STS 53rd Annual Meeting

Late-Breaking Abstracts

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*Presenting authors are listed in **bold** on each abstract.*

Monday, January 23

11:30 AM – 12:30 PM ***Room 320ABC***

Late-Breaking Abstracts I

Moderators: *Kevin L. Greason, Rochester, MN, and Thomas E. MacGillivray, Houston, TX*

The physician competencies addressed in this session are patient care and medical knowledge. These physician competencies will be addressed through a series of individual lectures and a brief question-and-answer session after each topic.

11:30 AM

Incidence and Consequence of Patient-Prosthesis Mismatch After Surgical Aortic Valve Replacement: An Analysis of the STS Adult Cardiac Surgery Database

J. M. Fallon[1]*, J. DeSimone*[1]*, M. Brennan*[3]*, S. O'Brien*[4]*, D. Thibault*[4]*, A. W. Discipio*[1]*, J. P. Jacobs*[5]*, D. J. Malenka*[1]

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Purpose: There remains concern about the consequences of patient-prosthesis mismatch (PPM) after aortic valve replacement (AVR). The goal of this study was to determine the relationship of PPM to long-term survival and to assess whether growing concern about PPM has resulted in a decreased incidence over time.

Methods: Using the STS Adult Cardiac Surgery Database, we identified 59,779 patients ≥65 years old who underwent isolated surgical AVR between 2004 and 2014 and were linked to Medicare claims data. The degree of PPM was calculated using literature-derived effective orifice areas for commonly used valves. Outcomes were stratified by degree of PPM (none: >0.85 cm^2/m^2, moderate: ≤0.85 to ≥0.65 cm^2/m^2, severe: <0.65 cm^2/m^2) and included long-term survival and readmissions for heart failure or repeat AVR. Case-mix adjustment was performed using a modified list of variables derived from the STS mortality risk model for isolated AVR.

Results: The distribution of PPM was 35% none (n=21,053), 54% moderate (n=32,243), and 11% severe (n=6,483). Compared to those with none, patients with moderate or severe PPM had significantly increased risk of readmission for heart failure (HR 1.15, 95% CI 1.09-1.21; HR 1.37, 95% CI 1.26-1.48) and redo AVR (HR 1.41, 95% CI 1.13-1.77; HR 2.68, 95% CI 2.01-3.56). Late survival was significantly worse for any degree of PPM with 5-year adjusted survival rates of 74%, 72%, and 68% for none, moderate, and severe (*P* <.001), respectively. Two groups showed additional risk of mortality from PPM: those with BMI ≥30 kg/m^2 (HR 1.44, 95% CI 1.32-1.56) and age ≤75 years (HR 1.54, 95% CI 1.42-1.68). The incidence of severe PPM decreased by 55% over the study period from 13.8% in 2004 to 6.2% in 2014, while the incidence of moderate PPM decreased by 22% (60.1% in 2004 and 46.8% in 2014).

Conclusions: In this large national sample, PPM significantly decreased long-term survival and increased readmission rates for both heart failure and reoperation for AVR. While temporal trends show growing awareness of this problem, identifying patients at risk for PPM and effective strategies for avoiding it should remain a priority.

11:50 AM

Subclavian Access for Self-Expanding Transcatheter Aortic Valve Replacement Renders Equivalent Outcomes as Transfemoral

T. G. Gleason[1], *J. Schindler*[1], *R. C. Hagberg*[2], *G. Deeb*[3], *D. H. Adams*[4], *J. V. Conte*[5], *G. L. Zorn*[6], *G. C. Hughes*[7], *J. Popma*[8], *M. Reardon*[9]

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COMMERCIAL RELATIONSHIPS T. G. Gleason: Research Grant, Medtronic; D. H. Adams: Icahn School of Medicine at Mount Sinai receives royalty payments from Edwards Lifesciences and Medtronic; J. V. Conte: Research Grant, Medtronic, Boston Scientific, St Jude Medical; Consultant/Advisory Board, Medtronic; G. L. Zorn: Consultant/Advisory Board, Edwards Lifesciences, Medtronic; G. C. Hughes: Consultant/Advisory Board, Medtronic; Research Grant, Bolton Medical, Cook Medical, Medtronic, W. L. Gore & Associates; Speakers Bureau/Honoraria, Cook Medical, Medtronic; J. Popma: Research Grant, Medtronic, Boston Scientific, Abbott; Consultant/Advisory Board, Boston Scientific, Direct Flow Medical; Other Research Support, Direct Flow Medical; Ownership Interest, Direct Flow Medical; M. Reardon: Research Grant, Medtronic; Consultant/Advisory Board, Medtronic

Purpose: Iliofemoral arterial disease and/or caliber limitations regularly preclude transfemoral transcatheter aortic valve replacement (TAVR). Transthoracic access via either direct aortic or transapical approach imparts greater risk of complications and mortality compared to transfemoral (TF). We hypothesized that subclavian arterial (SCA) access offers equivalent risks/outcomes as TF.

Methods: A total of 202 patients from the CoreValve US Pivotal Trial Program treated via SCA access were propensity matched with patients treated via TF access, and outcomes were analyzed.

Results: Matching was successful with no significant baseline differences between the SCA group and the TF group, except for significantly more past or present smokers (79.2% vs 61.4%, $P < .001$) and fewer patients with anemia requiring transfusion (18.5% vs 27.5%, $P = .04$) in the SCA group. SCA-treated patients experienced a significantly longer time from enrollment to procedure, 8.6 days ± 19.1 days vs 5.3 days ± 6.3 days, $P = .02$, likely due to case planning. The significant differences in procedural outcomes included less post-TAVR balloon dilation (17.9% vs 26.7%, $P = .03$) and more general anesthesia (99.0% vs 89.6%, $P < .001$) for the SCAs. There were no differences in procedure time (57.8 minutes ± 45.3 minutes vs 57.5 minutes ± 32.1 minutes, $P = .94$) or VARC-I-defined procedure success between groups ($P = .89$). There were no differences in event rates at 30 days or 1 year, with a trend toward fewer pacemakers in the SCA groups.

Conclusions: Major morbidity and mortality rates with TAVR via SCA access are equivalent to TF access. The SCA should be the preferred secondary access site for TAVR, offering no additional risk or operative time over TF, and is applicable to the majority of patients in whom TF is not.

TABLE. Clinical Outcomes at 30 Days and 1 Year

KM rates as %	Subclavian Access N=202	Transfemoral Access N=202	P Value
30 Days			
All-cause mortality	5.4	5.9	0.83
Major stroke	4.5	3.0	0.42
Reintervention	1.0	1.5	0.66
Life threatening or disabling bleed	11.4	10.4	0.74
Major vascular complications	11.9	10.4	0.64
Acute kidney injury	10.0	14.4	0.18
Permanent pacemaker	19.5	26.4	0.09
1 Year			
All-cause mortality	23.3	24.8	0.70
Major stroke	6.7	5.4	0.52
Reintervention	1.6	2.0	0.70
Permanent pacemaker	21.7	29.4	0.08

12:10 PM

The Mitral Arm of the COMMENCE IDE Trial: Near-Term Outcomes of Mitral Valve Replacement Using a Pericardial Mitral Valve With a Novel Tissue Designed for Improved Longevity

D. Heimansohn[1], *M. Mumtaz*[2], *V. A. Starnes*[3], *E. Rodriguez*[4], *F. Dagenais*[5], *D. S. Talton*[6], *J. Puskas*[7], *H. Takayama*[8], *S. Melby*[9], *A. Mangi*[10]

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COMMERCIAL RELATIONSHIPS D. Heimansohn: Other/Proctor, LivaNova; M. Mumtaz: Research Grant, AtriCure, DirectFlow, Abbott, Edwards Lifesciences, Medtronic, Millipede, NeoChord, St Jude Medical; Speakers Bureau/Honoraria, AtriCure, DirectFlow, Abbott, Edwards Lifesciences, Medtronic, Millipede, NeoChord, St Jude Medical; Consultant/Advisory Board, AtriCure, DirectFlow, Abbott, Edwards Lifesciences, Medtronic, Millipede, NeoChord, St Jude Medical; E. Rodriguez: Research Grant, Abbott, Edwards Lifesciences; A. Mangi: Research Grant, Edwards Lifesciences; Speakers Bureau/Honoraria, Edwards Lifesciences

REGULATORY DISCLOSURE This presentation will describe the use of a pericardial mitral valve using a novel tissue by Edwards Lifesciences, which has an FDA status of investigational.

Purpose: A novel pericardial tissue designed for use in heart valve replacement has exhibited reduced tissue calcification and improved durability in preclinical studies. The aim of this study was to evaluate the near-term clinical safety and effectiveness of a pericardial tissue valve designed with this new tissue.

Methods: Between January 2013 and February 2016, 689 patients were prospectively enrolled in 27 centers in the US and Europe as part of the COMMENCE IDE trial. Seventy-three patients were entered in the MVR arm (age 69.1 years ± 9.5 years) and 72 patients underwent valve implant. The mean EuroSCORE II was 8.1 ± 7.8. Preoperative variables included mitral insufficiency in 87% of patients, mitral stenosis in 52%, and 46% had prior cardiac surgery. Follow-up was completed in 65 patients at 1 month (early) and 15 patients at 1 year (total 28.5 patient-years).

Results: A full sternotomy was used in 57% (41 patients) and right thoracotomy in 43% (31 patients). Length of stay was 8.8 days ± 6.8 days. At 1 year, 93.3% of patients (14/15) were in New York Heart Association Class I. Early and late all-cause mortality was 0% in-hospital, 1.4% early (30 day), and 7.7% at 1 year. Relevant early and late safety outcomes are shown in the Table and include thromboembolism 3.9%/patient-year, major bleeding (anticoagulation related) 7.7%/patient-year, and minor bleeding 3.9%/patient-year. One patient had a paravalvular leak early (1.4%), and none seen late. No cases of structural valve deterioration, hemolysis, reoperation, or valve explant were seen. The mean mitral gradient at discharge (53 patients) was 4.1 mm Hg ± 1.5 mm Hg, and at 1 year was 3.9 mm Hg ± 1.5 mm Hg (13 patients).

Conclusions: These early-term results from the COMMENCE IDE trial demonstrate that MVR with a mitral pericardial valve using a novel tissue performed as expected in the surgical treatment of mitral valve disease. Longer-term follow-up will be needed to determine if this novel tissue proves to be more durable than presently available tissue valves.

Table 1: Safety Endpoints

	Early (≤ 30 days) N = 72		Late (>30 days) 25.8 pt-yrs	
Event	n	Total %	n	%/pt-yr
All Cause Mortality	1	1.4	2	7.7
Stroke	2	2.8	1	3.9
Valve Thrombosis	1	1.4	0	0
Major Bleeding	1	1.4	2	7.7
Minor Bleeding	1	1.4	1	3.9
Paravalvular leak	1	1.4	0	0
Structural Valve Deterioration	0	0	0	0
Reoperation	0	0	0	0
Endocarditis	0	0	0	0

Tuesday, January 24

3:30 PM – 4:30 PM ***Room 320ABC***

Late-Breaking Abstracts II

Moderators: *David T. Cooke, Sacramento, CA, and Howard Song, Portland, OR*

COMMERCIAL RELATIONSHIPS D. T. Cooke: Consultant/Advisory Board, Core Mobile, Emmi Solutions; H. Song: Research Grant, HeartWare; Consultant/Advisory Board, Oregon Heart

The physician competencies addressed in this session are patient care and medical knowledge. These physician competencies will be addressed through a series of individual lectures and a brief question-and-answer session after each topic.

3:30 PM

Impact of Annular Size on Hemodynamics and Incidence of Prosthesis-Patient Mismatch Following Surgical Aortic Valve Replacement or Transcatheter Aortic Valve Replacement With a Self-Expanding Bioprosthesis

G. Deeb[1]*, S. Chetcuti*[1]*, S. Yakubov*[2]*, N. Kleiman*[3]*, J. C. Heiser*[4]*, W. Merhi*[4]*, G. L. Zorn*[5]*, P. Tadros*[6]*, G. Petrossian*[7]*, N. Robinson*[7]*, M. Mumtaz*[8]*, T. G. Gleason*[9]*, J. V. Conte*[10]*, J. Popma*[11]*, M. J. Reardon*[3]

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COMMERCIAL RELATIONSHIPS S. Chetcuti: Consultant/Advisory Board, Medtronic; Research Grant, Edwards Lifesciences, Medtronic; S. Yakubov: Consultant/Advisory Board, Medtronic; Speakers Bureau/Honoraria, Medtronic; N. Kleiman: Research Grant, Medtronic; Speakers Bureau/Honoraria, Medtronic; J. Heiser: Consultant/Advisory Board, Medtronic; G. L. Zorn: Consultant/Advisory Board, Edwards Lifesciences, Medtronic; P. Tadros: Consultant/Advisory Board, Medtronic, St Jude Medical; M. Mumtaz: Research Grant, AtriCure, Abbott, Direct Flow Medical, Edwards Lifesciences, Medtronic, Millipede, NeoChord, St Jude Medical; Other Research Support, AtriCure, Abbott, Direct Flow Medical, Edwards Lifesciences, Medtronic, Millipede, NeoChord, St Jude Medical; Speakers Bureau/Honoraria, AtriCure, Abbott, Direct Flow Medical, Edwards Lifesciences, Medtronic, Millipede, NeoChord; St Jude Medical; Consultant/Advisory Board, AtriCure, Abbott, Direct Flow Medical, Edwards Lifesciences, Medtronic, St Jude Medical; T. Gleason: Research Grant, Medtronic; J. V. Conte: Research Grant, Medtronic, Boston Scientific, St Jude Medical; Consultant/Advisory Board, Medtronic; Research Grant, Medtronic, Boston Scientific, Abbott; Consultant/Advisory Board, Boston Scientific, Direct Flow Medical; Other Research Support, Direct Flow Medical; Ownership Interest, Direct Flow Medical; M. J. Reardon: Consultant/Advisory Board, Medtronic; Research Grant, Medtronic

Purpose: To study the relationship of annular size to hemodynamics and the incidence of prosthesis-patient mismatch (PPM) in surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR).

Methods: The CoreValve US Pivotal High Risk Trial was a randomized, prospective, multicenter trial comparing TAVR using a self-expanding valve and SAVR of any bioprosthetic variety. Multislice computed tomography was used to categorize TAVR and SAVR subjects according to annular size: small (<23 mm), medium (23 mm to <26 mm), and large (≥26 mm). We then analyzed the incidence of PPM (EOAi ≤0.85 cm^2/m^2) at 30 days post-procedure, and mean aortic valve gradient (MVG) and effective orifice area (EOA) for up to 2 years for each group.

Results: In subjects receiving SAVR, the frequency of PPM was significantly associated with annular size, with small annuli having the greatest incidence. No difference in PPM incidence by annular sizing was observed with TAVR (Figure). Additionally, TAVR subjects had significantly less PPM than SAVR subjects in small and medium annuli ($P < .001$) with no difference in the incidence of PPM between TAVR and SAVR in large annuli ($P = .10$). At all post-procedure visits, MVG were significantly lower for TAVR compared to SAVR in small and medium size annuli ($P < .001$; Table). Annular size was significantly associated with MVG after SAVR, with small annuli having the highest gradients ($P < .05$ at all timepoints), but gradients were similar across all annular sizes after TAVR. EOA significantly decreased with smaller annuli for TAVR and SAVR at all timepoints ($P < .01$), but was significantly greater for all sizes with TAVR vs SAVR at all post-procedure timepoints ($P < .05$).

Conclusions: Annular size has a significant effect on hemodynamics and the incidence of PPM in SAVR subjects, not observed in TAVR subjects. With respect to annular size, TAVR results in better hemodynamics and less PPM and should be strongly considered when choosing a valve for small and medium size annuli.

Figure: Frequency of prosthesis-patient mismatch (PPM) ($\leq 0.85 cm^2/m^2$) at 30 days, according to method of aortic valve replacement, by annular size. P-values are from the Chi-square test and represent the difference across annular sizes for TAVR or SAVR.

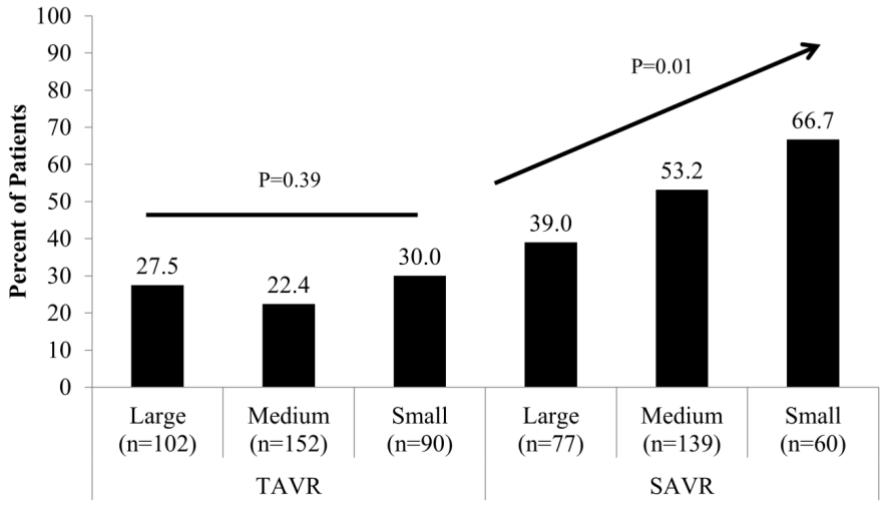

Table: Mean aortic valve gradient over time, according to annular size group.

	Small (<23mm)	Medium (23 - <26mm)	Large (≥ 26mm)
	TAVR / SAVR	TAVR / SAVR	TAVR / SAVR
Baseline	n=103 / n=74	n=168 / n=176	n=115 / n=95
Mean ± SD	51.0±16.7 / 51.5±16.0	49.3±15.3 / 47.3±13.9	44.5±13.1 / 45.8±11.5
30 Days	n=90 / n=65	n=161 / n=154	n=105 / n=86
Mean ± SD	8.4±3.7 / 12.7±5.1*	8.9±4.1 / 11.8 ± 6.1*	9.2 ± 3.7 / 10.4±5.0
12 Months	n=79 / n=51	n=135 / n=107*	n=81 / n=66
Mean ± SD	9.0±3.7 / 13.9±6.6*	9.0±3.4 / 12.9±8.7*	9.5±3.4 / 10.4±4.5
24 Months	n=60 / n=44	n=112 / n=86	n=68 / n=50
Mean ± SD	8.4±3.9 / 14.0±6.9*	8.4±3.7 / 11.8±6.0*	8.9±3.7 / 10.8±5.9

Values represent mean ± standard deviation.

Across size groups, gradients are significantly different in SAVR patients ($P<0.05$) at all time points. No significant differences in post-procedure gradients according to annular size are seen among TAVR patients.

*$P<0.001$, TAVR vs. SAVR.

3:50 PM

Comparison of Operative Mortality Following Multiarterial vs Single Arterial Coronary Artery Bypass Grafting: An Analysis From the STS National Database

T. A. Schwann[1], *R. Habib*[8], *J. Puskas*[2], *P. A. Kurlansky*[3], *S. O'Brien*[4], *A. Wallace*[5], *M. R. Bonnell*[1], *M. C. Engoren*[6], *R. F. Tranbaugh*[2], *R. Chakravarti*[7]

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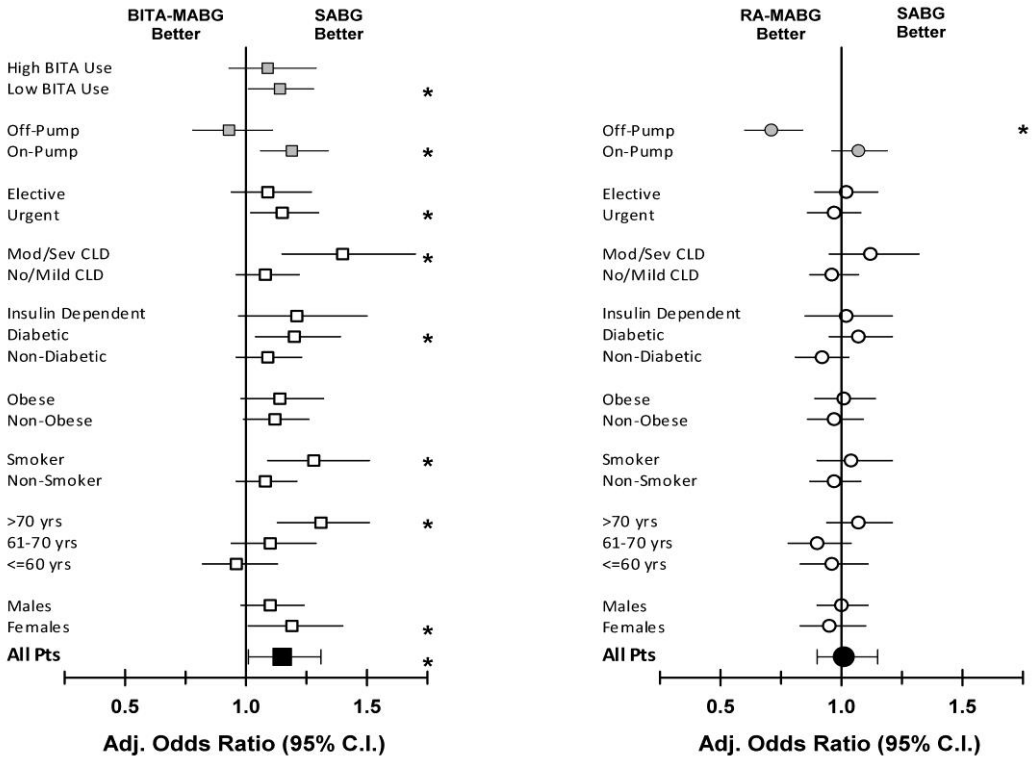
Purpose: Multiarterial CABG (MABG) is associated with improved long-term survival compared to traditional single arterial left internal thoracic artery (LITA)-based CABG (SABG), which is currently performed in more than 90% of patients. Possible increased acute MABG mortality is an obstacle to wider adoption of MABG. We hypothesize that MABG is equally safe to SABG.

Methods: We used the 2004-2015 isolated CABG nationwide experience in the STS National Database (n=1,872,422 cases; 1,227 hospitals) to derive the LITA-based SABG, bilateral internal thoracic artery-based CABG (BITA-MABG), and radial artery/LITA-based CABG (RA-MABG) study groups. Patients were excluded if the cases were emergency/salvage, redo CABG, non-LITA, a single coronary graft, or had missing/unknown operative mortality (OM) status. Pairwise logistic regression analyses generated risk-adjusted OM odds ratios (AOR [95% confidence interval]) based on the STS CABG risk models. Confirmatory sensitivity analyses were conducted to elucidate primary findings in patient subgroups derived based on demographic, comorbidity, or operative factors.

Results: SABG (n=1,334,511; 73.8% men; 66 years [median]), BITA-MABG (n=73,054; 85.1% men; 59 years), and RA-MABG (n=97,623; 82.5% men; 61 years) showed distinctly different distribution of demographic and risk factors. Observed OM was higher for SABG (1.6%) compared to both BITA-MABG (1.0%; $P < .001$) and RA-MABG (1.1%; $P < .001$). Multivariate analysis showed that, compared to SABG, BITA-MABG carried a modest borderline significant OM increase (AOR = 1.14 [1.00-1.30]; $P = .05$) and RA-MABG was associated with similar OM risk (AOR = 1.01[0.89-1.15]; $P = .85$). Subgroup sensitivity analyses showed that, compared to SABG, BITA-MABG was associated with increased OM in urgent operations, on-pump cases, female patients, the elderly (>70 years), diabetics, smokers, patients with moderate or severe chronic lung disease (CLD), and in centers with low institutional BITA utilization rates. (Figure-Left) RA-MABG and SABG were associated with similar OM risk in all subgroups except for decreased OM for RA-MABG in off-pump cases (Figure-Right).

Conclusions: This analysis showed equipoise between RA-MABG and SABG. BITA-MABG is as equally safe as SABG in selected patients. These findings, combined with recent evidence that only MABG, but not SABG, is associated with survival advantage over third-generation intracoronary stents, indicate a need for a comparative outcomes study of MABG vs SABG to facilitate informed, shared decision making regarding optimal surgical revascularization.



*P<0.05; CLD = chronic lung disease

4:10 PM

Video-Assisted Thoracoscopic Surgery vs Axillary Thoracotomy for Early Stage Non–Small-Cell Lung Cancer: Short-Term Outcomes of a Phase 3, Multicenter, Randomized Trial

D. Situ[1], *H. Long*[1], *Q. Tan*[2], *Q. Luo*[3], *Z. Wang*[4], *G. Jiang*[5], *T. Rong*[1]

[1]*Sun Yat-sen University Cancer Center, Guangzhou, China,* [2]*Daping Hospital, Third Military Medical University, Chongqing, China,* [3]*Shanghai Chest Hospital, Shanghai Jiaotong University, China,* [4]*Shenzhen People's Hospital, Jinan University, China,* [5]*Shanghai Pulmonary Hospital, Tongji University, China*

Purpose: Video-assisted thoracoscopic surgery (VATS) rapidly has been gaining popularity worldwide in the treatment of early stage non–small-cell lung cancer (NSCLC) because it is potentially less invasive. However, there has not been a large randomized controlled trial (RCT) to prove its superiority over thoracotomy. Therefore, a multicenter RCT that recruited 508 patients in China was performed in order to verify the role of VATS.

Methods: A non-inferiority phase 3 trial was undertaken at five tertiary hospitals. Patients aged 18-75 years who were diagnosed with clinical early stage NSCLC without hilar and mediastinal lymphadenopathy were randomized in a 1:1 ratio into VATS and axillary thoracotomy groups. Radical lobectomy plus hilar and mediastinal lymph node dissection was the standard surgical intervention as per protocol. The study was not masked. The short-term outcomes were reported and compared between the two groups.

Results: Between January 2008 and March 2014, 508 patients were recruited and 481 patients were eligible for randomization. A total of 236 patients were randomly assigned to the VATS group, while 245 were assigned to the thoracotomy group. Finally, 425 were eligible for analyses (215 and 210, respectively). Eight thoracoscopic procedures were converted to open surgery intraoperatively (3.72%). Median operation time in VATS group was significantly less than that in thoracotomy group (150 minutes vs 166 minutes, $P = .009$). Patients who underwent VATS procedures had significantly less intraoperative blood loss ($P = .001$). There was no difference between the two groups in terms of duration and volume of chest drainage, length of hospitalization, morbidity, and mortality. Cancer residual margins were found in one patient with VATS and five with open surgery ($P = .128$). No significant difference was observed regarding the yield of lymph nodes from either surgical approach (10 vs 12, $P = .389$).

Conclusions: Our study has demonstrated that VATS is a safe and reliable procedure for the treatment of clinical early stage NSCLC and may be superior to axillary thoracotomy in terms of operation time and intraoperative blood loss.

Commercial Relationships of the Late-Breaking Abstract Reviewers

The Society would like to thank the following STS leaders for reviewing the late-breaking abstracts submitted for presentation consideration at the STS 53rd Annual Meeting. Unless otherwise noted, the abstract reviewers have no commercial relationships to disclose:

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