

Complicated Pleural Infection is Associated With Prolonged Recovery and Reduced Functional Ability

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Background: Management of complicated pleural infections (CPIs) had historically been surgical; however, following the publication of the second multicenter intrapleural sepsis trial (MIST-2), combination tissue plasminogen (tPA) and dornase (DNase) offers a less invasive and effective treatment. Our aim was to assess the quality of life (QOL) and functional ability of patients' recovery from a CPI managed with either intrapleural fibrinolytic therapy (IPFT) or surgery.

Methods: We identified 565 patients managed for a CPI between January 1, 2013 and March 31, 2018. There were 460 patients eligible for contact, attempted through 2 phone calls and one mailer. Two questionnaires were administered: the Short Form 36-Item Health Survey (SF-36) and a functional ability questionnaire.

Results: Contact was made in 35% (159/460) of patients, and 57% (90/159) completed the survey. Patients had lower QOL scores compared to average US citizens; those managed with surgery had higher scores in physical functioning (surgery: 80, IPFT: 70, $P=0.040$) but lower pain scores (surgery: 58, IPFT: 68, $P=0.045$). Of 52 patients who returned to work, 48% (25) reported an impact on their work effectiveness during recovery, similarly between management strategies (IPFT: 50%, 13/26 vs. surgery: 46%, 12/26; $P=0.781$).

Conclusion: Patients with a CPI had a lower QOL compared with average US citizens. Surgically managed patients reported improved physical functioning but worse pain compared with patients managed with IPFT. Patients returned to work within 4 weeks of discharge, and nearly half reported their ability to work effectively was impacted by their recovery. With further research into recovery timelines, patients may be appropriately counselled for expectations.

Key Words: pleural infection, quality of life, functional ability, intrapleural fibrinolytics, pneumonia

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Pleural infection affects more than 65,000 individuals annually in the United States and the United Kingdom and is associated with a mortality rate of 10% to 20%.¹ The American College of Chest Physicians defines a complicated pleural infection (CPI) as having positive cultures in the pleural fluid or a pleural fluid pH of less than 7.20 (complicated parapneumonic effusion) and an empyema as having frank pus present.¹ The standard of care management for patients with a CPI is antibiotics and chest tube drainage of the infected pleural fluid; however, more aggressive measures are often needed when initial management fails.² Debate still exists on whether additional surgical versus medical management is more effective in patients with failed initial management.^{3,4} While surgical management has historically been recommended, it is associated with a prolonged hospital length of stay and high costs.⁵⁻⁷ Medical management, consisting of dual-agent intrapleural fibrinolytic therapy (IPFT), has, however, been gaining popularity.

While CPI outcome data has been previously published, quality of life (QOL) and functional ability of patients following a CPI have been less commonly reported. One study evaluating forced expiratory volume over 1 second (FEV₁) following management of a CPI identified FEV₁ to return to normal in 58% (60/104) of patients at a median of 62 months follow-up.⁸ Another study identified patient return to work following surgical management of an empyema to be a median of 34 days in the thoracotomy group and a median of 25 days in the video-assisted thoracoscopy group.⁹ In addition, previous reports of patients with pneumonia identified full symptomatic recovery to take up to 4 weeks following infection and the infection to have a deleterious impact on QOL in elderly patients up to a year following discharge.¹⁰⁻¹²

Currently, there is a paucity of data assessing the QOL and functional ability of patients following surgical versus medical management of a CPI. In addition, a comparison of which management strategy results in superior long-term outcomes is lacking. We aimed to determine the QOL and functional ability of patients who underwent inpatient management of a CPI and sought to compare QOL and functional ability between individuals who underwent IPFT versus surgical management within a multistate, community-based hospital system.

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MATERIAL AND METHODS

Study Population

Adult patients who underwent IPFT and/or surgical management of a CPI between January 1, 2013 and March 3, 2018 at Swedish Medical Center and Providence Health and Services locations were reviewed. This health care network spans 5 states, including Alaska, California, Montana, Oregon, and Washington.

Patients who underwent IPFT management were identified using a pharmacy billing database for inpatient intrapleural DNase alpha administration. The only other indication for this medication is for patients with cystic fibrosis, who would not be initially included in this cohort. Thus, this criteria identifies the specific patient population of interest. Patients who underwent surgical management were identified using billing data for surgical decortication (thoracotomy or thoracoscopy) based on procedural and ICD-9 and ICD-10 codes. Specific clinical and outcome data relating to this patient population have been published separately.¹³

Medical management of a CPI was defined as receiving any dose/schedule of dual-agent IPFT therapy, while surgical management was defined as receiving either a video-assisted thoracoscopic or thoracotomy decortication. In patients who were managed with both IPFT and surgery, the initial management strategy was considered the primary management.

Study Design

Patients were contacted to complete questionnaires to determine QOL and functional ability following IPFT and/or surgical management of a CPI. Patient contact was initially attempted telephonically. If the first attempt was not successful, a second call was attempted on a separate day. If neither phone call was successful, a mailer containing an introduction to the study, comment on informed consent, and both questionnaires were sent to the patient's address and recorded in their electronic medical record. If both calls were unsuccessful and the mailer was not returned, the patient was recorded as "no contact" and excluded. The study protocol was approved by the Swedish Medical Center Institutional Review Board (STUDY2019000344).

The first questionnaire, the widely validated RAND 36-Item Short Form Survey Instrument (SF-36) [appendix A, Supplemental Digital Content 1, <http://links.lww.com/LBR/A319>], was utilized to assess QOL metrics. This questionnaire measured attributes with scaled scores: physical functioning, physical role limitations, emotional role limitations, energy/fatigue, emotional wellbeing, social functioning, pain, and general health within the 30 days before completing the survey. Responses to this questionnaire were thus related to the period around completion of the questionnaire.

The second questionnaire was designed to assess employment and functional ability [appendix B, Supplemental Digital Content 2, <http://links.lww.com/LBR/A320>]. This questionnaire has not been previously validated. Employment and functional ability were assessed at 3 separate time points for comparison: before infection, following discharge, and at the time of questionnaire completion. Components of the questionnaire included employment status, hours worked, type of work, time to return to work, change in occupation due to CPI, and if CPI recovery affected work effectiveness. When assessing

functional ability in patients who were retired, employment was expanded to include childcare, volunteering, and weekly hobbies such as writing, landscaping, and caregiving. The type of work was considered "other" if not strictly stationary or active.

Statistical Analysis

Categorical variables were summarized as frequencies and percentages, and continuous variables as median and interquartile range (IQR) values. Differences between the IPFT and surgical groups were compared using χ^2 or Wilcoxon tests. The SF-36 scaled scores were created from a pre-determined group of questions for each scale, and each applicable answer was recorded and averaged to determine the scaled score as per RAND SF-36 Scoring Instructions.¹⁴

Under consideration of the potential differences among patients' risk, generalized linear mixed modeling was applied to adjust the outcome. The *p* values to detect the difference between IPFT and surgery patients were generated by including gender, race, body mass index, purulence status, rapid score, type of work, and time to follow-up as covariates, while the state was a random effect in the model.

A reference population for QOL values was comprised of a "normal" data set of individuals from United States (US) aged 55-65 years.¹⁵ This data set only contains summary median, mean, and SD values, and not raw data; thus, statistical analyses for comparative purposes could not be performed.

RESULTS

During the study period, 565 patients who underwent IPFT and/or surgical management of a CPI were identified. Following 105 exclusions (Fig. 1), 460 patients met the inclusion criteria for the study. Of the 460 patients meeting inclusion criteria, 90 (20%) completed both questionnaires. Both surgical management and IPFT, coincidentally, had 45 patients. Overall, the median patient age was 61 (IQR: 50-66) years, 63% (57) were male, 89% (80) were White, and the median body mass index was 27 (IQR: 24-31) kg/m² (Table 1). Median RAPID score was 3 (IQR: 2-4), and 42% (38) had an empyema. The time to follow-up from hospital discharge was 43 months (IQR: 31-55). The majority (61%, 55) of patients received management in Washington State, and these patients received IPFT (91%) compared with surgery (8%) at a higher frequency than patients in other states (31% vs. 69%) *P*=0.001. In terms of QOL, patients managed with surgery had higher median physical functioning scores than IPFT patients (surgery: 80, IPFT: 70, *P*=0.040) (Table 2, Fig. 2). Patients managed with IPFT reported less pain than those managed with surgery (surgery: 58, IPFT: 68, *P*=0.045). The median scaled scores for the total population were all lower than the US normal scores except for emotional limitations, which were equivalent.

Of the 90 patients, 57 (63%) stated they were employed before CPI with a median of 40 hours worked per week (IQR: 30-50) (Table 3). Following hospital discharge, 93% (53/57) of patients reported continuing their work/activity at a median return to work of 4 weeks (IQR: 2-8). Once returned to work, patients reported a median of 40 (IQR: 20-40) hours worked per week, and 48% (25/52) [1 did not answer work effectiveness and occupation change] reported they felt their work effectiveness was impacted by their CPI.

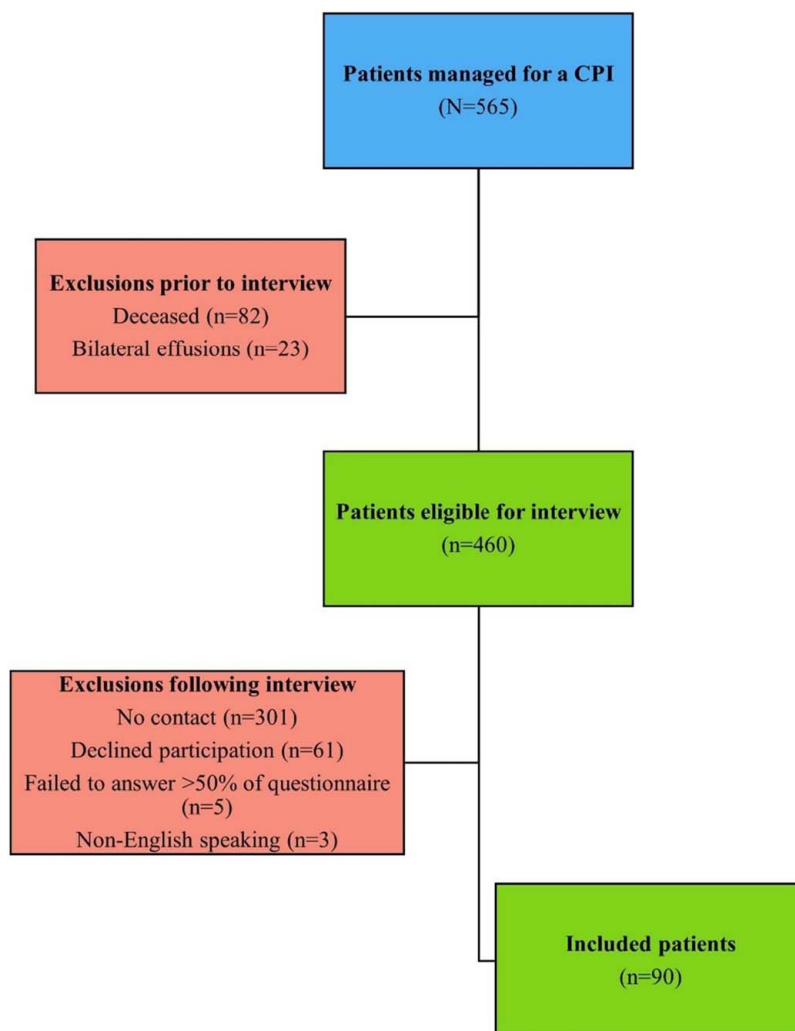


FIGURE 1. Consort diagram of the cohort.

Five of those 52 (10%) patients reported a change in occupation during recovery from their CPI. At the time of the questionnaire completion, 81% (43/53) of the patients who had returned to work were still working. The median hours worked per week for these 43 patients was 40 hours (IQR: 30–40). Return to work and functional ability was similar between patients stratified by IPFT and surgery groups.

DISCUSSION

This study represents the first effort to evaluate QOL and functional ability of patients who underwent aggressive, local treatment of a CPI, with an emphasis on comparison between nonsurgical and surgical treatment. There is a paucity of data on recovery in CPIs and how differing management strategies can impact a patient's recovery. We sought to provide a framework regarding recovery for a CPI to enable counseling of patient expectations following management and spur additional research. Our data is notable for reporting and comparing QOL between management strategies, reporting how recovered patients' QOL compares to the average US citizen, and reporting the time to return to work and the impact on a patient's employment.

The data from this study identifies lower QOL in patients following recovery from a CPI compared with the average United States citizen, regardless of the management they received. When comparing the QOL of patients managed with IPFT versus surgery, those who underwent surgical management had increased physical functioning but more pain. We hypothesize this may be the result of intensive physical therapy protocols following surgical management, as well as a bias to send patients to surgery according to their health and age. This could allow for greater physical functioning while having more pain due to trauma from surgical management. The median time of return to work was 4 weeks, and the type of management the patient received did not affect their return to work. This aligns with previously published data where patients with a surgically managed CPI returned to work in 24 to 35 days, regardless of their surgical approach.⁹ When patients did return to work, 48% noted feeling less effective, and 10% changed careers due to issues with their recovery. This may suggest that recovery from a CPI may impact a patient's future employment. Interestingly, despite patients noting their decreased effectiveness, the median of 40 hours worked per week did not fluctuate from before infection, following

TABLE 1. Demographics and Characteristics of the Total Cohort and the Cohort Stratified by Management Strategy

	Total (N = 90)	IPFT (n = 45)	Surgery (n = 45)	P
Age, median (IQR)	61 (50–66)	61 (47–66)	62 (52–66)	0.735
Male (%)	57 (63)	30 (67)	27 (60)	0.512
Race	—	—	—	0.079
White	80 (89)	37 (82)	43 (96)	—
Asian	3 (3)	3 (7)	0 (0)	—
American Indian/Alaska Native	1 (1)	1 (2)	0 (0)	—
Other	1 (1)	0 (0)	1 (2)	—
Unknown	5 (6)	4 (9)	1 (2)	—
BMI, median (IQR)	27 (24–31)	27 (24–33)	27 (24–30)	0.549
RAPID Score, median (IQR)	3 (2–4)	3 (2–5)	2 (2–3)	0.493
Phase of infection (%)	—	—	—	0.088
Complicated parapneumonic effusion	52 (58)	30 (67)	22 (49)	—
Empyema	38 (42)	15 (33)	23 (51)	—
Source of infection (%)	—	—	—	> 0.99
Community	83 (92)	41 (91)	42 (93)	—
Hospital	7 (8)	4 (9)	3 (7)	—
Months to follow-up, median (IQR)	43 (31–55)	44 (31–53)	41 (30–55)	0.781
Year of treatment (%)	—	—	—	0.980
2015	26 (29)	14 (31)	12 (27)	—
2016	24 (27)	12 (27)	12 (27)	—
2017	31 (34)	15 (33)	16 (36)	—
2018	9 (10)	4 (9)	5 (11)	—
State (%)	—	—	—	< 0.001
Washington	55 (61)	41 (91)	14 (31)	—
Oregon	21 (23)	1 (2)	20 (44)	—
Montana	6 (7)	0 (0)	6 (13)	—
Alaska	5 (6)	3 (2)	2 (4)	—
California	3 (3)	0 (5)	3 (7)	—

P < 0.05 values are in bold.

BMI indicates body mass index; IPFT, intrapleural fibrinolytic therapy; IQR, interquartile range; RAPID, renal, age, purulence, infection source, and dietary factors.

hospital discharge, or at the time of questionnaire completion.

There are similarities comparing the results of this study to reports on patients with pneumonia. Multiple studies on patients with pneumonia have reported symptom resolution and a return to baseline health within 2 to 4 weeks following their infection.^{16–18} In addition, the American Lung Association notes that some patients with pneumonia return to their baseline routine 1 week following infection, but full recovery can take up to 4 weeks.¹¹ A recent study reported patients with pneumonia returned to work at a median of 15 to 24 days, but 18% to 50% failed to

return to baseline 4 weeks following infection.¹⁹ In addition, in patients older than 50 years, surviving at least 1 hospitalization for pneumonia has been associated with functional and cognitive impairments.²⁰ Further study may help caregivers provide expectations for patients following CPI management, with pneumonia as a reference point as to what to expect.

This study is the first attempt to analyze the recovery process following treatment for a CPI with an eye toward characterizing the timeline and physical outcomes following recovery to better counsel patients on discharge expectations and return to function. Our study contacts patients across a

TABLE 2. Quality of Life Components of the Total Cohort, the Cohort Stratified by Management Strategy, and a Reference US Population

SF-36 category	Total (N = 90) median (IQR)	IPFT (n = 45) median (IQR)	Surgery (n = 45) median (IQR)	P Multivariate adjusted	US normal (55–64 y) median (IQR)
Physical functioning	75 (50, 90)	70 (40, 90)	80 (55, 90)	0.040	85 (60, 95)
Physical limitations	75 (25, 100)	75 (0, 100)	75 (50, 100)	0.148	100 (50, 100)
Emotional limitations	100 (33, 100)	100 (33, 100)	100 (67, 100)	0.584	100 (67, 100)
Energy/fatigue	50 (35, 65)	50 (35, 65)	50 (40, 60)	0.812	65 (45, 80)
Emotional wellbeing	80 (64, 88)	76 (64, 84)	80 (64, 88)	0.330	80 (64, 92)
Social functioning	88 (63, 100)	88 (50, 100)	88 (63, 100)	0.215	100 (63, 100)
Pain	61 (45, 90)	68 (35, 90)	58 (50, 90)	0.045	72 (51, 84)
General Health	55 (40, 65)	50 (40, 65)	60 (40, 65)	0.120	67 (50, 82)

P < 0.05 values are in bold.

When comparing IPFT to surgery, the model was adjusted for age, gender, race, body mass index, purulence status, rapid score, type of work, time to follow, and state.

IPFT indicates intrapleural fibrinolytic therapy; US, United States.

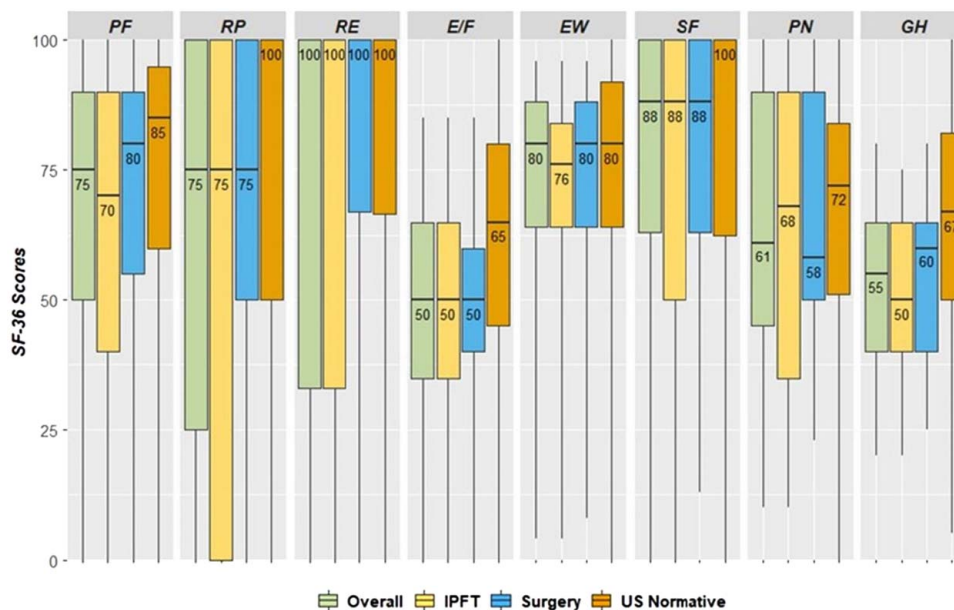


FIGURE 2. Quality of life components of the total cohort, the cohort stratified by management strategy, and a comparative United States population. Data represented as median and interquartile values. Higher scores are considered better health. BP indicates bodily pain; GH, general health; IPFT, intrapleural fibrinolytic therapy; MH, mental health; PF, physical functioning; RP, physical role limitations, RE, emotional role limitations, SF, social functioning; VT, vitality/energy.

TABLE 3. Work and Functional Ability of the Total Cohort and the Cohort Stratified by Management Strategy

	Total (N = 90)	IPFT (n = 45)	Surgery (n = 45)	P
Prior to infection				
Employment Status, n (%)	—	—	—	0.512
Employed prior to infection	57/90 (63)	27/45 (60)	30/45 (67)	—
Retired/Disabled/Failed to Report	33/90 (37)	18/45 (40)	15/45 (33)	—
Median hours worked (IQR)	40 (30-50)	40 (25-40)	40 (32-50)	0.154
Type of Work, % (n)	—	—	—	0.523
Stationary Job	17/57 (30)	10/27 (37)	7/30 (23)	—
Active Job	23/57 (40)	10/27 (37)	13/30 (43)	—
Other	17/57 (30)	7/27 (26)	10/30 (33)	—
Following discharge from hospital				
Employment Status, % (n)	—	—	—	0.614
Employed following discharge	53/57 (93)	26/27 (96)	27/30 (90)	—
Retired/Disabled/Failed to report	4/57 (7)	1/27 (4)	3/30 (10)	—
Median hours worked (IQR)	40 (20-40)	40 (20-40)	40 (2-40)	0.722
Median weeks to return to work (IQR)*	4 (2-8)	4 (2-6)	4 (2-8)	0.858
Type of Work, % (n)	—	—	—	0.183
Stationary Job	20/53 (38)	13/26 (50)	7/27 (26)	—
Active Job	19/53 (36)	8/26 (31)	11/27 (41)	—
Other	14/53 (26)	5/26 (19)	9/27 (33)	—
Change in occupation as result of infection, % (n)†	5/52 (10)	3/26 (12)	2/26 (8)	> 0.99
Infection affected work effectiveness, % (n)†	25/52 (48)	13/26 (50)	12/26 (46)	0.781
At questionnaire completion				
Employment status, % (n)	—	—	—	> 0.99
Employed at follow-up	43/53 (81)	21/26 (81)	22/27 (81)	—
Retired/disabled/failed to report	10/53 (19)	5/26 (19)	5/27 (19)	—
Median hours worked (IQR)	40 (30-40)	40 (30-40)	40 (40-50)	0.128
Type of work, % (n)	—	—	—	0.241
Stationary job	17/43 (40)	11/21 (52)	6/22 (27)	—
Active job	16/43 (37)	6/21 (29)	10/22 (45)	—
Other	10/43 (23)	4/21 (19)	6/22 (27)	—

*One patient in each of the IPFT and surgery categories did not answer.

†One patient in the surgery category did not answer.

IPFT indicates intrapleural fibrinolytic therapy; IQR, interquartile range.

variety of different care centers across five states. This, however, presents a double-edged sword due to the retrospective nature of our study. Different sites may have different criteria and expertise of how to manage CPI's and whether or not a patient should be sent for surgery, as well as follow-up mechanisms following infection. This weakens our study's findings due to the possible confounding effects from different levels of care on patient QOL following discharge. The study was not designed to provide objective benchmarks on the recovery process but rather to provide a representation of the patient's experiences and prompt additional research in this area.

A large limitation of the study is the presence of participation bias, with a participation rate of 20%. An attempt to improve participation was made by expanding to 2 methods of contact: phone and mail. However, evidence suggests study participation has been declining over the last 2 decades.²¹ In addition, older populations (median of 65 y) have shown decreased response rates to surveys sent by mail compared with hand delivery of surveys.²² The low response rate makes this study increasingly susceptible to a selection bias. Patients with a better QOL may have not felt the need to participate in the study, and those who did may have been more motivated to share their negative experiences. A consequence of improving the response rate with mail surveys in this study was losing the ability to guide patients through the questionnaires to ensure that all questions had been answered, which is not uncommon when utilizing the SF-36 questionnaire.²³ Another limitation was significant recall bias. The median time of follow-up was 43 months, and many patients could have been septic during management or had an altered mental status following discharge. In addition, patients can be susceptible to overestimating pre-infection health when asked about their QOL. This may have resulted in a QOL deterioration following CPI to appear more drastic than reality. We utilized the RAPID score as an objective baseline for our patients' severity of disease at presentation; however, due to the retrospective nature of a study across multiple sites within different structures of care, we are limited in our ability to further strengthen an objective baseline of health before infection. Our solution to this problem was to use generalized linear mixed modeling, as stated in our statistical analysis. While our study represents diversity in levels of care and geographic location, our patient population does lack racial diversity, as 89% were white, lessening the generalizability of our findings to a broader population. Further studies should strive to create a more representative picture of patients across different socioeconomic criteria. In addition, the SARS-CoV-2 pandemic began amid patient follow-up, which was conducted from August 2019 to January 2021. Patient's answers were possibly influenced by difficulties associated with SARS-CoV-2, including stress, depression, and loneliness.^{24,25} Lastly, the US population reference data was published in 1993; we acknowledge using a data set from 30 years ago is a limitation.

CONCLUSIONS

In conclusion, we identified patients with a CPI had a lower QOL compared with the average US citizen, and surgically managed patients reported worse pain but improved physical functioning compared with patients

managed with IPFT. Patients returned to work within 4 weeks of discharge, regardless of management. Nearly half of the patients reported their ability to work effectively was impacted by their recovery, and 10% of patients reported a change in occupation. With further research, clinicians may provide an informed discussion with patients regarding expectations following a CPI.

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