Improved Quality of Life in Patients with Gastroenteropancreatic NETs with Lutetium PRRT

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Background

- The incidence of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) is increasing
- Lutetium therapy is an established treatment with benefit towards progression-free survival (PFS) in metastatic GEP-NETs with median PFS of up to 36 months
- The effect of ^{177}Lu-DOTATATE on quality of life (QoL) is not yet well established
- Symptoms are diverse and related to both tumor burden and function
- The impact of treatment on patient QoL must be considered with the goal of improvement or maintenance in patient function and symptom control.

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 and GI.NET21
- At baseline and prior to every treatment

Data Analysis

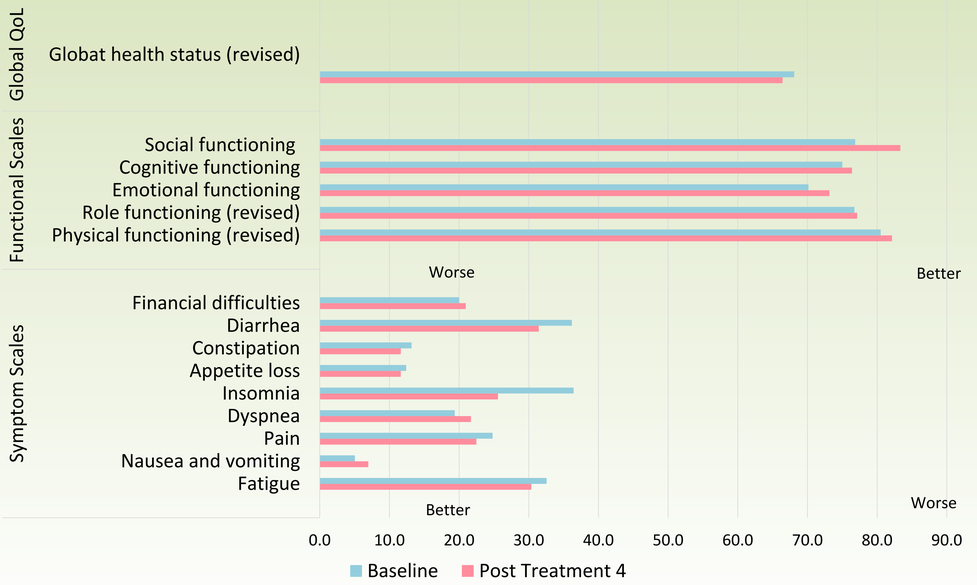
- STATA 15
- Repeated measures ANOVA

Results (Click)

- 85 patients included for analysis
  - 68% G.I. 24% pancreatic and 11% unknown but suspected GI primary
- Relatively high baseline mean global health status of 68.1
- Mean global health status maintained after four treatment cycles
- Clinically and statistically significant improvement in insomnia, endocrine symptoms and G.I. symptoms
- Clinically significant improvement in mean social functioning,,
- No statistically or clinically significant deterioration in any QoL parameters assessed

Figure 1. QLQ C-30 Scores

EORTC QLQ-C30



Discussion

- Unique to our study we establish improved aspects of QoL in patients with GEP-NETs with documented progression at baseline
- Our population is very representative of that found in clinical practice and can be applied directly
- Critically, endocrine and G.I. symptoms were improved which remain some of the most difficult to treat symptoms in patients with NETs
- Further analysis at study completion will assess if these benefits are maintained over a prolonged treatment course in our modified protocol

Conclusion

^{177}Lu-DOTATATE is not only effective in improving PFS for patients with metastatic GEP-NETs but also maintains overall quality of life and importantly provides patients with improvement in specific symptoms such as insomnia, endocrine and GI symptoms

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Disclosure

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Alberta Health Services
AHFMR Alberta Heritage Foundation for Medical Research
University of Alberta

Materials and Methods

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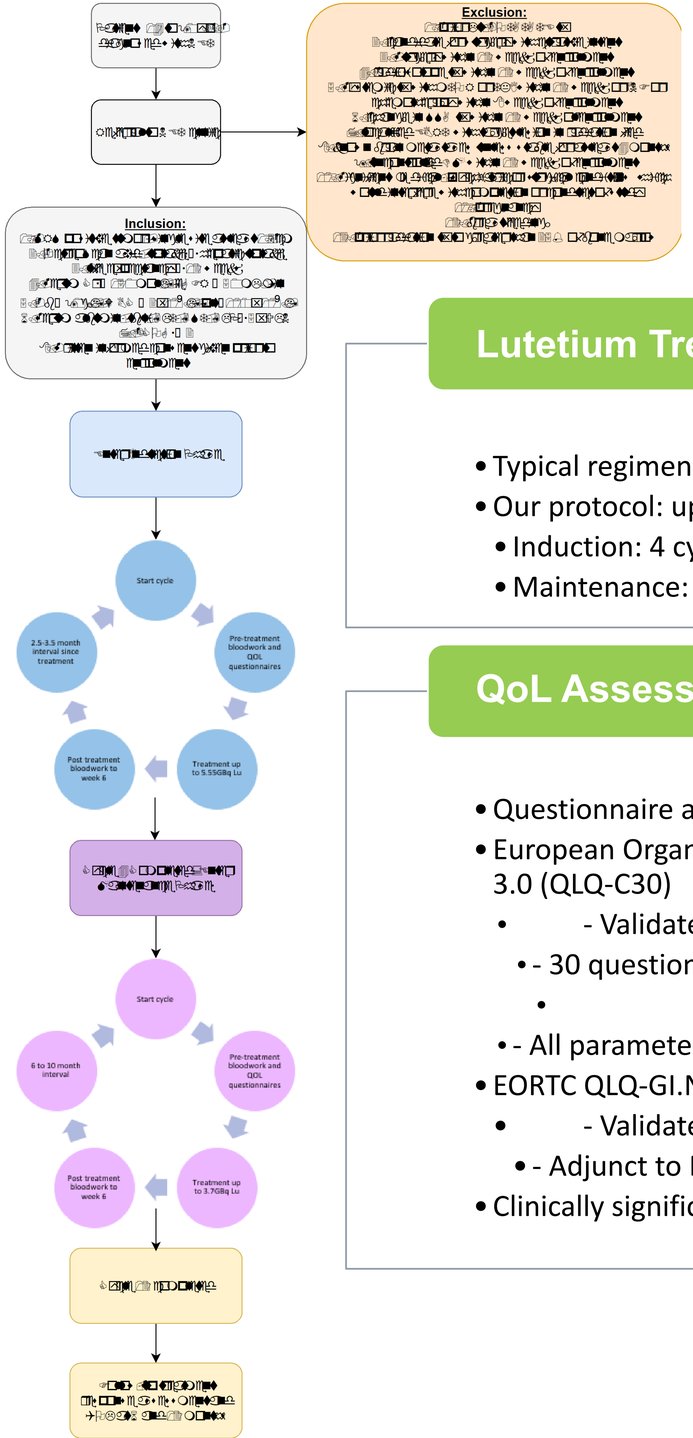


Lutetium Treatment

- 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)
  - - 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 to 100 point scale
- EORTC QLQ-GI.NET 21
  - - Validated QoL questionnaire specifically for G.I. related neuroendocrine tumors
  - - Adjunct to EORTC QLQ-C30
- Clinically significant changes are established as mean score change of at least **5 to 10** points

Therapy Number	Year	Frequency	Evaluations
Induction 1 - 4	1	Every 10 - 12 weeks	CT/MRI scans and blood work/urine 4 months after therapy 4.
Maintenance 5 - 6	2	Every 6 months (range 5 – 8 months)	CT/MRI scans and blood work/urine 4 months after therapy 5 & 6.
7 - 8	3	Every 6 months (range 5 – 9 months)	CT/MRI scans and blood work/urine 4 months after therapy 7 & 8.
9 +	4	Every 6 - 9 months (range 6 – 12 months)	CT/MRI scans and blood work/urine 4 months after each subsequent therapy.

Results

Table 1. Patient Characteristics

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

Table 2. NET Diagnosis

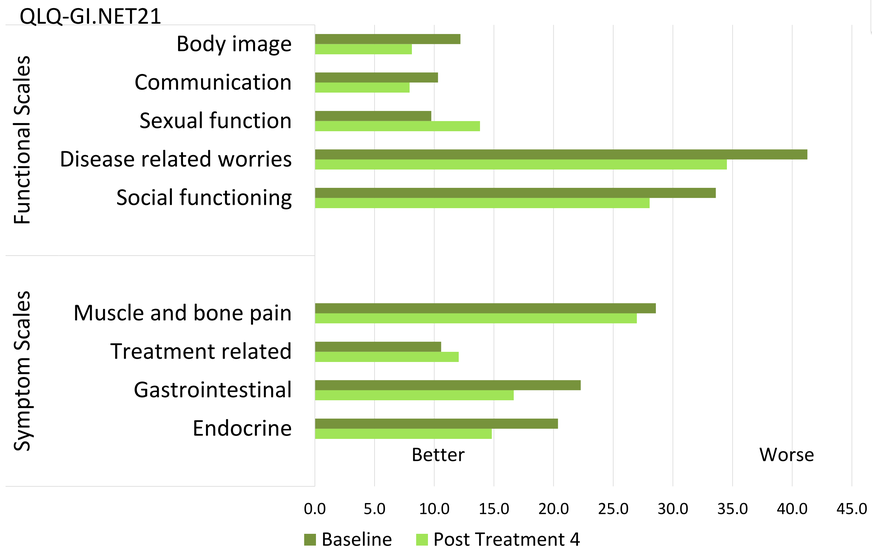
		N (n=85)	(%)
Site of Primary			
	Pancreas	20	24
	GI	58	68
	Unknown Primary (presumptive GNET)	9	11
Metastasis			
	Liver	77	91
	Bone	19	22
	Mesentery	18	21
	Lymph Nodes	20	24
Ki-67			
	<2%	26	31
	2-20%	33	39
	>20%	3	4
	Unknown	23	27

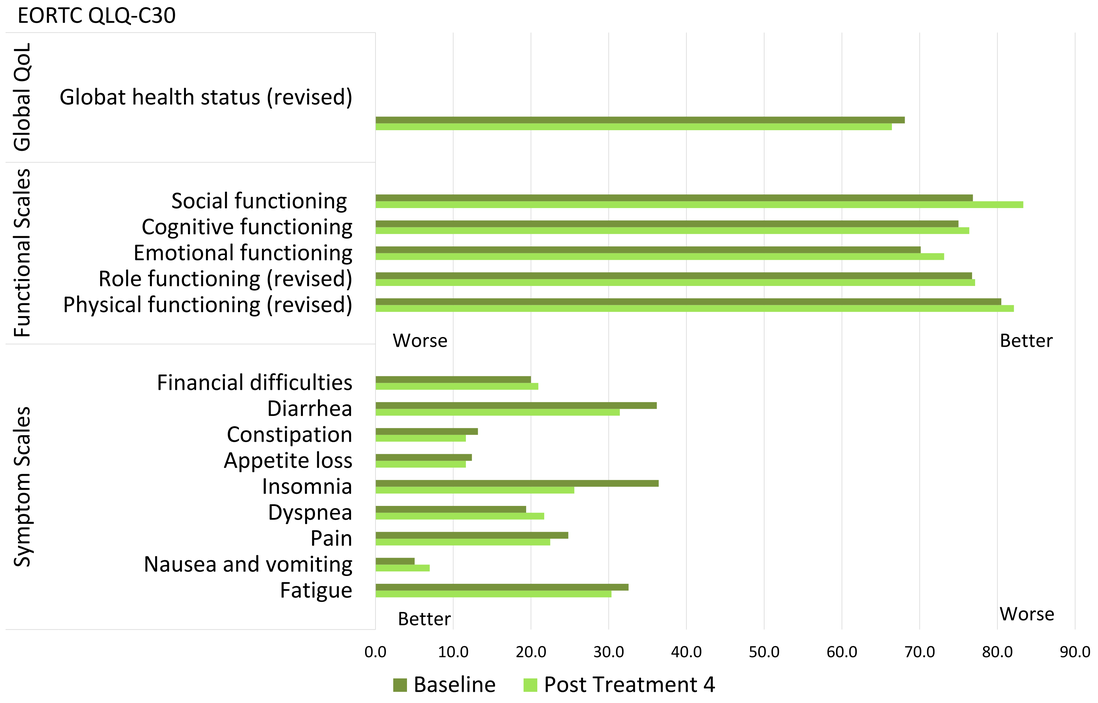
Table 3. EORTC QLQ C-30 and GI.NET21

EORTC scale	*Mean (p-value)* *Baseline*	*Post Treatment 4*
Global Health Status	68.1 [60.57, 75.62]	66.4 [57.33, 75.52]
Functional Scales		
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	**76.85 [68.09, 85.62]**	**83.33** [75.02, 91.64]**
Symptom Scales		
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	**36.43 [26.47, 46.40]**	**25.58** [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	**20.37 [13.58, 27.16]**	**14.81** [9.37, 20.26]**
GI Symptoms	**22.28 [16.16, 28.39]**	**16.67** [12.17, 21.17]**

** P < 0.05

Figure 1. QLQ-GI.NET21 Scores





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