Effectiveness of the AngioVac system in removal of intravascular masses: a single center experience

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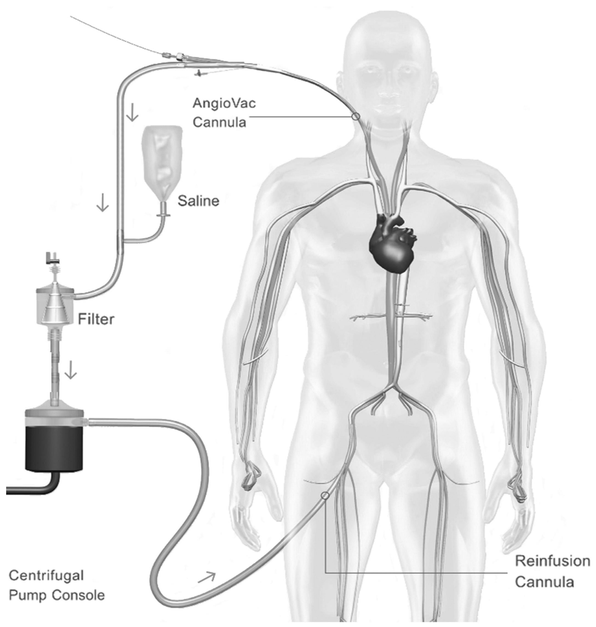
Introduction

Cardiovascular diseases including endocarditis, deep vein thrombosis, and septic emboli remain highly mortal diseases, resulting in numerous hospitalizations and deaths each year (15, 16, 20, 21). In addition to anticoagulation and thrombolytic therapies that are used for acute and chronic management of these conditions, surgical debridement can also be performed. However, critically ill and hemodynamically unstable patients are often not viable candidates for these procedures, owing to the stress placed on the body during sternotomy.

Furthermore, patients presenting with comorbidities such as coronary artery disease, heart failure, renal disease, obesity, and diabetes are predictors of early mortality in these invasive procedures (1 – 3, 17). An alternative to these invasive procedures is the Angiovac system designed by AngioDynamics in Latham, NY. Performed either percutaneously or open, this minimally invasive technique has been shown as an effective replacement for the removal and filtration of acute thrombi or emboli. This method is also indicated for the debridement of vegetations seen in right sided endocarditis and right atrial tumors (6, 8)

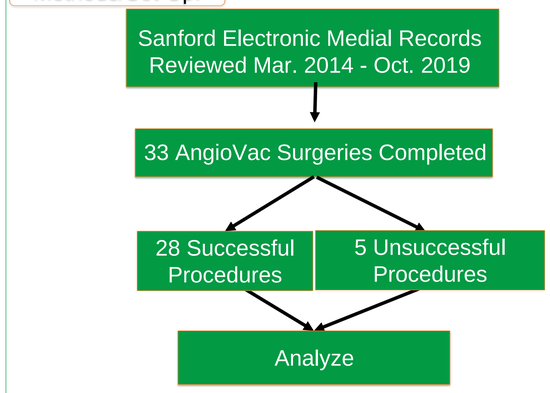
AngioVac Set-Up



This method requires two cutaneous access points: one for the AngioVac canula and the other for the return canula. These are inserted in a circuit fashion using a combination of patients' femoral and jugular veins. (6, 10, 12). The AngioVac canula is then guided through the vasculature to the site of thrombi, emboli, or vegetation. With the device's balloon inflated, funnel shaped tip, it facilitates aspiration using an external pump

Methods/ Results

Methods/Set-Up:



Data:

Table 1: Patient Demographics	Total
Number or Procedures:	33
Average Age (years)	46.5
Male (n)	22 (67%)
Average BMI (Kg/(m²)):	**28.63**
Underweight (< 18.5 Kg/(m²))	0
Normal (18.5 - 24.9 Kg/(m²))	11 (33%)
Overweight (25 - 29.9 Kg/(m²))	9 (27%)
Obese (30 - 34.9 Kg/(m²))	5 (15%)
Severely Obese (35 - 39.9 Kg/(m²))	3 (9%)
ASA physical status (counts):	-
1	0
2	0
3	6 (18%)
4	24 (73%)
5	3 (9%)
Average ASA Score	**3.9**
Diabetes I or II	12 (36%)
Hypertension	17 (52%)
Coronary Artery Disease	10 (30%)
COPD	3 (9%)
Heart Failure (systolic or diastolic)	10 (30%)
Prior Venous Thromboembolism	7 (21%)
Prior CVA (ischemic or hemorrhagic)	3 (9%)
Patent Foramen Ovale	6 (18%)
Immunosuppression - Drug Induced	4 (12%)
Immunosuppression - Other	1 (3%)
Intravenous Drug User (IVUD)	14 (42%)
Median Age IVDU (years)	29 [33-24]
Median Age Non-IVDU (years)	63 [74-51]
Malignancy	**8 (24.24%)**
Active	5 (15%)
Remission	3 (9%)
Endocarditis	24 (73%)
DVT/PE	2 (6%)
RA/ RV mass	5 (15%)
ICV Thrombus	1 (3%)
Vegetations on Pacemaker Leads	1 (3%)

Results Continued

Table 3: Post-Procedure Complications/ Outcomes	Total (33)
Median Time to procedure (days)	5
Median Total Length of Hospital Stay (days)	15
Median Length of stay s/p (days)	10
Median Length of ICU stay s/p (days)	8
Pneumonia	1 (3%)
Aspiration Pneumonia	3 (9%)
Sepsis	4 (12%)
Hemolysis	0
Liver Dysfunction	1 (3%)
Leg Ischemia	0
Venous Thrombus	1 (3%)
GI Bleed	0
DIC	1 (3%)
Embolic Events	1 (3%)
Shock	13 (39%)
Bleed Requiring Surgical Intervention	1 (3%)
Stroke	0
Pleural Effusion	9 (27%)
Tracheostomy	3 (9%)
Intubation	15 (45%)
30 Day Mortality	1 (3%)
Failed Procedure	5 (15%)
Successful Procedures	28 (85%)
Procedure Repeated	0

AngioVac® Cannula and Circuit

Summarized Major Findings:

1. The most common indications for the procedure were endocarditis (n = 24; 73%), RA/RV mass (n = 5; 15%), and DVT/PE (n = 2; 6%).

2. Patient preexisting comorbidities included hypertension (n = 17; 52%), IVDU (n = 14; 42%), CAD (n = 10; 30%), and diabetes (n = 12; 36%).

3. Post-procedurally the median length of hospital stay s/p was 10 days (IQR = 18-8) with nearly all patients being directed to the ICU directly following the procedure (n = 32; 97%)

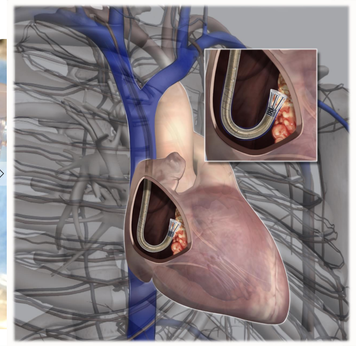
4. The most common complications seen after the procedure were shock requiring vasopressors (n = 13; 39%), pleural effusion (9; 27%), and sepsis (n = 4; 12%).

5. Single occurrence of 30-day mortality post procedurally

Conclusion

- The 85% success rate that was reported in our institution is comparable to a previous reported rate of 70% (10).
- AngioVac procedure offered a less invasive option to high-risk surgical patients presenting with right sided endocarditis requiring vegetation debulking, intravascular thrombi or cardiac masses
- Success rate was fairly high with relatively low complication rates with no direct mortality observed after 30 days

Angiovac is an effective and safe option in removal of vascular clots or masses



References

1. Farag, Mina et al. 2017. "Surgery for Infective Endocarditis: Outcomes and Predictors of Mortality in 360 Consecutive Patients." *Medical Science Monitor: International Medical Journal of Experimental and Clinical Research* 23: 3617–26.
2. Kiefer, Todd et al. 2011. "Association between Valvular Surgery and Mortality among Patients with Infective Endocarditis Complicated by Heart Failure." JAMA 306(20): 2239–47.
3. Ragnarsson, Sigurdur et al. 2015. "Clinical Presentation of Native Mitral Valve Infective Endocarditis Determines Long-Term Outcome after Surgery." Journal of Cardiac Surgery 30(9): 669–76.
4. nSeet, Raymond C. S., and Alejandro A. Rabinstein. 2012. "Symptomatic Intracranial Hemorrhage Following Intravenous Thrombolysis for Acute Ischemic Stroke: A Critical Review of Case Definitions." Cerebrovascular Diseases (Basel, Switzerland) 34(2): 106–14.
5. Brinjikji, Waleed, Alejandro A. Rabinstein, David F. Kallmes, and Harry J. Cloft. 2011. "Patient Outcomes with Endovascular Embolectomy Therapy for Acute Ischemic Stroke: A Study of the National Inpatient Sample: 2006 to 2008." Stroke 42(6): 1648–52.
6. Hameed, Irbaz et al. 2019. "AngioVac for Extraction of Venous Thromboses and Endocardial Vegetations: A Meta-Analysis." Journal of Cardiac Surgery 34(4): 170–80.
7. Resnick, Scott A. et al. 2016. "Single-Center Experience Using AngioVac with Extracorporeal Bypass for Mechanical Thrombectomy of Atrial and Central Vein Thrombi." Journal of vascular and interventional radiology: JVIR 27(5): 723-729.e1.
8. Patel, Nikhil et al. 2018. "AngioVac Debulking in Endocarditis Patients with Large, Device-Related Vegetations." The Journal of Innovations in Cardiac Rhythm Management 9(8): 3291–96.
9. Jabaar, Ali Abdul, and J. Stephen Jenkins. 2018. "The Role of Vacuum Assisted Thrombectomy (AngioVac) in Treating Chronic Venous Thromboembolic Disease. Systematic Review and a Single Center's Experience." Cardiovascular Revascularization Medicine: Including Molecular Interventions 19(7 Pt A): 799–804.
10. Lu, Shu Y., Adam A. Dalia, Maximilian Lang, and Michael G. Fitzsimons. 2021. "Perioperative Outcomes of Thrombectomy Patients Using Venovenous Bypass and Suction Filtration With General Anesthesia." Journal of Cardiothoracic and Vascular Anesthesia 35(4): 1040–45.
11. Donaldson, Cameron W. et al. 2015. "Thrombectomy Using Suction Filtration and Veno-Venous Bypass: Single Center Experience with a Novel Device." Catheterization and Cardiovascular Interventions: Official Journal of the Society for Cardiac Angiography & Interventions 86(2): E81-87.
12. Michelson, Cara M. et al. 2017. "Use of a Modified Cardiopulmonary Bypass Circuit for Suction Embolectomy with the AngioVac Device." The Journal of Extra-Corporeal Technology 49(4): 299–303.
13. Vranken, Nousjka Pa, Zaheer Ud Babar, Jesse A. Montoya, and Patrick W. Weerwind. 2020. "Retrograde Autologous Priming to Reduce Allogeneic Blood Transfusion Requirements: A Systematic Review." Perfusion 35(7): 574–86.
14. Balachandran, Subramaniam et al. 2002. "Retrograde Autologous Priming of the Cardiopulmonary Bypass Circuit Reduces Blood Transfusion after Coronary Artery Surgery." The Annals of Thoracic Surgery 73(6): 1912–18.
15. White, Richard H. 2003. "The Epidemiology of Venous Thromboembolism." Circulation 107(23 Suppl 1): I4-8.
16. Silverstein, M. D. et al. 1998. "Trends in the Incidence of Deep Vein Thrombosis and Pulmonary Embolism: A 25-Year Population-Based Study." Archives of Internal Medicine 158(6): 585–93.
17. nJakuska, Povilas et al. 2020. "Predictors of Early Mortality after Surgical Treatment of Infective Endocarditis: A Single-Center Experience." Perfusion 35(4): 290–96.
18. Hou, Xiaotong et al. 2009. "Retrograde Autologous Priming of the Cardiopulmonary Bypass Circuit Reduces Blood Transfusion in Small Adults: A Prospective, Randomized Trial." European Journal of Anaesthesiology 26(12): 1061–66.
19. Saczkowski, Richard, Pierre-Luc Bernier, Christo I. Tchervenkov, and Ramiro Arellano. 2009. "Retrograde Autologous Priming and Allogeneic Blood Transfusions: A Meta-Analysis." Interactive Cardiovascular and Thoracic Surgery 8(3): 373.

Association of Race and Utilization of Pain Medication in Pediatric Patients with Upper and or Lower Extremity Fractures

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Introduction

- Despite efforts, children's pain remain undertreated in emergent settings[1]
  - Fear of potential side effects in children
  - Inappropriate pain assessment tools
- Prior studies showed undertreated pain in self-identified adult Hispanic and Black patients[2]
- What about the kids?
  - Gap as it relates to pediatrics, opioid use in acute fracture management, and race
- We sought to: Determine the association of race and the utilization of pain medication in children who have suffered an upper and/or lower extremity fracture
- Our hypothesis was as follows: "There will be a statistically significant difference in the percentage of white versus black and other race patients who receive opioid pain medication"

Methods

- Retrospective, cross-sectional analysis using the 2011-2018 National Hospital Ambulatory Care Survey-Emergency Department (NHACS-ED)
- Patients' selection criteria: <18 years old and Upper and/or lower limb fracture using associated ICD-9/10 codes
- Clinical Variables: upper/lower limb fracture diagnosis, pain rating, analgesic received, services provided
- Demographic Variables: Age, race, sex, year of visit, insurance status, metropolitan statistical area (MSA) status
- Data analyzed using summary statistics and bivariate comparisons (Chi-squared tests and GLM means)
- Significance tests two-sided (p-value < 0.05)

Results

Table 1. Characteristics of U.S. Emergency Department Visits Subdivided by Race, 2011-2018

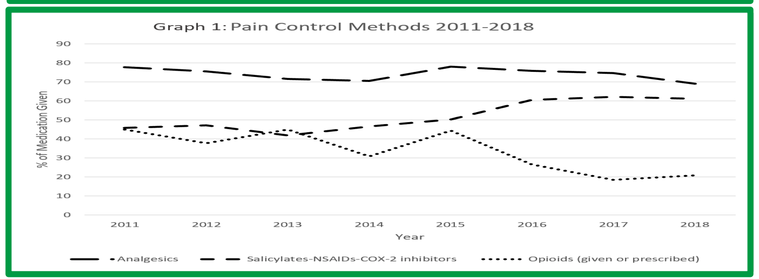
Characteristics	Total Estimated=8,149,544 Unweighted N=1417	White Estimated=6,465,463 Unweighted N=1104 78%	Black Estimated=1,295,660 Unweighted N=232 16%	Other Estimated=388,420 Unweighted N=81 6%	*P value*
Age	9.5 ± 0.3	9.6 ± 0.2	9.9 ± 0.5	8.9 ± 0.9	0.538
Gender %					0.534
Male	62.6	62.7	64.8	54.7	-
Female	37.4	37.3	35.2	45.3	-
Insurance Status %					0.003*
Private	38.8	41.1	21.7	53.8	-
Government	52.5	50.1	71.1	32.9	-
Other	8.7	8.7	7.2	13.3	-
Pain Rating #/10	6.3 ± 0.2	6.0 ± 0.2	6.2 ± 0.3	6.7 ± 0.6	0.498
None %	7.0	6.9	7.8	5.1	-
Mild (1-3) %	10.1	10.2	9.2	11.1	-
Moderate (4-6) %	35.9	36.2	35.5	33.5	-
Severe (7+) %	47.0	46.7	47.5	50.4	0.995
Metropolitan Statistical Area Status (MSA) %					0.004*+
MSA	84.0	81.7	95.3	84.2	-
Non-MSA	16.0	18.3	4.7+	15.8+	-
Pain Control Method					
Analgesics %	74.2	74.2	71.7	83.0	0.348
Salicylates-NSAIDs-COX-2 inhibitors %	52.3	52.3	53.6	47.0	0.796
Opioid (given or prescribed) %	33.2	33.4	26.8	51.6	0.032*
Services Provided %					
Imaging	92.5	92.5	93.7	88.1	0.490
Diagnostic Services	80.9	79.9	86.5	78.9	0.367
Procedures	75.7	75.8	75.6	75.3	0.978

* Denotes significant value
+ Unreliable estimate. Results are preliminary.

Table 2: Pain Control Methods 2011-2018

Year	2011	2012	2013	2014	2015	2016	2017	2018	p-value
Analgesic Use	77.7	75.6	71.6	70.6	78.0	75.8	74.7	69.0	0.831
Salicylates-NSAIDs-COX-2 inhibitors	45.9	47.1	41.8	46.6	50.2	60.6	62.2	61.2	0.085
Opioids (given or prescribed)	44.9	37.8	44.9	30.8	44.4	26.5	18.5	20.8	0.000*

* Denotes significant value (p=<0.05)



Discussion

- Strengths
  - NHACS-ED is a very large dataset from across the United States
    - Allows us to compare multiple variables while still having reliable estimates, Allows generalization to the population, Weighting for nonresponse bias
  - Specificity of ICD-9 & 10 Codes
    - Many other studies investigate all long bone fractures (i.e. phalanx fractures), some may not warrant opioids
- Limitations
  - Different races may preferentially decline certain pain medications, Patients may be misclassified by race, no data on analgesics given prior to ED visit

Conclusions

- The overall pain medication administration for children did not change over the study period
  - Utilization of opioids for children with fractures significantly decreased, but SNC-2 use did not increase proportionally to compensate
- Our study showed other races were more likely to receive opioids, contradicting previous studies
  - Minority children from 2014-2017 were more likely to receive analgesics, but less likely to receive opioids and achieve optimal pain reduction[3]
- Future Considerations: Investigate specific reasons for reduced used of opioid in children
- Further break down opioid utilization by ethnicity in addition to race (other race category non-specific)

Sources

1. Le May S, Ali S, Khadra C, Drendel AL, Trottier ED, Gouin S, Poonai N. Pain Management of Pediatric Musculoskeletal Injury in the Emergency Department: A Systematic Review. Pain Res Manag. 2016;2016:4809394. doi: 10.1155/2016/4809394. Epub 2016 Apr 11. PMID: 27445614; PMCID: PMC4904632.
2. Todd KH, Samaroo N, Hoffman JR. Ethnicity as a risk factor for inadequate emergency department analgesia. JAMA. 1993 Mar 24-31;269(12):1537-9. PMID: 8445817.
3. Goyal MK, Johnson TJ, Chamberlain JM, Cook L, Webb M, Drendel AL, Alessandrini E, Bajaj L, Lorch S, Grundmeier RW, Alpern ER; PEDIATRIC EMERGENCY CARE APPLIED RESEARCH NETWORK (PECARN). Racial and Ethnic Differences in Emergency Department Pain Management of Children With Fractures. Pediatrics. 2020 May;145(5):e20193370. doi: 10.1542/peds.2019-3370. Epub 2020 Apr 20. PMID: 32312910; PMCID: PMC7193974.

Outcomes from Malignant Pleural Effusion Treatments: An investigation into length of stay, survival rates, and dyspnea scores in patients receiving indwelling pleural catheters, talc pleurodesis, or both.

Megan DeVillers, Zachary Mohs, Stephanie Ziegler, Marc Basson, MD, William Newman, MD

Background

- Malignant pleural effusions (MPEs) affect approximately 150,000 people and almost 15% of cancer patients yearly. MPE patients have a poor prognosis with most only surviving 3-12 months post-diagnosis.
- Due to the short life expectancy, MPE treatments are often palliative in nature and highly symptom-dependent, with most patients primarily complaining of shortness of breath.
- The most common treatments include pleurodesis (TPS) or insertion of indwelling pleural catheters (IPC).
- Previous MPE research studies have been done on non-US populations and have come to contradicting conclusions about the optimal treatment approach.
- The objective of this study was to further compare three of the most common treatments by investigating three outcome variables (length of stay, survival rate, and dyspnea score) to determine which treatment may be best suited for patients with MPE.

Methods

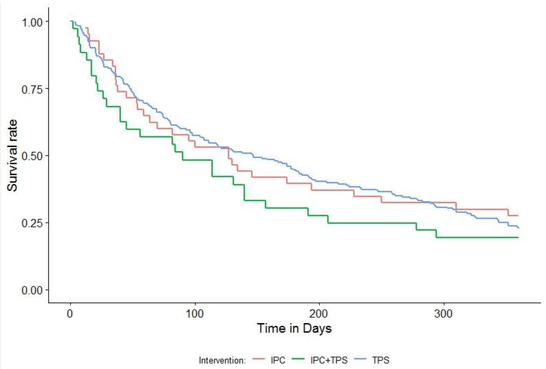
- Retrospective chart analysis was conducted for 314 MPE patients that underwent talc pleurodesis, insertion of an indwelling pleural catheter, or a combination of both procedures between January 1, 2010 and December 31, 2020. The talc pleurodesis group had 228 patients, the IPC group totaled 48 patients, and the combination group had 38 patients.
- Demographics were similarly distributed in each group, with the majority of patients being Caucasian males between the ages of 66 and 70.
- Survival rate (Figure 1) was measured by finding the number of days between date of procedure and death/censor date. This data was then run through a Cox proportional hazard regression model to adjust for likelihood of mortality when patients are chosen for each of the three interventions and adjusted for baseline dyspnea and ECOG scores.

Methods Continued

- Dyspnea scores (Figure 2) were estimated by researchers after reviewing patient complaints in the chart and were ranked as either none, mild, moderate, or severe. Scores were collected both prior to the procedure and until end of study or patient death/loss to follow up.
- Length of Stay (Figure 3) was determined by finding the cumulative time between all hospital admission duration following the procedure, truncated at 400 days.
- Non-parametric comparison tests for multiple comparisons were used for continuous and ordinal variables. Chi-squared tests were used for categorical variables. Bonferroni adjustment was used for multiple comparisons. R version 4.0.2 and StataMP version 15 were used for statistical calculations.

Results

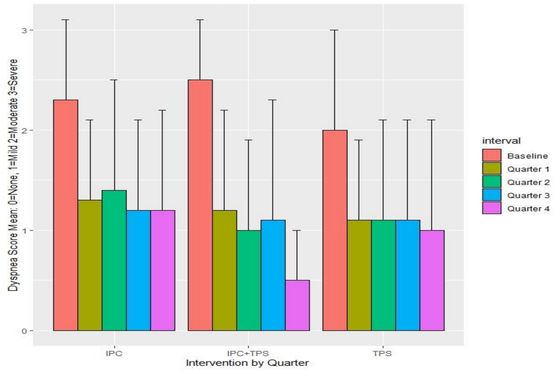
Figure 1: Cox Adjusted Survivability Curves: Adjusted for Intervention, Baseline ECOG, and Dyspnea Scores



- ***Figure 1*** depicts the likelihood of survival over a period of 400 days. The curve demonstrates that the downward trend between all intervention groups is nearly identical after adjusting for baseline ECOG and dyspnea scores (p between all groups ns).

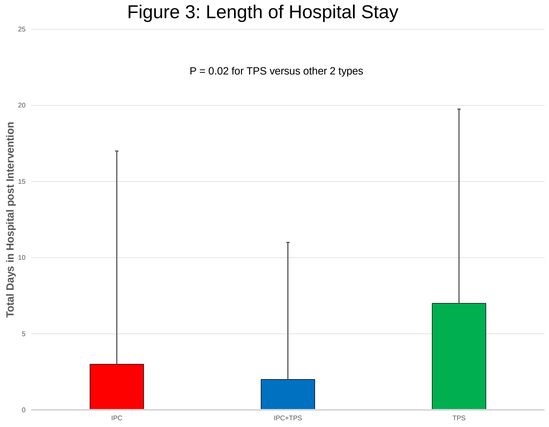
Results Continued

Figure 2: Quarterly Dyspnea Scores Following Intervention



- ***Figure 2*** displays baseline pre-procedure average dyspnea scores for patients as well as quarterly average dyspnea scores post-intervention. While there is improvement in dyspnea noted after each procedure, there is no significant difference in improvement among the groups.

Figure 3: Length of Hospital Stay



- ***Figure 3*** displays total number of days spent in the hospital for each test group (truncated at 60 days. The results show that the IPC and the IPC + TPS groups have a relatively similar LOS at 3 and 2 days, respectively. The TPS group, however, has a median LOS of 7 days.

Limitations

This study has several limitations that were noted throughout the project:

- The population studied was primarily made up of middle-aged Caucasian males. The data collected and conclusions made may not apply to other genders, races, or ethnicities.
- The dyspnea scores were estimated by researchers based on patient complaints within the charts, meaning they may not be reliable from patient to patient or physician to physician. Some patients also describe their shortness of breath as pain, which can make scoring unreliable.
- The difference in number of patients between the three groups could affect the results. More research should be done with a larger sample to obtain a higher statistically and clinically powerful result.

Conclusions

- Given the collected data, intervention type does not appear to be a statistically significant or clinically relevant factor in post procedure survival after adjusting for baseline ECOG and dyspnea scores.
- There were also no statistically significant or clinically relevant differences in dyspnea scores post-procedure between the three treatment groups.
- The primary outcome variable reviewed was Length of Stay. There was a statistically significant and clinically relevant difference between LOS for patients that received TPS (7 days) and those that received IPC/combination treatments (3 and 2 days). This information could be useful for clinicians to provide to patients if they are deciding between multiple treatment options for their MPE. In addition, these results could be valuable to hospital systems as they are acutely attuned to length of stay and how it relates to overhead costs.

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Complications Associated with Malignant Pleural Effusion (MPE) Interventions

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Abstract

- There are three commonly used approaches to the management of symptomatic malignant pleural effusion (MPE) patients: placement and drainage of the effusion via an indwelling pleural catheter (IPC), obliteration of the pleural space via talc pleurodesis (TPS), or a combination of both. To our knowledge, no published studies have looked at the complications associated with these interventions in a purely U.S. population. This prompted us to utilize the VA Health Care System's VINCI database to retrospectively review the chart of each subject who had undergone one of these interventions from 1/1/2010 to 12/31/2020. The demographics of the subjects were evenly distributed between the three intervention groups. Subjects meeting the inclusion criteria were distributed as n=48 for IPC, n=228 for TPS, n=38 for IPC + TPS. Complications were recorded as either pulmonary or extrapulmonary. Pulmonary complications included intervention failures (i.e., change to an alternative form of management), pneumonia/chest infections, lung infarctions, lung entrapments, and other complications (i.e., pneumothorax, intubation, etc.). Extrapulmonary complications included medication/chemo adverse events, non-pulmonary infections, cardiac arrhythmias, chest tube dislodgement, and chest tube inadvertent removals. It was found that there were no statistical or clinically significant differences in extrapulmonary complications based on intervention. The most common extrapulmonary complication was medication/chemo adverse events, seen in 43.8% of IPC and 36.5% of the TPS or dual treatment group. There were significant differences seen in the pulmonary complications, with intervention failure rates being the most striking. While there was no difference in failure rates over the first 90 days, IPC exhibited a significantly higher failure rate than the other two approaches one-year post-intervention (37.5 vs 20.7%; p=0.015). Pneumonia/chest infection rate (31.3 vs 16.2%; p=0.013), lung entrapment (14.6 vs 4.5%; p=0.015), and other complications (22.9 vs 12.4%; p=0.05) were higher in the IPC group as well. Based on the data collected and noting the limitations of this data, it is reasonable to conclude that in this U.S. population, IPC is associated with more adverse events, and importantly, can lead to higher long term failure rates compared to other management strategies.

Introduction

- A growing problem in the U.S is the development of pleural effusions secondary to underlying malignancy with more than 150,000 individuals diagnosed each year.
- The exact pathophysiology of MPE formation is unknown, and management is strictly aimed at reducing dyspnea .
- There are many different interventions available for treatment of MPE, with indwelling pleural catheters (IPC) and talc pleurodesis (TPS) being most common.
- IPC allows for continuous drainage of the pleural fluid, reducing intrapleural volume, and subsequent dyspnea.
- TPS works to fuse the visceral and parietal pleural preventing accumulation of fluid into the pleural space.
- These two intervention strategies can also be used in tandem and have been shown to shorten hospital stays and allow for earlier removal of the IPC.
- There have been no published studies that have looked at the complications associated with these interventions in a strictly U.S. population.

Methods

- The VA Heath Care System's VINCI database was utilized for retrospective chart review.
- All patients who had been coded as having an MPE from 1/1/2010 to 12/31/2020 were obtained.
- Subjects were then filtered down to those coded as having either IPC or TPS.
- From those, 314 fit the criteria for inclusion into the study.
- Subjects' social security number and date of birth were utilized to access their charts via the Joint Legacy Viewer (JLV).
- The information was then de-identified using patient SID numbers and recorded.
- Demographic data such as age, sex, race, ethnicity, cancer treatment, tumor histopathology, and baseline ECOG were collected and summarized in Table 1.
- Through review of each of the 314 charts, extrapulmonary and pulmonary complications associated with each intervention were recorded.
- All variables, with the exception of age, demonstrated a significant distributional departure from normality and thus are represented as median with intra-quartile range (IQR) in parenthesis.
- Non-parametric comparison tests were used for continuous and ordinal variables. Chi-squared/Fischer-exact tests were used for categorical variables. Bonferroni adjustment was made for all variable comparisons.
- R version 4.0.2 and StataMP version 15 were used for statistical calculations.

Demographics	N (available)	Intervention				p	
		Overall (N=314)	IPC (N=48)	TPS (N=228)	IPC + TPS (N=38)	Overall	IPC versus TPS
Age*	313	69.2 (9.7)	70.1 (9.7)	66.7 (8.8)	69.4 (9.8)	0.18	0.68
Male (%)	313	92.7	94	83.3	93.8	0.07	0.96
Race (%)	300					0.37	1
White		73.6	73.3	70.3	74.3		
Black or African-American		19.7	17.8	24.3	19.3		
Other		6.7	8.9	5.4	6.4		
Hispanic (%)	300	3.7	2.2	4.1	2.7	0.52	1
ECOG baseline	303	1.0 (1.0)	1.0 (1.0)	1.0 (1.0)	1.0 (1.0)	0.72	0.62
Cancer treatment (%)							
Chemotherapy	314	65.9	77.1	68.4	63.2	0.17	0.74
Radiotherapy	314	35	33.3	28.9	36.4	0.65	0.74
Tumor histopathology (%)	314					0.42	0.27
Lung		54.5	60.4	60.5	52.2		
Mesothelioma		18.8	10.4	10.5	21.9		
Hematological/Lymphoma		4.1	6.2	5.3	3.5		Table.1
Other		22.6	22.9	23.7	22.4		

Results/Discussion

- The demographics (Table 1) were evenly distributed across all three intervention groups.
- There were no statistically, or clinically significant differences seen in Extrapulmonary complications in any group (Table 2).
- There were 103 med/chemo adverse events reported with hematologic events (34.95%), nausea (16.50%), rash (10.68%), and vomiting (9.71%) being most common.

Extrapulmonary Complications	Intervention		p
	IPC (N=48)	TPS or IPC + TPS (N=266)	
Med/Chemoadverse Events (%)	43.8	36.5	0.34
Non-pulmonary Infections (%)	16.7	12.4	0,42
Cardiac Arrhythmia (%)	6.2	6.0	1
Chest Tube Dislodgement (%)	2.1	1.1	0.49
Chest Tube Inadvertant Removal (%)	4.2	1.5	0.23

Table.2

- There were 50 reported non-pulmonary infections with sepsis (24%), chest tube/wound infection (24%), and UTI (22%) being most common.
- Pneumonia/chest infection (31.3%), lung entrapment (14.6%), and other complications (22.9%) rates were higher in the IPC group (p=0.01, p=0.01, p=0.05).
- Pneumonia was extremely common making up 81.58% of the 38 recorded pneumonia/chest infection complications.
- Of the 48 other complications, pneumothorax (33.33%), intubation (29.17%), and clogged chest tube/IPC (14.58%) occurred most frequently.
- As seen in Figure 1, since failure rates between TPS and IPC+TPS were almost identical, these interventions were combined and compared in aggregate to IPC (Figure 2).
- As seen in Figure 2., significant differences in failure rates were observed one-year post intervention, with IPC being associated with a 37.5% failure rate (p=0.01)
- There were a total of 85 intervention failures between all the intervention groups, with a switch to IPC (32.94%), thoracentesis (29.42%), and TPS (14.12%) being most common.

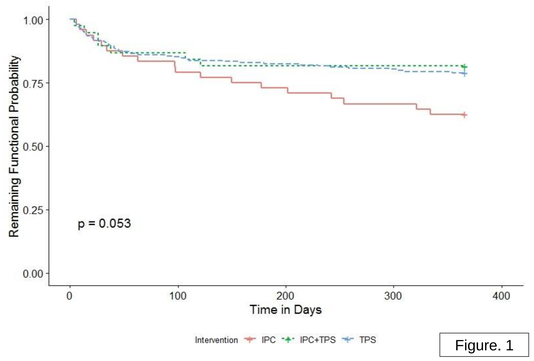

Figure. 1

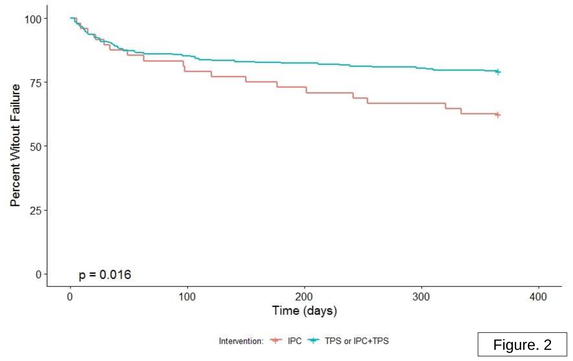

Figure. 2

Pulmonary Complications	Intervention		p
	IPC (N=48)	TPS or IPC + TPS (N=266)	
Pneumonia/Chest Infection (%)	31.3	16.2	0.01
Other Complications (%)	22.9	12.4	0.05
Lung Infarction (%)	4.2	3.4	0.68
Lung Entrapment (%)	14.6	4.5	0.01
Intervention Failure (%)			
7 Days	2.1	2.3	1
30 Days	10.4	9	0.79
90 Days	16.7	14.3	0.67
365 Days	37.5	20.7	0.01

Table. 3

Conclusions

- Based on the data collected and the limitations of the data, IPC is associated with higher long-term failure.
- We have also clearly shown that IPC is associated with greater rates of pneumonia/chest infections and other pulmonary complications.
- While IPC does seem to be associated with higher rates of lung entrapment, that may be artificially high since TPS is commonly avoided in patients with entrapped lungs due to its low efficacy.
- The information gathered from this study should assist U.S. patients and their physicians in picking a management strategy that minimizes the adverse events and maximizes their time outside of the hospital.

Disclaimer

- The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the United States government.

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UND School of Medicine & Health Sciences
University of North Dakota

Asymptomatic Preoperative COVID-19 Screening: A Single Center Study

Stacy Ploom, Tyler Beattie MD, Abe Sahmoun PhD, Dubert Guerrero MD

Introduction

- With the resumption of elective surgeries during the COVID-19 pandemic, patients required to undergo pre-procedural RT-PCR testing for SARS-CoV-2 to [1, 2]
  - Identify asymptomatic and pre-symptomatic carriers
  - Limit spread of virus
- Numerous risk factors correlated with severe COVID-19 [3]
  - Prescence of comorbid conditions [4,5,6,7,8]
  - African American and Hispanic race [9]
  - Smoking [10]
  - Age > 60 years [3,4]
  - Elevated CRP, ESR, WBC, ALP, AST, ALT, LDH, BUN, Cr and low PLT, Hgb, Alb [3]
- Limited studies conducted that identify risk factors for:
  - Symptom progression in initially asymptomatic cases
  - Surgical delay during the pandemic
    - Medical delays associated with worse health outcomes

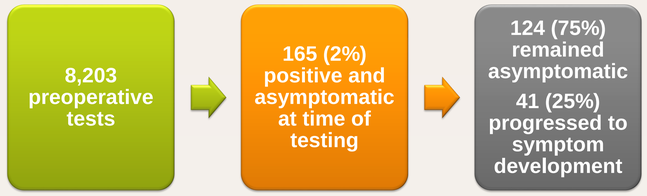
Objectives

- To describe our institutional experience with pre-operative screening at Sanford Hospital in Fargo, North Dakota from June 2020 to March 2021
- To determine best predictors of symptom progression in initially asymptomatic cases
- To investigate risk factors for surgical delay

Methods

- A retrospective chart review was conducted on 165 surgical patients who had
  - Positive pre-procedural COVID-19 tests
  - No symptoms at the time of testing
  - Minimum 14 day follow up
- Demographic, clinical, and/or biomarker data were collected and compared between
  - Truly asymptomatic and symptom progressor cases
  - Delayed and non-delayed surgical cases
- Risk factors for symptom progression or surgical delay were assessed
- Differences were analyzed for significance using Chi-Square or Fischer's exact test and Wilcoxon Signed-Rank Test
- P-values were two-sided and a p-value < 0.05 was considered significant

Results



Study Population Characteristics

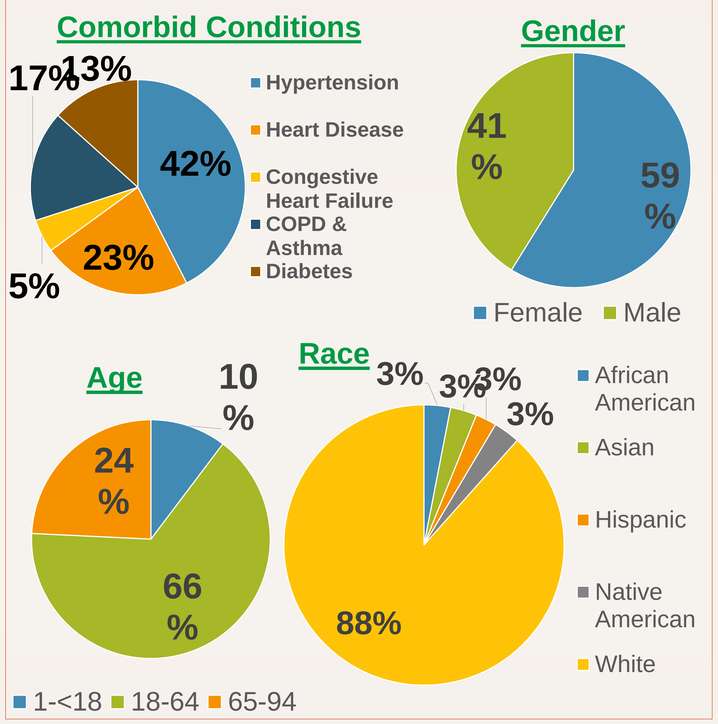


Table 1: Patient Biomarkers and Symptom Progression

Patient Biomarker		Remained Asymptomatic	Symptom Progression	P- value
Mean C-Reactive Protein (CRP) (mg/L)				
	Median	1.70	19.20	N/A
	Q1-Q3	0.53-5.00	0.80-36.90	
Mean Alkaline Phosphatase (ALP) (U/L)				
	Median	82.00	95.00	0.48
	Q1-Q3	67.00-94.50	72.00-116.00	
Mean Alanine Transaminase (ALT) (U/L)				
	Median	18.50	32.00	0.06
	Q1-Q3	13.50-31.00	16.00-39.00	
Mean Aspartate Aminotransferase (AST) (U/L)				
	Median	21.00	25.50	0.14
	Q1-Q3	16.50-25.00	17.00-37.00	
Mean Platelets (per mcL)				
	Median	220.00	277.18	0.07
	Q1-Q3	187.00-266.00	205.00-316.00	
Mean White Blood Cell Count (WBC) (10^9/L)				
	Median	7.90	7.15	0.25
	Q1-Q3	6.20-10.70	5.20-9.40	

Table 2: Patient Characteristics and Symptom Progression

Patient Characteristic		Remained Asymptomatic N (%)	Symptom Progression N (%)	P-value
Age				
	1-<18	12 (71)	5 (29)	0.07
	18-64	87 (81)	21 (19)	
	65-94	25 (63)	15 (38)	
Gender				
	Female	80 (78)	23 (22)	0.33
	Male	44 (71)	18 (29)	
Comorbid Conditions				
	Hypertension	39 (76)	12 (24)	0.79
	Heart Disease	17 (63)	10 (37)	0.11
	Congestive Heart Failure	5 (83)	1 (17)	1.00
	COPD & Asthma	13 (65)	7 (35)	0.28
	Diabetes	12 (75)	4 (25)	1.00
Body Mass Index				
	Normal	1 (71)	6 (29)	0.74
	Obese	62 (75)	21 (25)	
	Overweight	35 (80)	9 (20)	
Race				
	African American	4 (80)	1 (20)	1.00
	Asian	4 (80)	1 (20)	
	Hispanic	3 (75)	1 (25)	
	Native American	4 (80)	1 (20)	
	Caucasian	108 (74)	37 (25)	
Smoking Status				
	Smoker	15 (88)	2 (12)	0.25
	Non-smoker	109 (74)	39 (26)	

Table 3: Patient Characteristics and Delay In Surgery

Patient Characteristic		No Delay N (%)	Delay N (%)	P- value
Age				
	1-<18	1 (6)	16 (94)	0.010
	18-64	34 (31)	74 (69)	
	65-94	5 (13)	35 (88)	
Gender				
	Female	33 (32)	70 (68)	0.0026
	Male	7 (12)	55 (89)	
Comorbid Conditions				
	Hypertension	12 (24)	39 (76)	0.89
	Heart Disease	4 (15)	23 (85)	0.21
	Congestive Heart Failure	0 (0)	6 (100)	0.34
	COPD & Asthma	5 (25)	15 (75)	1.00
	Diabetes	6 (38)	10 (63)	0.22
Body Mass Index				
	Normal	2 (10)	19 (90)	0.17
	Obese	24 (29)	59 (71)	
	Overweight	13 (30)	31 (70)	
Race				
	African American	2 (40)	3 (60)	0.36
	Asian	1 (20)	4 (80)	
	Hispanic	2 (50)	2 (50)	
	Native American	2 (40)	3 (60)	
	White	33 (23)	112 (77)	
30 Day Symptom Progression				
	Progression	30 (24)	94 (76)	0.98
	No Progression	10 (24)	21 (76)	
Surgery Type				
	Elective	18 (13)	123 (88)	<0.0001

Conclusions

- Among pre-operative patients tested for COVID-19, 2% were asymptomatic and infected with SARS-CoV-2
- 25% were pre-symptomatic at time of testing and 75% remained truly asymptomatic over the minimum 14-day follow-up period
- While asymptomatic COVID-19 cases remain relatively low in pre-operative patients, it emphasizes a threat for transmission in the community or operating room
- Urgent or emergent cases proceeded without surgical delay, with most of these being obstetrical procedures
- No demographic, clinical, or laboratory features predicted symptom progression
  - May be due to small sample size or lack of biomarker values for select cases
- Large scale retrospective studies with detailed patient information needed

References

1. Preoperative COVID Testing: Examples From Around the U.S. Anesthesia Patient Safety Foundation. Accessed September 7, 2021. https://www.apsf.org/novel-coronavirus-covid-19-resource-center/preoperative-covid-testing-examples-from-around-the-u-s/
2. Han D, Li R, Han Y, Zhang R, Li J. COVID-19: Insight into the asymptomatic SARS-COV-2 infection and transmission. *Int J Biol Sci*. 2020;16(15):2803-2811. doi:10.7150/ijbs.48991
3. Henry BM, Oliveira MHS de, Benoit S, Plebani M, Lippi G. Hematologic, biochemical and immune biomarker abnormalities associated with severe illness and mortality in coronavirus disease 2019 (COVID-19): a meta-analysis. *Clin Chem Lab Med CCLM*. 2020;58(7):1021-1028. doi:10.1515/cclm-2020-0369
4. Zhou F, Yu T, Du R, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *The Lancet*. 2020;395(10229):1054-1062. doi:10.1016/S0140-6736(20)30566-3
5. Nishiga M, Wang DW, Han Y, Lewis DB, Wu JC. COVID-19 and cardiovascular disease: from basic mechanisms to clinical perspectives. *Nat Rev Cardiol*. Published online July 20, 2020:1-16. doi:10.1038/s41569-020-0413-9
6. Lippi G, Wong J, Henry BM. Hypertension in patients with coronavirus disease 2019 (COVID-19): a pooled analysis. *Pol Arch Intern Med*. 2020;130(4):304-309. doi:10.20452/pamw.15272
7. Gamble A, Pham Q, Goyal S, Cafazzo JA. The Challenges of COVID-19 for People Living With Diabetes: Considerations for Digital Health. *JMIR Diabetes*. 2020;5(2):e19581. doi:10.2196/19581
8. Lee SC, Son KJ, Han CH, Park SC, Jung JY. Impact of COPD on COVID-19 prognosis: A nationwide population-based study in South Korea. *Sci Rep*. 2021;11(1):3735. doi:10.1038/s41598-021-83226-9
9. Ballow M, Haga CL. Why Do Some People Develop Serious COVID-19 Disease After Infection, While Others Only Exhibit Mild Symptoms? *J Allergy Clin Immunol Pract*. 2021;9(4):1442-1448. doi:10.1016/j.jaip.2021.01.012
10. Patanavanich R, Glantz SA. Smoking Is Associated With COVID-19 Progression: A Meta-analysis. *Nicotine Tob Res*. 2020;22(9):1653-1656. doi:10.1093/ntr/ntaa082

UND SCHOOL OF MEDICINE & HEALTH SCIENCES
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Comparison of Prognostic Scoring Systems for Individuals with Malignant Pleural Effusion

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Background

- Malignant Pleural Effusion (MPE) is an aggressive condition with increasing prevalence amongst cancer patients.
- The life expectancy is 3-12 months, often with a poorer quality of life.
- The available treatment options, pleurodesis or indwelling pleural catheter, are therapeutic and palliative in nature.
- Prognostication with a scoring system could guide the decision of a therapeutic intervention.
- We initiated an investigation of comparing existing partially validated prognostic scoring systems, LENT and clinical PROMISE, using a large data set of VA patients afflicted by MPE. Additionally, each prognostic scoring system was modified to be compared to the comprehensive scores.

Methods

- Using the VA's VINCI database (Corporate Data Warehouse), medical charts were reviewed for MPE between 1/1/2010 and 12/31/2020 for those who had one of the following interventions: indwelling pleural catheter (IPC), talc pleurodesis (TPS), or both IPC and TPS in the same procedure.
- Using the Joint Legacy Viewer (JLV), each student individually reviewed patient charts for prognostic scoring system variables.
- LENT system criteria: pleural fluid lactate dehydrogenase, Eastern Cooperative Oncology Group (ECOG) performance status score, neutrophil-to-lymphocyte ratio, and tumor type
- PROMISE system criteria: previous chemotherapy and radiotherapy, hemoglobin, white cell count, and C-Reactive Protein, plus the same variables as the LENT criteria
- All variables, except for age, are represented as median with intra-quartile range (IQR) in parenthesis.
- Non-parametric comparison tests with Bonferroni adjustment for multiple comparisons were used for continuous and ordinal variables. Chi-squared tests were used for categorical variables.
- R packages survival and survminer were used for survival analysis and Kaplan-Meier curve development with pROC for ROC curve depiction and analysis.
- R version 4.0.2 and StataMP version 15

Results

			Intervention				
		Overall	IPC	IPC + TPS	TPS	P	
	Number in Group	314	48	38	228		
	N (available)					Overall	IPC versus TPS
Age*	313	69.2 (9.7)	70.1 (9.7)	66.7 (8.8)	69.4 (9.8)	0.18	0.68
Male (%)	313	92.7	94	83.3	93.8	0.07	0.96
ECOG baseline	303	1.0 (1.0)	1.0 (1.0)	1.0 (1.0)	1.0 (1.0)	0.72	0.62
Cancer treatment							
Chemotherapy (%)	314	65.9	77.1	68.4	63.2	0.17	0.74
Radiotherapy (%)	314	35	33.3	28.9	36.4	0.65	0.74
Death (%)	313	92.7	90	91.7	93.4	0.69	0.37
Tumor histopathology (%)	314					0.42	0.27
Lung		54.5	60.4	60.5	52.2		
Mesothelioma		18.8	10.4	10.5	21.9		
Hematological/Lymphoma		4.1	6.2	5.3	3.5		
Other		22.6	22.9	23.7	22.4		

Table 1. Demographics.

- Of the total 313 patients, the average age was 69.2 (IQR = 9.7) and 92.7% were male.
- 303 patients demonstrated an ECOG baseline of 1.0 (IQR = 1.0).
- 30 patients scored with the comprehensive LENT scoring system:
  - KM curves for 1 year survival by risk category were not statistically significant (p = 0.34)
- 33 patients scored with the comprehensive PROMISE scoring system:
  - KM curves for 1 year survival by risk category were not statistically significant (p = 0.11)
- 303 patients were scored separately with the modified LENT system and modified PROMISE system:
  - KM curves present statistically significant results for the risk categories for 1 year survival for the modified LENT score (p = 0.00022) and for the modified PROMISE score (p < 0.0001).
- To evaluate sensitivity and specificity, ROC curves review:
  - data from the modified ECOG and tumor pathology scoring system at 90 days
    - AUC of 0.63 (LENT) and 0.66 (PROMISE)
  - data from complete comprehensive scoring systems at 90 days
    - AUC of 0.57 (LENT) and 0.68 (PROMISE)

Score Risk Category	LENT Comprehensive Score	LENT ECOG+Tumor Pathology Score	PROMISE Comprehensive Score	PROMISE ECOG+Tumor Pathology Score
Low	0(0)	13(4.3)	22(66.7)	90(29.7)
Moderate	20(66.7)	59(19.5)	10(30.3)	113(37.3)
High	10(33.3)	231(76.2)	1(3.0)	100(33.0)
Total	30	303	33	303

Table 2. Data of Prognostic Scoring Systems (percentages in parenthesis)

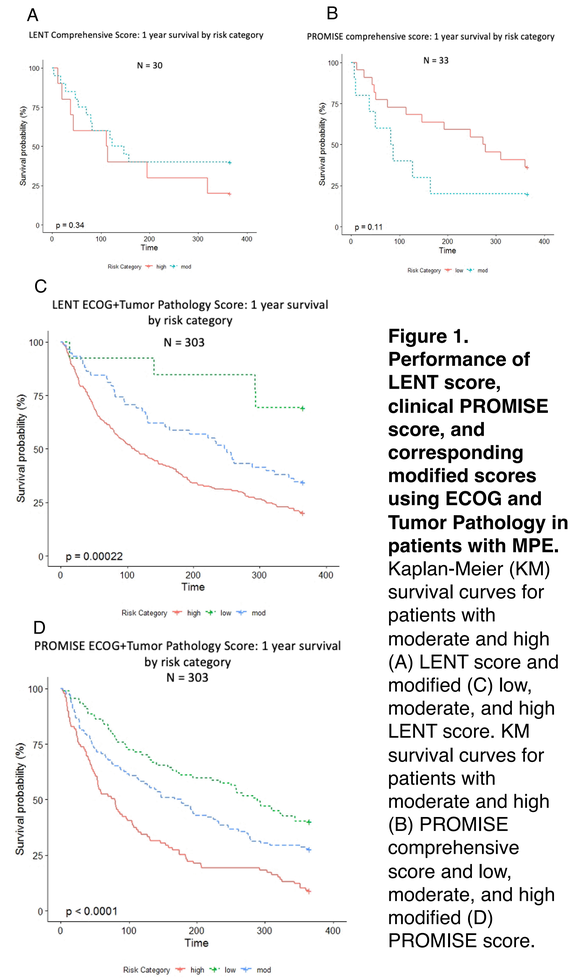

Figure 1. Performance of LENT score, clinical PROMISE score, and corresponding modified scores using ECOG and Tumor Pathology in patients with MPE. Kaplan-Meier (KM) survival curves for patients with moderate and high (A) LENT score and modified (C) low, moderate, and high LENT score. KM survival curves for patients with moderate and high (B) PROMISE comprehensive score and low, moderate, and high modified (D) PROMISE score.

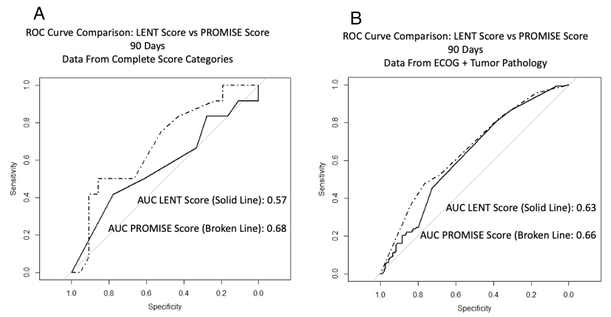

Figure 2. ROC curve analysis for the LENT score and PROMISE score at 90 days. (A) LENT score and PROMISE score using complete score categories. (B) LENT score and PROMISE score using data from ECOG and tumor pathology only.

Summary & Conclusion

- There is a larger difference when scoring a patient's prognosis using the clinical PROMISE comprehensive scoring system compared to the LENT comprehensive system.
- These results are clinically relevant; often, patients with a poor prognosis presumably desire to minimize their hospital days and discomfort. Therefore, patients with a poor prognosis could be identified using the clinical PROMISE score to assist in developing a care plan in correspondence with their health goals.
- The modified PROMISE and LENT scores using ECOG and tumor pathology alone resulted in statistically significant results when comparing survival curves.
- Despite the statistically significant survival results, the ROC curve analysis was insignificant with scores less than 0.7, deeming it to be only a marginally useful test.

Implications

- Prognostic scoring systems can add clinically relevant information that clinicians can present to patients in aiding a decision of therapeutic intervention.
- Prognostic scoring systems in the literature yield variable results and may not be an effective system for clinicians.
- Further investigation into biomarkers and other clinical evidence is needed to develop effective prognostic scoring systems for patients afflicted by MPE.

Limitations

- Some procedures were incorrectly coded in the U.S. VINCI system; however, with careful review, the correct information was gathered.
- Insufficient documentation of prognostic factors limits results.
- The small sample size of IPC patients, especially involving only U.S. Veterans with the majority being white, male patients.
- Failure of documentation of some ECOG scores required student estimation of the baseline ECOG scores.

Acknowledgements

- Special thanks to Dr. William P. Newman, PI, and the Fargo VA Healthcare System in Fargo, ND for providing the research opportunity
- UNDSMHS for granting the time and resources to learn the depths of clinical research
- Classmates for the support and meaningful discussions involving critical thinking

Psallidas, I, Kanellakis NI, Gerry S, et al. Development and validation of response markers to predict survival in pleurodesis success in patients with malignant pleural effusion (PROMISE): a multi-cohort analysis. 2018 Lancet Onco.; 19:930-939

Clive AO, Kahan BC, Hooper CE. Predicting survival in malignant pleural effusion: development and validation of the LENT prognostic score. 2014 Thorax; 69:1098-1104

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