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Monitoring Survival Following Lung Transplantation with Inclusion of Unaccounted Risks

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Abstract

Lung transplant (LTx) survival and quality of life have been steadily improving, partially from changes in candidate selection for transplantation. There are well-known high-risk factors that lead to poor LTx outcomes, which may be referred to as 'accounted' risks. However, there are also other 'unaccounted' risks that are not included in the existing model for expected LTx survival to help programs for resource allocation. We performed a retrospective cohort study of all LTx recipients over the age of 18 at UC San Diego Health between June 2019 and March 2021. Patient's 'unaccounted' risks were identified as low, moderate, or high risk in 4 discrete categories: Medical, Surgical, Psychosocial and Nutritional. The risks were entered into a software tool that calculated an 'unaccounted' risk adjusted observed to expected ratio (O:E), using calculations that mirror the Scientific Registry of Transplant Recipients (SRTR) risk-calculation methodology at the same six month intervals, termed Program-Specific Report (PSR) cycles. During the study period, 65 patients underwent lung transplantation. Of those, 25 had at least one high 'unaccounted' risk. The 'unaccounted' risk-adjusted O:E was 1.54

while the observed O:E was 0.46. The 'unaccounted' risk O:E is projected to increase to 4.72 while the projected observed O:E is 0.43 after two more PSR cycles. Having knowledge of the 'at risk' and identifying patients with 'unaccounted' risks for O:E helps LTx programs allocate resources in a more productive fashion to continue to achieve the level of expected outcomes and meet quality standards.

Keywords
Lung transplant; survival; quality; risk-adjustment model

1. Introduction

Solid organ transplantation programs are unique in the required level of data that is constantly collected and analyzed to assess quality and performance on a nationwide scale [1]. This level of scrutiny is necessary to ensure 1) superb post-transplant outcomes, 2) the limited number of donor organs are utilized to the best ability, and 3) to promote continual healthcare improvements. Nationwide data is gathered by the Organ Procurement and Transplantation Network (OPTN) from transplant centers, organ procurement organizations (OPOs), and histocompatibility laboratories [2]. Additional data is supplemented by the Centers for Medicare and Medicaid (CMS) and the Social Security Death Master File. The compilation of data in its entirety is maintained and analyzed by the Scientific Registry of Transplant Recipients (SRTR).

Since the first transplants performed for advanced lung disease, lung transplant (LTx) survival and quality of life has greatly improved. During the 1980s, the one-year post-LTx survival rates were 45% [3]. Based on the current Scientific Registry of Transplant Recipients (SRTR) outcomes, the one-year survival is now expected to be 89% in the United States [4]. During this timeframe, the selection and suitability of candidates has changed. With more experience over time and increased scientific evidence available, the achievement of successful outcomes following lung transplantation has become more attainable.

Through analyzing the nationwide data, certain negative predictors of lung transplant outcomes have become apparent. Recipient level of education, cardiac output, forced vital capacity (FVC) percent predicted, Lung Allocation Score (LAS), six-minute walk distance, number of HLA mismatches, age at transplant, body mass index (BMI), chronic steroid use, dialysis, medical condition, creatinine, total bilirubin, pulmonary arterial diastolic pressure, and total ischemic time are considered high-risk factors for a poor one-year survival outcome post-LTx [5]. Donor factors that are considered high risk for poor outcome include donor age, creatinine, PaO2 to FiO2 ratio, and Black or African American race. The aforementioned strong negative predictors are what is used by the SRTR to create a risk-adjustment model for expected graft and patient survival outcomes for transplant centers and will be referred to as 'accounted' risk factors. The program-specific report (PSR) cycle occurs once every six months, in January and July of each year. Through creating a risk-adjusted expected outcome measure, transplant centers can be monitored in respect to their patient population risks, which helps prevent transplant centers from becoming risk averse.

There are other negative predictors of lung transplant survival that are not included within the existing risk-adjustment model from SRTR to predict expected lung transplant outcomes. Russo et

al examined 8,780 adult lung transplant recipients and found that pre-operative extracorporeal membrane oxygenation (ECMO), hospitalization at the time of transplant, oxygen dependence, cardiac index <2, total bilirubin >2.0 mg/dL, decreased glomerular filtration rate, steroid dependence, donor:recipient weight ratio <0.7, all non-CF/COPD etiologies, age over 70 years, and female donor-to-male recipient have all been identified as strong negative predictors of 1-year survival [6]. Of these findings, many are not included within the SRTR risk-adjustment model. Some other examples of pre-transplant 'unaccounted' risks include rate of lung function decline, frequency of exacerbation, sarcopenia and degree of frailty, pre-operative vasopressors/inotropes, and presence of panel reactive antibodies. Post-transplant 'unaccounted' risks include transmission of unidentified donor infections at the time of organ procurement (e.g., Carbapenem resistant Acinetobacter), recipient explant lung cancer, and post-transplant requirement of VA- or VV-ECMO [7-9].

The SRTR risk-adjusted expected value is extremely important as this is what is used by the Centers for Medicare and Medicaid Services (CMS) and Membership and Professional Standards Committee (MPSC) to evaluate the performance of each transplant center. Both the CMS and MPSC have preset specific cutoffs for observed to expected (O:E) ratios for one-year graft and recipient survival. If a transplant center falls below the cutoff values, they are flagged for quality review. As a result, determining the degree a program can take risks to balance the goals of individual transplant candidates can be challenging with the requirements set for the lung transplant programs by CMS and MPSC.

Transplant centers at risk for being flagged by CMS or MPSC due to high O:E may choose to be more risk averse in order to minimize risk of losing condition level of participation. This also has contractual implications that inherently creates a pool of candidates with higher risk factors undergoing lung transplantation. XynManagement Solutions enables transplant programs to assess candidate and donor risks through the XynQAPI tool. As a result, we have utilized a customized tool in XynQAPI that uses identical methodology and Cox models to that of the SRTR. This tool allows us to document our patient's 'unaccounted' risks and creates calculated projections of what our future O:E ratios could be given to our higher-risk patients. The goal of this study is to review the one-year survival O:E ratios for recipients that have been determined to be at higher risk for mortality based on the 'accounted' risks by SRTR and to compare it with the additional 'unaccounted' risks entered either pre-operatively or events that occurred post-lung transplantation to mitigate poor survival.

2. Methods

We performed a retrospective single-center review of all LTx recipients at UC San Diego Health (UCSD) who were transplanted between June 19, 2019 and March 30, 2021. Given the increased acuity of overall patient issues during the pandemic, tools like this allowed our team to monitor patients more closely and determine need for various monitoring methods. All LTx recipients were over the age of 18 years and IRB approval was obtained through UCSD.

The negative predictors of one-year post-LTx survival outcomes included in the current SRTR model (July 2021 PSR cycle) will be referred to as 'accounted' risks. The negative predictors that are not included in the current SRTR model will be referred to as 'unaccounted' risks. Our 'unaccounted' risks were obtained by ranking each of our patients as either low, moderate, or high risk in each of the four distinct categories: medical, surgical, psychosocial, and nutritional. The rankings of the

'unaccounted' risks are subjective and were determined by the individual department lead expert opinion at the time of consideration for lung transplant listing. There is no numerical value assigned to this rating. Table 1 outlines the specific indicators for high risk in each category.

Table 1 Specific indicators for high-risk category for unaccounted risk.

Medical	Surgical	Psychosocial	Nutritional
Greater than 2 exacerbations in the prior 12 months	Prior chest surgery	Limited income for relocation ($7000); [fundraising is always encouraged]	Fried frailty score ≥3
Prior intubations required with exacerbations	Concomitant need for CABG, valve surgery	Caregiver availability post lung transplant	Sarcopenia
Rate of lung function decline ≥10% over 3 months	Post-transplant ECMO requirement	SIPAT score >40	
Post-transplant donor infection by culture positivity (eg. Acinetobacter, Aspergillus, Scedosporium, Mucor mycosis)	Unanticipated return to the OR	Residence >2 hours away from the transplant center	
Post-transplant renal replacement therapy		Worsened depression and/or anxiety based on the PHQ9 and GAD-7 scale along with continued psychiatric and psychology follow up	

We entered the 'accounted' and 'unaccounted' risks for each of our patients into a customized tool through XynManagement. Within the XynQAPI tool, we recorded the level of risk (low, moderate, or high) for each of the four categories for each pre-lung transplant patient. The 'accounted' risks were also entered into our customized XynQAPI tool.

We then utilized our customized XynQAPI tool to calculate our projected O:E ratios for the next three PSR cycles. XynQAPI was designed utilizing identical Cox models and methodology to the SRTR, allowing for a more accurate representation and comparison of O:E ratios. The O:E ratios termed "Observed O:E" were calculated normally utilizing only the current SRTR risk-adjustment model for the next three PSR cycles. The O:E ratios termed "Unaccounted At-Risk O:E" were calculated through an equation built into our custom XynQAPI tool to include the 'unaccounted' risks.

The equation utilized in XynQAPI to calculate the "Unaccounted At-Risk O:E" is (Observed + At-Risk)/Expected. The observed and expected values are the same values used in the future predictions model covering only the current SRTR risk-adjustment model ("Observed O:E"). The calculation uses the same cox models as SRTR. The At-Risk variable is where we include the 'unaccounted' risks that were categorized as low, moderate, or high risk in the medical, surgical, nutritional, and psychosocial categories.

The purpose of the "At-Risk O:E" is to illustrate what our O:E could be given our current patient population risks when taking unaccounted risks. This helps to predict post-LTx survival based on center performance with the additive tool in order to assess and make internal care model changes as necessary to account for the individual patient needs while maintaining the high level of program outcomes required to maintain a conditional level of participation by CMS and MPSC.

It should be noted that the study population took place during the SARS-COV-2 pandemic. At no point was the program placed on temporary pause. The program's position was to be mindful of the COVID-19 infection in both the recipients and donors at the time of transplantation. Both the recipient and the donors had to be tested and confirmed negative for COVID-19 by PCR analysis. No LTx recipient in this analysis contracted COVID-19 during the study period.

3. Results

During the timeframe of our study, 65 patients underwent lung transplantation (LTx) at UC San Diego Health. Baseline demographics are included in Table 2. Of the 65 LTx recipients, 25 (61.5%) were considered to have at least one high 'unaccounted' risk in any of the four categories: surgical, medical, psychosocial, or nutritional as seen in Figure 1.

Table 2 Baseline demographics of the 65 lung transplant recipients.

LTx Recipients (n = 65)	Total	Percentage
Female Sex	35	53.8
Type of Transplant, Bilateral LTx	52	80.0
Age (average: 53 years)		
19-40	14	21.5
41-60	26	40.0
61-70	22	33.8
≥71	3	4.6
Race/Ethnicity		
White	39	60.0
Hispanic/Latino	21	32.0
Other	5	8.0
Pre-LTx Diagnosis:		
Idiopathic Pulmonary Fibrosis (IPF)	22	33.8
COPD/Emphysema	9	13.8
Pulmonary Hypertension/Pulmonary Arterial Hypertension (PAH)	8	12.3
Pulmonary Fibrosis	5	7.6

Hypersensitivity Pneumonitis	4	6.1
Cystic Fibrosis	4	6.1
Nonspecific Interstitial Pneumonia	3	4.6
Mixed Connective Tissue Disease	2	3.0
Desquamative Interstitial Pneumonia	1	12.3%
Lymphangioleiomyomatosis	1	
Obliterative Bronchiolitis (Non-Retransplant)	1	
Pulmonary Veno-Occlusive Disease	1	
Sarcoidosis	1	
Silicosis	1	
Alpha-1-Antitrypsin Deficiency	1	
Congenital Malformation	1	

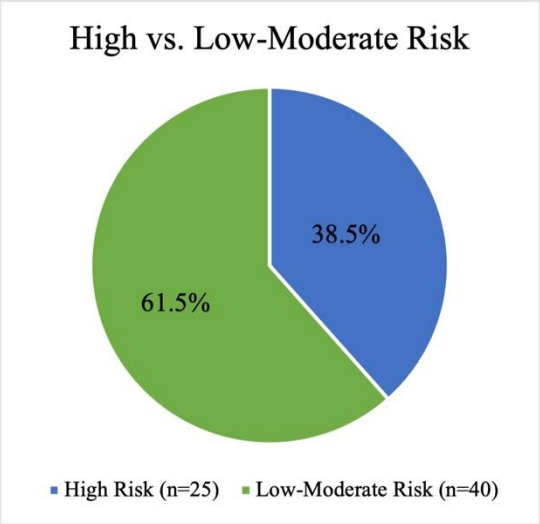

Figure 1 This graph illustrates the distribution of the 'unaccounted' risks.

The distribution of 'unaccounted' risks can be seen in Figure 2. Within the surgical category, 66% of patients were low, 22% moderate, and 12% were high risk. The medical category breakdown was 42% low, 52% moderate, and 6% high. For the psychosocial category, 46% of patients were low risk, 40% were moderate risk, and 14% of were high risk. A similar breakdown was seen with nutritional risk, 42% low, 42% moderate, and 17% high.

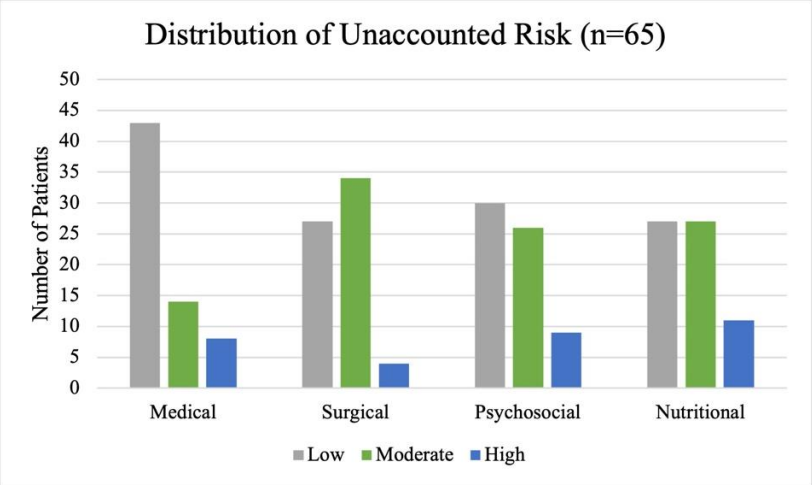

Figure 2 The graph illustrates the distribution of patients that experienced the various levels of 'unaccounted' risks for each category.

The calculated "Unaccounted At-Risk O:E" was compared against the "Observed O:E" ratios that included just the 'accounted' risks defined by the SRTR. The "Observed O:E" for the January 2022 report was 0.46 whereas the "Unaccounted At-Risk O:E" was 1.54. Looking ahead over the next three PSR cycles, the "Unaccounted At-Risk O:E" values continue to increase, reaching 4.72, while the "Observed O:E" values remain relatively stable at 0.43, as seen in Table 3 and Figure 3.

Table 3 This table shows the observed to expected (O:E) one-year survival comparison for 'accounted' and 'unaccounted' risk for the next three reporting cycles.

	Jan 2022 Report	July 2022 Report	Jan 2023 Report
Observed O:E	0.46	0.32	0.43
Unaccounted At-Risk O:E	1.54	3.54	4.72

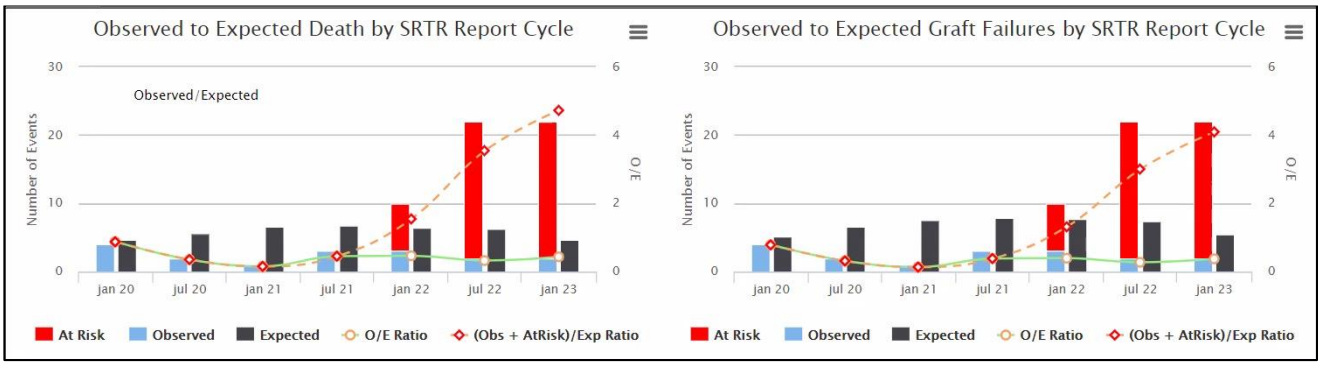

Figure 3 This graph showcases the difference in the pre-post identification of O:E for patient death and graft failures with and without 'at risk' categorization.

There was only 1 patient (1.5%) who developed primary graft dysfunction (PGD) grade 3 at 72 hours post-lung transplantation. Despite the higher risk for mortality, the overall survival of the 65 patients was higher than expected, Table 4. Two patients were above the age of 70 at the time of transplantation which contributed to the accelerated frailty, decreased tolerance to medications,

and ultimate decision to no longer continue medical therapy despite a lack of allograft rejection. Two patient's social factors changed after lung transplantation that ultimately lead to their passing. One patient had a borderline personality disorder that was unmasked after a lung transplant and performed self-harm acts. One patient died from non-medically related drowning event in the ocean. The remaining patients developed refractory rejection despite aggressive and proactive measures.

Table 4 Survival outcomes of the 65 LTx recipients.

Timepoint	Total	Percentage
Primary Graft Dysfunction Grade 3 Time 72 hours	1	1.5%
30 Day Patient Survival	65	100%
6 Month Patient Survival	65	100%
1 Year Patient Survival	61	93.8%
2 Year Patient Survival	56	86%

4. Discussion

The SRTR employs a model to calculate the risk-adjusted expected outcomes for transplant centers. This model is based on the nationwide data that has been gathered by SRTR to determine what risk-adjustments should be made for calculating expected transplant outcomes for transplant centers. The risk-adjusted expected outcome is a very important value, as this is used by CMS and MPSC to evaluate transplant center's quality and performance.

However, the issue with using a risk-adjustment model that is based on a nationwide set of data is that it struggles to account for transplant center specific risks. All transplant centers do not have the same subset of patients that is seen on the nationwide level based on medical, surgical, nutritional and psychosocial risk factors. For example, low-income income cut-offs, access to healthcare causing delayed treatment (eg. living in a rural area) or need for mental health care needs with Medicaid insurance are challenges other states may not face [9-14]. The combined composite of this stratification takes in to account factors that are accounted for and those unaccounted both pre- and post-transplantation. As a result, transplant programs would be not receiving an accurate risk-adjusted expected outcome of patient and graft survival to account for their center-specific risks. Ultimately, this would put the transplant center at an unfair advantage when it comes to evaluations by CMS and MPSC, particularly when trying to allow for more equitable opportunities for patients in need of lung transplantation.

In an attempt to resolve this issue, we obtained assistance with a calculated projected O:E values utilizing just the SRTR risk-adjustment model ("Observed O:E") and the O:E using an additive function to include 'unaccounted' risks ("At-Risk O:E"). The calculated "Observed O:E" over the next three Program-Specific Reporting (PSR) cycles remains relatively constant at 0.46, 0.32, and 0.43. By using the "At-Risk O:E" trends with XynQAPI tools, it shows a drastic increase when forecasting the next three PSR cycles at 1.54, 3.54, and 4.72. The "At-Risk O:E" values provide information about what the O:E ratios could look like due to our higher-risk patient population when taking into account both the accounted and unaccounted risks of each individual patient.

The current primary goal within our program has been to allow for the healthcare system to identify not only the account and unaccounted risks, but to be able to account for the inherent risks the program would face if not modifying practice patterns. This is done in a prospective manner. As most transplant programs have faced thus far, there are several events either prior to or following transplantation that places an individual lung transplant recipient at a higher risk of poor outcome within the first year of transplantation [7, 9, 13]. We identified certain factors that were either low, moderate or higher risk during the selection committee decision to list the patient. If a high-risk factor was identified, then we captured it in the XynQAPI tabulation. For individuals with low or moderate risk at the time of selection who developed factors that placed them at a high risk after that, then it would be tabulated in XynQAPI. This was to allow for proactive monitoring of the programs risk assessments and tailor our internal care model to accommodate the higher-risk patient population through more appropriate resource allocation. For example, instead of having a patient be seen in the clinic once every two weeks in the low to moderate risk category, high risk patients would be seen once every week. Additionally, testing protocols for the higher-risk patients would be more frequent to closely monitor for any potential complications. By utilizing this additive 'at risk' model, transplant programs can work proactively to ensure that the requirements of CMS and MPSC are met. Ultimately, the proactive efforts help to ensure that patients are receiving the best quality of care possible and to provide them the best chance of long-term post-transplant survival and allow for a larger equitable opportunity for lung transplantation.

It is important to consider the significance of the SRTR risk-adjustment model accurately calculating the expected transplant outcomes because of the broader implications that it may have. It is argued that the current regulatory criteria with preset O:E cutoffs are potentially encouraging risk averse behavior by transplant centers [2, 15]. Studies show that transplant centers tend to decrease their transplant volume if they are flagged by CMS or MPSC for further evaluation due to O:E ratios failing to meet cutoffs. White et al. found that centers with ongoing non-compliance with CMS had a transplant volume decline of 38% [16]. Interestingly, they found that these programs with ongoing non-compliance had an increased amount of high-risk patients. By encouraging risk averse behavior from transplant centers, the access to care for certain patients becomes restricted.

It has also been debated on a broad level that the SRTR risk-adjustment model fails to accurately predict and account for the variability seen with transplant outcomes. Schold and Howard performed statistical analysis on the SRTR risk-adjustment model for one-year graft loss and found that it had an approximate concordance index (also known as C-statistic) of 0.65 [17]. For reference, a value of 0.5 represents no predictive value (only accurately predicts 50% of the time) and 1.0 represents perfect predictive capabilities. Thus, a value of 0.65 illustrates that the predictive capabilities of the SRTR risk-adjustment model is failing to accurately represent the variations in outcomes. The SRTR did publish a counterargument report stating that the utilization of the C-statistic to analyze the accuracy of their risk-adjustment model is not an appropriate use of this datapoint as they believe this value is examining the variability at the level of individual transplants rather than at the level of transplant centers [18].

There are limitations in our study that are important to consider. First, this is a retrospective, single-center, cohort study because no other programs are currently utilizing this tool to look at projected 'unaccounted' at-risk O:E ratios. Additionally, our 'at risks' were categorized and rated utilizing both objective and subjective interpretations, rather than a qualitative measures for all unaccounted risk. This is the same type of assessments programs make inherent to determining the

suitability of lung transplant candidates. Future studies should be performed to validate calculating a O:E utilizing 'unaccounted' risks as well as to devise a method to quantify the 'unaccounted' risk factors. With a broader group, the study can be powered appropriately to best determine quantifiable variables of unaccounted risks or even demonstrate that certain risks should be accounted for normally.

In summary, the risk-adjustment model employed by the SRTR is not only important to the transplant centers for maintaining credentialing, but also to the transplant patients so they may not be limited access due to a transplant center becoming too risk adverse. It is important to continue identifying measures to mirror the current SRTR risk-adjustment model and to strive to create a combined pre/post lung transplant model to change monitoring paradigms for lung transplant recipient. Through employing a companion tool using calculations that mirror the SRTR risk-adjustment model, each transplant center could adequately monitor their risks and expected outcomes unique to their program. Lastly, the utility of flagging and monitoring patients deemed to be at higher risk from 'unaccounted' risks can help identify individual transplant resource allocation need in a more specific manner to continue to achieve the level of expected outcomes and to meet CMS and MPSC standards.

Abbreviations

Centers for Medicare and Medicaid	CMS
Extracorporeal Membrane Oxygenation	ECMO
Institutional Review Board	IRB
Lung transplant	LTx
Membership and Professional Standards Committee	MPSC
Overserved to Expected ratio	O:E
Organ Procurement and Transplantation Network	OPTN
Organ Procurement Organizations	OPOs
Program-Specific Report	PSR
Scientific Registry of Transplant Recipients	SRTR
UC San Diego Health	UCSD

Author Contributions

Kamyar Afshar: study concept and design, data entry, data analysis, manuscript writing/editing. Michelle N Bremer: Data analysis, manuscript writing/editing. Deepa Kurup: Data collection, data analysis, manuscript editing. Michael Bernales: Data collection, data analysis. Elizabeth Schonhoft: study design, manuscript editing. Luis Santana: Data collection. Caro Davila: Data collection. Gina Schooler: Data collection. Gordon Yung: Study design, data analysis. Travis Pollema: Study design, data analysis. Eugene Golts: study concept and design, manuscript editing.

Competing Interests

The authors have declared that no competing interests exist.

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