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Longitudinal validation of the PROFFIT questionnaire to assess financial toxicity in cancer patients

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A B S T R A C T

Background: Financial toxicity (FT) is a growing issue for cancer patients worldwide. The PROFFIT questionnaire was developed in Italy to measure FT and identify its determinants in cancer patients within a public health system.

Methods: A prospective study was conducted with 221 cancer patients from 10 Italian centres between March 2021 and July 2022 to validate the PROFFIT questionnaire in patients undergoing active treatment. The PROFFIT and EORTC-QLQ-C30 questionnaires were administered. Statistical analyses were performed on the PROFFIT-score (items 1–7), the financial difficulties item (Q28), and the global health status/quality of life (HR-QOL) scale from the EORTC-QLQ-C30. Geographic disparities were also analysed.

Results: A total of 1149 questionnaires were completed (83 % paper-based, 17 % electronically). The median observation period was 5 months (IQR 4.5–5.8). Missing phenomenon increased over time but was not affected by the baseline PROFFIT-score. PROFFIT-score remained stable throughout treatment, with patients in

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Southern Italy reporting higher (worse) values. Significant associations ($p < 0.0001$) were found between PROFFIT-score and Q28 at all time-points. Moderate inverse correlations were observed between PROFFIT-score and HR-QOL.

Conclusions: PROFFIT shows strong longitudinal validity for assessing FT in cancer patients. PROFFIT-score does not significantly change during treatment, but regional disparities highlight the need for targeted interventions, particularly in underserved areas. Further research will define cut-off values and explore FT dynamics across different patient populations.

Policy Summary: PROFFIT validation analyses make the instrument suitable to measure FT in cancer patients within public health systems. In addition, it may represent a valuable tool to plan specific local health policies being sensible to macro-regional variability. Finally, on the long run, it might be useful to test the impact of policies implemented against FT.

1. Introduction

In recent years, financial toxicity has become a significant issue in oncology, particularly in private or partially privatized healthcare systems [1]. Literature shows that economic difficulties faced by cancer patients and their families are linked to both direct medical costs and indirect expenses and can negatively impact their quality of life, treatment adherence and survival [2–7].

Evidence suggesting that financial difficulties affect cancer patients' outcomes was also found in Italy, where a public healthcare system exists based on universal coverage and ensuring free access to cancer treatments [5]. Therefore, we developed the PROFFIT (Patient--Reported-Outcome for Fighting FInancial Toxicity) questionnaire to measure financial toxicity (FT) of cancer and identify its determinants in Italy [8–10]. The external validation of the questionnaire was done in 2024 in a cohort of patients receiving anticancer treatment, using the EORTC-QLQ-C30 financial difficulties item and the global health status/quality of life scale as anchors [11]. We herein report the additional external validation using the longitudinal data collected in the same cross-sectional study.

2. Patients and methods

The study was performed according to International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines [12].

The enrolled patients were over 18 years old, with a diagnosis of solid cancer or haematological malignancy, and were scheduled to begin medical treatment.

The study protocol was registered at clinicaltrials.gov (NCT03473379) and was approved by independent ethical review boards at enrolling centres. Written informed consent was required.

2.1. Instruments for collection of Patient-reported outcomes (PROs)

Two instruments were used for collection of PROs.

PROFFIT questionnaire contains 16 items. Seven items (number 1–7) are combined to generate the PROFFIT-score estimating the amount of the financial toxicity. The remaining 9 items are managed as single items, indicating possible determinants of the financial toxicity, roughly pertaining to three major areas, medical expenses (items 8–11), transportation (items 12 and 13) and support from the health staff (item 14–16). Questionnaire is reported in Appendix Fig. 1.

Responses to PROFFIT items are coded in four categories of agreement with the statement of each item, scoring from 1 to 4 (1 = I do not agree at all, 2 = I agree partially, 3 = I agree substantially, 4 = I very much agree). All the scores are normalised to 0–100 %, where 100 indicates the highest toxicity [8].

Selected items of the EORTC QLQ-C30 questionnaire were used to test the external validity of PROFFIT [13]. In particular, question 28 (Q28), which assesses financial difficulties, was used as primary anchor; Q28 has responses ranked on a scale from 1 to 4 (1 = not at all, 2 = a little, 3 = quite a bit, 4 = very much). Questions 29 and 30 assesses the global health status/quality of life within a scale of response options ranging from 1 ('very poor') to 7 ('excellent') and were used as secondary anchor with descriptive aims. The two responses are combined and transformed into a score (HR-QOL) ranging from 0 to 100, according to the EORTC QLQ-C30 Scoring Manual.

A threshold for defining a clinically significant change in Q28 and HR-QOL scales has been previously proposed by Osoba et al [14]. Namely, a 10-point change in the score is considered as a conservative threshold while a 5-point change is considered as a less conservative one. In the present analysis, we considered a 10-point decrease to define a worsening; on a single patient basis.

Both PROFFIT and EORTC QLQ-C30 questionnaires were administered at baseline, soon after registration in the study, and at intervals consistent with the planned schedule of treatment, namely every 2 or 3 or 4 weeks, always before the initiation of the following cycle. The two questionnaires were collected either as a paper hardcopy (consecutive pages within one document) or as consecutive pages within the electronic CRF on tablet, with patients having the option to request a paper version if preferred. All data were collected using a dedicated electronic case report form within the web-based platform for management of clinical trials hosted at the coordinating centre at the National Cancer Institute of Naples, Italy.

2.2. Statistical analysis

Missing data may significantly affect longitudinal analyses of PROs because of the typical phenomenon of attrition, with the number of completed questionnaires decreasing over time. The increase in missing questionnaires over time, indeed, could bias the estimation of the trajectory of scores, due to the progressive loss of patients with a worse prognosis, who may be at higher risk of worsening their outcomes. For this reason, a cumulative description of administered and missing questionnaires (for known clinical conditions or unknown reasons), and of available PROFFIT-score, Q28-score and HR-QOL-score at each subsequent evaluation point was the first step of data analysis, graphically described with histograms. The distribution of the time from enrolment at each subsequent evaluation point was checked and described by using box plots. To verify whether a selection bias might affect reliability of the present analysis and to describe its magnitude, we also plotted the distribution of baseline PROFFIT-score, Q28-score and HR-QOL-score among subgroups of patients for whom the scores were available at subsequent evaluation points.

Description of the dynamic over the time of PROFFIT-score and Q28-score and HR-QOL-score was performed in the overall series and scattered by macro-region of patients' residency that was the only covariate significantly correlated with PROFFIT-score at baseline [11].

The longitudinal validation of the PROFFIT-score was performed using Q28 as primary anchor. The convergent analysis over time between the PROFFIT-score and Q28 was graphically displayed with box plots, and the association was evaluated with the Jonckheere-Terpstra test to account for the ordinal nature of the variables.

The correlations between PROFFIT-scores and HR-QOL-scores, considered as a secondary anchor, were also described and Spearman's correlation coefficients (r) were calculated and reported at different time points.

An exploratory, hypothesis-generating analysis was also conducted to identify a potential threshold value for PROFFIT-change using Q28 change as an anchor for which a widely accepted threshold to define

clinically significant deterioration exists.14 Three empiric cut-offs of maximum change in the PROFFIT-score (increase of 5, 10, and 20 points) were tested to assess their association with a clinically significant deterioration of Q28-score (defined as a ≥10 % increase).

All analyses were considered significant with an alpha level of 0.05. Statistical analyses were performed with Stata 18 (Stata, College Station, TX, USA).

3. Results

From March 3rd, 2021 to July 4th, 2022, 221 patients were enrolled at 10 Italian centres. Median age was 65 years, 116 (52.5 %) were females, 96 (43.4 %) had low education level (Table 1).

Crude numbers of available ad missing PROFFIT-score and Q28-score and HR-QOL-score are graphically described in Fig. 1. Overall, 1149 questionnaires, each including 16 items of PROFFIT and 30 items of EORTC C30 questionnaires, were administered. Namely, 17 % of the questionnaires were filled using tablet while 83 % using paper.

All enrolled patients completed the PROFFIT questionnaire, and there were no missing responses among the items required for PROFFIT-score calculation. Baseline Q28-score was missing for 4 patients and 3 for HR-QOL-score. As expected, the cumulative rate of questionnaires decreased over time; most of them were not administered for unknown reasons rather than for explicit clinical worsening.

Variability of timing of assessment of both scores combined at each subsequent evaluation point increased over time, as graphically displayed in Fig. 2 Appendix. Among patients who filled all the planned questionnaires, median time of observation was 5 months (IQR 4,5–5,8).

There was no evidence of change in the distribution of baseline values for both scores among subgroups of patients for whom the scores were available at subsequent evaluation points (Fig. 3 Appendix).

The convergent analysis across the time between PROFFIT-score and Q28 is reported in Fig. 2. The relationships between them were highly statistically significant at all the time points planned for questionnaire administration. Additionally, the correlation between PROFFIT-scores and HR-QOL scores across different time points was described, revealing a moderate inverse correlation (r coefficients ranging from −0.18 to −0.38) consistent across the time points (Figure 4 Appendix).

Distribution of PROFFIT-score and Q28-score and HR-QOL-score over the time for the overall population and scattered by geographic region is reported in Fig. 3. There was no trend over time for either scores, as both remained stable. However, patients living in southern Italy consistently had higher mean scores for both measures compared to those in the North.

The exploratory hypothesis-generating analysis conducted to identify a potential cut-off for changes in the PROFFIT-score to detect significant financial toxicity worsening, as indicated by Q28 change, was conducted with empirical thresholds of 5, 10, and 20 points increase. Data shown in the Appendix Table 1 reveal that sensitivity in capturing Q28 deterioration decreased only slightly with increasing PROFFIT change cutoff, giving a value of 64 % with a change of the PROFFIT-score ≥ 5.

Table 1
Characteristics of patients.

	N = 221	
Sex at birth, n(%)		
Female	116	(52.5)
Male	105	(47.5)
Age, n(%)		
<65	106	(48.0)
> =65	115	(52.0)
Macro-region where the patient lives, n(%)		
North	92	(41.6)
South	129	(58.4)
Education level, n(%)		
None/primary	32	(14.5)
Middle school	64	(29.0)
Upper secondary/tertiary	125	(56.6)
Working status at diagnosis, n(%)		
Permanent/temporary/flexible	62	(28.1)
Freelancer/craftsman/trader	21	(9.5)
Housewife/unemployed	36	(16.3)
Retired	102	(46.2)
Performance status at baseline, n(%)		
0	146	(66.1)
≥ 1	75	(33.9)
Primary tumour site, n(%)		
Breast	50	(22.6)
Lower gastrointestinal tract	44	(19.9)
Genito-urinary	40	(18.1)
Upper gastrointestinal tract	37	(16.7)
Other	30	(13.6)
Thoracic	20	(9.0)

4. Discussion

Financial toxicity, linked to the heavy economic burden caused by cancer treatment, has become an increasingly relevant issue in various demographic and healthcare contexts. This problem affects cancer patients not only in low- and middle-income countries [15] but also in high-income ones, regardless of the type of healthcare system, public or private. At variable degrees, patients face severe economic difficulties due to either the high costs of cancer treatments or to indirect costs deriving, in any case, from cancer diagnosis and treatment [16].

The financial burden caused by cancer treatments deeply impacts the patients' quality of life, leading to emotional, psychological, and social challenges. Cancer patients experiencing high levels of financial toxicity are more likely to suffer from mental health issues, such as depression and anxiety. Furthermore, cancer survivors with financial difficulties are more prone to health problems, difficulties in social interactions, and psychological disorders, particularly among young adults [17]. These patients, in the United States, are often forced to make difficult choices, such as foregoing treatments or medications to avoid accumulating further debt.

In addition to the psychological impacts, financial toxicity also compromises the physical well-being of patients. Some delay or avoid essential treatments due to their inability to afford them, which can lead to worse health outcomes and lower survival rates. Therefore, addressing financial toxicity is crucial not only for alleviating psychological stress but also for ensuring better treatment adherence and improving the chances of recovery.

Increasing transparency and access to financial assistance is a key component in reducing the financial burden. Moreover, improving communication between doctors and patients regarding treatment costs is another essential strategy. More frequent and open discussions about costs between doctors and patients could help alleviate the financial burden [18]. Although most patients desire to discuss costs with their doctors, only a small percentage report having actually had these conversations. Closing this gap could improve patient outcomes by making them feel more empowered to make informed decisions about their care.

The generation and validation of the PROFFIT (Patient-Reported Outcome for Fighting Financial Toxicity) questionnaire represents an important step in recognizing and measuring financial toxicity of cancer patients in the context of public or prevalently public health systems [8, 11].

The aim of the present study was to further validate the instrument using longitudinal data and describe their relationship with quality of life, and some considerations are worthy to be done.

First, when facing longitudinal data, the attrition bias may cause non-random missing data that were, in fact, observed in the present study and increased over time. However, the baseline values among cohorts of patients fulfilling subsequent questionnaires did not vary, suggesting that the selection bias might be low, if any. Lack of a clear time trend of the PROFFIT-score values does suggest that FT does not

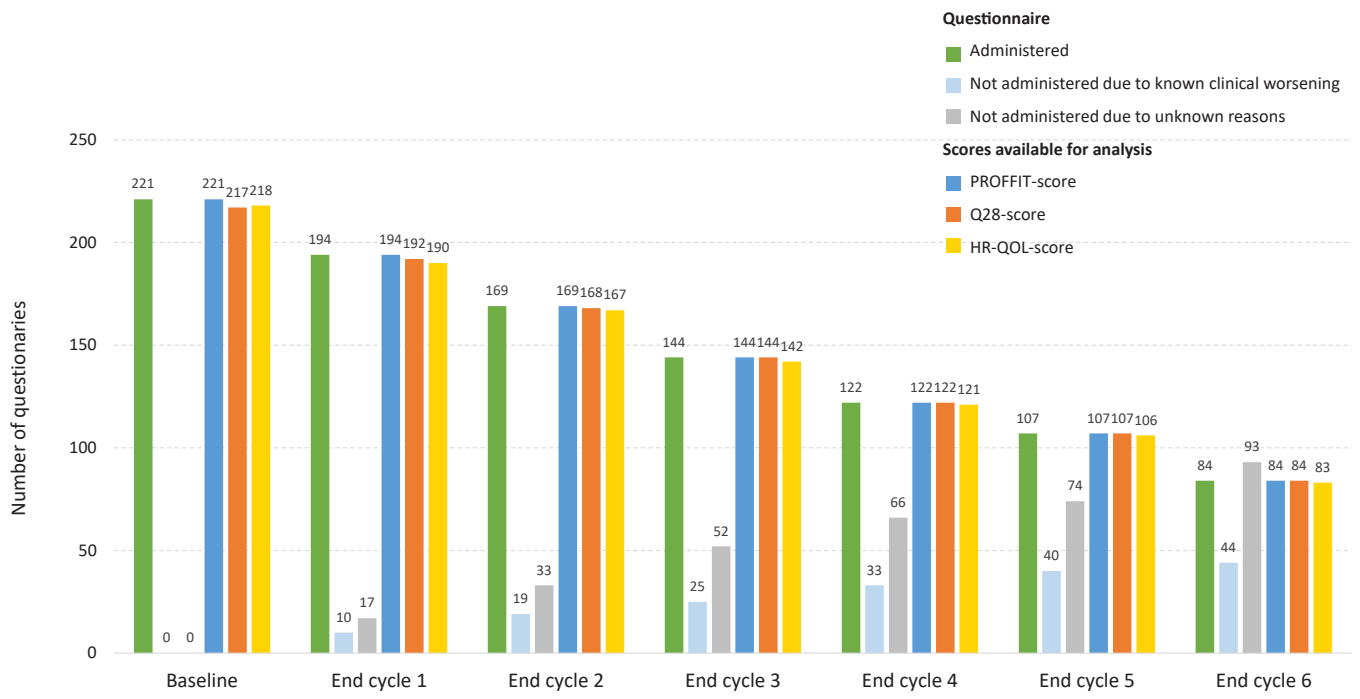

Fig. 1. Numbers of available and missing PROFFIT-score, Q28-score and HR-QOL-score data

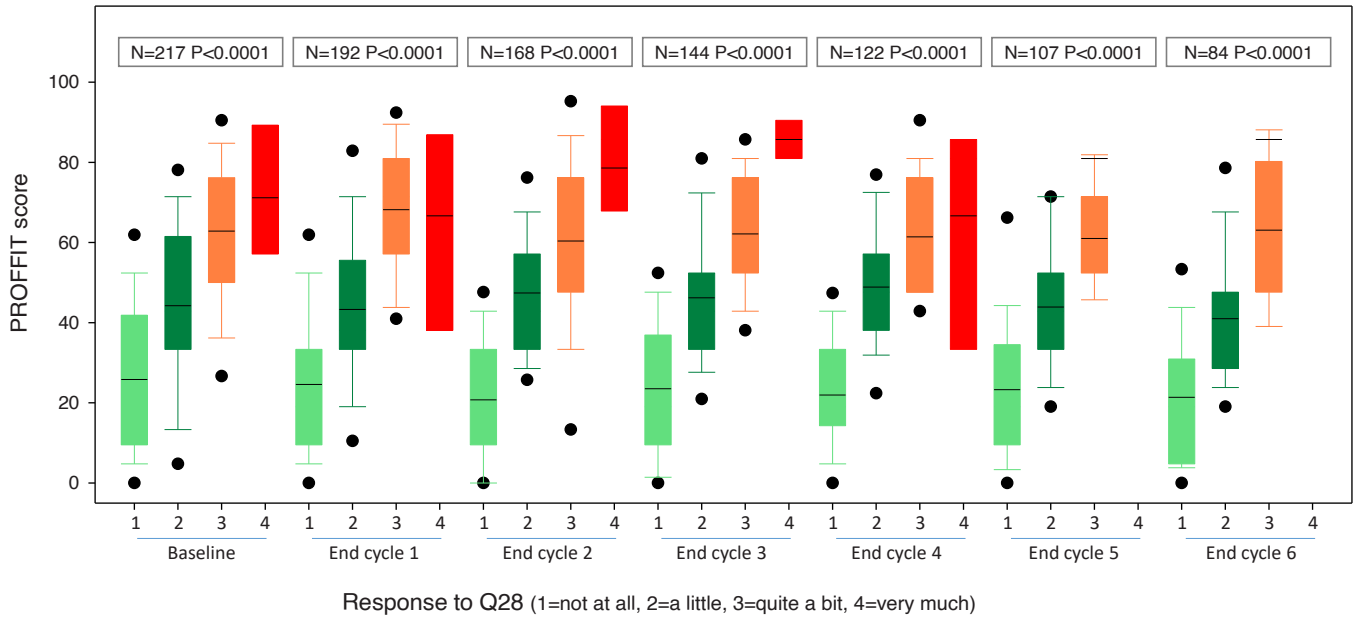

Fig. 2. Associations across the time between PROFFIT-score and response to Q28

rapidly change, at least within a quite short window of around 5 months.

Second, the analysis of the association between PROFFIT-score and responses to Q28 over time showed good performance in capturing the levels of toxicity detected by Q28. In addition, the moderate inverse correlation found between PROFFIT-score and HR-QOL over time is consistent with the values expected in the study protocol and may be explained considering FT as a piece, possibly indirect, of the wider domain of HR-QOL [9,11]. Therefore, the present longitudinal validation of the questionnaire reinforces that PROFFIT is a valuable tool for understanding the burden of financial difficulties within a public healthcare system. Moreover, PROFFIT is gaining recognition at a European level, with validation already completed in the UK [19] and ongoing validation processes in Turkey.

Third, the data reveal a significant regional disparity, with patients living in the South of Italy facing greater disadvantages compared to those in the North, consistently with previous similar findings [4,5]. Many reasons may historically justify this expected finding, both on a socio-economic and cultural basis. For the future, a wider use of PROFFIT might be useful to suggest differential policy approaches to be implemented at a macro-regional scale to contrast financial toxicity.

Among limitations of the PROFFIT instrument, we acknowledge that data available until now (either cross-sectional or longitudinal) are restricted to patients undergoing active anticancer medical treatment. Therefore, we have not enough knowledge on the performance of the

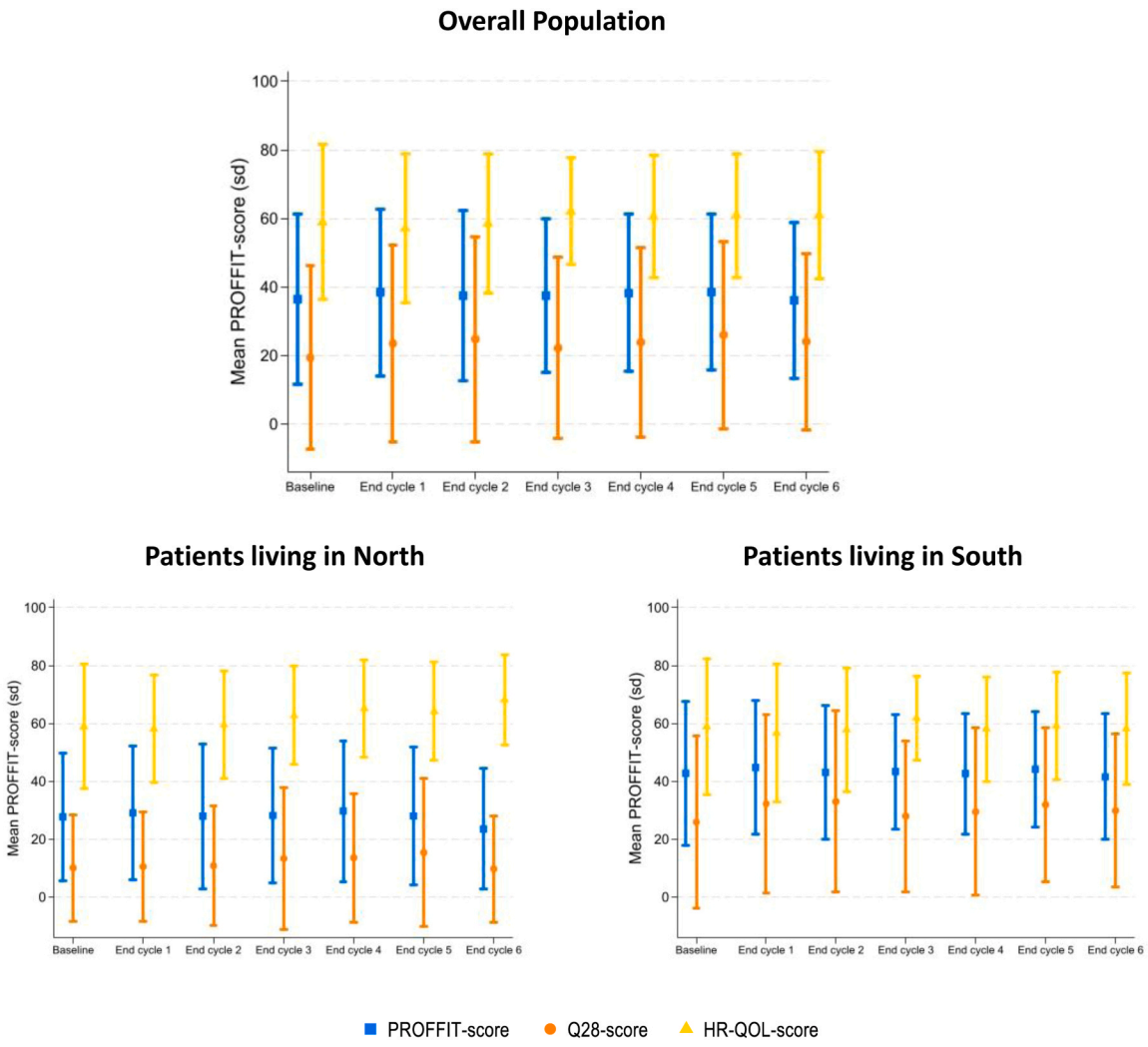

Fig. 3. Distribution of PROFFIT-score, Q28-score and HR-QOL-score over the time for the overall population and scattered by geographic region

instrument as a tool in the settings of other types of treatment, diagnostic, surveillance, survivorship and supportive care alone. Ongoing or close-to-start studies are dealing with longer time-windows across subsequent treatment lines in ovarian cancer (NCT06032975) and other settings like surgical treatment of urological malignancies (NCT06955910), treatment of solid tumors with adrotherapy (NCT05947149), and colonoscopy (NCT06887244).

Another limitation of this study is that the available data were not sufficient to define a threshold value with clear clinical value. Since the sample size was originally designed for a different purpose, we included patients with various tumor types to ensure robust validation; however, this approach limited us to empirically exploring different thresholds rather than determining an optimal one. Further studies are ongoing to address this issue more comprehensively.

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Declaration of Competing Interest

Massimo Di Maio

- Honoraria for consulting or advisory role: Pfizer, Takeda, AstraZeneca, Janssen, Eisai, Novartis, Roche, Astellas Pharma, MSD Oncology, Boehringer Ingelheim, Viatris, Ipsen

Fabio Efficace

- Honoraria for consulting or advisory role: ovartis, AbbVie, Incyte

Carmine Pinto

- Honoraria for consulting or advisory role: Daiichi Sankyo, Astra Zeneca, Ipsen, Astellas, BMS, AMGEN
- Research Funding: Astra Zeneca, BMS, GSK
- Travel, Accommodations, Expenses: Merck, Servier, Roche

Francesco Perrone

- Honoraria for consulting or advisory role: Viatris

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- Honoraria for consulting or advisory role: Abbvie, Amgen, Astellas, AstraZeneca, Bayer, BMS, Boehringer Ingelheim, Gilead, GSK, Roche
- Research Funding: Ichi Sankyo, Egualia, Gilead, Incyte, Janssen Cilag, Lundbeck, MSD, Novartis, Roche, Pfizer, Sandoz, Sanofi, Takeda, Teva
- Speakers' bureau: Bayer, Gilead

Concetta Maria Vaccaro

- Honoraria for consulting or advisory role: Astra Zeneca
- Research Funding: MSD, Roche, Pfizer, Lundbeck

The other authors have no conflicts of interest to declare

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Appendix

Item type and n°	Italian version	English version (for comprehension only)
Outcome items (FT-score)		
1.	Sono in grado di sostenere le mie spese mensili senza difficoltà (ad esempio per affitto, elettricità, telefono…)	I can afford my monthly expenses without difficulty (for example rent, electricity, phone…)
2.	La mia malattia ha ridotto le mie disponibilità economiche	My illness has reduced my financial resources
3.	Sono preoccupata/o dei problemi economici che potrei avere in futuro a causa della mia malattia	I am concerned by the economic problems I may have in the future due to my illness
4.	La mia condizione economica incide sulle mie possibilità di curarmi	My economic situation affects the possibility of receiving medical care
5.	Ho ridotto le spese per attività ricreative come vacanze, ristoranti o spettacoli per affrontare le spese della mia malattia	I have reduced my spending on leisure activities such as holidays, restaurants or entertainment in order to cope with expenses related to my illness
6.	Ho ridotto le spese per acquisti essenziali (ad esempio il cibo) per affrontare le spese per la mia malattia	I have reduced spending on essential goods (for example food) in order to cope with expenses related to my illness
7.	Sono preoccupata/o di non riuscire a lavorare a causa della mia malattia	I am worried that I will not be able to work due to my illness
Determinant items (single items)		
8.	Il Servizio Sanitario Nazionale copre tutti i costi sanitari associati alla mia malattia	The National Health Service covers all health costs related to my illness
9.	Ho sostenuto spese per una o più visite private per la mia malattia	I have paid for one or more private medical examinations for my illness
10.	Ho sostenuto spese per farmaci supplementari o integratori per la mia malattia	I have paid for additional medicines or supplements related to my illness
11.	Devo sostenere spese per cure integrative a mio carico (es. fisioterapia, psicoterapia, cure odontoiatriche)	I have to pay for additional treatment myself (for example physiotherapy, psychotherapy, dental care)
12.	Il centro di cura è lontano dalla mia abitazione	The treatment centre is a long way from where I live
13.	Ho dovuto sostenere rilevanti costi di trasporto per curarmi	I have spent a considerable amount of money on travel for treatment
14.	Il personale sanitario (cioè medici, infermieri, etc.) ha agevolato il percorso di cura	Medical staff (that is doctors, nurses etc.) have been helpful throughout my medical care
15.	Il personale ospedaliero amministrativo (cioè centro di prenotazione, segreterie, etc.) ha agevolato il percorso di cura	Staff in hospital administration (that is for booking appointments, secretaries, etc.) have been helpful throughout my medical care
16.	C'è stata comunicazione tra i medici e le strutture sanitarie che mi seguono	Medical staff and medical facilities I attended communicated with each other

Figure taken from Riva et al., (2022) BMJ Open

Fig. 1. PROFFIT instrument. Figure taken from Riva et al., (2022) BMJ Open

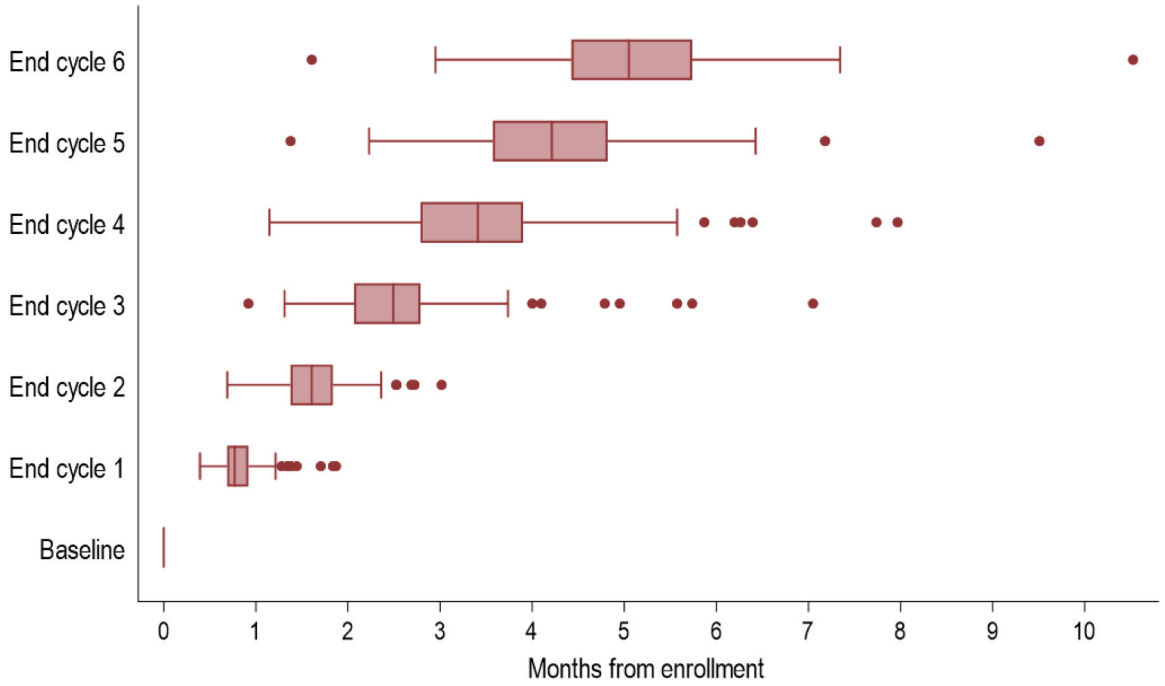

Fig. 2. Box-plot of timing of the fullfilled questionnaires among cycles of treatment

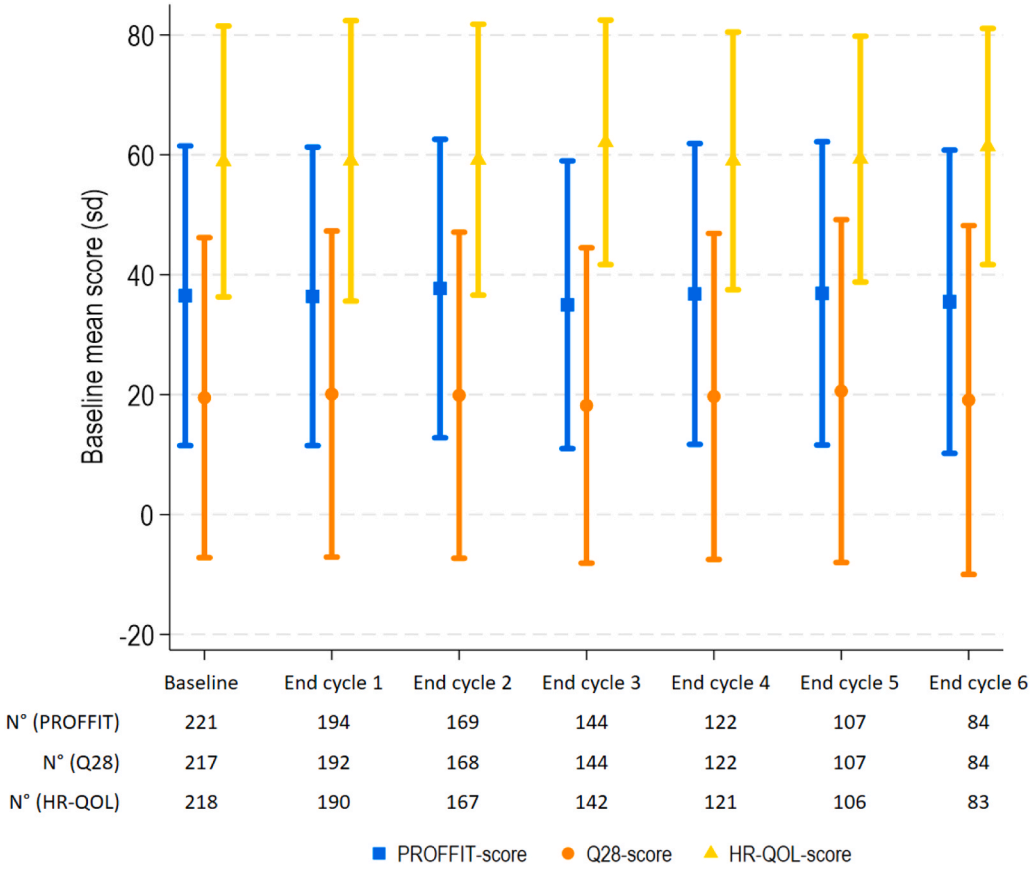

Fig. 3. Distribution of mean values of baseline PROFFIT-score Q28-score and HR-QOL-score among subgroups of patients available at subsequent time points

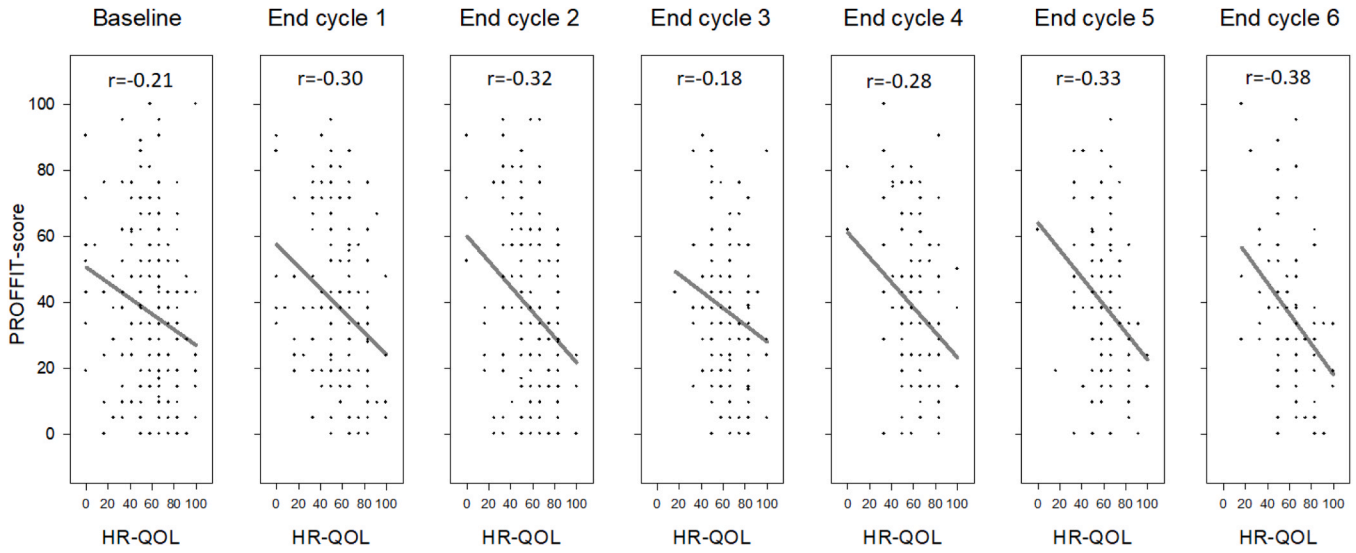

Fig. 4. Correlation between PROFFIT-score and HR-QOL-score at subsequent time points

Table 1
Exploratory analysis of empiric thresholds for maximum PROFFIT-score and its association with Q28 worsening

Maximum size of PROFFIT-score worsening	Worsening of Q28 from baseline		
	No	Yes	
≤ 5	78 (64,5 %)	27 (36 %)	105
> 5	43 (35,4 %)	48 (64 %)	91
≤ 10	92 (76 %)	32 (42,7 %)	124
> 10	29 (24 %)	43 (57,3 %)	72
≤ 20	106 (87,6 %)	43 (57,3 %)	149
> 20	15 (12,4 %)	32 (42,7 %)	47
Total	121	75	

Data availability

Data are available at DOI 10.5281/zenodo.14870284.

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