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Review Article

Esophageal Stent Placement for Therapeutic and Palliative Indications

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Introduction:

The use of esophageal stents has evolved as a useful adjust in the treatment of complex esophageal disorders. Alternative therapies, such as esophagectomy, carry a high risk of morbidity and mortality[1].There are studies which document well the expected results of self-expanding metal stents (SEMS)[2], however data are lacking which specifically examine complications and outcomes as compared to the primary indication for stent placement. We thus sought to review our own stenting experience to determine if there is a correlation between the primary indication with regards to post-procedural expectations, outcomes and complications.

Methods:

Wereviewed all patients operated by the UTHSCSA Thoracic Surgery Department between 2006 and 2014 for stent placement, revision or removal. This restrospective chart review was approved by the Institutional Review Board (IRB) #12-083H,and informed consent was waived.De-identified Data was collected from the electronic medical records maintained by University Hospital and Christus Santa Rosa Hospital. Age, gender, preoperative esophageal diagnoses, type of stent placed, duration of stent placement, number and type of re-interventions, complications and overall outcomes were gathered.

Indications for stent placement were divided into two groups: Palliative and Therapeutic. Palliative stents were placed with an ultimate goal of *alleviating symptoms* associated with the primary esophageal diagnosis (dysphagia, obstruction, etc). This category included malignant strictures, and malignant trachea-esophageal fistula (TEF). Therapeutic stents were placed with an *intent-to-treat* the primary esophageal diagnosis. This category included benign and postoperative strictures, esophageal leaks and perforations, benign tracheo-esophageal fistulas and achalasia.

We studied any re-intervention after stent placement, including all stent revisions, replacements, dilations, and unplanned or early removal. The following complications related to stentswere identified: recurrent stricture, intolerance of stent (including pain and respiratory symptoms), migration, perforation, persistent leak, obstruction, and hemorrhage. Complications were then further categorized into major and minor complications. Major complications included death and life-threatening complications such as hemorrhage or perforation. Less significant adverse events, such as migration or stent intolerance, were considered minor.

Overall patient outcomes were classified as successful or unsuccessful, based on the following criteria: A successful outcome would depict a patient for whom interventions accomplished the desired goal, whether this goal was palliation or treatment. Successful outcomes may have required several interventions, and all attempts (placements, removals, revisions) were included when grading the overall patient outcome. If there was a major, life-threatening complication *or* the patient's primary esophageal diagnosis was not treated or palliated by the interventions, the patient outcome was considered unsuccessful.

Statistical analysis was then performed on the data collected. Descriptive statistics were used to summarize the

data. The differences between the groups were analyzed using Fisher's Exact test and t-test.A p-value < 0.05 was considered statistically significant.

Results:

Sixty-seven patients were treated for esophageal diagnoses with stent interventions within the UTHSCSA system between 2006 and 2014. A total of 94 stents were placed, revised or removed within this time period. All interventions were performed by the UTHSCSA Thoracic Surgery department, which included two primary surgeons on faculty at that time who oversaw all procedures and patient care.

Forty-four percent (n =29) of the patients had 34 stentsplaced for palliative indications. The primary esophageal diagnoses for palliative stent placement were malignant esophageal strictures for 32 stents, and malignant TEF for two stents.Conversely, fifty-six percent of the patients (n = 38) underwent 60 total therapeutic stent interventions (64% of all stents placed). The indications for therapeutic stentswere as follows: benign stricture (n = 20), perforation (n = 15), postoperative leak (n =14), postoperative stricture (n = 6), tracheoesophageal fistula (n =3), and achalasia (n = 2).

In reviewing all 94 stent interventions, the largest overall indication was malignant stricture (n= 29), which made up 31% of all procedures, and was followed by benign strictures (n =19), esophageal perforation (n = 15), and postoperative anastomotic leak (n =14) or stricture (n =10).

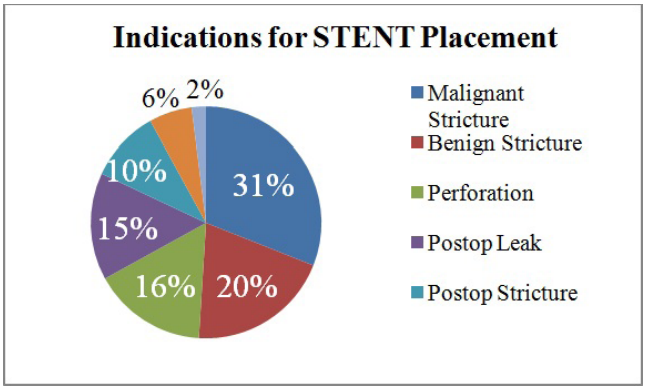

Figure 1: Indications for Stent Placement.

The most common complication within the Palliative group was stent migration (n=6), followed by recurrent stricture (n = 4), intolerance (n=1), stent obstruction (n=1), perforation (n =1) and hematemesis (n =1). There were two major complications, perforation and hematemesis (due to aorto-esophageal fistula), and both of these patients died with one death in the perioperative period as defined by STS.Within the Therapeutic group, the most common complication was also migration (n =28), followed by persistent leak/TEF (n =8), intolerance (n =7), stent obstruction (3), recurrent stricture (n =2) and perforation (n =1). There were two major complications (perforation, and persistent leak leading to sepsis) and both patients lived through the perioperative period. Overall, the most common complication encountered was stent migration (n=34). Overall, the risk of any complication was 67% in all stents placed. This was lower in the palliative group as compared to the therapeutic group (41% versus 72%, p = 0.0046).

More patients within the therapeutic group required subsequent interventions. Within the palliative cohort of 29 patients, there were 8 patients(28%) who required repeated interventions (replacements, unplanned removal and repositioning).Of these 8 patients, 5 had one repeat intervention, and 3 required multiple interventions. When averaged per patient, 1.2 stents per patient were placed for palliation. Conversely, of the 38 patients who had stents placed for therapeutic indications, there were 46 reinterventions in 19 patients (50%). Of these 19 patients who required repeated interventions, 10 had one intervention while 9 had more than one intervention. The highest number of encounters for any one patient was eight encounters, and this included placements, multiple adjustments to positioning, and removals. When averaged per patient, the total number of stents placed was 1.6 per patient.

Overall, 60% of patients who had esophageal stents placed had their primary esophageal diagnosis successfully treated without a major complication. In turn, 33% of patients had an unsuccessful outcome, and 7% of patients were lost to follow up. We did not have follow up information for five patients, and all of these were within the palliative group. Of the remaining 24 patients, 75% (n =18) had successful palliation of symptoms without a major complication, and 25% patients did not (n = 6). For the 38 patients who had stents placed for therapeutic interventions, there were 22 successful outcomes (58%), and 16 unsuccessful outcomes (42%). We had follow up on all of these patients. The difference between the two groups was not statistically significant with p = 0.19.

	Palliative	Therapeutic	p-value (Fischer's Exact Test)
Patients	29	38	
Stents	34	60	
Total Complications/ Stents Placed	14/34 (41%)	43/60 (72%)	0.0046*
Stent Migration/ Stents Placed	6/34 (18%)	28/60 (46%)	0.0069*
Major Complications/ Stents Placed	2/34 (5.8%)	2/60 (3.6%)	0.62
Major Complications/ Patients Stented	2/29 (7%)	2/38 (5.2%)	1.00
Repeat Intervention/ Patients Stented	8/29 (28%)	19/38 (50%)	0.081
Known successful Outcome/ Patients Stented	18/24 (75%)	22/38 (58%)	0.19

Table 1: Differences between palliative and therapeutic groups.

Discussion

In general, stenting was more likely to be successful within the palliative group.There is a large range of reported ranges of success (between 44-85%), with varying definitions of exactly what designated clinical success[3, 4].To our knowledge, this

study is the first to suggest a correlation between the primary indication for stent placement with regards to expectations, outcomes and complications.

The risk of any complication was 67% in all stents placed, but this was higher in the therapeutic group and statistically significant (72% versus 41%, p = 0.0046). This compares favorably with open conventional esophagectomy where the major morbidity rate ranges up to 50%, with the most common complications being respiratory failure or pneumonia[5].It should be noted, however, that most stent complications were minor with the most common being stent migration (43% overall). Migration occurred in therapeutic stents more frequently than the palliative stents (46% versus 18%, p = 0.0069). This particular difference between the groups may be related to the condition of the esophagus itself. We suggest that migration occurs more frequently in a normal or dilated esophagus as may be the case for a leak, perforation or TEF, than in a strictured esophagus where an hourglass figure is often present surrounding the stricture and holding the stent in place. Similarly, we noted the rate of re-intervention was higher in the therapeutic group, and that these patients were also more likely to require more than one additional intervention. It is important to mention that although there was a higher rate of migration within the therapeutic group, the majority of these patients still had a successful outcome.

There with four major complications occurring in 94 stent placements (4%), and did not reach statistical significance when differences were compared between the palliative or therapeutic stents. The four major complications also included two known perioperative deaths (2.9% of patients) which were both in the palliative group. One death was due to a perforation of a very tight stricture in a terminal man with pulmonary hypertension and a squamous carcinoma that obstructed even the passage of saliva. The other case involved possible stent erosion into the descending aorta, although imaging and presentation made it impossible to determine if the patient's esophageal cancer itself had progressed or if the stent accelerated his death. The risk of traditional esophagectomy mortality rates vary across literature, ranging from 3-22% operative mortality, and representing one of the highest risk surgeries performed in modern day[1]. In one study reviewing a prospective cohort of 1775 esophagectomy VA, 30-day mortality was estimated at 9.8%[5].It is important to remember that up to 50% of esophageal cancer patients are diagnosed at late stage[1], and thus quality of life becomes a major concern when no potential cure may be offered. Along those lines, one limitation of our study was that some of the palliative patients were lost to follow up. One can surmise that these patients died as a result of their underlying esophageal cancer, and were satisfied with their stent or likely would have returned, but obviously this would be only an assumption and thus these patients were not included when determining outcomes.

In closing, the most valuable aspect of this retrospective reviewis its use as a tool to guide discussions of potential outcomes and morbidities, based on therapeutic versus palliative indications. Stents carry acceptable and relatively minor complications when compared to complex, reconstructive esophageal surgery. Despite the possibility of multiple interventions, reasonable success can be expected. Additional interventions and increased complications, particularly stent migration, may be expected for therapeutic stents. Categorizing stent placement as palliative or therapeutic may help guide preoperative counseling and develop reasonable post-procedural expectations.

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