

## Post-Frey Procedure Quality of Life in South African Patients with Painful Chronic Pancreatitis

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### ABSTRACT

**Context** Pre- and post-Frey procedure data assessing quality of life in South African patients with painful chronic pancreatitis were compared using two instruments of measure. **Objective** The objective was to evaluate the post-Frey procedure quality of life and to evaluate which of the two instruments was most appropriate in such patients. **Methods** A prospective, observational, longitudinal study using the EORTC QLQ-C30 and a locally developed structured interview was performed. **Results** Between January 2002, when the QLQ-C30 was introduced, and February 2009, 45 consecutive patients underwent a Frey procedure at the Chris Hani Baragwanath Hospital in Soweto, Johannesburg, South Africa. Thirteen of these patients were lost to follow up. Thirty two participants answered both instruments before and after the procedure. Follow up data were analyzed until June 2009. The mean follow up was 24.8 months ranging from 1 to 83 months. There were clinically relevant improvements in most QLQ-C30 domains and structured interview items at the last post-operative visit. The mean pain levels (VAS 0-10 and QLQ-C30 PA) were significantly reduced post-operatively. Twenty five participants answered both instruments within six months and again later at a minimum of six months after surgery with no significant differences in the overall QLQ-C30 functional (P=0.967) and symptom (P=0.253) scale scores between the two time periods. In general, outcomes measured by the two instruments were similar. **Conclusions** Although the follow up period was short, results suggest that benefits were mostly made manifest within six months post-operatively and were sustained during the follow up period. The structured interview included a counseling component and locally pertinent issues not addressed in the QLQ-C30 and it is therefore recommended as the instrument of choice in this setting.

### INTRODUCTION

Quality of life (QoL) is a subjective concept. QoL measures, however focused on need-satisfaction and relatively less subjective they may therefore be, may not address the issues relating to a specific intervention such as the Frey procedure in the South African population drawn mainly from the black townships. The socio-economic situation of these people is invariably very poor which may itself impact on the outcome of the surgery. The patients experience a host of problems that either result from chronic pancreatic pain or from their own life circumstances that may lead to substance abuse. Depression and low self-esteem

arising from poor education and unemployment are associated with high risk behaviors such as substance abuse according to Petersen [1]. Gastric pain in South Africa tends to be treated empirically and presumed to be due to peptic ulcer disease. Consequently the diagnosis of chronic pancreatitis is often made at advanced stages of the disease once absenteeism and job loss have occurred, and post-surgical QoL improvements are measured from a very low baseline.

The classical symptoms of chronic pancreatitis are pain and exocrine and endocrine insufficiency. Other dimensions of concern include weight loss, inability to work, early retirement, and addiction to opioids. In 1987 Frey and Smith described an operation for chronic pancreatitis that combined drainage and organ-preserving resection: local resection of the pancreatic head with lateral pancreaticojejunostomy [2]. A number of studies have found this Frey procedure to be effective in the management of painful chronic pancreatitis [3, 4, 5, 6].

### AIMS AND OBJECTIVES

The objectives of this study were to facilitate long-term follow-up of patients undergoing the Frey procedure; to compare their pre- with their post-surgical physical,

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**Keywords** Pancreatitis, Chronic; Quality of Life

**Abbreviations** EORTC: European Organisation for Research and Treatment of Cancer

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role, emotional, cognitive, and social functioning, as well as symptoms and global health status/QoL and to relate the findings of this self-administered QLQ-C30 to those of a face-to-face locally developed structured interview that included some issues not addressed in the QLQ-C30 (Appendix). Predictors capable of modifying the outcome of the intervention were considered and the focus was on extracting information relevant to the improvement of QoL in patients undergoing the Frey procedure.

## PATIENTS AND METHODS

### Patients

The Frey procedure was performed on 112 patients in the Hepato-Pancreato-Biliary (HPB) Unit of the University of the Witwatersrand from 1998 to 2009. The structured interview was developed in the HPB Unit in 1999 and the QLQ-C30 was introduced in January 2002. Forty five consecutive candidates underwent a Frey procedure between January 2002 and February 2009 at the HPB Unit of the Department of Surgery of the University of the Witwatersrand, Gauteng Province, Republic of South Africa. Surgery was performed at the Chris Hani Baragwanath Hospital in Soweto, Johannesburg. Confirmation of a diagnosis of painful chronic pancreatitis was based on a clinical history, physical examination, ultrasonography, computed tomography scan, an endoscopic retrograde or a magnetic resonance pancreatography, and histology.

Only patients who answered the QLQ-C30 and the structured interview pre- and post-operatively were included in the study. Thirteen patients were lost to follow-up, including two patients who died within a month of surgery, one who died in a motor vehicle accident, one who declined participation in the study, and one who did not understand the QLQ-C30 at all. Therefore, thirty two answered the QLQ-C30 and the structured interview before and after the Frey procedure. Data up to June 2009 were analyzed. There were 25 men and 7 women. Mean $\pm$ SD age at surgery was 42.5  $\pm$ 7.11 years (range: 31-61 years). Mean follow-up period was 24.8 months ranging from one to 83 months.

### Questionnaires

The comparison of pre- and post-Frey procedure pain in a prospective, observational, longitudinal study of South African patients with painful chronic pancreatitis was undertaken and included a number of other dimensions of QoL, the improvement of which is the goal of the procedure. Outcomes in terms of the possible achievement and sustainability of improved global health status, protective influences, and risks associated with poor post-surgical outcome were analyzed.

Structured interviews were conducted by a single researcher not involved in treatment decisions with the

aid at times of a translator. The interviewer had no interpretive agenda and treating surgeons did not have access to the responses of participants.

### European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 Questionnaire

The QLQ-C30 version 3 comprises a functional scale with a high score representing a healthy level as does a high score for the global health status/QoL (QL2). A high score for the symptom scale represents a high level of problems [7]. The English version of the QLQ-C30 was adopted and a number of participants required assistance understanding and answering the QLQ-C30 questions. For illiterate patients verbal translations were done in IsiZulu and Setswana.

The functional, symptom and global health scales were linearly transformed to 0-100 in order to obtain the standardized scores according to the EORTC QLQ-C30 general principles of scoring. The overall functional, symptom, and global health status scale scores were computed as means of the overall set of scores. Global health status/QoL score was also dichotomized as "Good" (equal to, or greater than, 50) and "Poor" (less than 50). The structured interview variables were also observed as dichotomous (i.e.: "Absent", less than 50; "Present", equal to, or greater than, 50).

As stipulated in the QLQ-C30 title of measure, changes in QoL scores were categorized into three groups: clinically relevant improvement, clinically relevant deterioration, and no change [8, 9]. The foremost category was considered clinically relevant if the follow-up score exceeded the previous score by at least ten points. Deterioration was considered clinically relevant if the difference was at least ten points less than the previous score. Failure to meet either criterion was interpreted as no change in the third category. With symptom scales an increase of ten points or more in the level of symptoms implied deterioration.

### Structured Interview

A face-to-face locally developed structured interview included some issues not addressed in the QLQ-C30 (Appendix). In addition to the visual analogue scale (VAS 0-10: 0 indicating no pain and 10 indicating unbearable pain) for pain, self-reported judgment of pain intensity (none, mild, moderate, severe), use of analgesics (yes, no), and pre-surgical pain duration, the structured interview included questions relating to issues such as ability to work, employment, disability grants, retirement, alcohol consumption (nil, special occasions, weekends only, daily, alcoholic), smoking (0, 1-5, 6-10, 11-20, >20 cigarettes per day), good or bad feelings about life, hopelessness or hopefulness, loss or gain of weight, non-insulin or insulin dependent diabetes mellitus (NIDDM, IDDM, respectively), clinically evaluated steatorrhea, nausea and vomiting, and whether the surgery benefited the patient from her or his perspective.

## ETHICS

Approval of the study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand, protocol number M050425. All participants provided written informed consent. The study protocol conforms to the ethical guidelines of the "World Medical Association (WMA) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects" adopted by the 18<sup>th</sup> WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 59<sup>th</sup> WMA General Assembly, Seoul, South Korea, October 2008

## STATISTICS

The Wilcoxon matched pairs sign-rank test was employed to compare pre- and post- (last visit) operative QLQ-C30 global health status/QoL scores, functional scale scores, overall functional scale scores, symptom scale scores, overall symptom scale scores, and comparisons of overall functional and symptom scale scores within six months *versus* at least six months post-operatively. Association between structured interview parameters, e.g. categorical with continuous, continuous with continuous, were assessed using the Spearman's rank correlation coefficients and the Mann-Whitney U-test. To assess agreement between structured interview and QLQ-C30 variables, the kappa statistic was used and percentages of agreement and disagreement were also reported. Dichotomous data were analyzed by means of the Fisher's exact or the McNemar tests when paired or unpaired data were involved. Testing was done at the two-tailed 0.05 level of significance. Stata (release 11, StataCorp LP, College Station, TX, USA) statistical software was used for data analysis.

## RESULTS

### EORTC QLQ-C30 Questionnaire

There was a statistically significant improvement at last post-operative visit in the score of QLQ-C30 global health status/QoL ( $P < 0.001$ ) in the 32 participants compared with their pre-operative scores. The improvement in global health status/QoL was clinically relevant (Table 1).

As far as the functional scores are concerned, there was a statistically significant improvement at last post operative visit in emotional and social functioning while no significant modifications were observed in physical functioning, role functioning, and cognitive functioning in comparison with the QLQ-C30 pre-operative answers. The improvements in role, emotional, and social functioning were clinically relevant. In addition, the overall QLQ-C30 functional score at last visit was compared with that of the pre-operative score and the improvement was found to be both statistically significant and clinically relevant (Table 1).

Apart from diarrhea that increased, there was a clinically relevant reduction of all QLQ-C30 symptom items post-operatively. Reductions in dyspnea and insomnia were not statistically significant while the increase in diarrhea was near the significant limit ( $P = 0.068$ ). The overall QLQ-C30 symptom scale score at the last visit improved significantly when compared with the pre-operative value (Table 1).

Taking into account QLQ-C30 global health status/QoL, functional, and symptom scale scores, they did not differ significantly between the two post-operative time periods ( $P = 0.839$ ,  $P = 0.967$ , and  $P = 0.253$ , respectively). The percentage benefits within

**Table 1.** QLQ-C30 pre-operative and last visit scores (n=32).

<b>EORTC QLQ-C30 scores</b>	<b>Pre-operative</b>	<b>Last visit</b>	<b>Difference</b>	<b>P value<sup>a</sup></b>
<b>Global health status/QoL score (QL2)</b>	27.4±23.2	54.0±27.1	26.6±33.3	<0.001
<b>Functional scores</b>				
- Physical functioning (PF2)	65.0±24.9	64.2±19.2	0.85±24.7	0.524
- Role functioning (RF2)	48.9±35.4	64.1±29.1	15.2±52.3	0.090
- Emotional functioning (EF)	34.1±25.4	49.5±27.5	15.4±33.7	0.017
- Cognitive functioning (CF)	47.4±27.8	55.7±33.5	8.3±39.7	0.263
- Social functioning (SF)	50.0±37.9	71.3±31.5	21.4±31.2	0.001
<b>Overall functional score</b>	<b>49.1±21.0</b>	<b>61.0±21.0</b>	<b>11.9±26.1</b>	<b>0.040</b>
<b>Symptom scores</b>				
- Fatigue (FA)	70.0±24.7	56.8±30.4	-13.2±30.2	0.004
- Nausea and vomiting (NV)	54.7±33.1	35.9±37.7	-18.8±44.4	0.023
- Pain (PA)	80.2±24.1	55.7±33.8	-24.5±34.9	0.001
- Dyspnea (DY)	50.0±37.9	37.5±39.5	-12.5±44.6	0.267
- Insomnia (SL)	56.3±38.3	42.7±39.9	-13.5±48.5	0.066
- Appetite loss (AP)	69.8±34.3	37.5±40.4	-32.3±48.3	0.004
- Constipation (CO)	64.6±38.8	29.2±32.5	-35.4±43.1	<0.001
- Diarrhea (DI)	13.5±25.2	27.1±34.3	13.5±40.5	0.068
- Financial difficulties (FI)	74.0±37.6	55.2±43.7	-18.8±43.9	0.026
<b>Overall symptom score</b>	<b>59.2±18.4</b>	<b>42.0±24.8</b>	<b>-17.3±21.4</b>	<b>&lt;0.001</b>

<sup>a</sup> Wilcoxon matched pairs test

**Table 2.** Comparison of overall scores between values observed within 6 months and those observed with a minimum of 6-month follow-up post-operatively (data for both time periods were available in 25 participants only).

Quality of life scores	Follow up		P value <sup>a</sup>
	0-6 months	>6 months	
Global health status/QoL	49.7±29.8	53.2±28.9	0.839
Overall functional scores	62.6±19.5	62.7±20.7	0.967
Overall symptom scores	46.1±21.7	41.0±25.5	0.253

<sup>a</sup> Wilcoxon matched pairs test

the first six months over the pre-operative scores of 25.3%, 47.5%, and 58.7%, respectively, seem to have been sustained in the second period (mean follow-up: 31 months, range 6-83 months; Table 2).

**Structured Interview**

Apart from two patients (6.3%) who reported having moderate pain pre-operatively the other thirty (93.8%) had self-reported severe pain during the structured interview. The mean±SD VAS score pre-operatively was 8.5±1.3 and it fell to a mean of 3.8±3.2 post-operatively at last visit (P<0.001). Median pain duration prior to surgery in the 32 participants was 72 months ranging from 10 to 264 months. Fifteen participants (46.9%) had been diagnosed with peptic ulcer disease prior to admission to the surgical HPB Unit. There was no significant correlation between the pre-operative pain duration and the pain VAS score (r<sub>s</sub>=0.181; P=0.338) or the self-reported judgment of pain intensity (r<sub>s</sub>=0.281; P=0.119) of the structured interview pre-operatively. There was significant correlation between the VAS score for pain of the structured interview and the symptom scale for pain (PA) of the QLQ-C30 at the last visit (r<sub>s</sub>=0.705; P<0.001).

Participants who continued drinking after surgery did not differ from those who stopped drinking with respect to pain measured on the VAS scale of the structured interview (P=0.903; 3.83±4.40 versus 3.82±2.90) or on the pain score of the QLQ-C30 (P=0.695; 50.0±46.0 versus 57.1±31.3). There was an

association between the post-operative use of analgesics and a higher VAS score for pain (P<0.001; 5.43±2.60 versus 1.46±2.30) and a higher pain score of the QLQ-C30 (P=0.039; 65.8±29.1 versus 41.0±35.8). Mean VAS scores for pain of the structured interview were significantly lower for good global health status/QoL (i.e., QL2 score equal to, or greater than, 50) of the QLQ-C30 at last visit (P=0.028; 2.65±3.18 versus 4.85±2.80 for poor global health status/QoL, i.e., QL2 score less than 50). A similar association was found for the QLQ-C30 pain score and the QL2 score (P=0.019; 41.1±36.7 versus 68.6±25.6 for good and poor global health status/QoL, respectively).

Only nine of the 32 (28.1%) were employed prior to surgery and ten (31.3%) were employed at last visit. There was a significant association between employment and the ability to work well (P=0.001) at last visit, i.e. among the 19 participants with poor ability to work only 3 (15.8%) had employment while all 5 who reported ability to work well were employed (data on ability to work were available in 24 cases only). Among the 22 unemployed participants, 11 (50.0%) were receiving disability grants at last visit.

Diabetes was defined clinically by the use of anti-diabetic medication. Three participants (9.4%) had diabetes pre-operatively: two participants had NIDDM and one had IDDM. At the last visit there was one participant with NIDDM and five with IDDM (6/32, 18.8%). Fifteen participants (46.9%) had pre-operative steatorrhea and post-operatively at the last visit 17 (53.1%) were found to have steatorrhea during the structured interview while 16 (50.0%) reported having diarrhea at the QLQ-C30 questionnaire. A poor agreement was found (59.4%; 19 cases: 9 negative and 10 positive; kappa=0.188) between the two instruments of measure with regard to this symptom of pancreatic exocrine insufficiency. There was no bias towards a particular instrument (P=0.782; McNemar test for symmetry); in fact 7/32 (21.9%) cases were positive at the structured interviews and negative at QLQ-C30 while in 6/32 (18.8%) cases it was the other way round. Four continuous QLQ-C30 scores recorded at the last

**Table 3.** Comparison between structured interview (SI) and QLQ-C30 variables.

	Role functioning (RF2) vs. ability to work <sup>b</sup>	Global health status/QoL (QL2) vs. feel good about life <sup>c</sup>	Nausea and vomiting (NV) vs. nausea and vomiting	Appetite loss (AP) vs. loss of weight
<b>Agreement:</b>	10/24 (41.7%)	23/28 (82.1%)	25/32 (78.1%)	20/32 (62.5%)
- Absent (<50)	5/10 (50.0%)	11/23 (47.8%)	14/25 (56.0%)	11/20 (55.0%)
- Present (≥50)	5/10 (50.0%)	12/23 (52.2%)	11/25 (44.0%)	9/20 (45.0%)
<b>Disagreement:</b>	14/24 (58.3%)	5/28 (17.9%)	7/32 (21.9%)	12/32 (37.5%)
- Present at QLQ-C30 and absent at SI	14/14 (100%)	2/5 (40.0%)	2/7 (28.6%)	4/12 (33.3%)
- Absent at QLQ-C30 and present at SI	0/14 (0%)	3/5 (60.0%)	5/7 (71.4%)	8/12 (66.7%)
<b>P value (discordance)<sup>a</sup></b>	<0.001	0.655	0.257	0.066
<b>Kappa</b>	0.123 (poor)	0.643 (moderate)	0.563 (moderate)	0.259 (poor)
<b>Comment/bias</b>	QLQ-C30 was more prone to "Present" than SI	No marked bias	No marked bias	Trend of SI to be more prone to "Present" than QLQ-C30

<sup>a</sup> McNemar test for symmetry

<sup>b</sup> Ability to work had information on both scales for 24 participants only

<sup>c</sup> Feel good about life' had information on both scales for 28 participants only

visit, corresponding to some variables of the structured interview, were dichotomized (cut-off point 50%) and then compared with those recorded in the interview: role functioning (RF2 vs. ability to work), global health status/QoL (QL2 vs. feel good about life), nausea and vomiting (NV vs. nausea and vomiting), and appetite loss (AP vs. loss of weight). Overall the QLQ-C30 dichotomized scales variables and the structured interview did not agree well. Best agreement was observed for nausea and vomiting and feel good about life (Table 3).

Finally, global health status/QoL categories (good and poor) at last visit were compared with structured interview categorical parameters. The proportions of participants who used analgesics or alcohol, who smoked, who were retired, who had diabetes and steatorrhea were not significantly different between the two global health status/QoL groups. Participants employed, together with those able to work well, were significantly more frequent in the good global health status/QoL group, as well as participants with disability grant were significantly less frequent in this group. A significantly larger proportion of participants of the good global health status/QoL group reported that they benefited from the Frey procedure than those of the poor global health status/QoL group (100% versus 58.8%) (Table 4).

**DISCUSSION**

Seventeen years ago the reliability and validity of the European Organisation for Research and Treatment of Cancer’s Quality of Life Questionnaire (EORTC QLQ-C30 version 3) was endorsed in clinical studies of patients with chronic pancreatitis before and after duodenum-preserving resection of the head of the pancreas [10]. The QLQ-C30 was originally formulated with the QLQ-PAN26 to assess oncology interventions and appeared to Fitzsimmons *et al.* “to be an appropriate assessment system for chronic

pancreatitis” [11]. In their 1993 study of the natural course of chronic pancreatitis Lankisch *et al.* found that “Pancreatic surgery led to pain relief immediately after operation, but later pain course between operated and non-operated patients was not significantly different” [12]. Strate *et al.* stressed “the development of pancreatic insufficiency probably develops independent of the surgical procedure and seems to be related to the chronic feature of the disease”. They found a marked reduction of pain and improved QoL post-operatively despite reduced exocrine and endocrine pancreatic function [13].

The surgical HPB Unit of the University is a centre of choice for the surgical management of chronic pancreatitis in the public health service in the region. Consequently many patients were referred from outlying districts for surgery and were unavailable for follow up, as well as a number of patients who returned to the private sector for their post-surgical care. Despite attempts to contact participants by phone and/or mail their visits to the HPB outpatient clinic were erratic and unpredictable.

There was duplication of some issues addressed in dissimilar ways in the two instruments of measure. When participants required help from the interviewer in answering the QLQ-C30 questions there was no way of gauging if there could have been a degree of critical inter-subjectivity.

The VAS for pain is a simple way of quantifying pain. The participant marks pain level on the blank side of a rule with 0 indicating no pain and 10 unbearable pain. The QLQ-C30 pain scale is a combination of answers to the questions “Have you had pain?” and “Did pain interfere with your daily activities?”. The answers to the questions are chosen from “Not at all” (1), “A little” (2), “Quite a bit” (3), and “Very much” (4). Both measures are influenced by past memories of pain and other subjective factors such as reporting severe pain in order to be prescribed opiates. During the face-to-face interview the participant was asked to score specific pancreatic pain whereas the QLQ-C30 pain measurement was non-specific. There was moderate correlation between the two instruments with regard to pain and significantly reduced mean post-operative levels at last visit.

The long period of pre-operative pain and the presentation of many participants with a prior diagnosis of peptic ulcers endorses the observation that a diagnosis of chronic pancreatitis was often delayed resulting in unemployment for a number of participants and increasing the risk of opiate dependence. Vigilance at primary and secondary levels of health care would ameliorate the problem. A common complaint was an inability to lift heavy things post-operatively making heavy manual work difficult, impinging on employment, and necessitating disability grants. The evaluation of the outcome of the Frey procedure indicated that employment predicts a better post-operative QoL in this population of working class chronic pancreatic patients. Ironically exposure to

**Table 4.** Relationship between interview parameters and dichotomized global health status/QoL (QL2) (n=32).

Structured interview at last visit	Global health status/QoL		P value <sup>a</sup>
	Good: QL2≥50 (n=15)	Poor: QL2<50 (n=17)	
Analgesics	7 (46.7%)	12 (70.6%)	0.280
Alcohol	4 (26.7%)	2 (11.8%)	0.383
Cigarettes	13 (86.7%)	15 (88.2%)	1.000
Employed	8 (53.3%)	2 (11.8%)	0.021
Ability to work well	5 (33.3%)	0	0.015
Retired	0	1 (5.9%)	1.000
Disability grant	2 (13.3%)	9 (52.9%)	0.028
NIDDM	0	1 (5.9%)	1.000
IDDM	3 (20%)	2 (11.8%)	0.645
Steatorrhea	7 (46.7%)	10 (58.8%)	0.723
Benefited from surgery	15 (100%)	10 (58.8%)	0.008

<sup>a</sup> Fisher’s exact test

NIDDM: non insulin dependent diabetes mellitus

IDDM: insulin dependent diabetes mellitus

many workplace hydrocarbons has been posited as a cause of pancreatitis and preventative measures are essential [14]. The high unemployment rate in the country compounds the problems faced by those with chronic disease. Occupational rehabilitation for educationally disadvantaged adults is a universal challenge that requires particular attention in the case of those with chronic pancreatitis.

There was sustained improvement in QLQ-C30 overall functional and symptom scale domains that was mostly manifested within six months post-operatively. The finding that last visit diarrhea (QLQ-C30) and steatorrhea (structured interview) were associated in the entire group of 32 suggests that the increase in diarrhea at last visit was caused in large part by steatorrhea. Pancreatic enzyme replacement therapy has not been consistently available with dosage schedules having not been uniformly applied, and therefore evaluation of its efficacy in reducing steatorrhea and weight loss, and improving QoL was not feasible. Poverty made regular healthy meals unaffordable for many.

The role played by post-Frey procedure alcohol use is equivocal with traditionalists assuming that abstinence mitigates pain and others suggesting that poor pain control might lead to alcohol misuse. It has been postulated that abstinence contributes to survival rather than to pain relief [15]. This study had limited mortality data but found that continued alcohol consumption (as admitted by respondents at last visit) was not implicated in pain aggravation. Furthermore the proportion of participants who drank post-operatively was greater in the good global health status/QoL category.

Despite limiting post-operative QoL issues such as continued use of analgesics, unemployment, an inability to work well, dependence on a disability grant, diabetes, and steatorrhea, the majority (25/32) of participants reported that they benefited substantially from the surgery that is therefore not necessarily contraindicated for indigent patients. In their recent study of 414 patients with self-identified pain and chronic pancreatitis, Mullady *et al.* found “no association between the duration of the disease and the quality or severity of the pain” [16]. This study concurs with Mullady’s finding suggesting that deferment of surgery in anticipation of future pain “burn-out” is probably not valid. This inference was recently suggested by Liu *et al.* [17].

The structured interview was essentially descriptive, narrative, and included a counseling element. However, as the need to test the relevance of universalist conceptions of well being and QoL in low or no income societies became increasingly pertinent, the EORTC QLQ-C30 was introduced as a more quantitative instrument to be combined with that of the less positivist interview. The majority of participants were manual workers, some of whom were illiterate who had difficulty understanding some of the QLQ-C30 concepts without explanation from the

interviewer. Tension, irritability, and depression of the QLQ-C30, for instance, are not African concepts with direct translations. It was necessary in many instances for the interviewer to go through the QLQ-C30 with the participant when understanding was limited and African translations did not help those who could not read. In such instances the QLQ-C30 effectively became a structured interview. Without a relevant gold standard it was not possible to evaluate which of the two instruments was more reliable and valid, nor whether possible inter-subjectivity amounted to bias. In general outcomes measured by the two instruments were similar with regard to comparable issues. However, the structured interview included some pertinent issues not considered in the QLQ-C30 and participant/interviewer interaction was considered useful. It is therefore proposed that in the context of this population of chronic pancreatic patients the structured interview be the measure of choice, and that suitable methods be devised to transform it into a fully quantitative instrument while retaining its narrative essence.

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**Appendix 1**  
**CHRONIC PANCREATITIS PATIENTS' INTERVIEW**  
**(PRE LR-LPJ)**

DATE OF INTERVIEW \_\_\_\_\_  
 NAME \_\_\_\_\_  
 FEMALE \_\_\_ MALE \_\_\_ HOSPITAL NUMBER \_\_\_\_\_  
 DATE OF BIRTH \_\_\_\_\_  
 PLACE OF BIRTH \_\_\_\_\_  
 AGE AT MIGRATION TO JOHANNESBURG \_\_\_\_\_ (YEARS)  
 NATIONALITY \_\_\_\_\_ HOME LANGUAGE \_\_\_\_\_  
 MARITAL STATUS \_\_\_\_\_ NUMBER OF DEPENDENTS \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 TEL. NO. (H) \_\_\_\_\_ (W) \_\_\_\_\_ CELL \_\_\_\_\_  
 NEXT OF KIN/CONTACT PERSON \_\_\_\_\_ TEL. \_\_\_\_\_  
 CURRENTLY EMPLOYED: YES \_\_\_ NO \_\_\_  
 RETIRED: YES \_\_\_ NO \_\_\_

**EMPLOYMENT HISTORY**

EMPLOYER/INDUSTRY	OCCUPATION	DATES OF SERVICE	REASON FOR LEAVING

EXPOSURE TO RISK SUBSTANCES

ALCOHOL: YES\_\_ NO\_\_ BEER\_\_ WINE\_\_ SPIRITS\_\_  
SPECIAL OCCASIONS\_\_ WEEKENDS ONLY\_\_ DAILY\_\_ ALCOHOLIC\_\_  
DURATION (YEARS) \_\_\_\_\_  
DRUGS/NARCOTICS: YES\_\_ NO\_\_ TYPE \_\_\_\_\_  
DURATION (YEARS) \_\_\_\_\_  
CIGARETTES: YES\_\_ NO\_\_ 1-5/DAY\_\_ 6-10/DAY\_\_ 11-20/DAY\_\_ >20/DAY  
DURATION (YEARS) \_\_\_\_\_  
PASSIVE SMOKING: YES\_\_ NO\_\_ DURATION (YEARS) \_\_\_\_\_  
ORAL/INJECTABLE CONTRACEPTIVES: YES\_\_ NO\_\_ DURATION (YEARS) \_\_\_\_\_  
BURNING FIREWOOD: YES\_\_ NO\_\_ SOURCE \_\_\_\_\_  
VEHICLE EMISSIONS: YES\_\_ NO\_\_ \_\_\_\_\_  
UNSATURATED FATTY ACID COOKING OILS \_\_\_\_\_  
PETROLEUM PRODUCTS: PARAFFIN: YES\_\_ NO\_\_ SOURCE \_\_\_\_\_  
BENZENE: YES\_\_ NO\_\_ SOURCE \_\_\_\_\_  
OTHER \_\_\_\_\_  
SOLVENTS: THINNERS: YES\_\_ NO\_\_ \_\_\_\_\_  
TURPENTINE: YES\_\_ NO\_\_ \_\_\_\_\_  
OTHER \_\_\_\_\_  
PAINT: YES\_\_ NO\_\_ MASKED\_\_ UNMASKED\_\_ DOMESTIC\_\_ WORK\_\_  
DIESEL: YES\_\_ NO\_\_

NUTRITION

CHILDHOOD: POOR\_\_ OK\_\_ GOOD\_\_  
ADULT: POOR\_\_ OK\_\_ GOOD\_\_  
BADLY AFFECTED BY CP: YES\_\_ NO\_\_  
BADLY AFFECTED BY ALCOHOL: YES\_\_ NO\_\_

PSYCHOMETRY

WORK PERFORMANCE/ABILITY TO WORK \_\_\_\_\_  
FAMILY AND SOCIAL INTERACTION \_\_\_\_\_  
FEEL GOOD ABOUT LIFE: YES\_\_ NO\_\_  
FEEL BAD ABOUT LIFE: YES\_\_ NO\_\_  
HOPELESS \_\_ HOPEFUL\_\_

CLINICAL INFORMATION

DATE OF CP PAIN ONSET \_\_\_\_\_  
ORIGINAL DIAGNOSIS \_\_\_\_\_ SOURCE \_\_\_\_\_  
DATES OF FIRST AND SUBSEQUENT HOSPITAL/CLINIC ADMISSIONS \_\_\_\_\_  
\_\_\_\_\_  
DATE OF FIRST CP DIAGNOSIS \_\_\_\_\_ SOURCE \_\_\_\_\_  
DATE OF PRESENTATION AT CHB HPB UNIT \_\_\_\_\_

PAIN DETAILS BEFORE HOSPITAL ADMISSION

LOCATION OF PAIN: EPIGASTRIC\_\_ LUQ\_\_ RUQ\_\_ RADIATING TO BACK\_\_  
INTENSITY: ABSENT\_\_ MILD\_\_ MODERATE\_\_ SEVERE\_\_  
INTERMITTENT\_\_ FREQUENT\_\_ PERSISTENT\_\_ INCREASING OVER TIME\_\_ DECREASING OVER TIME\_\_  
PAIN MEDICATION USE: NSAIDS\_\_ NARCOTICS\_\_ ANALGESICS\_\_  
EFFECTIVE: YES\_\_ NO\_\_  
NON-PANCREATIC CAUSES OF ABDOMINAL PAIN \_\_\_\_\_  
PAIN SCALE (0-10) \_\_\_\_\_

SEQUELAE

STEATORREA: YES\_\_ NO\_\_ STOOLS/DAY \_\_\_\_\_  
PANCREATIC ENZYME SUBSTITUTES: YES\_\_ NO\_\_  
DIABETES: YES\_\_ NO\_\_ IDDM\_\_ NIDDM\_\_  
HYPOGLYCAEMIC AGENTS \_\_\_\_\_  
SPECIAL DIET \_\_\_\_\_  
NAUSEA: YES\_\_ NO\_\_ VOMITING: YES\_\_ NO\_\_  
LOSS OF WEIGHT\_\_\_\_ WEIGHT GAIN\_\_\_\_ FLUCTUATING WEIGHT\_\_\_\_



**Appendix 2**  
**CHRONIC PANCREATITIS PATIENTS' INTERVIEW**  
**(POST LR-LPJ)**

DATE OF INTERVIEW \_\_\_\_\_  
 NAME \_\_\_\_\_  
 FEMALE \_\_\_ MALE \_\_\_ HOSPITAL NUMBER \_\_\_\_\_  
 DATE OF BIRTH \_\_\_\_\_  
 MARITAL STATUS \_\_\_\_\_ NO. OF DEPENDENTS \_\_\_\_\_  
 ADDRESS \_\_\_\_\_  
 TEL. NO. (H) \_\_\_\_\_ (W) \_\_\_\_\_ CELL \_\_\_\_\_  
 NEXT OF KIN/CONTACT PERSON \_\_\_\_\_ TEL. \_\_\_\_\_  
 CURRENTLY EMPLOYED: YES \_\_\_ NO \_\_\_ RETIRED: YES \_\_\_ NO \_\_\_

**POST SURGICAL EMPLOYMENT**

EMPLOYER/INDUSTRY	OCCUPATION	DATES OF SERVICE	REASON FOR LEAVING

WORKMEN'S COMPENSATION: YES \_\_\_ NO \_\_\_  
 UIF: YES \_\_\_ NO \_\_\_  
 DISABILITY GRANT: YES \_\_\_ NO \_\_\_  
 PENSION: STATE \_\_\_ PRIVATE \_\_\_

**POST LR-LPJ EXPOSURE TO RISK SUBSTANCES**

ALCOHOL: YES \_\_\_ NO \_\_\_ BEER \_\_\_ WINE \_\_\_ SPIRITS \_\_\_  
 SPECIAL OCCASIONS \_\_\_ WEEKENDS ONLY \_\_\_ DAILY \_\_\_ ALCOHOLIC \_\_\_  
 DURATION SINCE SURGERY \_\_\_\_\_  
 CIGARETTES: YES \_\_\_ NO \_\_\_ 1-5/DAY \_\_\_ 6-10/DAY \_\_\_ 11-20/DAY \_\_\_ >20/DAY \_\_\_  
 DURATION SINCE SURGERY \_\_\_\_\_  
 PASSIVE SMOKING: YES \_\_\_ NO \_\_\_  
 ORAL/INJECTABLE CONTRACEPTIVES: YES \_\_\_ NO \_\_\_  
 BURNING FIREWOOD: YES \_\_\_ NO \_\_\_ SOURCE \_\_\_\_\_  
 VEHICLE EMISSIONS: YES \_\_\_ NO \_\_\_  
 UNSATURATED FATTY ACID COOKING OILS \_\_\_\_\_  
 PETROLEUM PRODUCTS: PARAFFIN: YES \_\_\_ NO \_\_\_ SOURCE \_\_\_\_\_  
 BENZENE: YES \_\_\_ NO \_\_\_ SOURCE \_\_\_\_\_  
 OTHER: \_\_\_\_\_  
 SOLVENTS: THINNERS: YES \_\_\_ NO \_\_\_  
 TURPENTINE: YES \_\_\_ NO \_\_\_  
 OTHER \_\_\_\_\_  
 PAINT: YES \_\_\_ NO \_\_\_ MASKED \_\_\_ UNMASKED \_\_\_ DOMESTIC \_\_\_ WORK \_\_\_  
 DIESEL: YES \_\_\_ NO \_\_\_

**NUTRITION**

POOR \_\_\_ OK \_\_\_ GOOD \_\_\_  
 FOODS AVOIDED \_\_\_\_\_  
 BADLY AFFECTED BY SURGERY: YES \_\_\_ NO \_\_\_  
 BADLY AFFECTED BY ALCOHOL: YES \_\_\_ NO \_\_\_

**PSYCHOMETRY**

WORK PERFORMANCE/ABILITY TO WORK \_\_\_\_\_  
 FAMILY AND SOCIAL INTERACTION \_\_\_\_\_  
 FEEL GOOD ABOUT LIFE: YES \_\_\_ NO \_\_\_  
 FEEL BAD ABOUT LIFE: YES \_\_\_ NO \_\_\_  
 HOPELESS \_\_\_ HOPEFUL \_\_\_

POST LR-LPJ PAIN

HAVE YOU HAD PAIN AROUND THE STOMACH? YES\_\_ NO\_\_  
WAS IT THE SAME AS THE PAIN IN YOUR PANCREAS? YES\_\_ NO\_\_  
IF YES, WHEN DID THE PAIN COME? \_\_\_\_\_  
WOUND PAIN? \_\_\_\_\_  
LOCATION OF PAIN: EPIGASTRIC\_\_ LUQ\_\_ RUQ\_\_ RADIATING TO BACK\_\_  
INTENSITY: ABSENT\_\_ MILD\_\_ MODERATE\_\_ SEVERE\_\_  
INTERMITTENT\_\_ FREQUENT\_\_ PERSISTENT\_\_ INCREASING OVER TIME\_\_ DECREASING OVER TIME\_\_  
PAIN MEDICATION USE: NSAIDS\_\_ NARCOTICS\_\_ ANALGESICS\_\_  
EFFECTIVE: YES\_\_ NO\_\_  
POST CODEINE CONSTIPATION: YES\_\_ NO\_\_  
NON-PANCREATIC CAUSES OF ABDOMINAL PAIN \_\_\_\_\_  
PAIN SCALE (0-10) \_\_\_\_\_

SEQUELAE

STEATORRHEA: YES\_\_ NO\_\_ STOOLS/DAY \_\_\_\_\_  
PANCREATIC ENZYME SUBSTITUTES: YES\_\_ NO\_\_  
DIABETES: YES\_\_ NO\_\_ IDDM\_\_ NIDDM\_\_  
HYPOGLYCAEMIC AGENTS \_\_\_\_\_  
SPECIAL DIET \_\_\_\_\_  
NAUSEA: YES\_\_ NO\_\_ VOMITING: YES\_\_ NO\_\_  
LOSS OF WEIGHT\_\_ WEIGHT GAIN\_\_ FLUCTUATING WEIGHT\_\_

DO YOU THINK THE PANCREAS OPERATION HELPED YOU?

YES\_\_ NO\_\_ MAYBE\_\_

COMMENTS \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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