



International Cross-cultural Field Validation of an EORTC questionnaire module for patients with primary liver cancer, HCC18

Preliminary results, September 2010
Wei-Chu Chie, MD, MS, PhD
National Taiwan University



Collaborators

■ Co-investigators

- Europe: Jane M Blazeby, Philip J Johnson, Nigel Heaton (UK), Anna Costantini (Italy), Ludovic Trinquart (France),
- Asia: Ronnie T. Poon (Hong Kong), Heng-Chia Chiu, PhD (Taiwan), Naoko Mikoshiba (Japan)

■ Statistician

- Chin-Fu Hsiao, PhD, Data management centre: Division of Biostatistics and Bioinformatics, National Health Research Institutes, Taiwan



Aims of the project

- The objective of this study is to
 - test the
 - Reliability (consistency and stability)
 - Psychometric validity
 - Clinical validity
 - of the EORTC QLQ-HCC18 in an international sample of patients with primary liver cancer (hepatocellular carcinoma, HCC)



Groups of patients

- **A:** hepatectomy or other surgeries (including transplant, etc.)
- **B:** any kind of ablation (radiofrequency, ethanol, etc.) alone
- **C:** any kind of embolisation (lipiodol, chemo-etc.) alone
- **D:** systemic therapy alone
- **E:** off-treatment for at least 12 months
- Patients may have past treatments



Timing of assessments

- First assessment (for psychometric tests and known-groups comparison)
 - **A, B, C, D:** before treatment
 - **E:** after completion of any treatment for at least 12 months without evidence of recurrence
- Second assessment (A to D: for responsiveness)
 - **A:** at three months (range: 12-15 weeks) after surgery
 - **B:** at one month (range: 4-6 weeks) after ablation
 - **C:** at one month (range: 4-6 weeks) after embolisation
 - **D:** at one week (range: 7-10 days) of completion of systemic therapy
 - **E:** re-test one week later (for test-retest reliability)



Required clinical evaluations

- Major Measurement Instruments
 - the EORTC QLQ-C30 (version 3.0)
 - the primary liver cancer module (QLQ-HCC18)
- Debriefing questionnaire
 - the time taken to complete the QLQ-C30 and QLQ-HCC18
 - the need for help in completing the questionnaires
 - querying whether any of the items were confusing; difficult to answer or upsetting, suggestions of re-wording, etc.
- Case Report Form



Forms to return

- First assessment
 - Forms 1 & 2 (demographic & clinical)
 - Questionnaires
 - Patient debriefing (Forms 4)
- Second assessment
 - Forms 3 & 5 (clinical & treatment)
 - Questionnaires
 - Off-study form (missing questionnaires)



Schedule and budgets

- Two + One years
 - From November 2007
 - To September 2010
- Total budget: Euro 48500 + 13000
 - Interview fee paid directly to co-PIs by the EORTC
 - Other expenses paid to NTU (PI)
- Newsletter: monthly since August 2008

Table 1 Patients registered and CRFs received in data centre

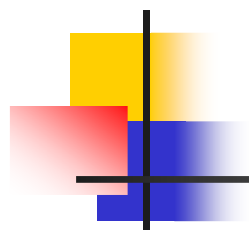
Hospital	Registered Number	# of CRFs in Statistical Center					Total
		Group A	Group B	Group C	Group D	Group E	
National Taiwan University Hospital, Taiwan(002)	46	11	7	10	7	11	46
Kaohsiung Medical University, Taiwan(005)	50	30	0	20	0	0	50
United Bristol Healthcare Trust, UK(B01)	14*	1	3	8	0	1	13
King's College Hospital, UK(B03)	24**	0	3	13	3	2	21
Beaujon Hospital,Fr(F01)	4	0	0	0	4	0	4
Sant'Andrea Hospital 2nd Faculty of Medicine Sapienza University of Rome, Italy(I01)	7	2	0	1	4	0	7
The University of Tokyo Hospital , JP(J01)	42	0	30	0	0	12	42
Queen Mary Hospital, HK(P01)	48***	10	10	10	6	10	46
Total	235	54	53	62	24	36	229

*:no.4 patient is repeated on no.5 – only one record will be taken.

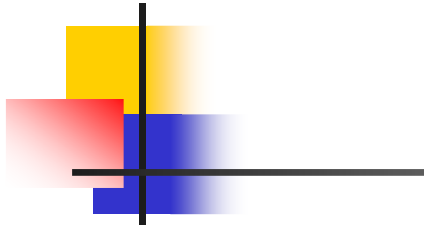
** :no.2 patient didn't go to any group.

***:no.1 and no.16 patients didn't go to any group.

Table 2 Demographic characteristics




	Total (N=232)
Age	63.24± 12.50
Gender	
Male	177 (76.29%)
Female	55 (23.71%)
Race	
European	40 (17.24%)
Asian	184 (79.31%)
Others	8 (3.45%)
Highest level of education completed	
compulsory or less	113 (48.71%)
post-compulsory	116 (50.00%)
missing	3 (1.29%)

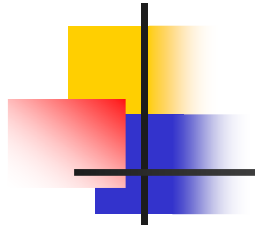


	Total (N=232)
Employment status	
full time + self	79 (34.05%)
others	153 (65.95%)
Marital status	
married or living with partner	182 (78.45%)
else	50 (21.55%)
Cohabitants	
living with family	201 (86.64%)
else	31 (13.36%)

Table 3 Basic clinical information



	Total (N=232)
Diagnosis of HCC by surveillance	185 (79.74%)
Histologically diagnosed	168 (72.41%)
Tumor number (one missing)	
single	142 (61.21%)
multiple	89 (38.36%)
Tumor involvement	
within one lobe	181 (78.02%)
more than one lobe	39 (16.81%)
Adjacent+meta	12 (5.17%)
Cirrhosis	164 (70.69%)
Clinical significant portal hypertension (varices, ascites)	25 (10.78%)
Child-Pugh grade for HCC	
A	181 (78.02%)
B or C	40 (17.24%)
missing	11 (4.74%)



	Total (N=232)
Comorbid disease	
Hypertension	64 (27.59%)
Diabetes	50 (21.55%)
Renal	16 (6.90%)
Cardiovascular	26 (11.21%)
Karnofsky score	
KPS = 100	104 (44.83%)
80 ≤ KPS ≤ 90	115 (49.57%)
KPS ≤ 70	13 (5.60%)
Bilirubin < 2 mg /dL	146 (62.93%)
α-FP < 20 ng /mL	126 (54.31%)
Past medical history	
surgery	56 (24.14%)
ablation	54 (23.28%)
embolisation	88 (37.93%)
systemic therapy	14 (6.03%)
No medical history	84 (36.21%)

Old Table 4 Internal consistency, item convergent and discriminant validity for 1st HCC18 (Overall, N=116) (The original scale structure)

Scales (no. of items)	Cronbach's α	Item - own scale correlation	Item - other scale correlation	Scaling error
Fatigue (3)	0.56	0.22 - 0.54	0.15 - 0.53	0/24
Nutrition (5)*	0.68	0.32 - 0.54	-0.11 - 0.83	1/40
Jaundice (2)	0.46	0.31	0.17 - 0.52	0/16
Pain (2)	0.44	0.28	0.05 - 0.50	0/16
Fever (2)	0.48	0.32	-0.02 - 0.39	0/16
Body image (2)*	0.10	0.05	-0.11 - 0.72	6/16
Thirsty (1)			0.15 - 0.33	
Abdominal swelling (1)			0.08 - 0.43	
Sexual interest (1)			0.02 - 0.35	

* One item overlaps.



Items with scaling error

- Nutrition
 - Q33 (lost muscle): with Body image
- Body image
 - Q33 (lost muscle): with Fatigue, Nutrition, and Pain
 - Q35 (appearance of abdomen): with Fatigue, Jaundice, and Pain
- Patients' questions
 - Shoulder pain is due to shoulder disorder
 - Itching is due to causes other than jaundice



Changes of scale structure

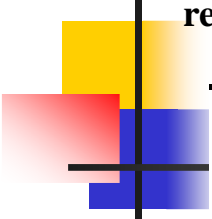
- **Symptom scales**

- Fatigue (fa) (3 items: 45, 46, 47)
- Nutrition (nu) (5 items: 32, 33, 42, 43, 44)
- Pain (pa)(2 items:38, 39)
- Fever (fe) (2 items: 40, 41)

- **Single items**

- Jaundice 1 (Q36) yellow
- Jaundice 2 (Q37) itching
- Thirsty (th) (Q31)
- Abdominal swelling (as) (Q34)
- Sexual interest (si) (Q48)
- Body image2 (Q35) appearance of abdomen

New Table 4 Internal consistency, item convergent and discriminant validity for 1st HCC18 after reorganizing the scales (Overall, N=232)



	Cronbach's α	Item to own scale correlation	Item to other scale correlation	Scaling error
Fatigue	0.72	0.48 - 0.59	0.15 - 0.51	0/27
Nutrition (incl. 33)	0.57	0.27 - 0.42	-0.03 - 0.41	0/45
Pain	0.34	0.21	-0.04 - 0.35	0/18
Fever	0.54	0.38	0.01 - 0.29	0/18
Jaundice 1 (36 yellow)			0.19 - 0.36	
Jaundice 2 (37 itching)			0.11 - 0.39	
Body image 2 (35)			0.12 - 0.43	
Thirsty			0.12 - 0.32	
Abdominal swelling			0.10 - 0.44	
Sexual interest			0.04 - 0.25	



Table 5a Test-retest for group E (multi-item scales)

	Between subject S.D.	Within subject S.D.	ICC
Fatigue	0.56	0.27	0.81
Nutrition	0.38	0.16	0.85
Pain	0.49	0.38	0.63
Fever	0.35	0.25	0.67

Table 5b Test-retest for group E (single-item scales)

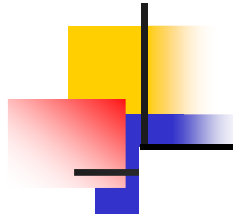
Items	Absolute score difference				Missi ng	Simple Kappa	Weighted Kappa
	0	1	2	3			
Thirsty	19	12	0	0	1	0.34	0.42
Abdominal swelling	18	11	2	0	1	0.22	0.25
Body image (35)	20	11	0	0	1	0.36	0.52
Jaundice1 (36)	27	4	0	0	1	0.69	0.77
Jaundice2 (37)	23	8	0	0	1	0.61	0.70
Sex interest	27	3	0	0	2	0.75	0.82

Table 6 - Correlation between 1st C30 & 1st HCC18

Subscales of C30	Subscales of HCC18									
	Fatigue	Nutrition	Pain	Fever	Thirsty	Jaundice1	Jaundice2	Abdominal swelling	Sexual interest	Body image
Physical functioning	0.63	0.44	0.44	0.35	0.26	0.19	0.28	0.39	0.09	0.32
Role functioning	0.62	0.36	0.37	0.32	0.13	0.21	0.17	0.44	0.22	0.37
Emotional functioning	0.38	0.41	0.26	0.18	0.25	0.24	0.19	0.21	0.28	0.30
Cognitive functioning	0.55	0.35	0.44	0.26	0.29	0.31	0.39	0.41	0.15	0.39
Social functioning	0.55	0.48	0.31	0.15	0.10	0.37	0.21	0.26	0.30	0.30
Global health status/QOL	-0.42	-0.36	-0.25	-0.16	-0.23	-0.19	-0.22	-0.36	-0.16	-0.14
Fatigue	0.64	0.46	0.46	0.29	0.28	0.26	0.31	0.38	0.22	0.38
Nausea and vomiting	0.30	0.38	0.35	0.30	0.22	0.11	0.15	0.19	0.12	0.14
Pain	0.61	0.46	0.46	0.30	0.30	0.25	0.30	0.36	0.20	0.35
Dyspnea	0.43	0.35	0.31	0.34	0.24	0.20	0.33	0.39	-0.02	0.39
Insomnia	0.44	0.33	0.38	0.27	0.28	0.28	0.27	0.22	0.14	0.19
Appetite loss	0.34	0.50	0.32	0.35	0.12	0.10	0.04	0.18	0.10	0.11
Constipation	0.37	0.33	0.27	0.30	0.18	0.14	0.12	0.26	0.11	0.20
Diarrhea	0.15	0.17	0.14	0.11	0.06	0.21	0.12	0.07	0.01	0.08
Financial difficulties	0.37	0.35	0.32	0.15	0.16	0.36	0.18	0.27	0.15	0.18

Table 7 Sensitivity: known-groups comparison

	Group A (n=54)		Group B (n=53)		Group C (n=62)	
	Mean ± S.D.	Median (Min, Max)	Mean ± S.D.	Median (Min, Max)	Mean ± S.D.	Median (Min, Max)
Fatigue	15.5± 16.6	11.1(0.00,66.7)	24.1± 20.9	22.2(0.00, 100)	25.6± 25.7	22.2(0.00, 100)
Nutrition	10.4± 13.0	6.67(0.00,53.3)	13.2± 10.7	13.3(0.00,40.0)	11.3± 12.2	6.67(0.00,53.3)
Pain	7.86± 10.1	0.00(0.00,33.3)	14.5± 15.0	16.7(0.00,50.0)	15.9± 22.1	0.00(0.00, 100)
Fever	2.52± 7.59	0.00(0.00,33.3)	5.35± 10.2	0.00(0.00,33.3)	2.96± 8.81	0.00(0.00,33.3)
Jaundice 1	7.55± 16.8	0.00(0.00,66.7)	13.8± 24.0	0.00(0.00, 100)	7.65± 18.7	0.00(0.00,66.7)
Jaundice 2	13.8± 25.7	0.00(0.00, 100)	25.2± 31.3	0.00(0.00, 100)	19.9± 25.9	0.00(0.00,66.7)
Thirsty	23.9± 29.5	0.00(0.00, 100)	25.8± 29.7	33.3(0.00, 100)	23.1± 26.0	33.3(0.00, 100)
Abdominal swelling	6.92± 17.7	0.00(0.00, 100)	18.2± 21.2	0.00(0.00,66.7)	18.8± 28.1	0.00(0.00, 100)
Sexual interest	16.4± 29.7	0.00(0.00, 100)	15.1± 29.6	0.00(0.00, 100)	16.1± 30.4	0.00(0.00, 100)
Body image	5.03± 13.7	0.00(0.00,66.7)	17.6± 24.1	0.00(0.00, 100)	13.4± 26.6	0.00(0.00, 100)



Group D (n=20)		Group E (n=32)		P-value of F-test	P-value of KW-test
Mean ± S.D.	Median (Min, Max)	Mean ± S.D.	Median (Min, Max)		
26.7± 18.9	33.3(0.00,55.6)	25.3± 19.8	22.2(0.00,77.8)	0.0718	0.0542
21.3± 16.0	20.0(0.00,53.3)	11.9± 13.5	6.67(0.00,60.0)	0.0197	0.0224
20.8± 13.1	16.7(0.00,50.0)	18.2± 18.6	16.7(0.00,66.7)	0.0125	0.0053
9.17± 15.7	0.00(0.00,50.0)	4.17± 10.4	0.00(0.00,33.3)	0.0885	0.1190
6.67± 13.7	0.00(0.00,33.3)	11.5± 23.4	0.00(0.00,66.7)	0.3817	0.4577
20.0± 27.4	0.00(0.00, 100)	29.2± 29.0	33.3(0.00, 100)	0.1128	0.0641
21.7± 27.1	0.00(0.00,66.7)	24.0± 21.1	33.3(0.00,66.7)	0.9792	0.9669
23.3± 21.9	33.3(0.00,66.7)	17.7± 22.4	0.00(0.00,66.7)	0.0192	0.0039
19.3± 32.0	0.00(0.00, 100)	14.0± 25.5	0.00(0.00, 100)	0.9791	0.9865
8.33± 14.8	0.00(0.00,33.3)	16.7± 23.9	0.00(0.00, 100)	0.0313	0.0126



	KPS= 100 (n=104)		80 ≤ KPS ≤ 90 (n=115)		0 ≤ KPS < 80 (n=13)		P-value of F-test	P-value of KW-test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	19.0± 18.6	11.1(0.00,66.7)	22.7± 20.3	22.2(0.00, 100)	49.6± 29.6	55.6(0.00, 100)	<0.0001	0.0008
Nutrition	11.5± 13.0	6.67(0.00,53.3)	12.2± 11.3	13.3(0.00,53.3)	22.6± 18.8	20.0(0.00,60.0)	0.0122	0.0472
Pain	12.4± 14.4	16.7(0.00,50.0)	14.1± 16.9	16.7(0.00, 100)	30.8± 27.9	33.3(0.00,83.3)	0.0011	0.0528
Fever	2.78± 8.15	0.00(0.00,33.3)	4.61± 10.8	0.00(0.00,50.0)	10.3± 12.8	0.00(0.00,33.3)	0.0279	0.0089
Thirsty	23.5± 27.2	33.3(0.00, 100)	23.5± 27.1	33.3(0.00, 100)	30.8± 25.3	33.3(0.00,66.7)	0.6443	0.5047
Jaundice 1 (36)	13.4± 22.1	0.00(0.00,66.7)	4.76± 14.7	0.00(0.00, 100)	17.9± 29.2	0.00(0.00,66.7)	0.0015	0.0017
Jaundice 2 (37)	18.3± 26.8	0.00(0.00, 100)	22.3± 28.1	0.00(0.00, 100)	33.3± 36.0	33.3(0.00, 100)	0.1585	0.2160
Abdominal swelling	12.4± 18.7	0.00(0.00,66.7)	17.6± 24.9	0.00(0.00, 100)	33.3± 33.3	33.3(0.00, 100)	0.0061	0.0364
Sexual interest	15.5± 26.9	0.00(0.00, 100)	16.4± 31.5	0.00(0.00, 100)	24.2± 36.8	0.00(0.00, 100)	0.6535	0.7027
Body image (35)	10.8± 22.1	0.00(0.00, 100)	12.5± 21.5	0.00(0.00, 100)	23.1± 28.5	0.00(0.00,66.7)	0.1720	0.1633

*** 1st KPS vs. 1st HCC18 old scale**

	KPS= 100 (n=104)		80 ≤ KPS ≤ 90 (n=115)		0 ≤ KPS < 80 (n=13)		P-value of F-test	P-value of KW-test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	19.0± 18.6	11.1(0.00,66.7)	22.7± 20.3	22.2(0.00, 100)	49.6± 29.6	55.6(0.00, 100)	<0.0001	0.0008
Nutrition	11.5± 13.0	6.67(0.00,53.3)	12.2± 11.3	13.3(0.00,53.3)	22.6± 18.8	20.0(0.00,60.0)	0.0122	0.0472
Pain	12.4± 14.4	16.7(0.00,50.0)	14.1± 16.9	16.7(0.00, 100)	30.8± 27.9	33.3(0.00,83.3)	0.0011	0.0528
Fever	2.78± 8.15	0.00(0.00,33.3)	4.61± 10.8	0.00(0.00,50.0)	10.3± 12.8	0.00(0.00,33.3)	0.0279	0.0089
Thirsty	23.5± 27.2	33.3(0.00, 100)	23.5± 27.1	33.3(0.00, 100)	30.8± 25.3	33.3(0.00,66.7)	0.6443	0.5047
Jaundice	15.8± 20.4	8.33(0.00,83.3)	13.5± 16.7	8.33(0.00,66.7)	25.6± 27.7	16.7(0.00,66.7)	0.0917	0.4340
Abdominal swelling	12.4± 18.7	0.00(0.00,66.7)	17.6± 24.9	0.00(0.00, 100)	33.3± 33.3	33.3(0.00, 100)	0.0061	0.0364
Sexual interest	15.5± 26.9	0.00(0.00, 100)	16.4± 31.5	0.00(0.00, 100)	24.2± 36.8	0.00(0.00, 100)	0.6535	0.7027
Body image	12.3± 15.7	0.00(0.00,66.7)	18.6± 19.2	16.7(0.00,83.3)	33.3± 28.1	33.3(0.00,83.3)	0.0002	0.0020

	cirrhosis or unknown (n=154) ??		No Cirrhosis (n=67)		P-value of F-test	P-value of KW-test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	23.8± 22.3	22.2(0.00, 100)	20.7± 19.0	11.1(0.00,77.8)	0.3248	0.4486
Nutrition	13.2± 13.6	6.67(0.00,60.0)	10.9± 10.9	6.67(0.00,40.0)	0.2233	0.3788
Pain	14.7± 16.9	16.7(0.00,83.3)	13.7± 17.9	0.00(0.00, 100)	0.6845	0.5590
Fever	4.25± 10.0	0.00(0.00,33.3)	3.98± 10.1	0.00(0.00,50.0)	0.8556	0.8805
Thirsty	23.1± 26.6	33.3(0.00, 100)	25.9± 28.3	33.3(0.00, 100)	0.4852	0.5294
Jaundice 1	11.2± 22.0	0.00(0.00, 100)	5.97± 14.1	0.00(0.00,66.7)	0.0761	0.1649
Jaundice 2	24.8± 29.5	33.3(0.00, 100)	12.4± 22.4	0.00(0.00,66.7)	0.0024	0.0016
Abdominal swelling	18.1± 23.9	0.00(0.00, 100)	11.4± 21.4	0.00(0.00, 100)	0.0514	0.0266
Sexual interest	15.5± 27.7	0.00(0.00, 100)	16.9± 32.9	0.00(0.00, 100)	0.7358	0.6834
Body image(35)	15.0± 24.8	0.00(0.00, 100)	6.47± 14.5	0.00(0.00,66.7)	0.0089	0.0139

	Bilirubin < 2 (n=140) ??		Bilirubin ≥2 (n=77)		P-value of F-test	P-value of KW-test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	19.8± 19.8	11.1(0.00, 100)	29.0± 22.8	22.2(0.00, 100)	0.0023	0.0020
Nutrition	11.5± 12.4	6.67(0.00,60.0)	14.4± 13.3	13.3(0.00,53.3)	0.1096	0.0966
Pain	13.1± 15.8	16.7(0.00,83.3)	16.9± 19.4	16.7(0.00, 100)	0.1189	0.2129
Fever	3.72± 10.0	0.00(0.00,50.0)	4.33± 9.52	0.00(0.00,33.3)	0.6626	0.3262
Thirsty	23.3± 27.4	0.00(0.00, 100)	26.0± 26.8	33.3(0.00, 100)	0.4835	0.3825
Jaundice 1	5.04± 15.0	0.00(0.00,66.7)	18.0± 25.2	0.00(0.00, 100)	<0.0001	<0.0001
Jaundice 2	19.2± 27.8	0.00(0.00, 100)	24.7± 28.3	33.3(0.00, 100)	0.1686	0.1069
Abdominal swelling	16.8± 24.9	0.00(0.00, 100)	14.7± 20.6	0.00(0.00,66.7)	0.5351	0.8093
Sexual interest	10.4± 25.1	0.00(0.00, 100)	25.3± 32.8	0.00(0.00, 100)	0.0003	<0.0001
Body image(35)	11.5± 21.9	0.00(0.00, 100)	14.3± 23.8	0.00(0.00, 100)	0.3882	0.3536

**Table 8 Responsiveness: 1st and 2nd
1st HCC18 vs. 2nd HCC18 (A: surgery, N=53)**

	1st		2nd		P-value of paired t-test	P-value of Wilcoxon- signed rank test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	15.5± 16.6	11.1(0.00,66.7)	13.0± 16.8	11.1(0.00,66.7)	0.3219	0.4006
Nutrition	10.4± 13.0	6.67(0.00,53.3)	7.80± 10.1	6.67(0.00,40.0)	0.1257	0.4544
Pain	7.86± 10.1	0.00(0.00,33.3)	13.8± 13.0	16.7(0.00,50.0)	0.0006	0.0003
Fever	2.52± 7.59	0.00(0.00,33.3)	1.26± 4.44	0.00(0.00,16.7)	0.2520	0.3984
Jaundice 1	7.55± 16.8	0.00(0.00,66.7)	5.03± 12.0	0.00(0.00,33.3)	0.2520	0.3984
Jaundice 2	13.8± 25.7	0.00(0.00, 100)	20.1± 24.8	0.00(0.00, 100)	0.1419	0.2534
Body image	5.03± 13.7	0.00(0.00,66.7)	6.29± 17.4	0.00(0.00, 100)	0.6418	1.0000
Thirsty	23.9± 29.5	0.00(0.00, 100)	19.5± 25.7	0.00(0.00, 100)	0.3671	0.1089
Abdominal swelling	6.92± 17.7	0.00(0.00, 100)	11.3± 19.5	0.00(0.00,66.7)	0.1278	0.8551
Sexual interest	16.4± 29.7	0.00(0.00, 100)	13.8± 24.8	0.00(0.00, 100)	0.4549	0.5649

1st HCC18 vs. 2nd HCC18 (B: ablation, N=47)

	1st		2nd		P-value of paired t-test	P-value of Wilcoxon-signed rank test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	24.1± 20.9	22.2(0.00, 100)	26.8± 22.5	22.2(0.00, 100)	0.4637	0.4739
Nutrition	13.2± 10.7	13.3(0.00,40.0)	17.8± 15.5	13.3(0.00,60.0)	0.0445	0.0321
Pain	14.5± 15.0	16.7(0.00,50.0)	13.8± 19.0	0.00(0.00,66.7)	0.7260	0.9365
Fever	5.35± 10.2	0.00(0.00,33.3)	8.70± 19.2	0.00(0.00,66.7)	0.3227	0.3259
Jaundice 1	13.8± 24.0	0.00(0.00, 100)	11.6± 23.5	0.00(0.00, 100)	0.5375	0.6818
Jaundice 2	25.2± 31.3	0.00(0.00, 100)	26.8± 27.8	33.3(0.00,66.7)	0.5375	0.7980
Body image	17.6± 24.1	0.00(0.00, 100)	26.1± 29.7	33.3(0.00, 100)	0.0078	0.0017
Thirsty	25.8± 29.7	33.3(0.00, 100)	18.1± 25.0	0.00(0.00, 100)	0.0075	0.0377
Abdominal swelling	18.2± 21.2	0.00(0.00,66.7)	21.0± 26.6	0.00(0.00, 100)	0.6271	0.5382
Sexual interest	15.1± 29.6	0.00(0.00, 100)	21.5± 31.9	0.00(0.00, 100)	0.1596	0.4987

1st HCC18 vs. 2nd HCC18 (C: embolisation, N=53)

	1st		2nd		P-value of paired t-test	P-value of Wilcoxon-signed rank test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	25.6± 25.7	22.2(0.00, 100)	23.8± 23.8	22.2(0.00, 100)	0.8582	0.7587
Nutrition	11.3± 12.2	6.67(0.00,53.3)	9.82± 13.5	6.67(0.00,60.0)	0.5184	0.7031
Pain	15.9± 22.1	0.00(0.00, 100)	14.3± 21.7	0.00(0.00, 100)	0.2087	0.2192
Fever	2.96± 8.81	0.00(0.00,33.3)	5.85± 12.4	0.00(0.00,50.0)	0.0769	0.0317
Jaundice 1	7.65± 18.7	0.00(0.00,66.7)	7.60± 19.9	0.00(0.00, 100)	0.6588	0.4375
Jaundice 2	19.9± 25.9	0.00(0.00,66.7)	20.5± 26.5	0.00(0.00, 100)	0.6868	0.0490 ?
Body image	13.4± 26.6	0.00(0.00, 100)	8.77± 24.0	0.00(0.00, 100)	0.1089	0.2656
Thirsty	23.1± 26.0	33.3(0.00, 100)	21.1± 23.3	33.3(0.00, 100)	0.3738	0.3746
Abdominal swelling	18.8± 28.1	0.00(0.00, 100)	14.6± 25.2	0.00(0.00, 100)	0.3888	0.7010
Sexual interest	16.1± 30.4	0.00(0.00, 100)	10.7± 23.0	0.00(0.00, 100)	0.1457	0.0375

1st HCC18 vs. 2nd HCC18 (D: systemic, N=16)

	1st		2nd		P-value of paired t-test	P-value of Wilcoxon-signed rank test
	Mean (S.D.)	Median (Min, Max)	Mean (S.D.)	Median (Min, Max)		
Fatigue	26.7± 18.9	33.3(0.00,55.6)	36.8± 28.9	33.3(0.00,88.9)	0.0754	0.0938
Nutrition	21.3± 16.0	20.0(0.00,53.3)	32.5± 27.8	30.0(0.00, 100)	0.0371	0.0645
Pain	20.8± 13.1	16.7(0.00,50.0)	25.0± 21.9	25.0(0.00,66.7)	0.2320	0.1953
Fever	9.17± 15.7	0.00(0.00,50.0)	10.4± 16.0	0.00(0.00,50.0)	0.8056	0.9063
Jaundice 1	6.67± 13.7	0.00(0.00,33.3)	12.5± 24.0	0.00(0.00,66.7)	0.1881	0.3750
Jaundice 2	20.0± 27.4	0.00(0.00, 100)	20.8± 29.5	0.00(0.00, 100)	1.0000	1.0000
Body image	8.33± 14.8	0.00(0.00,33.3)	20.8± 26.9	0.00(0.00,66.7)	0.0090	0.0313
Thirsty	21.7± 27.1	0.00(0.00,66.7)	25.0± 25.8	33.3(0.00,66.7)	0.5805	0.7813
Abdominal swelling	23.3± 21.9	33.3(0.00,66.7)	29.2± 40.1	0.00(0.00, 100)	0.5445	0.5156
Sexual interest	19.3± 32.0	0.00(0.00, 100)	27.1± 40.8	0.00(0.00, 100)	0.2064	0.3750



Table 9 - Patient debriefing

	Total (N=221)
How long did it take to complete C30 & HCC18	
less than 10 min.	148 (66.97%)
between 10 and 30 min.	68 (30.77%)
more than 30 min.	4 (1.81%)
Did any one help patient to complete	
No	124 (56.11%)
Yes	96 (43.44%)



Comments for each item

- Q42 (nourishment): confusing (3)
- Q43 to Q46: confusing (1)
 - Quickly full, low weight, less active, keep going
- Q48 (sexual life):
 - Confusing (3)
 - Difficult to answer (2)
 - Upsetting (2)
 - Irrelevant (10)



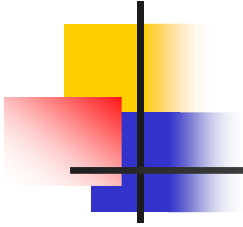
Summary

- Scale structure: Internal consistency & item convergent and discriminant validity
 - Keep: fatigue, nutrition, pain
 - Change (split): body image, jaundice*
- Test-retest: high to moderate (except abd swelling)
- Correlation with C30: low to moderate (a sign as good supplementary tool)
- Clinical validity
 - Sensitivity: as hypothesized in many scales (esp. KPS)
 - Responsiveness: fair, different in groups
- Debriefing: high acceptability, comments as expected



Further things to do before submitting

- QA / QC, final check
- Final decision about the scale structure
 - Psychometric properties vs. clinical validity
 - Jaundice: together or separate?
- Positive or negative scoring
 - Symptoms: high means poor QOL
 - Body image, sexual life?



- Thank you for attention
- Happy Moon Festival