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Methods: 56 patients with chronic pancreatitis were given the PANQOLI and compared with 52 healthy individuals (consisting of medical students and residents) who also completed the PANQOLI. Subgroup analysis was also performed to compare smokers and non-smokers, as well as malnourished and non-malnourished patients.

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Quality of Life Comparison in Chronic Pancreatitis Patients: A Case-Control Study

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Methods: 56 patients with chronic pancreatitis were given the PANQOLI and compared with 52 healthy individuals (consisting of medical students and residents) who also completed the PANQOLI. Subgroup analysis was also performed to compare smokers and non-smokers, as well as malnourished and non-malnourished patients.

Results: The chronic pancreatitis group scored significantly lower than the control group on the PANQOLI (56.2 vs. 92.3, $p < 0.0001$), with a lower PANQOLI score representing a worse quality of life. Within the chronic pancreatitis group, smokers had a lower PANQOLI score than non-smokers (52.8 vs. 60.1, $p < 0.05$), while there was no difference between malnourished patients and non-malnourished patients (55.1 vs. 58.5, $p < 0.46$).

Discussion: This study presents the 1st evaluation of a chronic pancreatitis population using the PANQOLI in comparison to a healthy population. As expected, the chronic pancreatitis population had a worse quality of life as did smokers compared to non-smokers, highlighting the potential use of the PANQOLI to objectively assess the impact of interventions in these patient groups.

I. INTRODUCTION

Chronic pancreatitis presents a significant medical problem to healthcare practitioners as it affects many aspects of a patient's health and has been found to be associated with a poor quality of life.¹⁻² A global problem, worldwide prevalence has been estimated to range from 3-20%.³⁻⁶ Most often caused by alcohol consumption, chronic pancreatitis may also be caused by metabolic disorders (hyperlipidemia and hypercalcemia), and genetic disorders (including Cystic Fibrosis, SPINK, cationic trypsinogen mutations) 4. Characterized by progressive inflammatory changes in the pancreas, chronic pancreatitis often causes

abdominal pain and symptoms of pancreatic insufficiency, such as steatorrhea and diabetes, are the predominant features of this disease. Studies have demonstrated the increased burden of chronic pancreatitis in areas such as physical health, most notably in pain, nutritional status, and diarrhea.¹⁻² Other areas affected include financial factors such as unemployment or early retirement, as well as mental health factors.² The socioeconomic burden has been found to be increasing as management of chronic pancreatitis entails the cost of admissions, the cost of pancreatic insufficiency, the cost of pain, and the cost of interventions, among other costs.⁸ This has been estimated to cost around \$638 million a year.⁸ Furthermore, complications can include pseudocyst formation, pancreatic ascites, splenic vein thromboses, and pancreatic cancer.⁹ All these features combine to play a large role in altering the quality of life of these patients.^{2,10,11}

To better manage patients with chronic pancreatitis and address patient-specific issues, an instrument called the Pancreatitis Quality of Life Instrument (PANQOLI) was developed.¹² This instrument consists of 18 questions, and provides a comprehensive measure of quality of life measures. Validated in two separate studies involving over 300 patients in eleven clinical sites, the PANQOLI has shown excellent reliability and construct validity.^{13,14} This instrument represents the 1st disease-specific instrument created for evaluating quality of life in patients with chronic pancreatitis and has been utilized extensively at our institution since its inception.

This study reports the initial evaluation of the PANQOLI at our institution on patients with chronic pancreatitis compared to other control patients in order to help provide a normal distribution curve that can be applied as a standard for future use of the instrument.

II. METHODS

The PANQOLI was administered to 56 patients previously diagnosed with chronic pancreatitis who regularly follow-up at our chronic pancreatitis clinic. The same instrument was given to a control population consisting of 52 individuals. The PANQOLI results were then compared between the groups. Subgroup analysis was also performed to compare smokers and non-

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smokers, as well as malnourished and non-malnourished.

a) Subjects

Patients with chronic pancreatitis required a diagnosis by either the presence of pancreatic calcifications on CT (Computed Tomography) scan or KUB (kidney, ureter, and bladder) imaging or the presence of 5 out of 9 criteria of pancreatic injury by

endoscopic ultrasound (Please see Table 1 for further inclusion and exclusion criteria). Institutional Review Board (IRB) approval of the study was obtained and patients who met the inclusion/exclusion criteria were asked during a regularly scheduled visit if they wished to participate in this study. Subjects were then asked to sign an informed consent if they agreed to participate.

Table 1 : Inclusion - exclusion criteria for chronic pancreatitis patients

Inclusion criteria	Exclusion criteria
<p>Patient must have abdominal pain, not related to other identifiable etiologies in conjunction with one of the following two features:</p> <p>(a) Presence of pancreatic calcification as demonstrated by an imaging study such as CT scan or KUB imaging</p> <p>(b) Presence of five out of nine criteria of pancreatic injury by endoscopic ultrasound in conjunction with a positive secretin stimulation test to confirm pancreatic insufficiency.</p>	<p>Patient to be excluded from the study if they have one of the following features:</p> <p>(a) Age less than 18 years</p> <p>(b) Comorbidities such as end-stage cancer (estimated survival < 6 months), HIV (T4 cell count < 50), end-stage congestive heart failure, end-stage chronic obstructive pulmonary disease, uncompensated cirrhosis, renal failure (on dialysis or with CrCl <25), or pre-existing diabetes mellitus</p> <p>(c) Non-English speaking</p>

CT: computed tomography; KUB: kidney, ureter, and bladder; CrCl: creatinine clearance

The control population consisted of a relatively healthy group of subjects consisting of medical students and residents at our institution who do not have chronic pancreatitis. Informed consent was obtained if the subject agreed to participate in the study.

Demographic data collected included age, gender, race, smoking status, opiate use, and endoscopic ultrasound (EUS) characterization of disease severity.

b) Sub-Groups

Within the chronic pancreatitis population, patients were identified as smokers if they reported that they were active smokers. In terms of identifying malnourished patients, patients regularly followed at our clinic were routinely asked to fill out a Malnutrition Universal Screening Tool (MUST).¹⁵ Those patients scoring >2 were defined as being malnourished.

c) Statistics

Multivariate analysis was performed utilizing the Anova test and power was calculated to be 80%.

Analysis was performed using SPSS software (IBM SPSS Version 21.0).

III. RESULTS

A total of 56 patients in the chronic pancreatitis group and 52 patients in the control group participated in this study. The mean score of the PANQOLI in the chronic pancreatitis group was 56.2, compared to 92.3 in the control group, which was highly significant ($p<0.0001$) adjusting for age, race, gender, and smoking status, with a higher score representing a better quality of life. In terms of the sub-groups within the chronic pancreatitis group, smokers ($n=30$) had a mean score of 52.8 in comparison to non-smokers ($n=26$), who had a mean score of 60.1 ($p<0.05$), accounting for age, race, gender, opiate use, and EUS grading. In comparing by nutritional status, malnourished ($n=18$) patients had a mean of 55.1, while the non-malnourished ($n=38$) had a mean of 58.5, which was not significant ($p<0.46$). Please see Tables 2-4.

Table 2 : Comparison of chronic pancreatitis group with control group

Category	Chronic Pancreatitis Group (n=56)	Control Group (n=52)	p-value
Age (years)	48.7 \pm 9.2	30 \pm 4.1	$p<0.0001$
Gender	36 Female 20 Male	28 Females 24 Males	$p<0.18$
Race	49 Caucasian 5 Black 2 Hispanic	36 Caucasian 7 Asian 5 Indian 3 Hispanic 1 Black	$p<0.025$
Tobacco Use	30 Smokers 26 Non-smokers	1 Smoker 51 Non-Smokers	$p<0.0001$

Opiate Use (mg of oral morphine/day)	125.4 ± 101.2	0	p<0.0001
EUS Grading of CP	Mild (28.6%) Mild-Moderate (7.1%) Moderate (48.2%) Moderate-Severe (5.4%) Severe (10.7%)	N/A	N/A
PANQOLI Mean Score	56.2 ± 14.6	92.3 ± 0.8	p<0.0001

EUS: endoscopic ultrasound; CP: Chronic Pancreatitis; PANQOLI: PANcreatitis Quality Of Life Instrument

Table 3 : Comparison of smokers with non-smokers

Category	Smoker (n=30)	Non-Smoker (n=26)	p-value
Age	45.8 ± 8.9	52.0 ± 8.6	p<0.01
Gender	Male (26.7%) Female (73.3%)	Male (46.2%) Female (53.8%)	p < 0.13
Race	Caucasian (93.3%) Black (6.7%)	Caucasian (80.8%) Black (11.5%) Hispanic (7.7%)	p < 0.23
Opiate Use (mg of oral morphine/day)	135 ± 93.9	114.3 ± 109.9	p < 0.45
EUS Grading of CP	Mild (33.3%) Mild-Moderate (6.7%) Moderate (43.3%) Moderate-Severe (6.7%) Severe (10%)	Mild (32.1%) Mild-Moderate (7.7%) Moderate (53.8%) Moderate-Severe (3.8%) Severe (11.6%)	p<0.90
PANQOLI mean score	52.8 ± 11.9	60.1 ± 16.5	p<0.05

EUS: endoscopic ultrasound; CP: Chronic Pancreatitis; PANQOLI: PANcreatitis Quality Of Life Instrument

Table 4 : Comparison of malnourished with non-malnourished subjects

Category	Malnourished (n=18)	Non-malnourished (n=38)	p-value
Age (years)	50.6 ± 7.0	47.7 ± 10.1	p < 0.28
Gender	Male (33.3%) Female (66.7%)	Male (36.8%) Female (63.2%)	p < 0.80
Race	Caucasian (83.3%) Black (11.1%) Hispanic (5.6%)	Caucasian (89.5%) Black (7.9%) Hispanic (2.6%)	p < 0.78
Opiate Use (mg of oral morphine/day)	132.5 ± 110.1	122 ± 98.1	p < 0.72
EUS Grading of CP	Mild (34.2%) Mild-Moderate (7.9%) Moderate (42.1%) Moderate-Severe (2.6%) Severe (13.2%)	Mild (16.7%) Mild-Moderate (5.6%) Moderate (61.1%) Moderate-Severe (11%) Severe (5.6%)	p < 0.11
PANQOLI mean score	58.5 ± 16.9	55.1 ± 13.5	p<0.46

EUS: endoscopic ultrasound; CP: Chronic Pancreatitis; PANQOLI: PANcreatitis Quality Of Life Instrument

In terms of demographic data, there were significant differences between the chronic pancreatitis group and the control group. The control group was significantly younger, more racially diverse, and had far less narcotic and tobacco use (Table 2). Within the sub-groups, the only significant demographic difference was in the smoker group, who had a significantly younger mean age (45.8) compared to the non-smoking group (52). Please see tables 2-4.

IV. DISCUSSION

This study presents an initial evaluation of the PANQOLI in chronic pancreatitis patients at a single

tertiary medical center. Quality of life in chronic pancreatitis patients was most notably evaluated in the North American Pancreatitis Study 2 (NAPS 2), which evaluated 540 patients with chronic pancreatitis. 16 443 of the 540 patients completed the Short Form-12 (SF-12), a instrument used commonly to evaluate quality of life, which gives a physical component and a mental component score. The NAPS 2 study found lower physical and mental component scores in the chronic pancreatitis group compared to a control population, which was consistent with other chronic diseases. 17 The SF-12, however, is not a disease-specific instrument

and primarily assesses the limiting effects of a disease. As quality of life entails a vast amount of factors such as depression, sleep, coping skills, and financial repercussions, the PANQOLI was developed to quickly assess in a single instrument the overall quality of life of patients with chronic pancreatitis.

As expected, this study revealed a significant difference in PANQOLI scores between the chronic pancreatitis population and the control population. The control population scored significantly higher, implying a higher quality of life, which is consistent with a healthy population. Furthermore, in terms of the sub-group analysis, there was a significant difference in PANQOLI scoring between the smoking and non-smoking groups. The non-smoking group scored higher on the PANQOLI than their counterparts which is not surprising considering that smoking would be expected to worsen quality of life.¹⁸⁻²⁰

The main limitation of this study is the control group in this study, which consisted of medical students and residents. While this group represented a younger population with relatively few co-morbidities, it did not guarantee a healthy population.

In summary, this prospective study describes the initial use of the PANQOLI in a chronic pancreatitis population in an attempt to create a normal distribution. While displaying that these patients have a poorer quality of life compared to a control population, it also displayed worse quality of life in patients who smoke. This invites further studies to be done to evaluate quality of life differences in this sub-group and hints at the possibility of therapeutic interventions addressing this risk factor. In line with this, further validation of the PANQOLI may also allow for objective assessment of the holistic impact of interventions in this disease process using the PANQOLI.

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