DVT Prophylaxis in Major Otolaryngology – Head and Neck Surgery

Clinical Practice Guidelines developed by the Department of Otolaryngology – Head and Neck Surgery – University of Toronto

P Singh

June 2017

Contents

Section 1 – General Information
Section 2 – Guideline Recommendations
Section 3 – Guideline Recommendations and supporting evidence
Section 1 – General Information

Aim

The aim of this guideline is to make recommendations for appropriate prophylaxis for patients who are high risk for venothrombotic events undergoing major head and neck surgery.

Guideline Goals

Creation of evidence-based recommendations for VTE prophylaxis for patients undergoing major head and neck surgery.

Outcome Goals

Reduce the incidence of VTE events in high-risk OTO-HNS patients. To increase the quality of care by reducing complication rates, reducing length of stay, and therefore the cost of care.

Rationale for a guideline on Venothrombotic Event Prophylaxis

Venothrombotic embolism (VTE) events are common place in hospital patients who undergo major surgery. It encompasses both deep vein thrombosis (DVT) and pulmonary embolism (PE). VTE events are vital for the quality of care for post surgical patients due to i) the increased complications a patient will experience ii) the increase in the length of stay. VTE events are the #2 cause for both of these areas of patient care [1,2]

Otolaryngology-Head and Neck surgery (OTO-HNS) is a very diverse area of surgery that involves complicated anatomy of the head and neck region. The complexity of surgery can range from quick out patient procedures to multi-hour complex head and neck cancer ablation and reconstructive surgeries that require significant post-operative care in a multi-disciplinary approach.

VTE events in OTO-HNS as a whole are considered to be low-risk. Historically, rates of VTE have been low in previous otolaryngology literature. These studies often looked at all operative patients in OTO-HNS, including smaller outpatient procedures. Moreano et al looked at the VTE rate retrospectively for patients undergoing both in-patient and out-patient surgery. The overall VTE rate was 1.01%[3]. A recent systematic review by Moubayed confirmed this low rate with an overall incidence of 0.4%[4]. However, it is important to risk stratify patients into low risk and high risk. When patients who undergo major head and neck surgery are examined in isolation, it becomes clear that the VTE risk is increased many fold. Studies by Thai, Shuman, Garritano, and Claybourg show various increased VTE risk when patients undergoing major surgery for malignancy are examined separately[1,5-7].

Target Population

Adult patients undergoing high risk head and neck surgery.

Intended Users

All surgeons who perform major head and neck surgery.
Methods for development

Available medical literature on VTE in OTO-HNS was reviewed, including any available retrospective studies, randomized trials and meta-analysis. The role of the Caprini Risk Assessment model in otolaryngology and other surgical specialties was also reviewed for its validity as a risk model. As there are no current guidelines for VTE prophylaxis is OTO-HNS, we used the available literature and expert opinion to create a set of guidelines for patients undergoing high risk OTO-HNS surgery.

Section 2. Guideline Recommendations

1. Any patient undergoing major head and neck surgery (Mucosal malignancy with or without reconstruction, surgery > 4hrs, or reduced mobility >72 hrs) should be assess with the Caprini Risk Assessment Model.
2. Patients should be treated with various mechanical and chemical VTE prophylaxis methods based on Caprini Score based on the most recent Risk Stratification Recommendations by the American College of Chest Physicians.
3. A low index of suspicion should be present for post-operative patients high risk for VTE and should receive early Doppler Ultrasound as clinically appropriate.

Section 3 – Supporting evidence for Guideline Recommendations

There is a large collection of available evidence for the rate of venous thrombotic events (VTE) in orthopedic and general surgery. Historically, Otolaryngology – Head and Neck Surgery (OTO-HNS) has been considered a low risk specialty[1,4,8-10]. Literature such as the study by Moreano et al[3] is frequently sited as evidence of this low risk classification. More recently however, several studies have started to look at what is believed to be higher risk populations in OTO-HNS; specifically patients with major malignancy that undergo prolonged surgeries and who may experience significantly reduced mobility post-operatively.

Table 1 summarizes many of the available studies looking at VTE rates across OTO-HNS. The majorities of the papers are retrospective in nature and include patients who were not given any VTE prophylaxis.

Table 2 is a summary of the papers involving patients under-going high risk procedures as described above. Several of the papers include the Caprini score as a predictor of patients who may experience a VTE event in the post-operative period.
Table 1 – Summary of Literature for VTE rates in OTO-HNS[1,5,7-18]

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Study Type</th>
<th>Patient Population</th>
<th>[N]</th>
<th>Patient / Procedure</th>
<th>VTE (%)</th>
<th>VTE %</th>
<th>Prophylaxis (Yes/No)</th>
<th>Prophylaxis type</th>
<th>Risk Assessment?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estomba et al</td>
<td>2015</td>
<td>Retrospective</td>
<td>ICD Coded – VTE in all patients</td>
<td>9007</td>
<td>Procedures</td>
<td>8</td>
<td>0.1%</td>
<td>No</td>
<td>Most Fed Caprini</td>
<td>ORN Oncology patients VTE Rate 0.4%</td>
<td></td>
</tr>
<tr>
<td>Clayburg et al</td>
<td>2012</td>
<td>Prospective Cohort</td>
<td>Otolaryngology Surgery</td>
<td>100</td>
<td>Patients</td>
<td>13</td>
<td>13.0%</td>
<td>No</td>
<td>Wells Criteria</td>
<td>8% Clinically symptomatic VTE</td>
<td></td>
</tr>
<tr>
<td>Garritano et al</td>
<td>2015</td>
<td>Retrospective Review</td>
<td>Surgical Procedures</td>
<td>56884</td>
<td>Procedures</td>
<td>407</td>
<td>0.7%</td>
<td>No</td>
<td>None</td>
<td>VTE 1.1% for cancer in-patients</td>
<td></td>
</tr>
<tr>
<td>Thai et al</td>
<td>2015</td>
<td>Retrospective</td>
<td>Cancer patients with Free Flap</td>
<td>139</td>
<td>Procedures</td>
<td>2</td>
<td>1.4%</td>
<td>No</td>
<td>Caprini</td>
<td>Increased Caprini for VTE or Suspicious VTE (12.8 vs 10.0)</td>
<td></td>
</tr>
<tr>
<td>Shum et al</td>
<td>2013</td>
<td>Retrospective Cohort</td>
<td>Surgical Procedure</td>
<td>1016</td>
<td>Patients</td>
<td>27</td>
<td>2.3%</td>
<td>No</td>
<td>Caprini</td>
<td>Caprini VTE 7.4 vs Caprini Non-VTE 4.4 (p&lt;0.001)</td>
<td></td>
</tr>
<tr>
<td>Invis et al</td>
<td>2009</td>
<td>Retrospective All Surgical Procedures</td>
<td>6122</td>
<td>Patients</td>
<td>6</td>
<td>0.4%</td>
<td>No</td>
<td>None</td>
<td>Malignancy VTE - 0.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gavriel</td>
<td>2012</td>
<td>Retrospective</td>
<td>Otolaryngology Surgery Inpatient</td>
<td>1018</td>
<td>Patients</td>
<td>0</td>
<td>0.0%</td>
<td>Yes</td>
<td>Most Mechanical</td>
<td>None</td>
<td>Patients experienced bleed</td>
</tr>
<tr>
<td>Ah et al</td>
<td>2013</td>
<td>Retrospective Review</td>
<td>ICD coding</td>
<td>433</td>
<td>Patients</td>
<td>12</td>
<td>2.9%</td>
<td>Yes</td>
<td>LAMH HIO</td>
<td>Caprini</td>
<td>Rosen VTE rate 6.2%</td>
</tr>
<tr>
<td>Yalagadda et al</td>
<td>2013</td>
<td>Retrospective</td>
<td>Inpatient Surgery / ICD Coding</td>
<td>704</td>
<td>Patients</td>
<td>15</td>
<td>2.1%</td>
<td>No</td>
<td>None</td>
<td>Caprini</td>
<td>Caprini VTE rate 6.2%</td>
</tr>
<tr>
<td>Hennawy et al</td>
<td>2012</td>
<td>Cross-Sectional Analysis</td>
<td>NS database H&amp;N Oncology ICD Coding</td>
<td>93663</td>
<td>Procedures</td>
<td>3731</td>
<td>4.0%</td>
<td>No</td>
<td>None</td>
<td>Otolaryngology patients only</td>
<td></td>
</tr>
<tr>
<td>Fournanou et al</td>
<td>2010</td>
<td>Retrospective</td>
<td>Surgical Patients</td>
<td>411</td>
<td>Patients</td>
<td>2</td>
<td>0.5%</td>
<td>No</td>
<td>None</td>
<td>High Risk Patients - 2%</td>
<td></td>
</tr>
<tr>
<td>Kei et al</td>
<td>2016</td>
<td>Retrospective</td>
<td>Oral Cancer / Reconstruction patients</td>
<td>133</td>
<td>Patients</td>
<td>3</td>
<td>2.3%</td>
<td>No</td>
<td>Caprini</td>
<td>High Caprini Risk associated with VTE</td>
<td></td>
</tr>
<tr>
<td>Ladders et al</td>
<td>2015</td>
<td>Retrospective</td>
<td>Oral Cancer / Reconstruction</td>
<td>233</td>
<td>Patients</td>
<td>10</td>
<td>4.2%</td>
<td>No</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Sinha et al</td>
<td>2017</td>
<td>Retrospective</td>
<td>Head and Neck Surgery</td>
<td>517</td>
<td>Procedures</td>
<td>9</td>
<td>1.7%</td>
<td>Yes</td>
<td>Heparin / Aspirin / SCD</td>
<td>None</td>
<td>7.3% Flap Hematoma</td>
</tr>
</tbody>
</table>

**TOTAL** | 17440 | 4275 | 2.5% |

Table 2 – Summary of Literature – VTE rates in high risk OTO-HNS patients.[5,7,10,14,16-18]

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Study Type</th>
<th>Patient Population</th>
<th>[N]</th>
<th>Patient / Procedure</th>
<th>VTE (%)</th>
<th>VTE %</th>
<th>Prophylaxis (Yes/No)</th>
<th>Prophylaxis type</th>
<th>Risk Assessment?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clayburg et al</td>
<td>2013</td>
<td>Prospective Cohort</td>
<td>Otolaryngology Surgery</td>
<td>100</td>
<td>Patients</td>
<td>13</td>
<td>13.0%</td>
<td>No</td>
<td>Wells Criteria</td>
<td>8% Clinically symptomatic VTE</td>
<td></td>
</tr>
<tr>
<td>Thai et al</td>
<td>2013</td>
<td>Retrospective</td>
<td>Cancer patients with Free Flap</td>
<td>139</td>
<td>Procedures</td>
<td>2</td>
<td>1.4%</td>
<td>No</td>
<td>Caprini</td>
<td>Increased Caprini for VTE or Suspicious VTE (12.8 vs 10.0)</td>
<td></td>
</tr>
<tr>
<td>Gavriel</td>
<td>2012</td>
<td>Retrospective</td>
<td>Otolaryngology Surgery Inpatient</td>
<td>1018</td>
<td>Patients</td>
<td>0</td>
<td>0.0%</td>
<td>Yes</td>
<td>Most Mechanical</td>
<td>None</td>
<td>Patients experienced bleed</td>
</tr>
<tr>
<td>Hennawy et al</td>
<td>2012</td>
<td>Cross-Sectional Analysis</td>
<td>NS database H&amp;N Oncology ICD Coding</td>
<td>93663</td>
<td>Procedures</td>
<td>3731</td>
<td>4.0%</td>
<td>No</td>
<td>None</td>
<td>Otolaryngology patients only</td>
<td></td>
</tr>
<tr>
<td>Kei et al</td>
<td>2016</td>
<td>Retrospective</td>
<td>Oral Cancer / Reconstruction patients</td>
<td>133</td>
<td>Patients</td>
<td>3</td>
<td>2.3%</td>
<td>No</td>
<td>Caprini</td>
<td>High Caprini Risk associated with VTE</td>
<td></td>
</tr>
<tr>
<td>Ladders et al</td>
<td>2015</td>
<td>Retrospective</td>
<td>Oral Cancer / Reconstruction</td>
<td>233</td>
<td>Patients</td>
<td>10</td>
<td>4.2%</td>
<td>No</td>
<td>None</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Sinha et al</td>
<td>2017</td>
<td>Retrospective</td>
<td>Head and Neck Surgery</td>
<td>517</td>
<td>Procedures</td>
<td>9</td>
<td>1.7%</td>
<td>Yes</td>
<td>Heparin / Aspirin / SCD</td>
<td>None</td>
<td>7.3% Flap Hematoma</td>
</tr>
</tbody>
</table>

**TOTAL** | 95949 | 3800 | 4.0% |

When selecting studies that involve patients undergoing surgery and/or reconstruction for malignancy, the overall combined rate of VTE climbs from 2.5% to 4%. A limitation of many of the studies above include the fact that they are retrospective in nature, which may lead to some VTE events being missed. In addition to this fact, many of the studies used ICD-9 coding from charts that were retrospectively reviewed. This detail also likely leads to a decrease in identifying VTE events, as some events may not have been coded appropriately and could be missed altogether.

**CAPRINI SCORE**

The Caprini risk model was developed by Joseph Caprini in 2005[19] and has been used extensively in the literature to calculate risk scores for VTE events in patients. It takes into account various demographics about patients, medical history and possible treatments and provides a risk factor score (see Figure 1). An overall score is given to each patient, which then correlates to a risk category of Low, Moderate, High or Very High.

The Caprini risk model has been validated in various studies, including a 2011 study by Pannucci et al[20]. This study looked at correlation between the Caprini score and the observed VTE rate. Based
on the results, a Caprini score of 3-4 corelates to an Odds Ratio (OR) of 1.0 for VTE events. Scores of 5-6 provide an OR of 2.1. Scores of 7-8 corelates to an OR of 4.5 and scores >8 have an OR of 20.9. (pannucci).

Some common risk factors seen for patients undergoing major OTO-HNS surgery include i) Surgery time > 45 minutes, ii) Obesity (BMI > 25), iii) Increased Age, iv) decreased mobility >72hrs post surgery, v) Malignancy and vi) Previous history of VTE[19].

AMERICAN COLLEGE OF CHEST PHYSICIANS – RECOMMENDATIONS

The American College of Chest Physicians (ACCP) publish guidelines for antithrombotic therapy and prevention of thrombosis[21]. The 9th edition provides helpful evidence based recommendations about prophylaxis for patients undergoing various surgical procedures is various surgical specialties[21]. In the latest edition, there are no specific recommendations for patients undergoing OTO-HNS surgery. For the purposes of this guideline, the recommendations for patients undergoing major abdominal surgery have been adopted. The ACCP uses the Caprini score and recommends prophylaxis recommendations based on the risk stratification for Low Risk (Caprini 0-1), Moderate Risk (Caprini 2), High Risk (Caprini 3-4) and Highest Risk (Caprini 5 or more). The recommendations for these categories can been seen in Figure 2.
Figure 1 – Caprini Score Calculation

Thrombosis Risk Factor Assessment

Patient's Name: ____________________ Age: ___ Sex: ___ Wgt: ___ lbs

Choose All That Apply

Each Risk Factor Represents 1 Point

☐ Age 41-60 years
☐ Minor surgery planned
☐ History of prior major surgery (< 1 month)
☐ Varicose veins
☐ History of inflammatory bowel disease
☐ Swollen legs (current)
☐ Obesity (BMI > 25)
☐ Acute myocardial infarction
☐ Congestive heart failure (< 1 month)
☐ Sepsis (< 1 month)
☐ Serious lung disease incl. pneumonia (< 1 month)
☐ Abnormal pulmonary function (COPD)
☐ Medical patient currently at bed rest
☐ Other risk factors

Each Risk Factor Represents 2 Points

☐ Age 60-74 years
☐ Arthroscopic surgery
☐ Malignancy (present or previous)
☐ Major surgery (> 45 minutes)
☐ Laparoscopic surgery (> 45 minutes)
☐ Patient confined to bed (> 72 hours)
☐ Immobilizing plaster cast (< 1 month)
☐ Central venous access

Each Risk Factor Represents 5 Points

☐ Elective major lower extremity arthroplasty
☐ Hip, pelvis or leg fracture (< 1 month)
☐ Stroke (< 1 month)
☐ Multiple trauma (< 1 month)
☐ Acute spinal cord injury (paralysis)< 1 month)

For Women Only (Each Represents 1 Point)

☐ Oral contraceptives or hormone replacement therapy
☐ Pregnancy or postpartum (<1 month)
☐ History of unexplained stillborn infant, recurrent spontaneous abortion (>3), premature birth with toxemia or growth-restricted infant

Total Risk Factor Score

Figure 2 – ACCP Suggested Prophylaxis Regimen

<table>
<thead>
<tr>
<th>TABLE 2. Prophylaxis regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Risk Factor Score</strong></td>
</tr>
<tr>
<td>0–1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3–4</td>
</tr>
<tr>
<td>5 or more</td>
</tr>
</tbody>
</table>

ES – Elastic Stockings
IPC – Pneumatic Stockings
LDUH – Low Dose Unfractionated Heparin
LMWH – Low Molecular Weight Heparin
References:


