

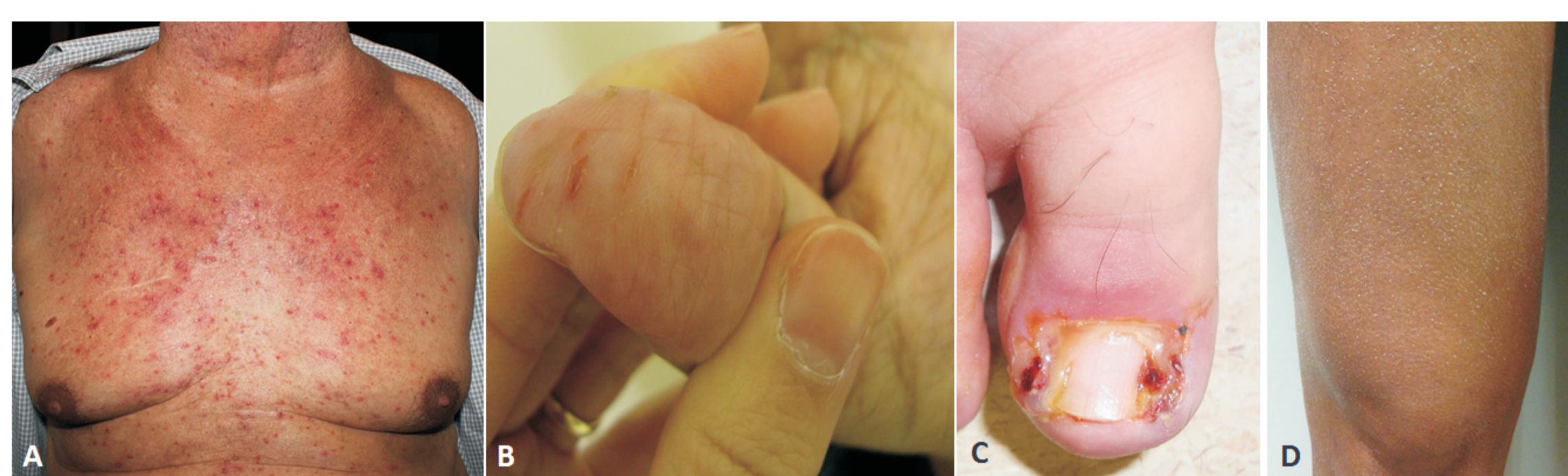
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INTRODUCTION

Therapy with epidermal growth factor receptor inhibitors (EGFRI) has increased the survival of cancer patients with less severe systemic side effects compared to conventional chemotherapy. Despite of that, skin reactions are frequent, and often associated with impairments in physical, emotional and social well-being, affecting patients' quality of life (QoL).

CUTANEOUS SIDE EFFECTS OF EGFR1

The most common cutaneous adverse events of EGFRI are papulopustular rash (fig. 1a), fissures (fig. 1b), paronychia and pyogenic granuloma (fig. 1c), trichomegaly and hypertrichosis, and xerosis (fig. 1d).



AIMS

The main objective of this study is the translation, cross-cultural adaptation and validation of the Functional Assessment of Cancer Therapy - Epidermal Growth Factor Receptor Inhibitor 18 (FACT-EGFRI-18) for its use in Brazil.

METHODS

Translation and cross-cultural adaptation of FACT-EGFRI-18 to Portuguese were carried out. The first stage consisted on the translation of FACT-EGFRI-18 from English to Portuguese, and was carried out in five steps. The first Portuguese version was submitted to the pilot test. In the second stage, the validation of the definitive version in Portuguese and the clinical and sociodemographic evaluation on the patients were performed. Dermatology Life Quality Index (DLQI) was used to evaluate the construct validity of FACT-EGFRI-18. We included 40 patients with colorectal cancer or non-small cell lung cancer treated with EGFRI. Ten patients responded to the pre-test of the Portuguese version. The remaining 30 patients participated in the validation phase of the questionnaire.

RESULTS

After the translation process, the pre-test showed that all patients understood the content of the questionnaire, and the final version in Portuguese (FVP) of FACT-EGFRI-18 was elaborated (fig. 2). The translated questionnaire showed strong internal consistency (Cronbach coefficient = 0.89). A strong correlation (Pearson's correlation = 0.66) between the FVP of FACT-EGFRI-18 and the DLQI was observed. The item means, and the domain and total scores of FACT-EGFRI-18 are shown in table 1. The socio-demographic data of the 30 patients who participated in the validation stage are shown in table 2.

Table 1. Item means and the domain and total scores of FACT-EGFRI-18.

Domains	Score	
	Item mean	Item SD
Physical		
ST4	1.47 (1.14)	
ST5	1.70 (1.24)	
ST6	1.77 (1.00)	
ST7	0.61 (1.03)	
ST9	0.90 (1.40)	
ST16	0.77 (1.10)	
ST15	1.23 (1.48)	
Physical total	1.22 (0.85)	23.9 (4.48)
Social / emotional		
ST22	0.48 (0.79)	
ST24	0.43 (0.82)	
ST37	0.30 (0.79)	
ST26	0.60 (1.10)	
B5	0.90 (1.40)	
ST11	0.33 (0.84)	
Social / emotional total	0.51 (0.76)	20.93 (4.56)
Functional		
ST32	0.30 (0.70)	
ST17	0.53 (0.90)	
ST34	0.40 (0.72)	
ST38	0.43 (0.86)	
ST29	0.57 (1.04)	
Functional total	0.45 (0.56)	17.77 (2.80)
TOTAL	0.77 (0.63)	58.23 (11.29)

Item mean (standard deviation) and scores are presented in mean (standard deviation). Domain scores are calculated as the sum of all corresponding items, taking into account that at least 50% of the items need to be answered for a reliable calculation. The total score is calculated by subtracting the domain scores from 72 (the maximum possible total score) and correct for the number of answered items. Therefore, a low QoL is reflected by a high domain score and a low total score.

Fig. 2. The final version in Portuguese.

Functional Assessment of Cancer Therapy-EGFRI 18					
Abaixo encontrará uma lista de afirmações que outras pessoas com a sua doença disseram ser importantes. Faça um círculo ou marque um número por linha para indicar a sua resposta no que se refere aos últimos 7 dias					
	Nem um pouco	Um pouco	Mais ou menos	Muito	Multissimo
ST4	A minha pele ou couro cabeludo está irritado.....0.....	1	2	3	4
ST5	A minha pele ou couro cabeludo está seco ou com descamação.....0.....	1	2	3	4
ST6	Sinto comichão/coceira na minha pele ou couro cabeludo.....0.....	1	2	3	4
ST7	A minha pele sangra com facilidade.....0.....	1	2	3	4
ST9	Sinto-me incomodado/a com a mudança da sensibilidade da minha pele ao sol.....0.....	1	2	3	4
ST12	O estado da minha pele interfere na minha capacidade de dormir.....0.....	1	2	3	4
ST12	O estado da minha pele influencia o meu humor.....0.....	1	2	3	4
ST17	O estado da minha pele interfere na minha vida social.....0.....	1	2	3	4
ST24	Sinto-me envergonhado/a pelo estado da minha pele.....0.....	1	2	3	4
ST26	Evito sair em público por causa da aparência da minha pele.....0.....	1	2	3	4
ST26	Sinto-me pouco atraente por causa da aparência da minha pele.....0.....	1	2	3	4
ST34	As mudanças do estado da minha pele dificultam o meu dia-a-dia.....0.....	1	2	3	4
ST38	Os efeitos do tratamento na minha pele interferem nas tarefas domésticas.....0.....	1	2	3	4
ST36	Os meus olhos estão secos.....0.....	1	2	3	4
ST15	Sinto-me incomodado/a com a sensibilidade ao redor das unhas das mãos e dos pés.....0.....	1	2	3	4
ST29	A sensibilidade ao redor das unhas das mãos dificulta as tarefas domésticas.....0.....	1	2	3	4
B5	Sinto-me incomodado/a com a queda do cabelo.....0.....	1	2	3	4
ST11	Sinto-me incomodado/a com o aumento de pelos no meu rosto.....0.....	1	2	3	4

Table 2. Background information of the patients (n=30).

	n (%)
Age (years)	
34-57	8 (26.7)
58-65	12 (40.0)
66-81	10 (33.3)
Sex	
Male	17 (56.7)
Female	13 (43.3)
Phenotype	
2	3 (10.0)
3	7 (23.3)
4	6 (20.0)
5	7 (23.3)
6	6 (16.7)
Missing data	2 (6.7)
Primary site	
Colorectal	20 (66.7)
Lung	10 (33.3)
Cancer staging	
2	1 (3.3)
3	7 (23.3)
4	22 (73.3)
Target therapy	
Cetuximab	20 (66.7)
Erlotinib	2 (6.7)
Gefitinib	8 (26.7)

CONCLUSION

FVP of FACT-EGFRI-18 has been shown to be easily understood by patients, and the findings support its reliability and validity.