Original Article

Chronic Postthoracotomy Pain in Transapical Transcatheter Aortic Valve Replacement

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Abstract

Objective: Chronic postthoracotomy pain (CPTP) is a persistent, occasionally debilitating pain lasting >2 months following thoracic surgery. This study investigates for the first time the prevalence and clinical impact of CPTP in patients who have undergone a transapical transcatheter aortic valve replacement (TA-TAVR). **Design:** This was a single-institution, prospective observational survey and a retrospective chart review. **Setting:** The study was conducted in the University Hospital. **Participants:** Patients. **Materials and Methods:** A survey of 131 participants with either a previous TA TAVR or transfemoral (TF) TAVR procedure was completed. A telephone interview was conducted at least 2 months following TAVR; participants were asked to describe their pain using the Short-Form McGill Pain Questionnaire. **Measurements and Main Results:** Odds ratio (OR) was calculated using the proportions of questionnaire responders reporting "sensory" descriptors in the TA-TAVR versus the TF-TAVR groups. Results were then compared to individual Kansas City Cardiomyopathy Questionnaire (KCCQ12) scores and 5-min walk test (5MWT) distances. A total of 119 participants were reviewed (63 TF, 56 TA). Among TA-TAVR questionnaire responders (n = 16), CPTP was found in 64.3% of participants for an average duration of 20.5-month postprocedure (OR = 10, [confidence interval (CI) 95% 1.91–52.5]; P = 0.003). TA-TAVR patients identified with CPTP had significant reductions in 5MWT distances (−2.22 m vs. 0.92 m [P = 0.04]) as well as trend toward significance in negative change of KCCQ12 scores OR = 18.82 (CI 95% 0.85–414.99; P = 0.06) compared to those without CPTP. **Conclusions:** CPTP occurs in patients undergoing TA-TAVR and is possibly associated with a decline quality of life and overall function.

Keywords: *Aortic valve replacement, chronic pain, thoracotomy, transapical transcatheter aortic valve replacement*

Introduction

Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure for high-risk surgical patients with severe aortic stenosis. The procedure is most frequently performed through a percutaneous transfemoral (TF) approach. However, there remains a subgroup of patients with unfavorable ileofemoral anatomy necessitating a transapical (TA) approach, performed through a minithoracotomy.

Chronic postthoracotomy pain (CPTP), also known as postthoracotomy pain syndrome, is defined as a persistent, occasionally debilitating pain that lasts at least 2 months after noncardiac thoracic surgery (including minimally invasive video-assisted thoracic surgery [VATS] procedures), occurs in approximately 50% of cases, and can remain symptomatic for 3–4 years in 30% of patients.[1,2] There is increasing evidence that CPTP poses limitations on day-to-day living for patients in other thoracic surgical procedures.[3-5] The exact etiology of CPTP is multifactorial but is likely to contain a neuropathic component. Some studies have suggested that intercostal nerve damage from compression and/or laceration or disruption of nerve conduction is associated with pain.[6,7] Neither the prevalence, nor the possible effect CPTP has on outcomes, has been studied in patients undergoing TA-TAVR.

The goal of this study is to measure the proportion of CPTP in participants undergoing a TA-TAVR and its impact on quality of life (QoL) and functional status. We hypothesized that CPTP in the form of "sensory" pain in TA-TAVR patients would (1) represent a significant but previously unappreciated cause of

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morbidity postprocedure and (2) represent that CPTP would be associated with decreased Kansas City Cardiomyopathy Questionnaire (KCCQ12) scores as well as 5-min walk test (5MWT) reflecting a lower QoL and functional status than patients without CPTP.

Methods

Following institutional review board approval, a retrospective chart review and a prospective observational study were performed. A compilation of TAVRs performed between October 1, 2012, and September 24, 2015, was formed using the Tufts Medical Center reporting Transcatheter Valve Therapy (TVT) Registry. All patients who underwent a TA- or TF-TAVR between the defined time periods were included in the study. Patients who refused to participate in the study during the telephone interview were excluded and their data were omitted during chart review. In addition, patients were excluded from the prospective portion if they could not be reached by phone after three attempts, deceased, or if the number obtained from the electronic medical record was no longer in service. If the patient could not be reached by phone, the data collected from the retrospective chart review were included [Figure 1].

A chart review between 1-month and 1-year post-TAVR was completed and used for the identification of baseline characteristics including gender, age, comorbidities, preoperative chronic pain syndromes, pre- and peri-procedural opiate consumption, and adjunctive pain therapies. Opiate consumption was reviewed at four points: (1) preprocedure, (2) intraoperative, (3) postprocedure, and (4) at discharge. Nonmorphine opiate medications were converted to morphine equivalents and compared between the two surgical approaches (TA vs. TF) as well as participants experiencing chronic pain versus no pain. Morphine equivalents were calculated using the multiplier of 0.15 mcg fentanyl, 4 mg hydromorphone, and 1.5 mg oxycodone. Chronic use of anxiolytics and antidepressants preprocedure was also compared between groups.

To estimate the proportion of TA-TAVR patients who experienced CPTP from the chart review, the following criteria were used: (1) participants who had explicit evidence of ongoing pain on follow-up visits at least 2-month postprocedure were defined as having CPTP and (2) participants with documented lack of pain at least 1-month postprocedure were defined as not having CPTP. Those without specific evidence of pain or no pain in the chart review and those who were lost to follow-up were not used in the calculation of proportions or final statistical review.

At Tufts Medical Center, the TVT Registry data were collected by the cardiology department and included the KCCQ12 as well as the 5MWT that is completed by the patient during the preprocedure evaluation as well as 1-month postprocedure. Patients with incomplete data or lost to follow-up were not included in the final analysis.

A scripted telephone interview conducted by a single individual followed by the completion of a Short-Form McGill Pain Questionnaire (SF-MPQ) was collected

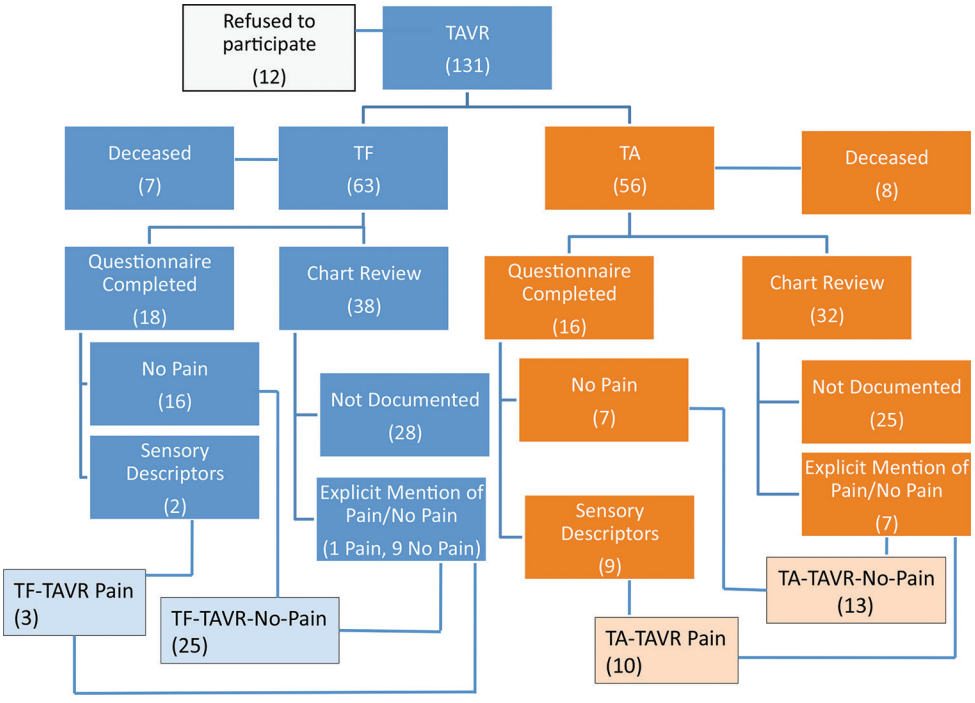

Figure 1: Inclusion and exclusion breakdown. Flow sheet describing the breakdown of study participants from the chart review and questionnaire responders. TA: Transapical, TAVR: Transcatheter aortic valve replacement, TF: Transfemoral

prospectively. The SF-MPQ separates "affective" descriptors from "sensory" (continuous, intermittent, and neuropathic) descriptors and applies a score to each as well as a total score. Responders who complained of incisional pain using "sensory" descriptors with or without "affective" descriptors were considered to have CPTP. Those with no complaints of pain or used "affective" descriptors only were defined as no pain. The consultant conducting the telephone interview completed the scripted portion before deviating or answering questions. The completed questionnaires were numbered with a corresponding random number blinding the data analysis from the data acquisition. A separate single investigator performed the patient identifier-free data analysis.

All patients in the study had general endotracheal anesthesia for the procedure. There was no standardization for intraoperative pain management; some patients received boluses while others were given infusions of opiate pain medications. Totals of intraoperative opiates were then converted to morphine equivalents. There was one surgeon for every TA-TAVR performed; approach and surgical technique were the same for every procedure.

Statistical methods

Differences in baseline, preoperative, and procedure characteristics between patients with and without CPTP in the TA-TAVR SF-MPQ responder groups were compared using Chi-square test, Fisher's exact test, or Student's *t*-tests, as appropriate. Two-tailed *t*-tests were used to test for group differences in: 5-min walk, KCCQ12 scores, left ventricular ejection fraction (EF), New York Heart Association (NYHA) classification, Society of Thoracic Surgeons (STS) risk scores, and Intensive Care Unit (ICU) length of stay.

The proportion of TA-TAVR patients who developed CPTP was calculated based on responses to the SF-MPQ. A range of CPTP was developed with the addition of participants identified in the chart review but could not be contacted to complete the SF-MPQ. Odds ratio (OR) was calculated using the proportions of questionnaire responders reporting "sensory" descriptors in the TA-TAVR versus the TF-TAVR group. All statistical tests were two-sided, and $P < 0.05$ was considered statistically significant. While there are no other articles describing CPTP in this patient population, 30%–50% of patients with other noncardiac thoracic procedures experience CPTP. With an estimated sample of 30 participants, we would be able to construct a 95% confidence interval (CI) with a width of 0.37 around a point estimate of 40%.

Results

Baseline characteristics

A total of 131 patients who underwent the TAVR procedure between October 1, 2012, and September 24, 2015 were included. Twelve (5 TA and 7 TF) refused to participate in the study when contacted by phone. Of the remaining group, 63 underwent the TF approach and 56 underwent the TA approach. Fifteen participants (8 TA and 7 TF) were found to be deceased within 2 months of the procedure and not included in the chart review. There were a total of 72 patients (34 TA and 38 TF) who could not be reached by phone. SF-MPQ was completed by a total of 34 patients (16 TA and 18 TF). The chart review of 32 TA-TAVR patients revealed seven documentations of participants explicitly mentioning either having pain or no pain at the surgical site. The remaining 25 had no specific mention of pain or no pain at the incisional site [Figure 1].

There was statistical significance in the occurrence of "sensory" descriptors as identified by the SF-MPQ in the TA-TAVR-pain group compared to the TF-TAVR-no-pain group (OR = 10 [$P = 0.003$, CI 95% 1.91–52.48]). Average time between telephone interview and TAVR procedure was 26.3 months for the TA group and 21.9 months for the TF group. For the CPTP group, average time between phone interview and procedure was 20.5 months.

Transapical transcatheter aortic valve-pain versus transapical transcatheter aortic valve replacement-no pain

Participant characteristics such as gender, age, opiate consumption, and medical history are found in Table 1. From the 14 completed SF-MPQ forms, significant "sensory" pain was found in 64.3% of interviewed participants; with the addition of seven participants identified in the chart review, a combined total 45.8% had complaints of pain at the incision site at least 2 months and an average of 20.5-month postprocedure.

There was a significant change in 5MWT distances in TA-TAVR-pain versus TA-TAVR-no pain (−2.22 vs. 0.92 m; $P = 0.04$). The pre-TAVR KCCQ12 scores for TA-TAVR-pain versus TA-TAVR-no pain were 47.80 versus 47.47; $P = 0.98$, respectively. Postprocedure, overall and change in KCCQ12 scores were lower in the TA-TAVR-pain group compared to the TA-TAVR-no-pain group (71.7 versus 77.8; $P = 0.50$ and 22.84 versus 31.19; $P = 0.47$) however were not statistically significant. A negative change in KCCQ12 scores in the TA-TAVR-pain group was identified in 4 of 9 versus 0 of 12 (OR = 18.82 [CI 95% 0.85–414.99; $P = 0.06$]) for the TA-TAVR-no pain group. There was no difference in intraoperative or postoperative opiate consumption between TA-TAVR-pain and TA-TAVR-no pain: 45.33 mg and 32.89 mg versus 49.84 mg and 29.2 mg morphine equivalents ($P = 0.76$ and $P = 0.75$) [Table 2].

Discussion

This is the first study that we are aware of to investigate the proportion of CPTP in participants who underwent a TA-TAVR and the clinical impact it may have. The data from our study populations suggest that CPTP may occur as

Table 1: Comparison of baseline characteristics between transapical transcatheter aortic valve replacement-pain and transapical transcatheter aortic valve replacement-no pain

Variable	TA-TAVR-pain	TA-TAVR-no pain	*n*	*P*
Age (years)	79.4±9.82	80.27±8.76	21	0.83
Female (%)	5 (50)	8 (73)		
Male (%)	5 (50)	3 (27)		
Preprocedure opiate use (%)	5 (50)	1 (9)	21	0.06
History of depression/anxiety (%)	4 (40)	0	21	0.04
Intraoperative opiate consumption (morphine equivalents [mg])	45.8±16.14	51.13±31.45	21	0.64
Postoperative opiate consumption (morphine equivalents [mg])	32.89±22.07	29.2±17.47	14	0.75
Discharged on opiates (%)	7 (70)	6 (55)	21	0.66
History of other chronic pain syndrome (%)	7 (70)	4 (36)	21	0.2

Values are mean±SD or *n* (%). TA-TAVR: Transapical transcatheter aortic valve replacement, SD: Standard deviation

Table 2: Comparison of transapical transcatheter aortic valve replacement-pain and transapical transcatheter aortic valve replacement-no pain before and after transcatheter aortic valve replacement

Variable	TA-TAVR-pain	TA-TAVR-no pain	*n*	*P*
5MWT preprocedure, distance (m)	7.71±2.79	8.35±4.58	21	0.74
5MWT postprocedure, distance (m)	6.76±2.95	6.07±4.06	21	0.72
Change in 5MWT, distance (m)	−2.22±1.86	0.92±2.92	23	0.04
EF preprocedure	50.6±12.45	58.67±7.67	23	0.06
EF postprocedure	48.8±11.45	54.64±7.46	23	0.14
NYHA class preprocedure	3.4±0.52	3.00±0.41	23	0.05
NYHA class postprocedure	1.9±0.57	1.54±0.52	23	0.13
STS risk score	9.64±7.64	8.65±4.69	23	0.73
ICU length of stay	101.3±107.75	98.60±63.60	23	0.94
KCCQ12 overall score preprocedure	47.8±26.17	47.47±22.55	20	0.98
KCCQ12 overall score postprocedure	71.7±15.36	77.55±21.29	20	0.47
Change in overall KCCQ12 score	22.84±33.05	31.19±18.68	21	0.47
Negative change in overall KCCQ12 score (%)	4 (44)	0	21	0.02

Values are mean±SD or *n* (%). 5MWT: 5-min walk test, EF: Ejection fraction, ICU: Intensive Care Unit, KCCQ12: Kansas City Cardiomyopathy Questionnaire, NYHA: New York Heart Association, STS: Society of thoracic surgeons, SD: Standard deviation, TA-TAVR: Transapical transcatheter aortic valve replacement

frequently in the TA-TAVR population as other noncardiac thoracic surgery procedures. Similarly, CPTP appears to negatively correlate with QoL and functional status measured by subjective and objective measurements, such as a negative trend in KCCQ12 scores and 5MWT distances.

Patients undergoing TA-TAVR are generally a higher risk cohort. Chronic obstructive pulmonary disease is a common comorbidity in patients presenting for both TA- and TF-TAVR; however, the TA population appears to be subject to higher rates of respiratory failure, need for re-intubation, occurrence of postprocedure pleural effusions, poorer respiratory function, and mortality from respiratory complications.[8-10] Comparison of the TA- and TF-TAVR groups did yield common similarities to other national registries. The TA group had significantly higher STS scores (9.37 vs. 6.48; $P = 0.05$), longer ICU length of stay (96.19 vs. 57.57 h; $P = 0.0001$), lower preprocedure NYHA scores (3.23 vs. 3.5; $P = 0.001$), and lower postprocedure EF (54.00 vs. 53.33%; $P = 0.001$). However, there was no difference in change in 5MWT (0.25 vs. −0.32; $P = 0.50$), unlike the change we see in the TA-TAVR-pain group [Table 3]. The 5MWT is a simple, inexpensive test that has been shown to correlate better with QoL and ability to perform daily activities than other measures such as peak oxygen uptake and FEV1.[11-14] Our observations suggest that CPTP may have an KCCQ12 (similar to participants following other noncardiac thoracic surgeries) and may be related to frequency of respiratory complications seen following TA-TAVR.[1,4,10]

The KCCQ12 questionnaire was originally developed to assess the functional status of patients with cardiomyopathies but has since been extrapolated and validated to patients with aortic valve stenosis.[15] It effectively correlates with QoL, functional status, morbidity, and mortality.[15-18] Similarly, changes in KCCQ12 scores correlate with changes in the clinical picture.[19] Although there appears to be significance in lower KCCQ12 scores in the TF-TAVR group that is experiencing "affective" symptoms, it does not correlate with a negative trend in KCCQ12 scores the same way it does in the TA-TAVR-pain group. This suggests that affective symptoms may still have an impact on the overall degree of improvement,

but it does not appear to cause the deterioration of functional status that CPTP does. In addition, there were two participants in the TF-TAVR group that were reporting "sensory" descriptors of pain in the chest. Chart review of these two revealed ongoing angina symptoms and may be the explanation for the response on the SF-MPQ. None of the participants in the TA-TAVR-pain group were found to have angina symptoms on chart review. These findings further suggest that the impact CPTP may have on QoL.

There is evidence that subjective measures such as KCCQ12 scores and NYHA classifications can be significantly influenced by depression and anxiety. Gottlieb *et al*. have shown that not only is depression common in patients with heart failure but also subjective measures such as KCCQ12 scores and NYHA classifications are significantly influenced by depression, while more objective measures such as exercise testing (5MWT) and EF are less influenced.[20] In our study, we had similar findings. In the TF-TAVR group that responded to the questionnaire, 42% (5 of 11) were taking anxiety/depression-related medications and were more likely to respond to the SF-MPQ with "affective" descriptors only. This group was also associated with a significant difference in postprocedure KCCQ12 scores (69.0 vs. 85.84 [$P = 0.004$]); however, none of the participants had a negative trend in KCCQ12 scores or in 5MWT distances as seen in the TA-TAVR-pain group [Table 4].

CPTP is a well-recognized and potentially modifiable entity that occurs following thoracic surgery. It not only has a major clinical impact but is also negatively associated with QoL, patient satisfaction, and increased hospital costs.[3-5] One study which investigated the effects of postthoracotomy pain showed a significant decline in physical functioning, vitality, and social functioning.[21] While our study focused on mainly two data points, objective measure of function and subjective measurement of QoL and perceived functional status, we did encounter similar findings. Although it was not the focus of our study, we did find that the ICU length of stay (which could potentially translate to hospital costs) was significantly different between TA and TF groups; however, no different between TA-TAVR-pain and TA-TAVR-no pain (101.3 vs. 89.18 h; $P = 0.76$) was observed.

Table 3: Comparison of transapical transcatheter aortic valve replacement and transfemoral transcatheter aortic valve replacement before and after transcatheter aortic valve replacement

Variable	TA-TAVR (*n*=53)	TF-TAVR (*n*=43)	*P*
5MWT preprocedure, distance (m)	5.64±4.60	4.75±4.30	0.91
5MWT postprocedure, distance (m)	7.20±3.12	7.67±20.4	0.79
Change in 5MWT, distance (m)	0.25±3.38	−0.32±3.05	0.50
EF preprocedure	54.13±11.80	45.25±9.94	0.50
EF postprocedure	53.97±10.33	53.33±5.94	0.001
NYHA class preprocedure	3.23±0.53	3.5±0.60	0.001
NYHA class postprocedure	1.79±0.66	2.0±0.55	0.45
STS risk score	9.37±6.82	6.48±4.63	0.05
ICU length of stay	96.19±66.05	57.75±45.97	0.0001
KCCQ12 overall score preprocedure	44.65±22.19	53.13±22.28	0.59
KCCQ12 overall score postprocedure	68.47±20.59	85.88±20.05	0.13
Change in overall KCCQ12 score	23.72±27.01	17.53±19.48	0.41
Negative change in overall KCCQ12 score (%)	9 (16.98)	2 (4.65)	0.08

Values are mean±SD or *n* (%). 5MWT: 5-min walk test, EF: Ejection fraction, ICU: Intensive Care Unit, KCCQ12: Kansas City Cardiomyopathy Questionnaire, NYHA: New York Heart Association, STS: Society of thoracic surgeons, TA-TAVR: Transapical transcatheter aortic valve replacement, TF-TAVR: Transfemoral transcatheter aortic valve replacement

Table 4: Comparison of baseline characteristics transfemoral transcatheter aortic valve replacement-pain versus transfemoral transcatheter aortic valve replacement-no pain

Variable	TF-TAVR-pain (*n*=12)	TF-TAVR-no pain (*n*=16)	*P*
Age (years)	84.82±7.64	80.75±10.25	0.29
Female (%)	6 (50)	4 (25)	
Male (%)	6 (50)	12 (75)	
Preprocedure opiate use (%)	1 (8.33)	2 (12.5)	1.0
History of depression/anxiety (%)	5 (41.67)	1 (6.25)	0.057
Intraoperative opiate consumption (morphine equivalents [mg])	75.04±67.33	55.00±38.67	0.40
Postoperative opiate consumption (morphine equivalents [mg])	8.91±10.57	3.14±4.30	0.33
Discharged on opiates (%)	2 (16.67)	2 (6.25)	1.0
History of other chronic pain syndrome (%)	7 (70)	8 (50)	0.71

Values are mean±SD or *n* (%). SD: Standard deviation, TF-TAVR: Transfemoral transcatheter aortic valve replacement

A plethora of studies suggests that multimodal approaches to pain management during the perioperative period have positive effects postprocedure. Specifically, there is strong evidence suggesting that thoracic epidural analgesia improves outcomes and reduces the prevalence of CPTP.[22,23] This may even be an explanation as to the positive correlation between epidural analgesia in TA-TAVRs and outcomes, such as lower maximal pain scores, higher rates of pulmonary complications, and higher 30-day in-hospital mortality which persisted to 1-year postprocedure seen by Amat-Santos *et al*.[24] Considering the TA-TAVR population is experiencing higher rates of respiratory failure, reintubation, and mortality associated with respiratory complications, application of a thoracic epidural when not clinically contraindicated may provide improvement in postsurgical outcomes.[9,10]

While not all TA-TAVR patients are amenable or even appropriate for epidural analgesia, paravertebral analgesia may be an adequate alternative approach. We know that one of the risk factors for the development of CPTP is significant pain and high opiate requirements postprocedure. Although CPTP was not a measured endpoint, Poltak *et al.* showed that paravertebral analgesia in TA-TAVRs was associated with a reduction of postprocedure opiate consumption and did not add additional risk to the patient.[25] There were too few study participants who had received a paravertebral block in this study to infer any relationship with outcomes or the development of CPTP. Similarly, Katz *et al.* showed a relationship between significant acute pain and CPTP and found the use of the McGill Pain Questionnaire helpful in predicting the development of CPTP.[26] Therefore, based on the current literature, it is not unreasonable to infer the potential of some benefit of paravertebral analgesia in the TA-TAVR population, especially given the low risk associated with the procedure. Differences in surgical approach, for example, thoracotomy versus VATS for wedge resection, have not been shown to change the incidence of CPTP.[5] This may be associated with the proposed mechanism of nerve damage/disruption leading to CPTP regardless of incision size.[6,7] On the other hand, there is some evidence that agents such as celecoxib and acetaminophen improve immediate postoperative pain management and patient satisfaction, suggesting that there may be some benefit in the prevention of CPTP; however, it has not been directly studied.[27,28] Ketamine both intravenous and through epidural has been associated with improved acute postprocedural pain but was not found to reduce the development of CPTP.[29,30] This further emphasizes that the impact preoperative anesthetic management approaches may have on patient outcomes.

With the increasing use of smaller delivery devices for the TF approach and the development of alternative access points such as transaortic (TAo) and transaxillary, there is potential for a decrease in the popularity of the TA technique. While outcome measures such as mortality, stroke, vascular complications, and bleeding appear to be similar between TA and TAo, the potential benefit with the TAo approach is potentially a lower frequency of CPTP.[31] The TAo technique is performed through a J-shaped ministernotomy, and some literature suggests that sternotomy is associated with a lower frequency of chronic postsurgical pain than a thoracotomy.[32-34] Despite these alternatives, the TA approach remains a valuable method when the poor arterial access precludes the TF technique.

Limitations

This was a single-center observational study with a limited sample size. We recognize that this is a small study with a questionnaire response rate of slightly above 30%. Such a low response rate alone might be disqualifying for a survey if it were not for the fact that our results are consistent with other larger studies specific to CPTP in noncardiac thoracic surgery and provide reasonable crossover. Importantly, we were able to find statistical significance in more than one outcome measurement. Considering the number of participants who were lost to follow-up, it is unknown how many of those may be deceased; the actual prevalence of CPTP in this population may be higher than what our study has captured. Similarly, we were unable to make references to the impact of CPTP on mortality. A prospective observational study would add significant power and would likely help resolve the loss to follow-up and missing data that we encountered. Finally, it would be interesting to see that the impact epidural and paravertebral analgesia may have on the reduction of CPTP in the TA-TAVR population and potential improvement of QoL and functional status.

Conclusions

While definitive statements obviously cannot be made given the low response rate, the data do provide a compelling foundation for the very important hypothesis that CPTP is common in patients undergoing the TA approach for a TAVR and is associated with a decline in subjective and objective measures of QoL and overall function. A prospective trial is needed to conclusively define the impact of CPTP in a definitive manner in TA-TAVR patients.

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Conflicts of interest

There are no conflicts of interest.

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