

## The impact of prophylactic external carotid artery ligation on postoperative bleeding after transoral robotic surgery (TORS) for oropharyngeal squamous cell carcinoma ☆



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### ABSTRACT

**Background:** Transoral robotic-assisted surgery (TORS) is increasingly utilized in the treatment of oropharyngeal squamous cell carcinoma (OPSCC). Postoperative bleeding is a significant and potentially fatal complication of TORS. Prophylactic ligation of ipsilateral external carotid artery (ECA) branches is a recognized strategy to reduce postoperative bleeding risk. We examined the incidence and sequelae of postoperative oropharyngeal bleeding with and without routine ECA ligation.

**Methods:** OPSCC patients treated with TORS between 2010 and 2015 with minimum 30 days follow up were included. Clinicopathological data, operative details, and postoperative course were abstracted for analysis. Cases of postoperative bleeding were classified as Minor, Intermediate, Major, and Severe. The incidence and severity of bleeding was compared between patients treated with and without prophylactic ECA ligation.

**Results:** Bleeding after TORS was documented in 13/201 (6.5%) patients. The majority of bleeding episodes were observed among anticoagulated or previously radiated patients. By surgeon preference, 52 patients had prophylactic ECA ligation during neck dissection while the remaining 149 patients did not. There was no significant difference in overall incidence of postoperative bleeding between patients with prophylactic ECA ligation (3/52, 5.8%) and patients without (10/149, 6.7%) [ $p = 0.53$ ]. However, severe bleeding complications (4, 2.0%) were only observed in patients without prophylactic ligation.

**Conclusion:** A small but meaningful risk of bleeding after TORS for OPSCC exists, particularly among anticoagulated or previously radiated patients. Prophylactic ECA ligation did not significantly impact the overall incidence of postoperative bleeding but may reduce the risk of severe (life-threatening) bleeding.

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### Introduction

The incidence of squamous cell carcinoma of the oropharynx (OPSCC) has increased at an alarming rate despite a decline in traditional risk factors [1,2]. This trend is attributed to the human papillomavirus (HPV) [3,4]. The prognosis of patients with HPV-associated OPSCC is significantly improved and, as such, consideration of functional outcomes has become increasingly important [5]. One approach for better tailoring therapies and optimizing long-term functional outcomes is primary treatment via transoral

robotic surgery (TORS). Since being cleared by the Food and Drug Administration (FDA) in late 2009, TORS has emerged as a safe, effective, and increasingly common treatment for tumors of the oropharynx [6–9].

Several studies have demonstrated that TORS is an effective alternative to open surgery. Advantages of TORS may include improved cosmesis, decreased length of hospital stay, a low rate of gastrostomy tube dependence, improved long term preservation of swallowing function, and the potential to deintensify adjuvant therapies if needed [10]. High rates of negative surgical margins have been reported, which correlate well with local disease control [6,11]. Previous studies have examined postoperative complications which include tooth injury, percutaneous endoscopic gastrostomy (PEG) dependency, pharyngocutaneous fistula, tracheotomy, and postoperative bleeding [12,13]. Of these, bleeding is the most

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serious potential complication because of the risk of airway compromise and death. As the application of TORS increases, the number of patients exposed to this risk will also increase [14].

The incidence of postoperative bleeding has been reported in 1.5–13% of TORS cases [12,13,15–17]. Various strategies to reduce the risk of bleeding after TORS have been proposed, including prophylactic ligation of the ipsilateral external carotid artery (ECA) during concomitant neck dissection. The objective of this study was to examine the incidence and sequelae of bleeding after TORS with and without routine ECA ligation.

## Methods

### *Surgical management*

All TORS procedures were performed by one of two surgeons using the da Vinci S and Si Surgical Systems (Intuitive Surgical Inc, Sunnyvale, CA) as previously described [18]. Exposure was achieved using either the Feyh-Kastenbauer retractor or Crowe-Davis retractor. Bovie cautery was used in all cases and titanium surgical clips were used on any exposed vessels. In select cases, retropharyngeal lymph node dissection was performed after extirpation of the primary tumor.

Neck dissection was performed routinely at the time of TORS. Prior to 2013, neither TORS surgeon ligated the ECA at the time of neck dissection. In 2013, one TORS surgeon (NDG) transitioned to routine prophylactic ligation of the ipsilateral ECA during neck dissection in an attempt to eliminate the risk of severe bleeding. This included both participating institutions but excluded patients undergoing simultaneous microvascular reconstruction. Routine ECA ligation was not performed in TORS cases undergoing microvascular reconstruction since the defect and underlying vessels were considered to be protected by the flap. A second TORS surgeon (PEA) continued to perform neck dissections without vessel ligation during the study period. So, selection for ECA ligation was determined by surgeon and not institution. When performed, the ECA was ligated above the level of the superior thyroid artery using silk ligatures, and in some case, also ligated at the distal branch(es) contributing to the primary surgical site. Routine ligation of all the distal branches of the ECA was not performed. Rather, selective ligation of distal branches in addition to the proximal ECA was performed in cases where the anatomy was favorable so as to minimize the risk of creating an intraoperative fistula. Patients taking aspirin were requested to stop its use one week prior to surgery. Those who were taking warfarin were transitioned to an enoxaparin bridge for one week prior to surgery. Postoperative deep venous thrombosis (DVT) prophylaxis with either heparin or enoxaparin was not routinely ordered. Patients were allowed to resume their aspirin or warfarin after discharge from the hospital.

### *Data collection and analyses*

To investigate the impact of prophylactic ECA ligation on the rate of postoperative bleeding a retrospective review was performed of the clinical registry of OPSCC patients treated with TORS between 2010 and 2015 at Oregon Health and Science University (OHSU). The registry was initiated in 2010 and has been maintained prospectively. Additional OPSCC patients treated by the senior author with TORS between 2014 and 2015 at MD Anderson Cancer Center were also included. Patients with a minimum of 30 days follow up were selected for evaluation. Clinicopathological data, operative details, and postoperative course including complications were abstracted from the electronic medical record. Any report of oral bleeding in the postoperative period was included

regardless of the severity. Any bleeding episode confirmed unrelated to TORS was excluded. Patients who underwent simultaneous microvascular free flap reconstruction were excluded. This study was Institutional Review Board approved.

The postoperative period was defined as any bleeding occurring after the patient had left the operating room. Bleeding was classified using the scale developed by Pollei et al. at the Mayo Clinic [19]: “normal” if the patient noted the presence of blood tinged mucus or saliva; “minor” if description included bright red blood or blood clots, but resolved without operative management; “intermediate” if diffuse venous oozing or small arterial source bleeding resulted in operating room (OR) evaluation, managed with cautery; “major” if brisk bleeding required OR management including transoral or transcervical vessel ligation, or interventional radiology (IR) embolization; “severe” if bleeding resulted in life threatening complications including airway compromise requiring tracheostomy or hemodynamic instability requiring blood transfusion.” Cases of bleeding after TORS were examined for potential correlation with risk factors including prior radiation, antiplatelet agent use or anticoagulation in the perioperative setting. Perioperative anticoagulation was defined as the use of aspirin, warfarin, enoxaparin, clopidogrel, or heparin during the week before or after surgery. For those patients who did experience bleeding, sequelae were recorded including need for surgery, transfusion, tracheostomy, and death.

Patients who developed bleeding after TORS were analyzed descriptively. Differences between patients who had prophylactic ECA ligation and those who did not were analyzed using GraphPad (GraphPad Software, La Jolla, CA). The Fischer exact test was used for computing difference in bleeding incidence and the Chi square test was used for comparing differences in bleeding severity. A  $P$  value  $< 0.05$  was considered significant.

## Results

There were 201 patients identified who underwent TORS for OPSCC between 2010 and 2015. The median age of patients undergoing surgery was 60, with a range from 35 to 88. There were 169 (84.1%) male patients and 32 (15.9%) female patients. Thirty-four (16.9%) patients had received previous radiation to the head and neck and 71 (35.3%) received perioperative anticoagulation (see Fig. 1). Bleeding after TORS for OPSCC was documented in 13 (6.5%) patients.

Fifty-two patients had prophylactic ECA ligation during neck dissection while the remaining 149 patients did not. The overall bleeding rates were similar between surgeons [ $p = 0.57$ ]. There was no significant difference in the incidence of postoperative bleeding between patients who had prophylactic ECA ligation (3/52, 5.8%) and patients who did not (10/149, 6.7%) [ $p = 1.0$ ]. Likewise, there was no significant difference in the severity of bleeding complications between patients receiving prophylactic ECA ligation and those who did not [ $p = 0.53$ ]. However, “Severe” bleeding complications (4, 2.0%) were only observed in patients who did not have prophylactic ECA ligation [ $p = 0.23$ , Fig. 2].

All patients who experienced bleeding after TORS for OPSCC are detailed in Tables 1–4. The median time to bleeding was 5 (range: 0–33) days. Two (15.4%) of the patients had bleeding classified as “Minor” which was observed without intervention and without sequelae (Table 1). Three (23.1%) of the patients had “intermediate” bleeding episodes managed in the OR (Table 2). Four (30.8%) bleeding episodes were classified as “Major” and included management by transoral or transcervical vessel ligation in the OR or by interventional radiology (Table 3).

One patient who experienced “Major” bleeding was found to have a bleeding source from the contralateral ECA distribution.

	Postoperative Bleeding (n=13)	No Postoperative Bleeding (n=188)	P value
Age 60 or greater, (n=106)	9, 69%	97, 52%	0.78
Male gender, (n=129)	12, 92%	117, 62%	0.002
Prior radiation, (n=34)	4, 31%	30, 16%	0.07
Perioperative anticoagulation, (n=71)	6, 46%	65, 35%	0.56
First 50 cases per surgeon, (n=100)	9, 69%	91, 48%	0.28

Comparison of selected variables between patients who experienced postoperative bleeding and those who did not after transoral robotic surgery (TORS).

Fig. 1. Comparison of selected variables between patients who experienced postoperative bleeding and those who did not after transoral robotic surgery (TORS).

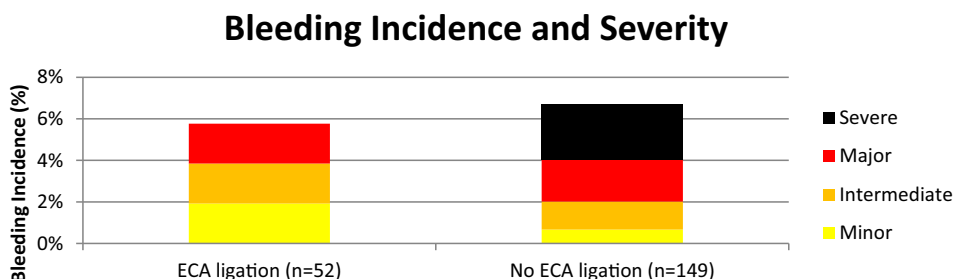


Fig. 2. The overall bleeding incidence was not significantly different between patients ligated (5.8%) and not ligated (6.7%) after transoral robotic surgery (TORS). [p = 0.53] However, severe bleeding complications (4, 2.7%) were only observed in patients who did not undergo prophylactic ECA ligation. [p = 0.23] Minor bleeding = orange, Intermediate bleeding = green, Major bleeding = yellow, Severe bleeding = red. ECA = external carotid artery. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Table 1

Details of patients who experienced minor postoperative bleeding after transoral robotic surgery (TORS). ASA = aspirin. ECA = external carotid artery, POD = postoperative day, BOT = base of tongue.

#	First 50 cases	Prior radiation	Anti-coagulation	ECA ligation	Primary site	POD	Details	Sequelae
1	n	n	ASA	y	BOT	2	Blood streaks in saliva, observation	None
2	y	n	Warfarin, ASA	n	Tonsil	5	Clot in tonsillar fossa, observation	None

This patient had a history of radiation treatment to the head and neck. He was taken to the operating room twice within a week of TORS for suspected arterial bleeding despite having undergone prophylactic ipsilateral ECA ligation. A computed tomography (CT) angiogram was performed after second examination under anesthesia without identification of a bleeding source. The CT angiogram showed an aberrant communication from the dorsal branch of the contralateral lingual artery. This vessel was

selectively embolized by IR without further bleeding or sequelae. This case may not be representative of the typical TORS patient given the history of radiation and aberrant anatomy. However, the utility of ECA ligation in this study was analyzed on an intent-to-treat basis and this case was included accordingly.

Four (30.8%) of the patients who had bleeding complications experienced bleeding that was classified as “Severe” (Table 4). Three of the patients required urgent tracheotomy to secure the

**Table 2**  
Details of patients who experienced intermediate postoperative bleeding after transoral robotic surgery (TORS). ECA = external carotid artery, POD = postoperative day, OR = operating room, BOT = base of tongue, IR = interventional radiology.

#	First 50 cases	Prior radiation	Anti-coagulation	ECA ligation	Primary site	POD	Details	Sequelae
1	n	y	Warfarin, enoxaparin	y	BOT	3	No bleeding source identified in OR; imaging showed communicating artery from contralateral ECA	None
2	y	y	n	n	BOT	8	Controlled with cautery in OR	None
3	y	y	Warfarin	n	BOT	15	Controlled with cautery in OR	None

**Table 3**  
Details of patients who experienced major postoperative bleeding after transoral robotic surgery (TORS). ASA = aspirin. ECA = external carotid artery, POD = postoperative day, BOT = base of tongue, OR = operating room, IR = interventional radiology.

#	First 50 cases	Prior radiation	Anti-coagulation	ECA ligation	Primary site	POD	Details	Sequelae
1	n	n	n	y	Tonsil	5	Controlled with cautery and suture ligation in OR	None
2	y	n	n	n	Tonsil	1	Controlled with suture ligation in OR	None
3	y	n	ASA	n	BOT	11	IR embolization of lingual artery bleed	None
4	n	n	n	n	BOT	7	IR embolization of lingual artery bleed	None

**Table 4**  
Details of patients who experienced severe postoperative bleeding after transoral robotic surgery (TORS). ASA = aspirin. ECA = external carotid artery, POD = postoperative day, OR = operating room, ED = emergency department, IR = interventional radiology, pRBCs = packed red blood cells.

#	First 50 cases	Prior radiation	Anti-coagulation	ECA ligation	Primary site	POD	Details	Sequelae
1	y	n	n	n	Tonsil	5	Unable to intubate secondary to bleeding; no bleeding source identified in OR after airway secured	Tracheostomy
2	y	y	n	n	Tonsil	30	Urgent tracheotomy performed at outside ED; IR embolization of ECA and hemoclip in OR	Tracheostomy
3	n	n	ASA	n	BOT	4	Unable to intubate secondary to bleeding; controlled with cautery in OR	Tracheostomy
4	y	n	n	n	Tonsil	2	Controlled with ligation of ECA in OR, transfused 3 units pRBCs	Transfusion

airway during bleeding after TORS, one performed at an outside hospital prior to transfer. Both urgent tracheotomies performed at OHSU were because of difficulty with intubation due to bleeding.

Two patients who died of bleeding deemed unrelated to TORS are mentioned here but were excluded from the analysis. One patient died 4 days after TORS for a T1 base of tongue OPSCC from a confirmed upper gastrointestinal bleed. The patient developed massive hematemesis before being discharged from the hospital but was unable to be resuscitated. A post mortem examination demonstrated large gastric ulcers as the source of bleeding and no evidence of bleeding from the operative site. A second patient suffered catastrophic oral bleeding 21 days after TORS as a complication of percutaneous gastrostomy tube placement. The patient developed an anoxic brain injury from the bleeding episode and supportive care was withdrawn per the family's request. A post mortem examination was not performed. However, bedside laryngoscopy after initial resuscitation noted no bleeding source from the operative site. Both of these cases were considered unrelated to TORS.

## Discussion

There are several factors that can contribute to the risk of bleeding after TORS. The surgical defect is usually left to granulate after surgery, and as with a simple tonsillectomy, bleeding can occur at the free mucosal edge and areas of dislodgment of the wound eschar. Bleeding in the postoperative setting can additionally occur from small tears in the mucosa, venous plexus, or end branches of named arteries. Similarly, surgical clips placed during TORS may not be able to withstand the stress of swallowing and saliva. This is particularly true after exposure to prior radiation where healing

can be dramatically delayed. Patients who are anticoagulated are also at increased risk of clinically meaningful bleeding after TORS [16]. Finally, the arterial and vascular anatomy of the oropharynx is complex and can be tortuous [19]. A thorough understanding of this anatomy as viewed from a transoral approach requires experience that is often not provided during surgical training. So experience of the surgeon is also an important factor in the risk of bleeding after TORS [12].

The consequences of bleeding after TORS can be dire. Our preference is that any report of bleeding after TORS warrants a thorough investigation including examination with a flexible fiberoptic laryngoscope. Patients with self-limiting bleeding after TORS are usually observed in the hospital for a defined period of time as an initial (sentinel) bleeding episode may foreshadow a more severe bleeding event. At the discretion of the treating surgeon, some patients with self-limiting bleeding after TORS will be managed more aggressively, either in the operating room or via interventional radiology. Of course, active bleeding after TORS requires some form of immediate intervention. Bleeding can occasionally be high volume, necessitating immediate intubation or tracheostomy for airway control. In addition to increasing the length of stay and cost of hospitalizations, bleeding after TORS can be psychologically traumatizing to patients and family members. Catastrophic bleeding after TORS, including death, is possible. Thus, every attempt should be made to minimize this risk, especially given the otherwise excellent prognosis of patients with HPV-associated OPSCC amenable to TORS.

There are a variety of ways to reduce the risk of bleeding after TORS. Of these, patient selection is paramount. Experienced TORS surgeons will select patients where the size of the defect can be minimized (small primary tumors favored) and the exposure maximized. Careful, coordinated technique during surgery, including the placement of surgical clips, is also critical. The selec-

Study	Technique	Number of Cases	Transcervical Ligation, n (%)	Non-Ligated Bleed Rate, %	Ligated Bleed Rate, %	Details of Ligation Method
Asher et al (2013)	TORS	147	0 (0.0)	7.5		Ligation not performed
Pollei et al (2013)	TLM, TORS	906	134 (15.6*)	5.5	6.7	Lingual artery (80/134), facial (71/134), superior thyroid (37/134), ascending pharyngeal (12/134), ECA (28/134)
Laccourreye et al (2014)	Direct, TLM, TORS	514	3, (0.6)	3.6	0.0	Lingual artery (3/514)
Mandal et al (2015)	TORS	224	33 (14.7)	9.9	9.1	ECA (22/33), lingual (3/33), facial (3/33), combination of lingual and ECA (5/33)
Gleysteen et al (2017)	TORS	201	52 (25.9)	6.7	5.8	ECA ligated above level of superior thyroid artery with selective ligation of distal branches (52/201)

Comparison of studies investigating effect of external carotid artery ligation on postoperative bleeding rate after TORS or TLM. \*Only 860/906 charts mentioned vessel ligation. ECA= external carotid artery, TORS= transoral robotic surgery,

**Fig. 3.** Comparison of studies investigating effect of external carotid artery ligation on postoperative bleeding rate after TORS or TLM. \*Only 860/906 charts mentioned vessel ligation. ECA = external carotid artery, TORS = transoral robotic surgery.

tive use of flap reconstructions during surgery and perioperative management of anticoagulation can also help minimize the incidence and severity of bleeding after TORS. Many experienced TORS surgeons have adopted additional techniques to reduce the risk of bleeding including ligation of branches of the ipsilateral ECA. In this study, we aimed to evaluate the utility of routine prophylactic ipsilateral ECA ligation on bleeding after TORS. Routine ECA ligation was not routinely performed in TORS cases undergoing microvascular reconstruction since the defect and underlying vessels were considered to be protected by the flap.

There have been several retrospective studies of postoperative bleeding after transoral surgery for OPSCC. Asher et al. [16] noted an overall postoperative bleeding rate of 7.5% after TORS, increasing to 17% in patients taking antithrombotic medications. Patients undergoing salvage surgery had a slightly higher rate of bleeding (10.3%) than primary surgery (6.8%), though this difference was not statistically significant. Chia et al. [12] used an electronic survey to query TORS surgeons throughout the United States to assess postoperative complications. Forty-five TORS surgeons voluntarily reported a total of 2015 transoral robotic cases with an overall postoperative bleeding rate of 3.1%. Six (0.3%) deaths were reported within 30 days of TORS, all from postoperative hemorrhage. Pollei et al. [20] reviewed 906 cases of OPSCC treated with transoral surgery, including TORS and transoral laser microsurgery (TLM). They reported an overall postoperative bleeding rate of 5.4%. In 15.6% of their cases, they performed selective ligation of branches of the ECA in the neck, typically those directly involved in the resection bed (i.e. lingual and facial arteries). The authors observed no difference in the overall rate of bleeding with selective vessel ligation. They did report a decreased incidence of severe bleeding after vessel ligation, but the difference was not statistically significant. Laccourreye et al. [15] retrospectively reviewed a cohort of 514 cancers of the lateral oropharynx that underwent transoral resection. The overall incidence of postoperative bleeding was 3.6%. Although robotic assistance was used in only 7.3% of cases in that series, the incidence of bleeding after TORS was significantly higher (13.1%,  $p = 0.009$ ). Importantly, in that series the TORS cases included were the first 38 performed at the institution, well within the known learning curve for TORS. Anecdotally, the authors noted no bleeding in the 3 (7.8%) TORS cases that included ligation of the ipsilateral lingual artery during neck dissection.

Most recently, Mandal et al. [21] reviewed 224 consecutive patients who underwent TORS, including those with benign indications, and reported a postoperative hemorrhage rate of 9.8%. Thirty-three of the patients in their cohort had prophylactic arterial ligation of either the ECA or one of its branches. While there was no significant difference in bleeding incidence between the ligated patients (9.1%) and the non-ligated (9.9%) [ $p = 1.0$ ], they observed that all the patients with “severe” bleeding were in the non-ligated group [ $p = 0.7$ ].

In our study, we observed bleeding in 6.5% of patients. Our results are within the reported range of 1.5–13% of TORS cases [12,13,15–17]. Similar to previous reports, we also observed a higher number of bleeding episodes after TORS in patients who were anticoagulated and patients who were treated early in our TORS experience (<50 cases for each surgeon). We also noted more bleeding episodes, and delayed bleeding episodes, in patients with a history of radiation exposure. We observed no significant difference in the overall incidence of postoperative bleeding between patients who had prophylactic ECA ligation and those who did not. This is not surprising since the majority of bleeding episodes likely represented small-volume venous bleeding from the mucosal edges or soft-tissue defect.

We did not observe a statistically significant difference in the severity of bleeding after TORS, though similar to Mandal et al. [21] there were no cases of “Severe” bleeding in patients who had prophylactic ECA ligation. Both studies were retrospective and therefore not powered to detect small differences in uncommon events. Even so, the data mirror the broader experience with TLM [20]. We believe that prophylactic ECA ligation may reduce the risk of “Severe” bleeding after TORS by minimizing the possibility of high-volume arterial bleeding. This study represents the results of ligating the proximal ECA above the superior thyroid artery with or without selective distal branches of the ECA. This redundant ligation approach was selected to eliminate the risk of failure to ligate the correct feeding artery because of tortuous vascular anatomy while minimizing the risk of creating a fistula. The results of our approach are compared to the existing relevant literature in Fig. 3. In general, ECA ligation strategies have only become more uniformly accepted in recent years. So the majority of the existing data includes patients treated without routine ECA ligation.

Unfortunately, not all bleeding after TORS is preventable. One of our cases of bleeding after TORS highlights the complex vascular anatomy of the oropharynx. In this case, the patient developed bleeding from a contralateral aberrant communication from the dorsal branch of the contralateral lingual artery. This would not have been prevented by prophylactic ipsilateral ECA ligation. Bleeding can also come from sources distal to the pharynx. In our series, we noted two deaths from bleeding unrelated to TORS, including one death from an acute upper gastrointestinal bleed and one death after percutaneous gastrostomy.

The potential benefits of prophylactic ipsilateral ECA ligation must be weighed against the potential for harm. There were no complications attributable to ipsilateral ECA ligation noted in our study. For example, there were no reported neurologic changes or delayed wound healing in patients who had ipsilateral ECA ligation. The resilience of the oropharynx to ipsilateral ECA ligation is likely attributable to the redundant vascular supply and possible retrograde flow to arteries distal to ligation. However, the retrospective nature of the investigation may underestimate more subtle deleterious effects of ipsilateral ECA ligation. There is also a theoretic concern that ECA ligation could impair the efficiency of postoperative radiation therapy by increasing tumor site hypoxia. Finally, ipsilateral ECA ligation precludes the use of arterial embolization if postoperative bleeding occurs [15]. Given the current data available from our study and prior reports, the risk-benefit ratio favors the routine use of prophylactic ipsilateral ECA ligation to minimize or eliminate the risk of “Severe” bleeding after TORS.

#### Conflict of interest statement

Dr. Gross has served as an unpaid consultant for Intuitive Surgical and MedRobotics. No other authors have any relevant conflicts of interest to disclose.

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