# STSA WEBINAR

SCIENTIFIC PAPERS

Thursday, November 5, 2020

4:00 p.m. – 6:00 p.m. ET

# 1. Experience with 100 patients with COVID-19 and Severe Pulmonary Compromise treated with Extracorporeal Membrane Oxygenation (Adult Cardiac)

## *Please note:*

## The accepted abstract below describes 46 consecutive patients; however, the presentation has been updated to include 100 patients.

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**Objectives:** The role of extracorporeal membrane oxygenation (ECMO) is uncertain in the management of severely ill patients with COVID-19 who develop acute respiratory and cardiac compromise refractory to conventional therapy. The purpose of this manuscript is to review our clinical experience in 46 patients with confirmed COVID-19 treated with ECMO.

**Methods:** A multi-institutional database was created and utilized to assess all patients who were supported with ECMO at 10 institutions. Data captured included patient characteristics, pre-COVID-19 risk factors and comorbidities, confirmation of COVID-19 diagnosis, features of ECMO support, specific medications utilized in an attempt to treat COVID-19, and short-term outcomes through hospital discharge. This analysis includes all patients with COVID-19 supported with ECMO at these 10 hospitals, with an analytic window starting March 17, 2020 when our first COVID-19 patient was placed on ECMO, and ending April 16, 2020. Potential differences by mortality group were assessed using chi-square and Fisher's exact tests in categorical variables and Kruskal-Wallis rank sum tests and Welch's ANOVA in continuous variables.

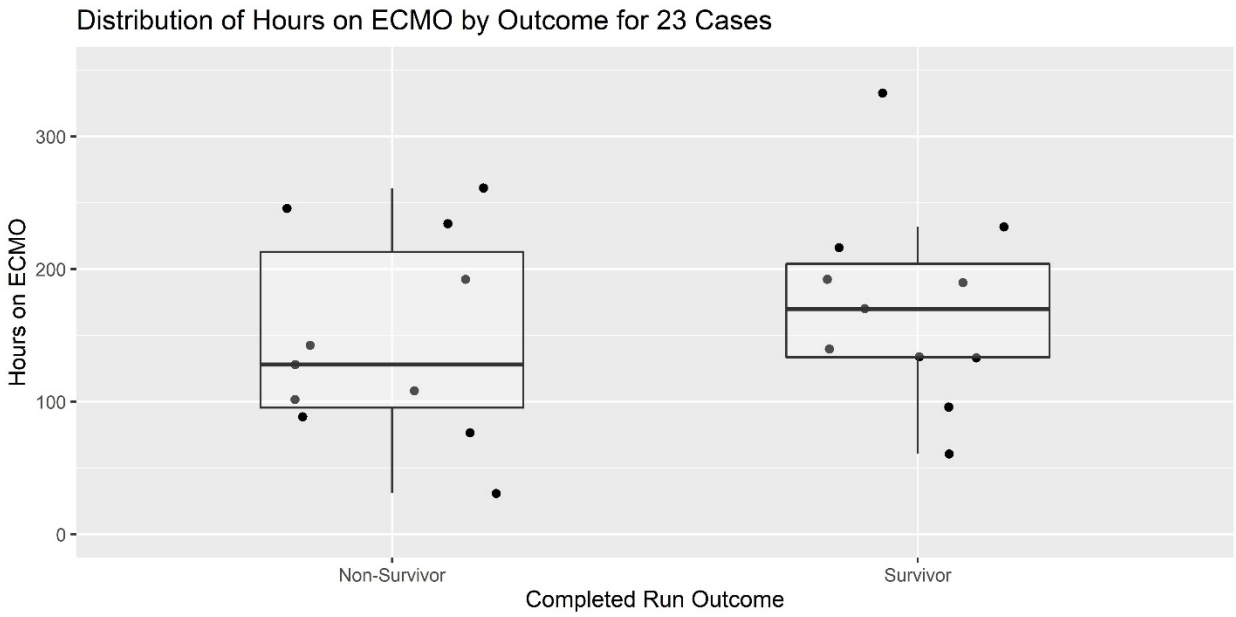
**Results:** During the 31 days of this study, 46 consecutive patients with COVID-19 were placed on ECMO at 10 different hospitals. As of the time of analysis, 23 remain on ECMO, 11 died prior to or shortly after decannulation, and 12 are alive after removal from ECMO. Of 12 survivors after separation from ECMO, 9 are extubated and 2 are discharged from the hospital. Five patients were supported with partial or complete veno-arterial ECMO: three have died and 2 remain on ECMO. All 12 survivors were supported with only veno-venous ECMO.

Of 19 patients receiving only veno-venous ECMO and separated from ECMO, 12 (63%) survive. Of 23 patients who have been separated from ECMO, 12/12 survivors (100%) were treated with only venovenous ECMO while only 7/11 (64%) of non-survivors were treated with only veno-venous ECMO ($p = 0.037$).

Adjunctive medication in the 12 surviving patients while on ECMO was as follows: 6 received antiviral medications (Remdesivir), 5 received intravenous steroids, 4 received hydroxychloroquine, and 3 received anti-interleukin-6-receptor monoclonal antibodies (Tocilizumab or Sarilumab).

**Conclusions:** An analysis of 46 COVID-19 patients with severe pulmonary compromise supported with ECMO suggests that ECMO may play a useful role in salvaging select critically ill patients with COVID-19. Survival of decannulated patients receiving only veno-venous ECMO is 63%, and all survivors received only veno-venous ECMO. Complete data will be available about the remaining patients currently ECMO by the time of the 2020 STSA meeting.

| Variable | Successful Wean from ECMO | Mortality on ECMO | p-value |
|---|---|---|---|
| Number | 12 | 11 | |
| Days from COVID Diagnosis to Intubation (mean (SD)) | 3.50 (3.24) | 1.50 (1.00) | 0.259 |
| Days from COVID Diagnosis to Intubation (median [IQR]) | 2.00 [1.00, 4.75] | 1.00 [1.00, 1.50] | 0.272 |
| Days from Intubation to Cannulation (mean (SD)) | 3.30 (2.21) | 4.00 (2.74) | 0.601 |
| Days from Intubation to Cannulation (median [IQR]) | 3.00 [1.25, 4.75] | 4.00 [3.00, 6.00] | 0.621 |
| Days on ECMO (mean (SD)) | 8.50 (4.62) | 6.55 (3.05) | 0.249 |
| Days on ECMO (median [IQR]) | 8.00 [6.00, 9.25] | 6.00 [4.50, 9.00] | 0.32 |
| Hours on ECMO (mean (SD)) | 197.25 (110.96) | 146.45 (76.18) | 0.219 |
| Hours on ECMO (median [IQR]) | 180.00 [133.75, 220.00] | 128.00 [95.50, 213.00] | 0.34 |
| Age (mean (SD)) | 50.00 (13.25) | 55.45 (12.83) | 0.328 |
| Age (median [IQR]) | 51.50 [43.75, 57.50] | 56.00 [44.00, 64.00] | 0.389 |
| Gender (Count (%)): Female | 6 (50.0) | 2 (18.2) | 0.193 |
| Cancer (Count (%)) | 1 (8.3) | 1 (9.1) | 1 |
| Diabetes (Count (%)) | 2 (16.7) | 5 (45.5) | 0.193 |
| Heart Disease (Count (%)) | 0 (0.0) | 1 (9.1) | 0.478 |
| Obesity (Count (%)) | 6 (50.0) | 6 (54.5) | 1 |
| Asthma (Count (%)) | 3 (25.0) | 1 (9.1) | 0.59 |
| Proned Before ECMO (Count (%)) | 11 (91.7) | 5 (45.5) | 0.119 |
| CVVH or CRRT Used (Count (%)) | 4 (33.3) | 5 (45.5) | 0.409 |
| ECMO Type = Veno-venous (Count (%)) | 12 (100.0) | 7 (63.6) | 0.037 |
| Anticoagulation = Heparin (Count (%)) | 12 (100.0) | 9 (81.8) | 0.421 |
| Anticoagulation = Argatroban (Count (%)) | 0 (0.0) | 2 (18.2) | |
| Anti-Viral Medication (Count (%)) | 6 (50.0) | 2 (18.2) | 1 |
| Intravenous Steroids (Count (%)) | 5 (41.7) | 1 (9.1) | 0.905 |
| Hydroxychloroquine (Count (%)) | 4 (33.3) | 2 (18.2) | 1 |
| Anti-Interleukin-6 receptor monoclonal antibodies (Count (%)) | 3 (25.0) | 0 (0.0) | 0.494 |


Distribution of Hours on ECMO by Outcome for 23 Cases
Hours on ECMO
300
200
100
0
Non-Survivor
Survivor
Completed Run Outcome

## 2. Sequential Staging of Univentricular Palliation Within a Single Hospitalization (Congenital)

**Authors: Ram Kumar Subramanyan**, Brandi Scully, Katherine Giuliano, Dylan Thibault, Kevin Hill, Karen Chiswell, Meena Nathan, James St. Louis, David Vener, Jeffrey Jacobs, Marshall Jacobs

**Presenter Institution(s):** *Children's Hospital Los Angeles, University of Southern California, Los Angeles, CA*

**Objectives:** Some neonates with functionally univentricular hearts remain hospitalized (either for reasons of medical or social necessity or programmatic preference) after the first stage of single ventricle palliation, until ready for a planned second stage procedure. We sought to describe frequency of this practice, variability over time and across centers, and outcomes for these patients.

**Methods:** Using the STS Congenital Heart Surgery Database (01/2010-06/2018), we identified patients undergoing either one of two specific scenarios of staged single ventricle palliation during the same hospitalization: 1) Norwood operation followed by any superior cavopulmonary anastomosis (SCPA), 2) Hybrid Stage I palliation followed by Norwood operation. We evaluated preoperative characteristics and outcomes for patients managed using each of these “same hospitalization” scenarios. To assess variability of practice across centers, we quantified, for each center, the fraction of patients with initial Norwood or Hybrid Stage 1 who fell into these scenarios.

**Results:** Following index Norwood operation, 7.1% (417/5880) stayed in hospital until SCPA (scenario 1). Following index Hybrid Stage I, 18.0% (204/1132) stayed in hospital until Norwood (scenario 2). The proportion of patients managed by each of these specific “staged and kept hospitalized” scenarios varied widely across centers (Figure). For both scenarios, the number of patients hospitalized through a second stage of palliation increased over time (Combined 6.3% for 2010-2013 vs 12.3% for 2014-2018, $P<0.001$). For both Scenario 1 and Scenario 2, patients kept in the hospital through a second stage palliation had significantly higher prevalence of pre-stage 1 risk factors including preoperative mechanical circulatory support, mechanical ventilation, renal dysfunction, and shock, in comparison to patients discharged alive before a second stage of palliation. Outcomes for each scenario are shown in the table. As expected, postoperative length of stay was prolonged. However, survival to hospital discharge was not lower compared to traditional discharge strategies for either scenario.

**Conclusions:** Stage 1 patients kept in hospital through a second stage of palliation are a higher risk group based on preoperative (pre-stage 1) risk factors, yet they do not have worse survival to hospital discharge despite hospitalization encompassing a longer at-risk time frame and a second stage surgery. These inclusive strategies appear to be increasing in prevalence albeit with wide variability across centers.

| | Norwood operation (n=5463) | Scenario 1 Norwood + SCPA (n=417) | P[1] | Hybrid stage I* (N=901) | Scenario 2 Hybrid stage I + Norwood (n=204) | P[2] |
|---|---|---|---|---|---|---|
| **Interval stage 1 to 2** | - | 106 (86, 134) | NA | - | 29 (15, 54) | NA |
| **Postop LOS** | 29 (18, 49) | 152 (112, 195) | <0.01 | 32 (16, 72) | 88 (56, 140) | <0.01 |
| **DC mortality n (%)** | 839 (15.4%) | 61 (14.6%) | 0.69 | 242 (26.9%) | 55 (27.0%) | 0.98 |

*DC: dischorge; LOS: length of stay; NA: not applicable; SCPA: superior cavopulmonary anastomosis*

* Excludes patients who received Hybrid Stage I and Hybrid Approach Stage II in the same hospitalization
Time intervals in days (interquartile range)

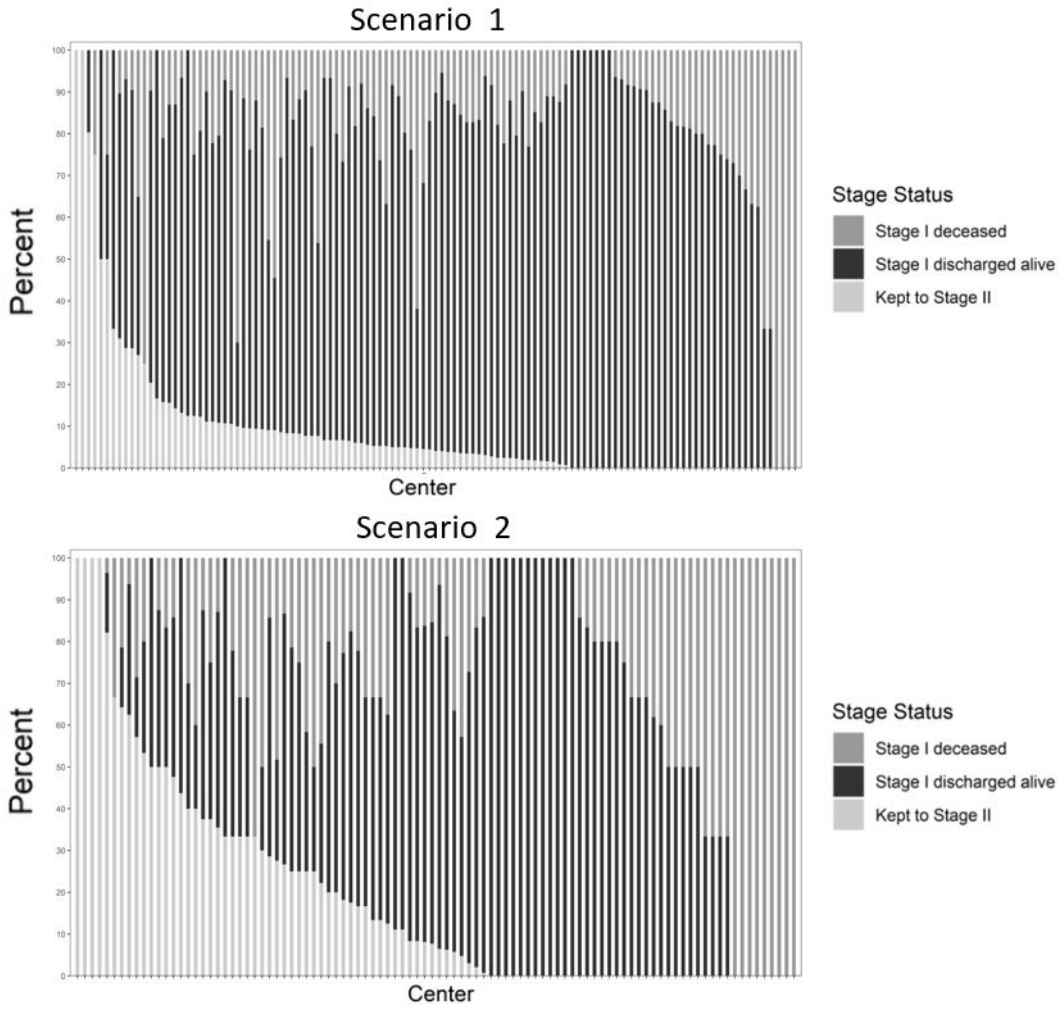



**Image Description:**
The proportion of patients deceased after first stage of palliation, discharged alive after first stage of palliation, and kept hospitalized to second stage of palliation. Scenario 1 (upper panel) and Scenario 2 (lower panel). Y-axis – percent; X-axis – individual center

# 3. Similar Long-Term Quality of Life Outcomes Following Robotic Versus Open Transhiatal Esophagectomy (Thoracic)

**Authors: Aaron Williams***, Tyler Grenda, Lili Zhao, Alexander Brescia, Curtis Bergquist, Keara Kilbane, Emily Barrett, Philip Carrott, Andrew Chang, Jules Lin, Elliot Wakeam, Mark B. Orringer, Kiran Lagisetty, Rishindra Reddy

**Presenter Institution:** *University of Michigan, Ann Arbor, MI*

**Objectives:** Minimally invasive esophagectomy has been associated with lower complications, shorter length of stay, and improved patient outcomes compared to open approaches. However, these studies almost always compare minimally invasive to open transthoracic or 3-hole approaches. Patient-reported outcomes (PROs), including quality of life (QoL) and fear of recurrence (FoR), comparing minimally invasive transhiatal esophagectomy (THE) and open THE have been limited.

**Methods:** At a single, high-volume academic center, patients undergoing open and robotic THE with gastric conduit for clinical stage I to III esophageal cancer from 2013 to 2018 were evaluated. The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ-C30), EORTC Quality of Life Questionnaire in Esophageal Cancer (QLQ-EOS18), and FoR survey were administered preoperatively, and at 1, 6 and 12 months post-operation. Raw scores underwent linear transformation (0-100 scale). Linear mixed-effects models, adjusting for patient characteristics and postoperative outcomes, were used for QoL and FoR score comparisons (Summary Scores, *$p < 0.05$; Subscores, *$p < 0.01$). Patient demographics, characteristics, and postoperative outcomes were also compared (*$p < 0.05$).

**Results:** 309 patients (212 open and 97 robotic THE) were included. There were no differences in patient survey completion rates between groups at each time point out to 1 year following surgery (open, 40% vs. robotic, 46%; $p = 0.3$). No differences were noted in preoperative patient (age, gender, BMI, race, ASA, comorbidities, smoking status) and tumor (clinical and pathologic staging, tumor type and location, and neoadjuvant therapy) characteristics between groups. The robotic THE cohort had a significantly higher number of nodes harvested (14 ±0.8 vs. 11.2 ±0.4; $p = 0.01$), shorter length of stay (days, 10.0 ±6.7 vs. 12.1 ±7.0; $p = 0.03$), lower rates of postoperative ileus (5% vs. 15%; $p = 0.02$), and had less patients prescribed opioids at discharge (71% vs. 85%; $p = 0.03$) (Figure 1). There were no significant differences in operative times, 30-day mortality, reoperation, readmission, discharge status, and other complications between groups. After adjustment, there were no significant differences in QLQ-C30 (Figure 2), QLQ-EOS18, and FoR summary scores and survey subscores between open and robotic THE patients at any time point following surgery.

**Conclusions:** There were no clear patient-reported benefits with robotic versus open THE for esophageal cancer. This is in contrast to the PROs of other minimally invasive approaches to esophagectomy. As PROs were similar, other factors such as perioperative outcomes and surgeon experience may be more important determinants for selecting open versus robotic approaches for THE.

**Table 1**: Postoperative Outcomes

**Table 1. Postoperative Outcomes**

| Variable | Open (n=212) | Robot (n=97) | P-Value |
|---|---|---|---|
| Operating Time (min) | 356.6 ± 110.0 | 373.4 ± 130.0 | 0.26 |
| Length of Stay (days) | 12.1 ± 7.7 | 10.0 ± 6.7 | **0.03** |
| Postoperative Events | 150 (71%) | 70 (72%) | 0.89 |
| Initial Vent Support >48 Hours | 1 (0.5%) | 0 (0%) | 0.50 |
| Reintubation | 5 (2%) | 1 (1%) | 0.43 |
| Myocardial Infarction | 2 (1%) | 1 (1%) | 0.99 |
| Renal Failure | 2 (1%) | 1 (1%) | 0.99 |
| Recurrent Laryngeal Nerve Paresis | 6 (3%) | 0 (0%) | 0.10 |
| Pneumonia | 14 (7%) | 4 (4%) | 0.38 |
| Pulmonary Embolus | 4 (2%) | 2 (2%) | 0.93 |
| Atrial Arrhythmia | 42 (20%) | 22 (23%) | 0.60 |
| Deep Vein Thrombosis | 3 (1%) | 1 (1%) | 0.78 |
| Urinary Tract Infection | 10 (5%) | 3 (3%) | 0.50 |
| Wound Infection/Dehiscence | 6 (3%) | 3 (3%) | 0.99 |
| Sepsis | 6 (3%) | 3 (3%) | 0.91 |
| Postoperative Packed Red Blood Cells Administered | 12 (6%) | 8 (8%) | 0.40 |
| Gastric Outlet Obstruction | 2 (1%) | 2 (2%) | 0.43 |
| Ileus | 29 (14%) | 5 (5%) | **0.02** |
| Anastomosis Leak | 32 (15%) | 9 (9%) | 0.15 |
| Chylothorax | 9 (4%) | 3 (3%) | 0.61 |
| Patient Disposition | | | |
| ICU | 13 (6%) | 6 (6%) | 0.99 |
| Intermediate Care Unit | 8 (4%) | 2 (2%) | 0.51 |
| Regular Floor Bed | 189 (90%) | 89 (92%) | 0.51 |
| 30 Day Status | | | |
| Alive | 210 (99%) | 95 (98%) | 0.99 |
| Dead | 1 (0.5%) | 1 (1%) | 0.8 |
| Unknown | 0 (0%) | 1 (1%) | 0.53 |
| Reoperation | 36 (17%) | 8 (8%) | 0.09 |
| Readmission | 33 (16%) | 19 (20%) | 0.38 |
| Discharge | | | |
| Extended Care/Transitional Care Unit/Rehab | 11 (5%) | 10 (10%) | 0.14 |
| Home | 199 (94%) | 85 (88%) | 0.13 |
| Nursing Home | 1 (0.5%) | 1 (1%) | 0.53 |
| Other Hospital | 0 (0%) | 1 (1%) | 0.31 |
| Other | 1 (0.5%) | 0 (0%) | 0.53 |
| Opioids at Discharge | 172 (82%) | 69 (71%) | **0.03** |
| Adjuvant Therapy | 21 (10%) | 9 (9%) | 0.78 |

Data are presented as count (frequency) or mean ± standard error unless specified otherwise.

**Table 2**: EORTC-QLQ-C30 Scores

**Table 2: EORTC-QLQ-C30 Categorical Score at Each Time Point**

| | Baseline/Preoperative | | | Postoperative return visit | | | 6-month visit | | | 12-month visit | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Survey Parameter** | **Open (n=212)** | **Robot (n=97)** | **P-Value** | **Open (n=184)** | **Robot (n=66)** | **P-Value** | **Open (n=139)** | **Robot (n=65)** | **P-Value** | **Open (n=85)** | **Robot (n=45)** | **P-Value** |
| Global health status | | | | | | | | | | | | |
| Global health status | 62.80 ± 5.43 | 64.25 ± 5.70 | 0.56 | 52.78 ± 5.52 | 52.02 ± 5.86 | 0.80 | 68.22 ± 5.60 | 65.04 ± 5.86 | 0.32 | 63.29 ± 6.02 | 68.21 ± 5.73 | 0.18 |
| Functional scale | | | | | | | | | | | | |
| Physical functioning | 78.02 ± 5.01 | 76.47 ± 5.27 | 0.49 | 62.96 ± 5.09 | 59.08 ± 5.41 | 0.14 | 76.92 ± 5.16 | 72.88 ± 5.41 | 0.15 | 75.65 ± 5.25 | 72.14 ± 5.53 | 0.28 |
| Role functioning | 73.29 ± 7.15 | 72.58 ± 7.54 | 0.83 | 45.28 ± 7.28 | 43.28 ± 7.77 | 0.62 | 75.91 ± 7.41 | 69.27 ± 7.77 | 0.13 | 74.10 ± 7.57 | 69.24 ± 8.00 | 0.33 |
| Emotional functioning | 70.74 ± 6.08 | 69.04 ± 6.37 | 0.54 | 70.56 ± 6.16 | 65.00 ± 6.52 | 0.08 | 74.25 ± 6.24 | 70.62 ± 6.52 | 0.28 | 74.19 ± 6.35 | 66.68 ± 6.66 | 0.04 |
| Cognitive functioning | 74.38 ± 5.61 | 74.59 ± 5.87 | 0.93 | 73.42 ± 5.68 | 70.84 ± 6.00 | 0.36 | 73.53 ± 5.75 | 73.03 ± 6.00 | 0.87 | 69.31 ± 5.85 | 67.88 ± 6.13 | 0.68 |
| Social functioning | 64.50 ± 7.45 | 64.78 ± 7.82 | 0.93 | 50.90 ± 7.57 | 46.61 ± 8.04 | 0.29 | 69.97 ± 7.69 | 64.91 ± 8.03 | 0.24 | 61.45 ± 7.85 | 64.42 ± 8.25 | 0.16 |
| Symptom scale | | | | | | | | | | | | |
| Fatigue | 41.80 ± 5.80 | 40.33 ± 6.11 | 0.59 | 55.25 ± 5.90 | 55.03 ± 6.29 | 0.95 | 37.46 ± 6.00 | 42.67 ± 6.29 | 0.13 | 36.15 ± 6.13 | 43.93 ± 6.46 | 0.05 |
| Nausea and vomiting | 18.26 ± 5.67 | 19.77 ± 5.98 | 0.57 | 18.31 ± 5.77 | 22.37 ± 6.16 | 0.20 | 19.96 ± 5.87 | 25.48 ± 6.16 | 0.11 | 12.86 ± 6.00 | 23.96 ± 6.34 | 0.02 |
| Pain | 33.45 ± 6.49 | 30.15 ± 6.83 | 0.26 | 40.29 ± 6.60 | 40.94 ± 7.02 | 0.85 | 32.44 ± 6.70 | 34.31 ± 7.02 | 0.62 | 40.48 ± 6.83 | 36.26 ± 7.20 | 0.18 |
| Dyspnea | 17.57 ± 6.64 | 17.79 ± 7.00 | 0.94 | 32.79 ± 6.76 | 30.19 ± 7.19 | 0.47 | 17.93 ± 6.86 | 19.29 ± 7.19 | 0.73 | 21.59 ± 7.00 | 21.09 ± 7.38 | 0.91 |
| Insomnia | 38.13 ± 8.49 | 41.86 ± 8.94 | 0.34 | 49.59 ± 8.63 | 46.23 ± 9.18 | 0.47 | 36.54 ± 8.76 | 35.03 ± 9.18 | 0.76 | 37.18 ± 8.94 | 39.75 ± 9.43 | 0.65 |
| Appetite loss | 34.45 ± 8.25 | 32.75 ± 8.71 | 0.67 | 47.92 ± 8.41 | 50.15 ± 9.00 | 0.64 | 26.32 ± 8.57 | 32.18 ± 9.00 | 0.26 | 28.92 ± 8.78 | 33.14 ± 9.28 | 0.48 |
| Constipation | 19.76 ± 6.55 | 22.82 ± 6.90 | 0.32 | 16.89 ± 6.66 | 23.13 ± 7.10 | 0.08 | 10.80 ± 6.77 | 20.12 ± 7.10 | 0.02 | 12.60 ± 6.92 | 21.17 ± 7.30 | 0.06 |
| Diarrhea | 14.23 ± 6.76 | 12.45 ± 7.10 | 0.57 | 33.76 ± 6.87 | 32.37 ± 7.30 | 0.71 | 30.08 ± 6.98 | 29.57 ± 7.29 | 0.90 | 24.03 ± 7.13 | 21.12 ± 7.49 | 0.52 |
| Financial difficulties | 25.28 ± 8.63 | 24.02 ± 9.01 | 0.73 | 27.21 ± 8.72 | 25.17 ± 9.18 | 0.62 | 26.27 ± 8.80 | 24.28 ± 9.18 | 0.65 | 19.96 ± 8.92 | 29.15 ± 9.33 | 0.06 |
| Summary Score | 77.70 ± 3.36 | 73.40 ± 3.54 | 0.7 | 62.87 ± 3.43 | 61.85 ± 3.70 | 0.60 | 75.14 ± 3.49 | 71.71 ± 3.67 | 0.11 | 74.97 ± 3.58 | 72.90 ± 3.79 | 0.10 |

# 4. Aortic Annular Enlargement: Short and Long-Term Outcomes in the United States
# (Adult Cardiac)

**Authors: James Mehaffey***, Robert Hawkins, Zachary Wegermann, Maria Grau-Sepulveda, John Fallon, Matthew Brennan, Vinod Thourani, Vinay Badhwar, Gorav Ailawadi

**Presenter Institution:** *University of Virginia, Charlottesville, VA*

**Objectives:** Patient prosthesis mismatch (PPM) is associated with significant long-term morbidity and mortality after aortic valve replacement. The role of annular enlargement (AE) to attenuate these effects remains poorly defined, especially given the rise of valve-in-valve transcatheter aortic valve replacement. We hypothesized that increasing rates of AE may lead to improved outcomes for patients at risk for severe PPM.

**Methods:** Patients undergoing surgical aortic valve replacement (SAVR) with or without coronary artery bypass grafting from 2008-2016 in the Society of Thoracic Surgeons Adult Cardiac Surgery Database (STS-ACSD) with matching Center for Medicare Services data were included (n=189,268). Univariate, multivariate, and time-to-event analysis was used to evaluate the association between AE and a patients short and long-term outcomes. Patients were stratified by projected degree of PPM based on calculated effective orifice area index (EOAi) from valve size and body surface area. Multivariate models included covariates from previously published STS 2008 valve models.

**Results:** A total of 5,412 (2.9%) patients underwent AE. Despite steadily increasing AE rates between 2013 and 2016 (2.4-3.3%), the trend over the whole study period was not statistically significant (p=0.295). Patients undergoing AE were similar to those without AE (STS predicted risk of mortality 2.97% vs 2.99%, p=0.052). Patients undergoing AE had higher risk-adjusted rates of short-term complications, although there were no differences in long-term rates of stroke re-hospitalizations, heart failure re-hospitalizations or aortic valve reoperation (Table). Survival analysis demonstrated a higher risk of mortality with AE during the first 3 years correlating with perioperative risk. After 3 years the survival curves cross with long-term benefit to AE (Figure). In subgroup analysis of 15,264 (8.1%) patients with predicted severe PPM (EOAi<0.65), only 455 (3%) underwent annular enlargement. In this small subgroup, AE was not associated with less heart failure re-hospitalizations (OR 0.82, 95% CI 0.64-1.05, p=0.407) or aortic valve reoperation (OR 0.81, 95% CI 0.42-1.56, p=0.572).

**Conclusions:** These data suggest that annular enlargement during SAVR is associated with increased short-term risk, in this population of Medicare patients. Survival curves crossed after three years, which may portend a benefit in younger patients. However, annular enlargement is still only done in the minority of patients who are at risk for PPM. Given these results, annular enlargement can be considered in young patients and those with expected severe PPM who may have a long-term survival benefit.

**Image Title:** Short and Long-term Risk Associated with Aortic Annular Enlargement

***Table:*** Short and Long-term Risk Associated with Aortic Annular Enlargement

| **Short-term Outcomes** | **OR* (95% CI)** | **P-Value** | **AOR** (95% CI)** | **P-value** |
|---|---|---|---|---|
| Operative Mortality | 1.59(1.41 - 1.80) | <0.0001 | 1.55 (1.37 - 1.75) | <.0001 |
| Major Morbidity | 1.30(1.22 - 1.39) | <0.0001 | 1.32 (1.23 - 1.40) | <.0001 |
| Composite | 1.34(1.25 - 1.43) | <0.0001 | 1.35 (1.26 - 1.45) | <.0001 |
| Pacemaker/ICD | 1.00(0.85 - 1.18) | 0.962 | 1.01 (0.86 - 1.20) | 0.863 |
| **Non-Fatal Long-term Outcomes** | **HR# (95% CI)** | **P-Value** | **AHR## (95% CI)** | **P-value** |
| Stroke Hospitalization | 1.01 (0.91 - 1.13) | 0.461 | 0.99 ( 0.89 - 1.10) | 0.278 |
| Heart Failure Hospitalization | 1.1 (0.97 - 1.18) | 0.462 | 1.04 (0.97 - 1.12) | 0.400 |
| Aortic Valve Reoperation | 1.1 (0.82 - 1.46) | 0.788 | 0.99 (0.75 - 1.31) | 0.846 |
| **Long-Term Mortality Landmark Analysis** | **HR# (95% CI)** | **P-Value** | **AHR## (95% CI)** | **P-value** |
| Survival (First 3 Years) | 1.14 (1.07 - 1.22) | 0.002 | 1.1 (1.02 - 1.19) | 0.015 |
| Survival (After Year 3) | 0.91 (0.84 - 0.99) | 0.024 | 0.94 (0.87 - 1.02) | 0.127 |

**OR – Unadjusted Odds Ratio – Logistic Model*

***AOR – Risk Adjusted Odds Ratio – Logistic Model*

*#HR – Unadjusted Sub-distribution Hazard Ratio – Fine & Gray Model for non-fatal outcomes and COX regression for Mortality.*

*##AHR – Risk Adjusted Sub-distribution Hazard Ratio – Fine & Gray Model for non-fatal outcomes and COX regression for Mortality.*

**Image Title:** Figure. Risk-Adjusted Survival Curves for Patients with and without Annular Enlargement

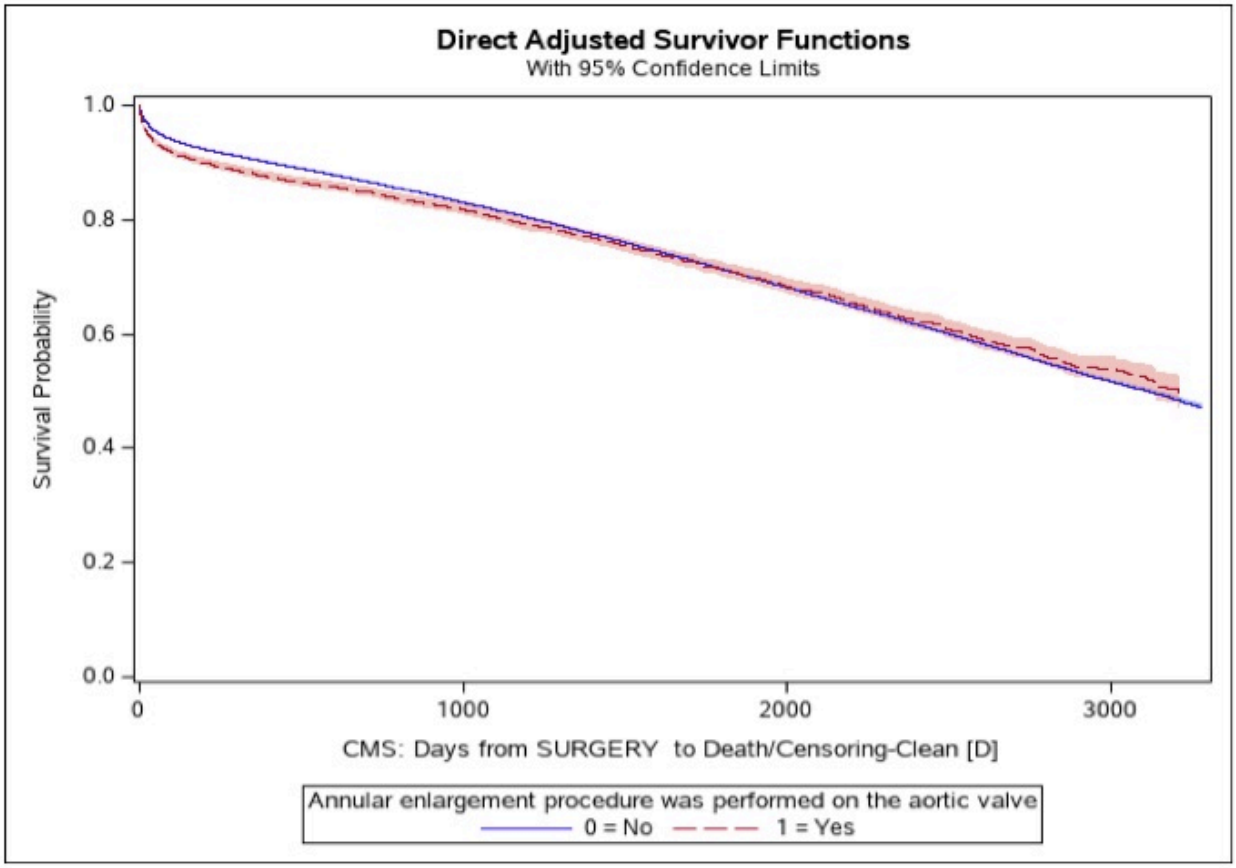



**Image Description:** Survival Curves for Annular Enlargement (red dashed) and no Annular Enlargement (blue solid) cross at 3 years.

# 5. Late Results Following Closure of Ventricular Septal Defects With Elevated Pulmonary Vascular Resistance and Pulmonary Hypertension Using the Flap Valve Double Patch Technique (Congenital)

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**Presenter Institution:** *University of Tennessee, Collierville, TN*

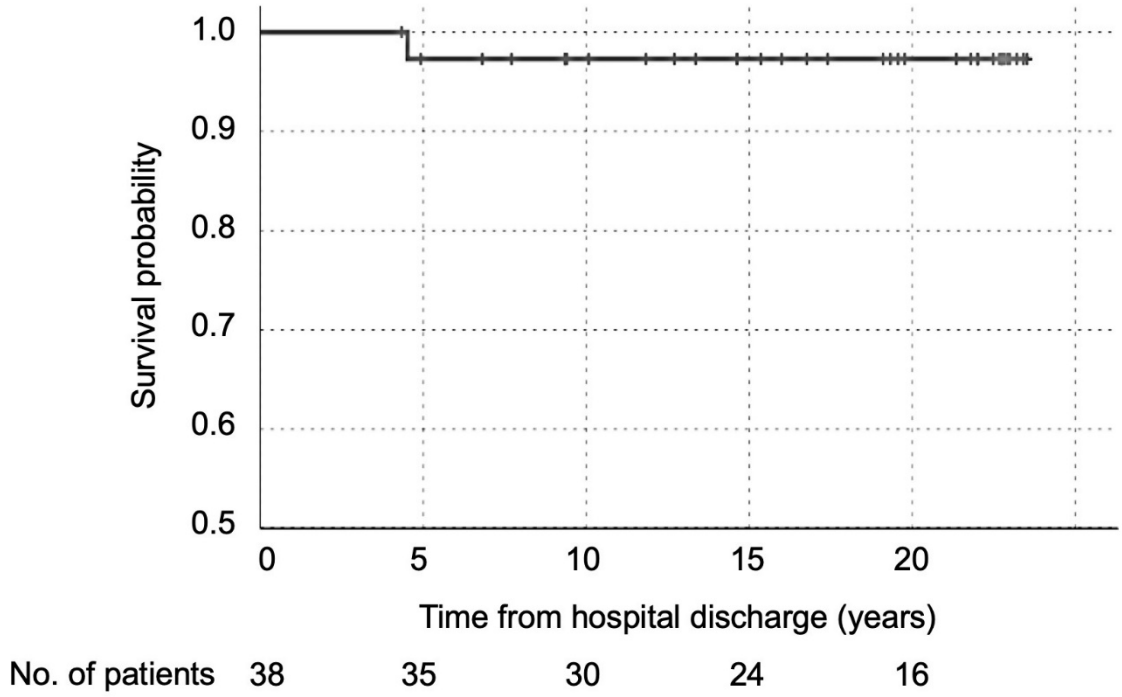
**Objectives:** Delayed diagnosis or intervention in children with VSD's is common in low- and middle-income countries. Frequently they present with bi-directional shunting across the VSD and have elevated pulmonary vascular resistance (PVR) and pulmonary hypertension (PHT). We introduced the flap-valved VSD patch technique (DFV) in 1996 to reduce early post-operative mortality risk. Long-term results are presented.

**Methods:** Retrospective single-institution study where the first double patch operation was performed in May 1996. Periodic follow-up with an echocardiogram was performed on all survivors. Beginning in 2005 all candidates for DFV were placed on sildenafil pre-operatively and post-operatively. Last evaluation for all survivors, 10/19-12/19. Hospital, 30-day and late mortality were analyzed. Pre-operative cath data was analyzed and use of sildenafil analyzed for impact on early and late results.

**Results:** Between 5/96 and 8/2015 40 patients received the DFV technique for VSD closure. There were 22 females, median age was 7.5 years (3.8, 12.8) and median weight 20.0 kgs (13.0; 31.3). Hospital and 30-day mortality were 2.5% (1/40). Lost to follow-up 1/39 (2.6%). Late mortality 1/38 (2.6%). Pre-op saturation was significantly higher in sildenafil group 95.2±2.4 vs none 89.5±5.9 ($p< 0.001$). The pressure response to vaso-active testing with O2 (93.6mmHg ±13.9) from baseline (79.6±17.5)was significantly different $p<0.001$, as was the systemic to PA systolic pressure ratio, baseline 1.0 (.89;1.0) provocation 0.81 (0.72;0.89) $p< 0.001$. The PVR at baseline was similar for sildenafil (8.5 Wu [6.9;10.6]) and the none group (10.1 [7.6;13.1]), $p=0.288$. Oxygen provocation PVR for sildenafil group was 4.5(1.9;7.0) WU and for non-group was 6.2 (3.3:8.9) WU and wasn't significantly different ($p=0.173$). The median age at late follow-up was 26.3 years (20.9; 29.9) and median time since operation was 19.2 years (11.4; 22.7) To date discharge survival is 97.3% (38/39). Late follow-up revealed no PHT is 21% (8/38), mild PHT 40% (15/38), moderate PHT 21% (8/38) and severe 18% (7/38). Multi-variable analysis revealed that only baseline PVR/SVR ≥ 0.8 is a significant predictor of late severe PAH ($p<0.002$), HR 13.7.

**Conclusions:** Children with VSD, elevated PVR and PHT should not be denied operation because of concerns regarding early mortality or the development of severe PHT late after operation. Our long-term follow-up demonstrates that 60% of the patients will achieve normal or near normal pulmonary artery pressures, potentially having a normal life expectancy after operation.

**Image Title:** KM Survival Curve after Discharge



# 6. Adjuvant Chemotherapy for Visceral Pleural Invasion in 3–4 Centimeter Non-Small Cell Lung Cancer Improves Survival (Thoracic)

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**Objectives:** Visceral pleural invasion (VPI) guidelines, for tumors £4 centimeters (cm) are ambiguous. Non-small cell lung cancers (NSCLC) >3-£4 cm are assigned the T2a designation. Similarly, any tumors with visceral pleural invasion, smaller than 4 cm, are upstaged and also assigned the same T2a designation. We hypothesized that adjuvant chemotherapy would significantly improve 5-year survival for NSCLC £4 cm with VPI.

**Methods:** The National Cancer Database (NCDB) was queried from 2010 to 2016 for cases of NSCLC with clinical stage I disease, £4 cm, who subsequently underwent surgical resection. These stage I NSCLCs were stratified according to clinical tumor sizes (0-£1 cm, >1-£2 cm, >2-£3 cm, and >3-£4 cm). This cohort was then divided into groups with and without VPI and further split based on the administration of adjuvant chemotherapy. Kaplan-Meier analysis was used to calculate 5-year overall survival (OS) for patients categorized by tumor size, VPI status, and receipt of adjuvant chemotherapy. Multivariable Cox regression adjusting for tumor size and VPI status was used to determine associations between use of adjuvant chemotherapy and OS.

**Results:** A total of 61,454 patients with NSCLC and clinical tumor sizes <4cm were identified and grouped based on size along with VPI and adjuvant chemotherapy (Table 1). The 5-year OS for combined tumor sizes without VPI was higher than for patients with VPI (66.2% versus 59.5%, $p<0.01$). The OS for tumor size (0-£1 cm, >1-£2 cm, >2-£3 cm, and >3-£4 cm) was lower for patients with VPI regardless of size (all $p\leq0.01$). When all tumor sizes were combined, patients with VPI who received adjuvant chemotherapy had an improved 5-year OS compared to patients without adjuvant chemotherapy (65.5% versus 58.8%, $p<0.01$). When cohorts were created by tumor size, only VPI tumors >3-£4 cm had a statistically significant increase in 5-year OS for patients receiving adjuvant chemotherapy (68.8% versus 49.9%, $p<0.01$) (Figure 1). On multivariable Cox regression for OS, adjuvant chemotherapy was associated with significantly longer 5-year OS in tumor size >3-£4 (HR=0.62, 95% CI 0.46-0.83, $p=0.001$).

**Conclusions:** VPI remains a poor prognostic factor in clinically node negative, T2a or less, NSCLC patients. Guidelines recommend chemotherapy for high-risk T2aN0, margin negative patients – including those patients with VPI. Based on the analysis, adjuvant chemotherapy should be considered specifically for >3-£4cm with VPI due to an observed 5-year OS advantage.

**Table Title:** Demographics by Visceral Pleural Invasion Cohorts

| | Total (N=61454) | No VPI (N=51072) | Yes VPI (N=10382) | p-value |
|---|---|---|---|---|
| **Age** | 68.2±9.2 | 68.1±9.2 | 68.8±9.2 | <0.0001 |
| | **Number (%)** | **Number (%)** | **Number (%)** | |
| **Sex** | | | | 0.0006 |
| Male | 26991 (43.9) | 22272 (43.6) | 4719 (45.4) | |
| Female | 34463 (56.1) | 28800 (56.4) | 5663 (54.6) | |
| **Race** | | | | 0.0354 |
| White | 54340 (88.4) | 45236 (88.6) | 9104 (87.7) | |
| Black | 4843 (7.9) | 3968 (7.8) | 875 (8.4) | |
| Other | 2271 (3.7) | 1868 (3.6) | 403 (3.9) | |
| **Payor** | | | | 0.0021 |
| Medicare | 39797 (64.8) | 32927 (64.5) | 6870 (66.2) | |
| Private Insurance | 16681 (27.1) | 14017 (27.4) | 2664 (25.7) | |
| Medicaid | 2902 (4.7) | 2385 (4.7) | 517 (5.0) | |
| Other Government | 625 (1.0) | 526 (1.0) | 99 (0.9) | |
| Not Insured | 872 (1.4) | 723 (1.4) | 149 (1.4) | |
| Unknown | 577 (1.0) | 494 (1.0) | 83 (0.8) | |
| **Charlson-Deyo Score** | | | | 0.0349 |
| 0 | 30176 (49.1) | 25158 (49.3) | 5018 (48.3) | |
| 1 | 20819 (33.9) | 17177 (33.6) | 3642 (35.1) | |
| 2 | 7404 (12.0) | 6196 (12.1) | 1208 (11.6) | |
| >=3 | 3055 (5.0) | 2541 (5.0) | 514 (5.0) | |
| **Surgery type** | | | | 0.3794 |
| Lobectomy | 47692 (77.6) | 39602 (77.5) | 8090 (77.9) | |
| Wedge | 10179 (16.6) | 8455 (16.6) | 1724 (16.6) | |
| Segment | 3146 (5.1) | 2650 (5.2) | 496 (4.8) | |
| Pneumonectomy | 437 (0.7) | 365 (0.7) | 72 (0.7) | |
| **Chemotherapy** | | | | <0.0001 |
| No | 59393 (96.7) | 50056 (98.0) | 9337 (89.9) | |
| Yes | 2061 (3.3) | 1016 (2.0) | 1045 (10.1) | |
| **Tumor size** | | | | <0.0001 |
| 0-≤1 cm | 5781 (9.4) | 5341 (10.5) | 440 (4.2) | |
| >1-≤2 cm | 27144 (44.2) | 23309 (45.6) | 3835 (37.0) | |
| >2-≤3 cm | 19269 (31.4) | 15377 (30.1) | 3892 (37.5) | |
| >3-≤4 cm | 9260 (15.0) | 7045 (13.8) | 2215 (21.3) | |
| **Surgical Margin** | | | | <0.0001 |
| Negative | 60512 (98.5) | 50413 (98.7) | 10099 (97.3) | |
| Positive | 702 (1.1) | 473 (0.9) | 229 (2.2) | |
| Missing | 240 (0.4) | 186 (0.4) | 54 (0.5) | |
| **Histology** | | | | <0.0001 |
| Adenocarcinoma | 43123 (70.2) | 35402 (69.3) | 7721 (74.4) | |
| Squamous Cell | 16985 (27.6) | 14506 (28.4) | 2479 (23.9) | |
| Other | 1346 (2.2) | 1164 (2.3) | 182 (1.7) | |

**Image Title:** Kaplan-Meier Plot of >3-4 cm tumors with visceral pleural invasion

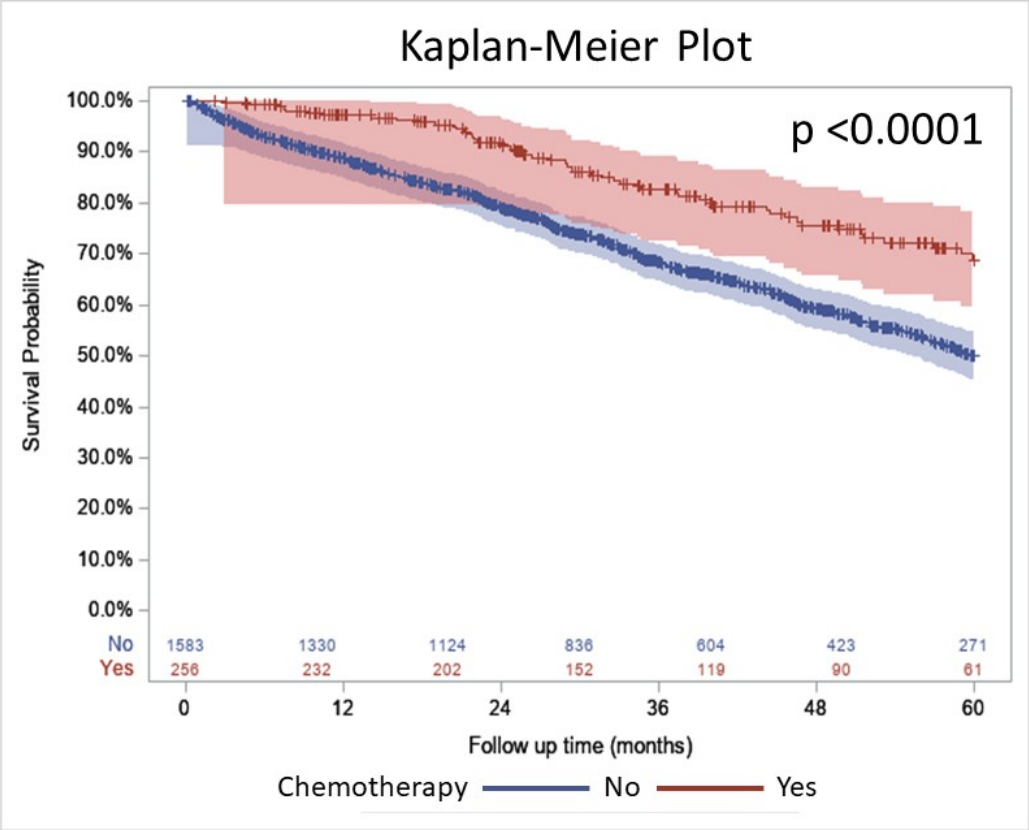


**Image Description:** Kaplan-Meier Plot of >3-4 cm tumors with visceral pleural invasion demonstrating survival for those who received adjuvant chemotherapy (red) versus no adjuvant chemotherapy (blue)