

# Comparison of Quality of Life Measurement Tools, EORTC GINET21 and ESAS-r, in Patients with Gastroenteropancreatic Neuroendocrine Tumors and Considerations for Clinical Implementation

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## Background

- Improved quality of life (QoL) with <sup>177</sup>Lu-DOTATATE treatment in GEP-NETs has been documented in clinical trials
- In clinical practice there is a focus from disease-centered to patient directed model
- Better integration of patient perspectives and improved communication between patients and physicians is facilitated by clinical use of QoL tools
- The standard QoL assessment for GEP-NETs is with the EORTC QLQ-C30 and QLQ-GI.NET21 which are time consuming and complex to score and interpret
- The ESAS-r is a simple validated tool designed for clinical QoL assessment but has not been assessed in NET populations

## Methods (Click)

### Study Design

- Prospective non-randomized open label phase II clinical trial
- Enrollment April 29, 2014 - ongoing

### Study Population

- Age ≥ 14 to 90 y.o.
- Metastatic un-resectable GEP-NETs
- Somatostatin receptor positive with size at least 1.5cm
- Bloodwork within accepted range

### QoL Assessment

- EORTC QLQ-C30 with GI.NET21 and ESAS-r
- Performed at baseline and prior to every treatment

### Data Analysis

- STATA 15
- Repeated measures ANOVA

## Results (Click)

- 85 patients included for analysis
  - 68% G.I. 24% pancreatic and 11% unknown but suspected GI primary
- Relatively high mean global health status of 68.1 by EORTC and low total symptom distress score (TSDS) of 18.2 by ESAS-r at baseline
- No change in mean global health status or TSDS after four treatment cycles
- Clinically and statistically significant improvement in insomnia, endocrine symptoms and G.I. symptoms in addition to social functioning by EORTC questionnaires
- Statistically but not clinically significant improvement in mean anxiety and emotional distress by ESAS-r questionnaire

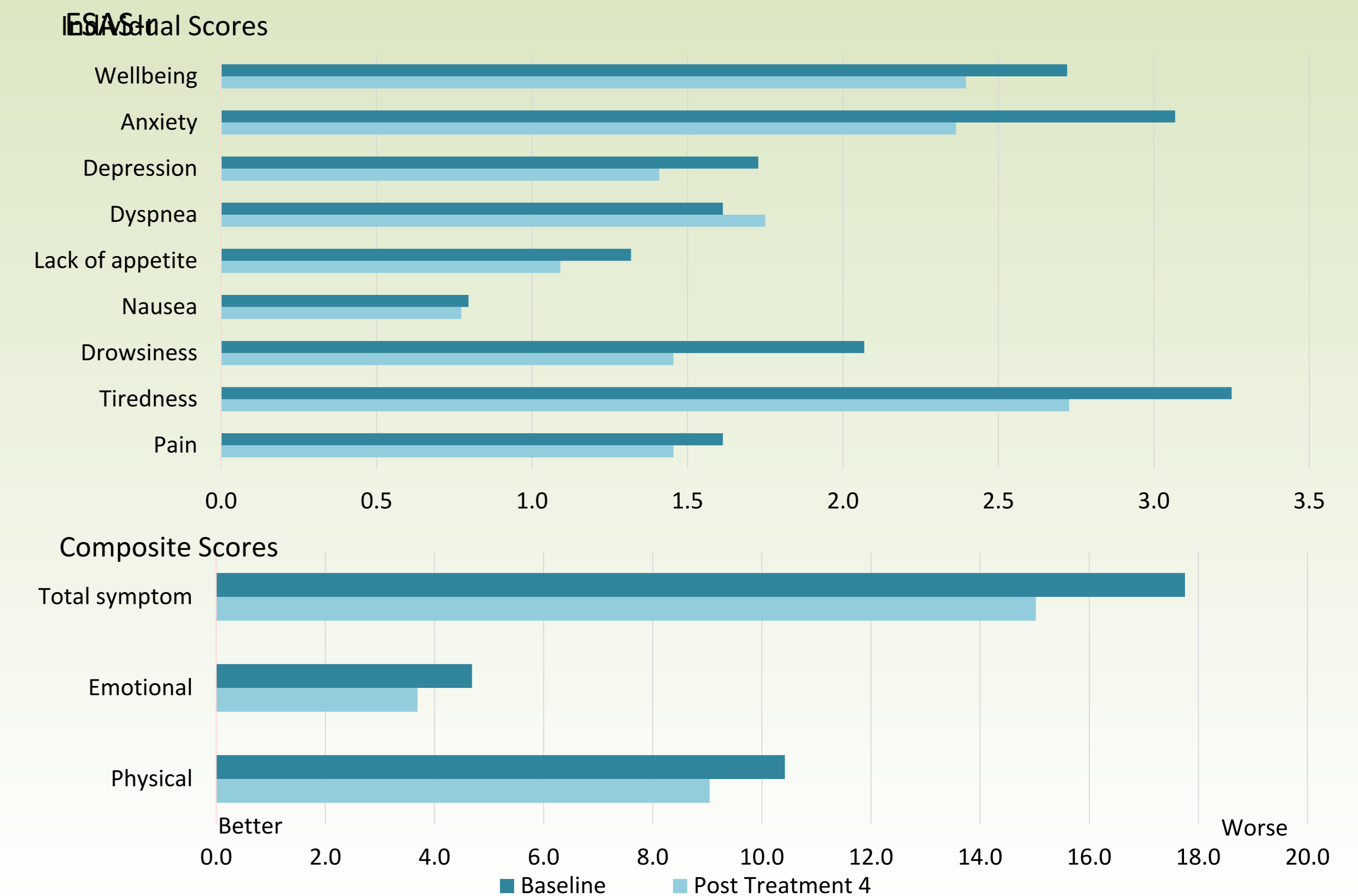
## Discussion

- Ours is the first study to evaluate QoL tools for direct clinical application in GEP-NETs
- ESAS-r provides a quick and easy to interpret tool for QoL evaluation
  - It is not NET specific and as such may not be as sensitive in this population
  - It does detect changes in QoL but not to the same degree as the EORTC QLQ questionnaires
- EORTC QLQ-C30 with GI.NET21 is a NET specific validated tool
  - It is more complex and time consuming, but better reflects QoL in the NET population

## Conclusion

Each QoL assessment tool has inherent benefits and limitations which must be considered in clinical use. The EORTC questionnaires remain the standard and incorporation into clinical practice with modifications such as computerized assessment and scoring could encourage its use. The utilization of a QoL tool, rather than none, is preferred; consequently, the utilization of a simple tool such as the ESAS-r can still offer some benefit to the patient and help direct treatment - as long as its limitations are kept in mind.

Figure 1. ESAS-r Scores



## Disclosure

The authors have no financial relationships to disclose

## Acknowledgements



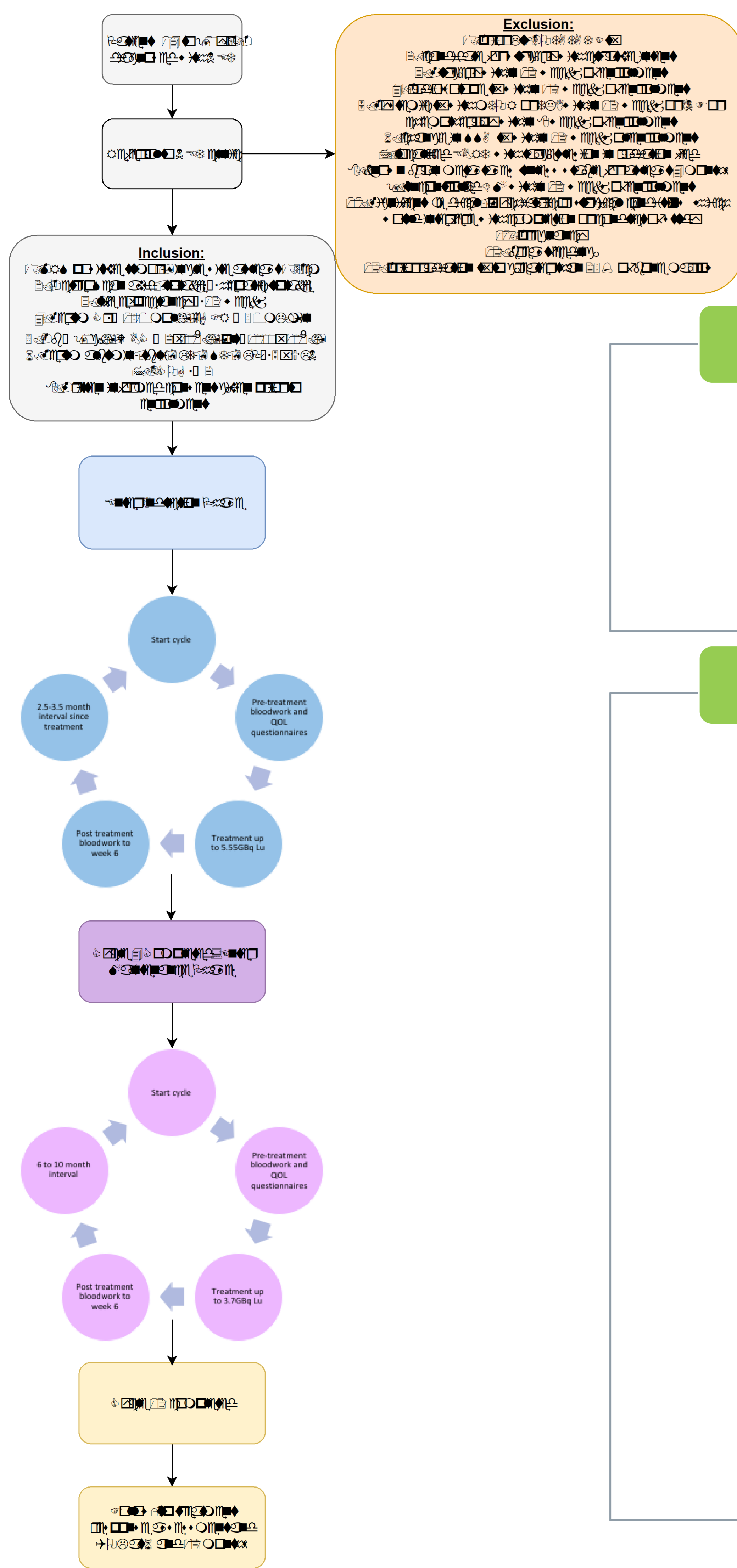
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# Materials and Methods

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## Lutetium Treatment

- Typical regimens consist of a maximum of four cycles of Lu with mean activity 5.2-5.55GBq per cycle
- Our protocol: up to 12 cycles
  - Induction: 4 cycles of up to 5.55GBq per cycle q10weeks
  - Maintenance: up to 8 cycles of low dose 3.7GBq per cycle q6months

## QoL Assessment

- Questionnaire administered at baseline and each follow-up visit
- European Organization for Research and Treatment of Cancer (EORTC) quality of life questionnaire, Version 3.0 (QLQ-C30) and [QLQ-GI.NET 21](#)
  - - Validated patient based QoL questionnaire
  - - 30 questions assessing parameters through single or multi item questions
    - - Global health status, functional scales, symptom scales
  - - All parameter scores transformed through grading scale calculations to 100 point scale
  - - Clinically significant changes are established as mean score change of at least **5 to 10** points
- [Edmonton symptom assessment system revised \(ESAS-r\)](#)
  - - Easily completed by patients within minutes
  - - Commonly utilized in both palliative care and general oncology
  - - Assesses 9 individual symptoms on a 10 point scale with option for additional patient reported symptom
  - - Scored as single symptom 10 point scores and three simple summative scores
    - - Total symptom distress score (TSDS), emotional score (ES), physical score (PS)
  - - Clinical significant changes for single items are 1 point, 3 points for TSDS and PS, 2 points for ES

**Edmonton Symptom Assessment System:**  
(revised version) (ESAS-R)

Please circle the number that best describes how you feel NOW:

No Pain	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Pain
No Tiredness <i>(Tiredness = lack of energy)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Tiredness
No Drowsiness <i>(Drowsiness = feeling sleepy)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Drowsiness
No Nausea	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Nausea
No Lack of Appetite	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Lack of Appetite
No Shortness of Breath	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Shortness of Breath
No Depression <i>(Depression = feeling sad)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Depression
No Anxiety <i>(Anxiety = feeling nervous)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Anxiety
Best Wellbeing <i>(Wellbeing = how you feel overall)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible Wellbeing
No _____ Other Problem <i>(for example constipation)</i>	0	1	2	3	4	5	6	7	8	9	10	Worst Possible _____

Patient's Name \_\_\_\_\_

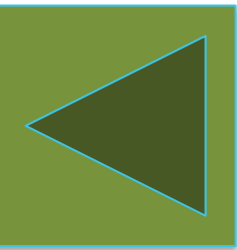
Date \_\_\_\_\_ Time \_\_\_\_\_

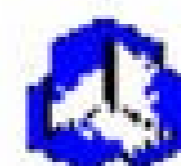
Completed by (check one):

- Patient
- Family caregiver
- Health care professional caregiver
- Caregiver-assisted

BODY DIAGRAM ON REVERSE SIDE

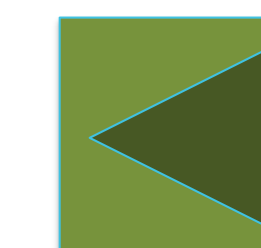
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**EORTC QOL – GINET21**

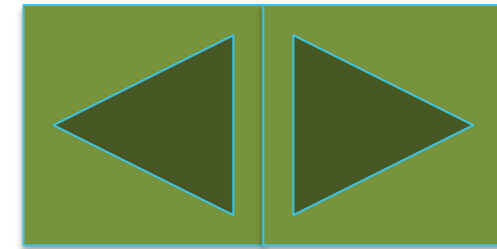
Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

<b>During the past week:</b>		<b>Not at all</b>	<b>A little</b>	<b>Quite a bit</b>	<b>Very much</b>	
31.	Did you have hot flushes?	1	2	3	4	
32.	Have you noticed or been told by others that you looked flushed/red?	1	2	3	4	
33.	Did you have night sweats?	1	2	3	4	
34.	Did you have abdominal discomfort?	1	2	3	4	
35.	Did you have a bloated feeling in your abdomen?	1	2	3	4	
36.	Have you had a problem with passing wind/gas/flatulence?	1	2	3	4	
37.	Have you had acid indigestion or heartburn?	1	2	3	4	
38.	Have you had difficulties with eating?	1	2	3	4	
39.	Have you had side-effects from your treatment? <i>(If you are not on treatment please circle N/A)</i>	N/A	1	2	3	4
40.	Have you had a problem from repeated injections? <i>(If not having injections please circle N/A)</i>	N/A	1	2	3	4
41.	Were you worried about the tumour recurring in other areas of the body?	1	2	3	4	
42.	Were you concerned about disruption of home life?	1	2	3	4	
43.	Have you worried about your health in the future?	1	2	3	4	
44.	How distressing has your illness or treatment been to those close to you?	1	2	3	4	
45.	Has weight loss been a problem for you?	1	2	3	4	
46.	Has weight gain been a problem for you?	1	2	3	4	
47.	Did you worry about the results of your tests? <i>(If you have not had tests please circle N/A)</i>	N/A	1	2	3	4
48.	Have you had aches or pains in your muscles or bones?	1	2	3	4	
49.	Did you have any limitations in your ability to travel?	1	2	3	4	
<b>During the past four weeks:</b>						
50.	Have you had problems receiving adequate information about your disease and treatment?	1	2	3	4	
51.	Has the disease or treatment affected your sex life (for the worse)? <i>(If not applicable please circle N/A)</i>	N/A	1	2	3	4

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# Results Part 1

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**Table 1. Patient Characteristics**

	N	(%)
	(n=85)	
<b>Age</b>		
20-49	10	11
50-69	49	57
70-90	26	31
<b>Sex</b>		
Male	49	58
Female	36	42
<b>ECOG</b>		
0	54	64
1	27	32
2	4	5
<b>Previous Treatment</b>		
Surgery	62	73
SSA	61	72
Chemotherapy	12	14
mTOR, TKI	5	6
Locoregional Therapy	6	7

**Table 3. EORTC QLQ C-30 and GI.NET21**

EORTC scale	Mean (p-value)	
	Baseline	Post Treatment 4
<b>Global Health Status</b>	68.1 [60.57, 75.62]	66.4 [57.33, 75.52]
<b>Functional Scales</b>		
Physical Functioning	80.50 [73.76, 87.25]	82.13 [75.86, 88.41]
Role Functioning	76.74 [68.14, 85.35]	77.13 [67.9, 86.36]
Emotional Functioning	70.14 [62.15, 78.13]	73.15 [64.51, 81.78]
Cognitive Functioning	75.0 [65.52, 84.48]	76.39 [66.45, 86.33]
Social Functioning	<b>76.85</b> [68.09, 85.62]	<b>83.33**</b> [75.02, 91.64]
<b>Symptom Scales</b>		
Fatigue	32.56 [24.78, 40.36]	30.36 [22.57, 38.15]
Nausea and Vomiting	5.04 [1.77, 8.31]	6.98 [1.47, 12.49]
Pain	24.81 [16.40, 33.21]	22.48 [13.68, 31.29]
Dyspnea	19.38 [10.36, 28.40]	21.71 [13.99, 29.42]
Insomnia	<b>36.43</b> [26.47, 46.40]	<b>25.58**</b> [16.96, 34.20]
Appetite Loss	12.40 [6.06, 18.74]	11.63 [5.76, 17.50]
Constipation	13.18 [6.05, 20.31]	11.63 [2.30, 20.26]
Diarrhea	36.19 [26.42, 45.96]	31.43 [21.83, 41.03]
Financial Difficulties	20.0 [10.71, 29.29]	20.95 [11.71, 30.20]
Endocrine Symptoms	<b>20.37</b> [13.58, 27.16]	<b>14.81**</b> [9.37, 20.26]
GI Symptoms	<b>22.28</b> [16.16, 28.39]	<b>16.67**</b> [12.17, 21.17]

\*\* P < 0.05

**Table 4. ESAS-r**

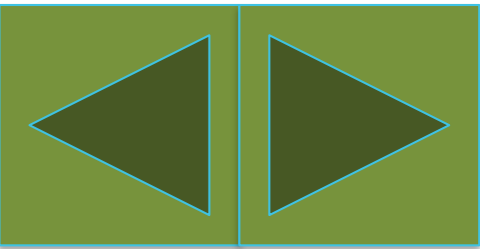
ESAS-r	Mean (p-value)	
	Baseline	Post Treatment 4
Pain	1.61 [0.94, 2.28]	1.46 [0.82, 2.09]
Tiredness	3.25 [2.56, 4.14]	2.73 [1.99, 3.47]
Drowsiness	<b>2.07</b> [1.22, 2.92]	<b>1.46**</b> [0.78, 2.13]
Nausea	0.80 [0.33, 1.26]	0.77 [0.28, 1.26]
Lack of Appetite	1.32 [0.66, 1.97]	1.09 [0.59, 1.59]
Dyspnea	1.61 [0.84, 2.39]	1.75 [1.1, 2.4]
Depression	1.73 [0.94, 2.52]	1.41 [0.77, 2.05]
Anxiety	<b>3.07</b> [2.15, 3.40]	<b>2.36**</b> [1.59, 3.13]
Overall Wellbeing	2.72 [1.92, 3.53]	2.40 [1.68, 3.12]
Physical Score	<b>10.66</b> [7.31, 14.01]	<b>9.25*</b> [6.39, 12.11]
Emotional Score	<b>4.80</b> [3.23, 6.37]	<b>3.77**</b> [2.44, 5.10]
Total Symptom Distress Score	<b>18.16</b> [12.95, 23.37]	<b>15.36**</b> [10.90, 19.83]

**Table 2. NET Diagnosis**

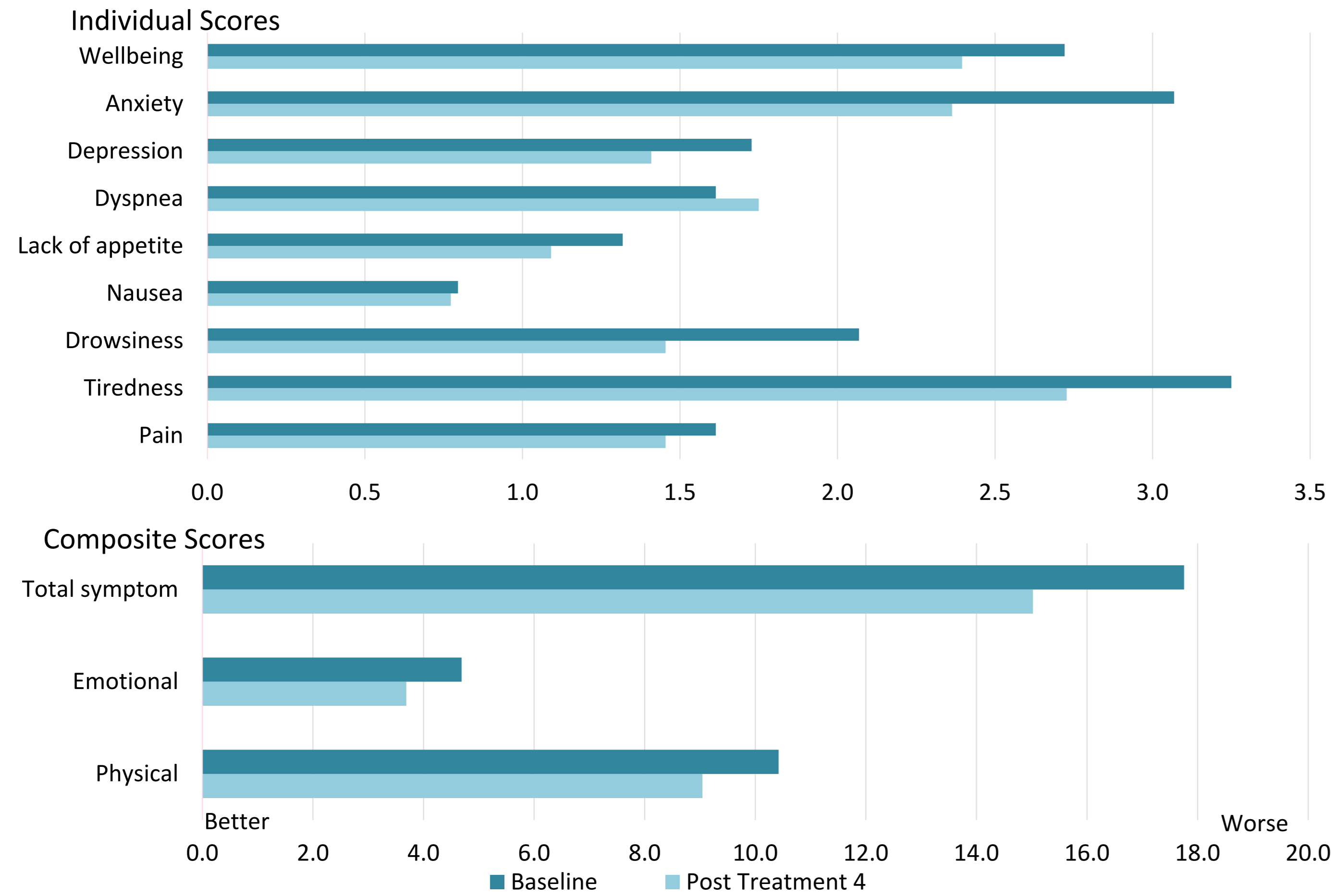
	N (n=85)	(%)
<b>Site of Primary</b>		
Pancreas	20	24
GI	58	68
Unknown Primary (presumptive GNET)	9	11
<b>Metastasis</b>		
Liver	77	91
Bone	19	22
Mesentery	18	21
Lymph Nodes	20	24
<b>Ki-67</b>		
<2%	26	31
2-20%	33	39
>20%	3	4
Unknown	23	27

# Results Continued

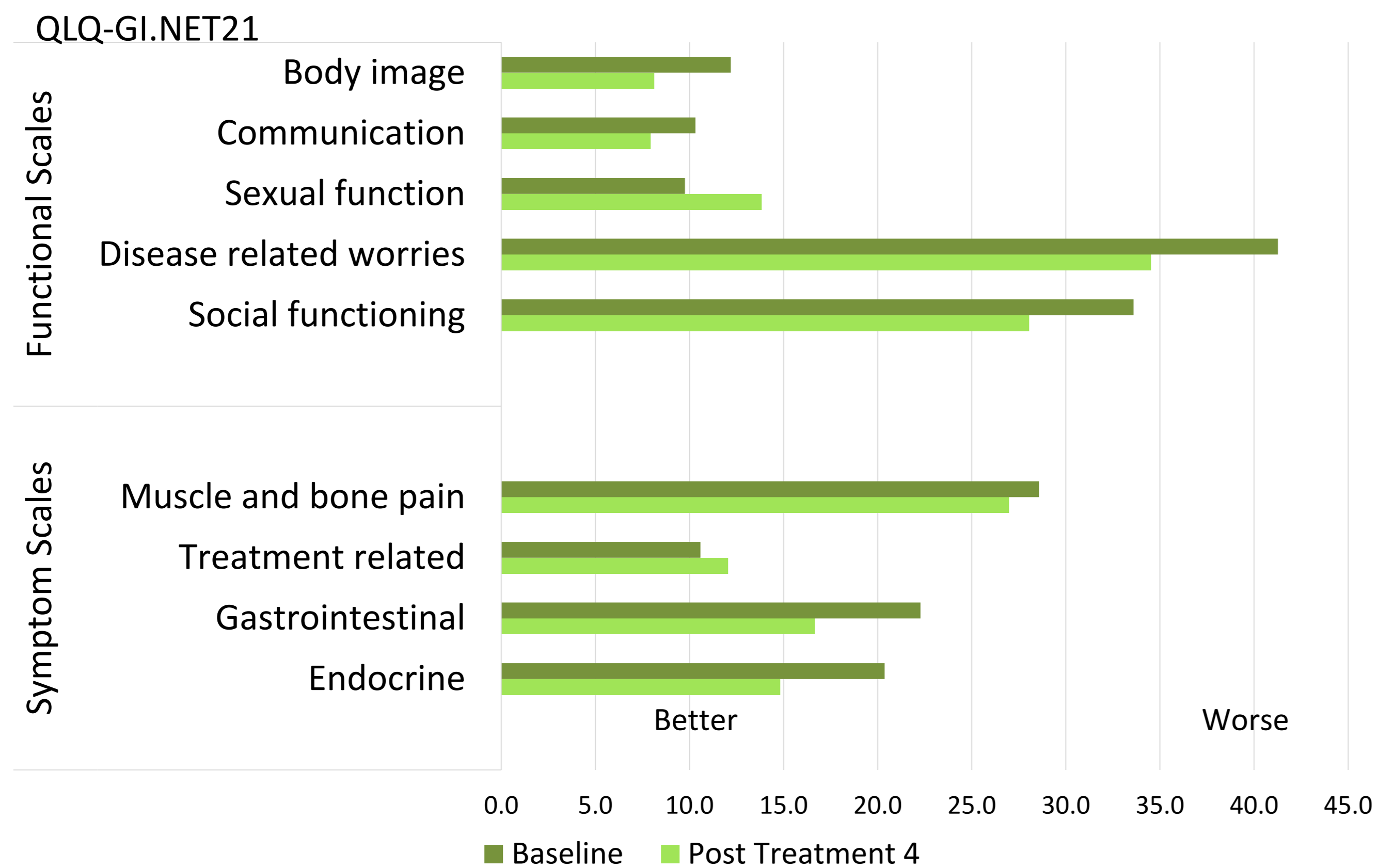
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**Figure 1. ESAS-r Scores**



**Figure 2. QLQ-GI.NET21 Scores**



**Figure 3. QLQ-C30 Scores**

