Assessing Quality of Life of Patients and their Caregivers on Phase I Clinical Trials

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Background

- Patients enrolled in Phase I oncological clinical trials represent a group that are often resilient despite being symptomatic from advanced disease burden and are willing to take chances on treatment.
- Healthcare providers largely focus on objective outcomes such as response and survival, and there is a paucity of data regarding quality of life (QoL) of patients and their caregivers.
- As these patients volunteer to help us in advancing cancer care through their participation, understanding their QoL and financial concerns can help in more effectively targeting their care.

Method

- Patients and their caregivers seen at the Phase I clinic were invited to participate.
- The table below summarises the instruments administered by a trained personnel at time of initiation of Phase I clinical trial and at 3 time intervals (1 month, 3 months and 6 months)
- Paired-sample t-tests were used to test for QoL differences at different time intervals.

Instrument	Description
EORTC-core (QLQ-C30)	30 item questionnaire: <ul style="list-style-type: none">5 functional domains: physical, role, cognitive, emotional and social3 symptoms scales: fatigue, pain and nausea/vomitingSingle items for symptoms: shortness of breath, loss of appetite, sleep, constipation, diarrhea and financial impact of disease2 global items: health and overall QoL
COMprehensive Score for financial Toxicity (COST)	11-item patient-reported outcome measure, provides a financial toxicity score ranging from 0 to 44, lower values indicating greater toxicity.
Zarit-Burden Interview (ZBI)	22-item questionnaire measuring caregiver's perceived burden of providing family care <ul style="list-style-type: none">Includes caregiver's health, psychological well-being, finances, social life, relationship between caregiver and patient.

Results

- So far, 35 patients have been recruited and 22 of them have completed at least one interval interview at one month.
- Table 1 summarises the patients' demographics

Patients' characteristics		N = 35 (%)
Age (median, range)		57 (42-83)
Gender	Female	21 (60)
	Male	14 (40)
Race	Chinese	26 (74.3)
Primary cancer	Gastrointestinal	18 (51.4)
	Gynecological	9 (25.7)
	Breast	3 (8.6)
	Lung	3 (8.6)
	Others	2 (5.7)
No. of lines of previous treatment (median, range)		3 (0-9)

Table 1: Patients' characteristics

QLQ-C30 Outcomes

- Higher scores for functioning/QoL represent higher levels of functioning or QoL, higher scores for symptoms represents higher level of symptom burden.
- Figure 1 illustrates the QLQ-C30 scores (ranging from 0-100) at baseline and at 1-month interval – higher scores represent higher level of functioning and QoL.

Figure 1: QLQ-C30 scores at baseline and at 1 month interval

- Overall, the mean QoL and functioning levels worsened at the 1 month interval, significantly so for physical, cognitive and emotional functioning scores ($p < .05$).
- Amongst the symptoms scored, patients were most bothered by fatigue (35.3) and pain (34.1); range 0-100.
- Patients reported significantly more fatigue, nausea, loss of appetite, constipation at the 1 month interval ($p < .05$).
- Table 2 summarises the involvement of palliative care for this group of patients symptomatic from their advanced cancer.

Referral to Palliative Care Services	No. of Patients (%)
Prior to study enrolment	2 (5.7)
During study	8 (22.9)
Never referred	25 (71.4)

Table 2: Palliative care involvement

Financial Toxicities (COST)

- Financial toxicities graded according to COST scores - Grade 0: 0 to ≤ 21 ; Grade 1: 22 to ≤ 40 ; Grade 3: ≥ 41
- Two-thirds of patients on Phase I clinical trials experienced significant level of financial distress (Figure 2).

Figure 2: Incidence and Grade of Financial Toxicity

Caregiver Burden (ZBI)

- 19 primary caregivers of these patients were interviewed (figure 3).

Figure 3: Incidence and Severity of Caregiver burden

Conclusions

This is the first Asian study reporting QoL of cancer patients and their caregivers in Phase I clinical trials. In this group of heavily pre-treated patients, QoL can significantly worsen. Almost half of caregivers experienced at least moderate levels of caregiver burden. Identifying QoL issues of patients and their caregivers will allow healthcare providers to improve care provided to them.

References

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