC as part of routine clinical care. 5

Mandating that patients sign a surveillance contract to avoid immediate FNA and surgery jeopardizes patient...