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HEMORRHAGE FOLLOWING TRANSORAL ROBOTIC SURGERY (TORS)

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Abstract

Background—To report our experience of postoperative hemorrhage in patients following transoral robotic surgery (TORS).

Methods—Data was collected on patients having TORS. Postoperative hemorrhage within 30 days was graded using the Mayo clinic grading system.

Results—TORS operations were performed on 122 patients. There were 23 bleeding events classified as minor to severe following 19 operations (16%). Hemorrhage requiring a return to the operating room occurred after 7 operations (6%). The odds of an emergent hemorrhage was 5.19 times greater in patients that had a staged neck dissection after TORS ($p=0.05$). The odds of a postoperative bleeding event were 2.6 times greater in patients receiving a larger resection ($p=0.107$). There were no hemorrhage events in the 36 patients who received a synchronous neck dissection with transcervical ligation of the external carotid artery.

Conclusions—Surgical intervention for TORS hemorrhage occurred in 6% patients. No haemorrhage occurred in patients who had ligation of the external carotid artery.

Keywords

TORS; hemorrhage; complications; predictors; robotic

Introduction

Transoral robotic surgery (TORS) received approval from the FDA in 2009 and has been utilized for a number of different indications in the upper aero-digestive tract (UADT)[1], particularly for the surgical treatment of selected patients with cancer of the oropharynx. Traditional open surgical approaches with either mandibulotomy or lateral pharyngotomy provide a good oncological standard against which TORS can be compared.[2]. TORS has the advantage of overcoming line of sight restrictions making it possible to access areas in

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the UADT that was not previously accessible and can avoid the morbidity of an open approach. TORS has been supported by a number of recent publications reporting the short and medium term oncological outcomes from single institutional studies [3, 4] and a multi-institutional study reporting a 3 year survival rate of 92.5% and a 3 year recurrence free rate of 88.8% [5]. There has also been promising functional outcomes of TORS with appropriate adjuvant therapy[6].

Hemorrhage remains a potential risk after any surgery. Post-operative hemorrhage after TORS has been described and can be life threatening[7]. It is an area of current interest because of the increasing adoption of TORS[8] and the active recruitment to current multi center randomized controlled trials, such as ECOG 3311(NCT01898494)[9] and PATHOS[10]. In open surgical approaches the main feeder vessels to the primary resection are divided and ligated and the defect repaired with a flap. In transoral robotic resections the primary defect is left open to heal by secondary intention.

The aim of this study is to describe our institutional experience of post-operative hemorrhage after TORS. We aim to report the incidence of all hemorrhage episodes, episodes of major hemorrhage and identify predictive factors.

Methods

Patient cohort

Memorial Sloan Kettering Cancer Center institutional review board approval was granted for a retrospective study of all TORS procedures at our institution. All patients receiving a TORS operation were included. Procedures were performed between June 2010 and August 2015. The initial TORS procedures had a staged neck dissection without routine ligation of the external carotid artery. As practice and expertise with TORS evolved, simultaneous neck dissection was performed and ligation of the external carotid artery done. Current practice is now simultaneous neck dissection with routine arterial ligation.

Data collection

The patient record was accessed to record demographics, clinical characteristics, health behaviors, oncologic characteristics, surgical details, outcomes and complications. Staging was recorded according to the American Joint Committee on Cancer Staging Manual 7th Edition[11]. To ensure capture of all possible events, medical notes, telephone correspondence, outside hospital communication and nursing/ allied health professional records were consulted.

Mayo clinic classification

Post-operative hemorrhage was classified using the Mayo Clinic classification system[12] for transoral hemorrhage (See Table 1). This is a scale of 5 categorizes that incorporates the level of intervention required and the short term sequelae of the hemorrhage event.

Minor and emergent hemorrhage

Using the Mayo Clinic classification, normal events, such as brown stained secretions were recorded but not classified as a hemorrhage event for analysis. Hemorrhage events that did not require medical intervention and were self-limiting were within the minor group. Events requiring intervention (groups intermediate, major and severe) were classed as emergent events for analysis.

Statistical analysis

Unadjusted odds ratios of clinical and pathologic factors predictive of hemorrhage were calculated for all events and emergent events using logistic regression. Firth's method was used to eliminate bias in variables with quasi-complete separation[13, 14]. Multivariable analysis was not possible because the number of events was too small to support a robust model. Statistical analysis was performed using SPSS (IBM Company Headquarters, Chicago, IL, USA) and R (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient, tumor and treatment characteristics (Table 2)

Between June 2010 and August 2015 there were 122 procedures that met the inclusion criteria. The majority of patients were male (93, 76.2%) with 47 (38.5%) over 60 years of age. The majority of procedures were indicated for the treatment of a primary tumor, 92 (75.4%).

Tumors were most commonly located in the oropharynx, with 52 (42.6%) in the base of tongue, 56 (45.9%) in the tonsil and 1 (0.8%) in the soft palate. Squamous cell carcinoma was the most common histological diagnosis, accounting for 106 (86.9%) of patients.

Ninety-four (77%) patients had a neck dissection. There were 11 (9%) modified radical neck dissections and 65 (53.3%) selective neck dissections. The size of surgical resection was recorded based on the number of subsites resected. A procedure with more subsites resected demonstrates a more complex resection with higher likelihood of exposing or damaging vital neurovascular structures. There were 44 (36%) resections involving a single subsite, 34 (28%) involving 2 subsites and 44 (36%) involving more than 2 subsites.

Seventy-one (58.2%) patients had a smoking history with 43.4% having more than 10 pack years. Alcohol use was reported in 79.5% of patients with 15.4% drinking more than 30 units a month. The American Society of Anesthesiologists (ASA) physical status classification system[15] was used to grade patients pre-operatively and 33 (27%) were graded either 1 or 2 and 89 (73%) were graded 3 or 4.

Tumor TNM staging

The 7th edition TNM system was used to stage all UADT mucosal tumors. This included 113 tumors. The pathological TNM stages are shown in Table 3. There were 8 T0 resections, 54 T1 tumors, 47 T2 tumors and 4 T3 tumors. There were 35 patients staged as N0, 16 N1, 27 N2a, 33 N2b and 2 N2c.

Incidence of hemorrhage

There were 19 patients (16%) that experienced a post-operative hemorrhage of any severity. Seven patients (6%) had hemorrhage events requiring a return to the operating room. Intermediate, major or severe grade bleeds occurred on 3, 4 and 2 occasions, respectively (1 patients had 3 events). Overall there were 23 hemorrhage events classified as minor to severe.

When did hemorrhage occur?

Figure 1 shows the post-operative day that a bleeding event occurred and when an intervention was required. The median time for post-operative hemorrhage was post-operative day 8. There were 2 unusually late hemorrhage events in this cohort. The first occurred at day 27 after a new cardiac ischemic event requiring antiplatelet and anticoagulation therapy. The patient experiencing a hemorrhage at day 41 had developed a lingual artery aneurysm. This was treated with embolization.

Trend in hemorrhage events

The percentage of hemorrhage events per year varied between 11–20% for all events and 0–11% for emergent events requiring intervention (Figure 2). There is no clear trend in the incidence of hemorrhage events over time.

Patient factors associated with minor and emergent hemorrhage (Table 4)

There were no statistically significant patient factors that correlated with bleeding of all severities combined or with emergent (intermediate, major or severe) events requiring intervention. Time to oral intake trended towards significance for all hemorrhage events. The odds of having a hemorrhage in a patient starting oral feeding after 3 days was 2.7 times greater than in a patient starting oral feeding sooner, ($p=0.070$).

Surgical factors associated with minor and emergent hemorrhage (Table 5)

When examining the extent of resection, the odds of a bleeding event were 2.6 times greater in patients receiving a larger resection, but this was not statistically significant ($p=0.107$). The odds of presenting with an emergent hemorrhage was 5.19 times greater in patients that had a staged neck dissection when compared to patients not receiving a staged neck dissection ($p=0.05$). The odds of presenting with an emergent hemorrhage was 6.67 times greater in patients that did not have arterial ligation when compared to patients not receiving ligation ($p=0.087$); there were no intermediate, major or severe hemorrhage events out of the 36 patients who received transcervical ligation compared to 7 events out of the 85 patients who did not receive ligation.

Outcomes in patients after hemorrhage (See Table 6)

The 2 severe hemorrhage events included 1 patient that received an emergency tracheostomy following a hemorrhage and 1 patient that was successfully resuscitated following cardiopulmonary arrest from hypovolemia shock. Both patients were successfully managed with the first patient being decannulated after the surgical defect had healed and the second patient being successfully resuscitated and having no long term medical sequelae. There were

7 arrest of hemorrhage procedures with embolization being done in 2 cases as an emergency and in a semi elective setting for 1 patient.

Discussion

Hemorrhage following transoral surgery is a serious complication that can be life threatening. Hemorrhage following transoral laser[16] and electrocautery resections has been previously described[12, 17]. With the increasing adoption of TORS in the treatment of selected patients with oropharyngeal cancer [18] it is of major importance to know the incidence and identify predictive factors for this complication.

In 122 TORS procedures at our institution there were 23 bleeding events after 19 operations, an incidence of hemorrhage of 16%. However, hemorrhage requiring a return to the operating room occurred in 7 patients, an incidence of 6%. These figures are quite similar to those reported in the literature as shown in Table 7.

In a questionnaire study by Chia [19], there were seven post-operative deaths with four related to hemorrhage. A postoperative hemorrhage rate of 3.1% (61/2015) was reported from the 45 respondents, with a higher incidence of hemorrhage of 4.5% in surgeons that had performed less than 25 TORS operations. Mandal et al reported a 9.8% post-operative hemorrhage rate[7] after 224 TORS procedures with an 8% rate of severe hemorrhage. Asher et al reported on 147 TORS procedures[20] and found a bleed rate of 7.5% with 6% requiring reoperation. In a French multi-institutional report on TORS[21] a post-operative hemorrhage rate of 18.5% was seen in 178 patients with 16.5% requiring a return to the operating room. Despite this being a serious problem following TORS, it is a complication that is seen in other trans-oral approaches and modalities. A large Mayo clinic study of 906 patients receiving trans oral surgery with TORS, TLM and electrocautery reported a post-operative hemorrhage rate of 5.4% [12]. 20% of the reported bleeds were classified as severe. The hemorrhage rates may be lower in patients treated with TLM. A study on laser resections reported a bleed rate of 1.4% in 701 procedures [17] with hemorrhage classed as life threatening in 1.1%. This lower rate is most likely due to a large number of laryngeal resections as well as the use of laser rather than electrocautery. From our study and other reports analyzing only TORS, it therefore appears that TORS has a higher incidence of post-operative hemorrhage compared with trans oral laser techniques. Whether this is a function of the approach, cutting and cautery method or a reflection that tumors in different anatomical positions are being approached with different techniques cannot currently be answered.

The identification of factors which predict for post-operative hemorrhage is clearly of importance. In our study, there were no statistically significant patient factors correlated with bleeding. Time to oral intake trended towards significances for all hemorrhage events ($p=0.070$). In other studies which report on post-operative TORS hemorrhage [7, 12, 19, 20], no patient factors have been found to predict post-operative hemorrhage.

Importantly, our study did identify surgical factors that were associated with hemorrhage. In our study, the odds of a postoperative bleeding event were 2.6 times greater in patients

receiving a larger resection ($p=0.107$). This has not been shown in TORS before and, although it is not significant in our study, larger resections have been correlated with more complications in open surgery of the head and neck[22]. The odds of presenting with an emergent hemorrhage was 5.19 times greater in patients that had a staged neck dissection when compared to patients not receiving a staged neck dissection ($p=0.05$). In the patients who had a synchronous neck dissection, 57% (36/63) also had ligation of a branch of the external carotid artery. These patients had a reduced odds of presenting with an emergent hemorrhage ($p=0.07$). This suggests it is the impact of arterial ligation rather than the timing of neck dissection which is associated with the lower rate of bleeds in our neck dissection cohort.

Trans-cervical arterial ligation is an area of major interest in the prevention of postoperative TORS hemorrhage. In our cohort there were no hemorrhage events requiring a return to the operating room out of the 36 patients who received trans-cervical ligation compared to the 7 events out of the 85 patients who did not receive ligation. Although this was not statistically significant, this may be due to the small sample size of patients receiving cervical ligation. This finding has also been seen by others[7]. Mandal et al showed that in the 224 patients in their cohort, 33 underwent prophylactic cervical ligation. The frequency of emergent postoperative hemorrhage was lower in the prophylactically ligated group, 3.0% versus 7.3% in the non-ligated group. The 5 patients who experienced a severe hemorrhage had not received prophylactic ligation. In the 10 patients who experienced a major postoperative hemorrhage, only 1 patient received prophylactic ligation.

This data therefore suggests that synchronous neck dissection and ligation of the ECA prevents major hemorrhage events following TORS. This may, therefore, be an important step to prevent post-operative hemorrhage.

Despite the recognized weaknesses of retrospective data collection, this paper highlights hemorrhage as an important risk after TORS and provides reliable data on incidence. It also supports current data that surgical techniques such as simultaneous neck dissection and trans-cervical ligation are important in TORS management.

Conclusion

TORS hemorrhage requiring surgical intervention occurred in 6% patients. Simultaneous neck dissection and ligation of the ECA reduced the odds of an emergent bleed.

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Figure 1.

Graph showing the distribution of hemorrhage events by post-operative day and the timing procedures to arrest hemorrhage

Figure 2.
Graph showing the percentage of hemorrhage and emergent events over time

Table 1

Mayo Clinic classification of transoral hemorrhage

Classification	Description
Normal	Patient noting the presence of blood-tinged mucus, flecks of blood, brown mucus, or red streaks
Minor	Any description of bright red blood or blood clots Resolved without operative management whether or not physician evaluation or hospitalization occurred
Intermediate	Diffuse venous oozing or small arterial source bleeding resulting in operating room evaluation or intervention Managed with monopolar or bipolar cautery
Major	Brisk or copious bleeding requiring operative intervention Managed with transoral or transcervical vessel ligation, or interventional radiology embolization
Severe	Bleeding resulting in life-threatening medical complications such as: Hypoxia/ airway compromise requiring a tracheostomy Cardiopulmonary arrest Hemodynamic instability requiring blood transfusion

Table 2

Demographic, comorbidity and tumor characteristics in transoral robotic surgery cohort

Variable		No. patients	%
Sex	Male	93	76.2
	Female	29	23.8
Age	60 yrs old	75	61.5
	>60 yrs old	47	38.5
Tobacco	Never to less than 1 yr	52	42.6
	1–9.9 yrs	16	13.1
	10–19.9 yrs	16	13.1
	20 yrs	37	30.3
	Unknown	1	
	Never	51	41.8
Alcohol	Ever	71	58.2
	Never, occasional, discontinued use	44	35.8
	1–12 drinks per month	38	30.9
	13–29 drinks per month	19	15.4
	>30 drinks per month	19	15.4
	Unknown	2	1.6
Malignancy	Never	25	20.5
	Ever	91	79.5
	No	87	71.3
	Head and Neck	11	9.0
ASA Grades	Other	24	19.7
	1	1	0.8
	2	32	26.2
	3	83	68.0
Indication	4	6	4.9
	Benign	3	2.4
	Primary	92	75.4
	Secondary	10	8.2
Tumor sites	Relapse	13	10.7
	Revision	4	3.3
	Base of tongue	52	42.6
	Hard Palate	1	0.8
	Larynx	2	1.6
	Nasopharynx	1	0.8
	Parapharyngeal	5	4.1
	Posterior pharyngeal wall	2	1.6
	Soft Palate	1	0.8

Variable		No. patients	%
	Tongue	2	1.6
	Tonsil	56	45.9
Pathology	Squamous Cell Carcinoma	106	86.9
	Salivary	8	6.6
	Thyroid	4	3.3
	Other	4	3.3
Subsites resected	1 Subsite	44	36.0
	2 Subsites	34	27.9
	More than 2 subsites	44	36.0
Neck dissection type	No Neck dissection	28	23.0
	Modified Radical Neck Dissection	11	9.0
	Selective Neck dissection	65	53.3
	Cervical Biopsy	18	14.8

Table 3

TNM classification of mucosal tumors treated with TORS

	N Stage						
T Stage	N0	N1	N2a	N2b	N2c		
T0	0	3	4	1	0		
T1	14	8	15	17	0		
T2	19	5	8	13	2		
T3	2	0	0	2	0		

Patient variables associated with any hemorrhage and emergent (intermediate, major or severe) hemorrhage requiring intervention: table of patient factors.

Table 4

Variable	Group	Any bleed (n=19)	Unadjusted OR (CI)	p value	Emergent bleed (n = 7)	Unadjusted OR (CI)	p value
Age	Age< 60	10/75	Reference	0.391	3/75	Reference	0.308
	Age> 60	9/47	1.54 (0.57–4.12)		4/47	2.23 (0.48–10.45)	
Smoking	No	11/51	Reference	0.127	4/51	Reference	0.404
	Yes	8/71	0.46 (0.17–1.25)		3/71	0.52 (0.11–2.42)	
Subsite	Base of tongue	10/52	Reference	0.868	4/52	Reference	0.854
	Tonsil	9/56	0.80 (0.30–2.17)		3/56	0.68 (0.14–3.19)	
	Other	0/14	0.00 (0.00–6×10 ¹⁶)		0/14	0.00 (0.00–4×10 ¹⁶)	
ASA	1 and 2	5/33	Reference	0.938	1/33	Reference	0.446
	3 and 4	14/89	1.05 (0.34–3.17)		6/89	2.31 (0.27–19.98)	
Time to oral intake	Less than 3 days	6/62	Reference	0.070	2/62	Reference	0.472
	More than 3 days	11/49	2.70 (0.92–7.93)		3/49	1.96 (0.31–12.20)	

(PO- per oral, ASA- American Society of Anesthetists, OR- odds ratio, CI- confidence intervals)

Table 5

Surgical variables associated with any hemorrhage and emergent hemorrhage requiring intervention: table of surgical factors.

Variable	Group	Any bleed (n=19)	Unadjusted OR (CI)	p value	Emergent bleed (n = 7)	Unadjusted OR (CI)	p value
Timing of neck surgery	No neck dissection	2/28	Reference	0.152	1/28	Reference	0.050
	Simultaneous	9/63	2.17 (0.44–10.75)		1/63	0.44 (0.03–7.22)	
	Staged	8/31	4.52 (0.87–23.50)		5/31	5.19 (0.57–47.50)	
Neck dissection	No neck dissection	2/28	Reference	0.177	1/28	Reference	0.580
	Neck dissection	17/94	2.87 (0.62–13.27)		6/94	1.84 (0.21–15.97)	
Subsites resected	1 subsite	5/44	Reference	0.107	2/44	Reference	0.493
	2 subsites	3/34	0.75 (0.17–3.41)		1/34	0.64 (0.06–7.33)	
	> 3 subsites	11/44	2.60 (0.82–8.25)		4/44	2.10 (0.36–12.11)	
Transcervical ligation	Yes	5/36	Reference	0.740	0/36	Reference	0.087
	No	14/86	1.21 (0.40–3.64)		7/86	6.89 (0.8–902) ^a	

(OR- odds ratio, CI- confidence intervals)

^aFirth's method was used to obtain this odds ratio due to quasi-complete separation

Table 6

Outcomes following emergent post TORS hemorrhage

Patient	Intervention	Outcome
T2N0M0 2nd H&N Primary Tonsil	Arrest hemorrhage and embolization	Delayed discharge
T2N0M0 Tonsil Primary	Arrest hemorrhage and tracheostomy Arrest hemorrhage Embolization	Full recovery
T2N1M0 Tonsil Primary	Arrest of hemorrhage and embolization	Cardiac arrest Delayed discharge
T2N0M0 Tonsil Primary	Arrest of hemorrhage	Full recovery
T2N2aM0 BOT Primary	Arrest of hemorrhage	Full recovery
T0N2aM0 BOT Primary	Arrest of hemorrhage	Full recovery
T1N2aM0 BOT Primary	Arrest of hemorrhage	Full recovery

Table 7

Summary of literature on transoral hemorrhage

Author	Year	Technique	Patients	Overall bleed rate (%)	Severe bleed rate (%)
Pollei et al[12]	2013	TLM/TORS/EC	906	5.2	3.6
Salassa et al[17]	2008	TLM	701	1.4	1.1
Mandal et al[7]	2016	TORS	224	9.8	8
Asher et al[20]	2013	TORS	147	7.5	6
Aubry et al[21]	2016	TORS	178	18.5	16.5
Chia et al ^a [19]	2013	TORS	2015	- ^b	3.1

^a Questionnaire survey

^b Minor bleeds not reported