Pain and Quality of Life of Cancer Patients: A Multi-Center Study in Thailand

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Objective: *To identify the association between Quality Of Life (QOL) and pain intensity, and the magnitude of change of pain scores that have a clinically significant impact on patients' QOL.*
Designs: *Multi-center, prospective cohort study.*
Material and Method: *Patients suffering from cancer pain were recruited from seven university hospitals and three tertiary care centers in Thailand. The FACT-G and the Brief Pain Inventory were used to assess QOL and cancer pain severity, respectively, at study entry and at two-week follow-up.*
Results: *Five-hundred-and-twenty patients were recruited with a mean age of 52. The majority (76%) reported two sites of pain with 80% being treated at either step 2 or 3 (WHO guidelines of pain management). After two weeks, the average level of maximum pain was reduced from 6.6 to 4.8 (mean difference = -1.8, $p < 0.001$) and the QOL was improved from 58.6 to 61.0 (mean difference = 2.4, $p < 0.001$). There was a high correlation between the average change of pain intensity and QOL scores ($r_s = -0.42$, $p < 0.001$). The results show that changes of pain scores of at least three points (3 out of 10) were required for a minimal important difference of FACT-G scores, indicating a significant change on patients' QOL. Pain deterioration had slightly more impact on QOL than pain improvement. A 3-point pain deterioration impaired QOL 10.3 points while 3-point reduction increased QOL only 7.6 points.*
Conclusion: *The present findings suggest the importance of pain management. The change of pain scores of at least three points (out of 10 points) had statistical and clinical significance to patients' QOL.*

Keywords: *Cancer, Pain, Quality of life*

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Cancer is ranked among the top three causes of death in Thailand, with an estimated age adjusted incidence rate of 150.4 per 100,000 for males and 123.0 for females[1]. The death rate from cancer has increased more than four-fold during the last three decades, from 12.6 per 100,000 in 1967 to 51.7 in 1996[2]. These rates are very similar to other Asian countries, but about half those of Western countries. The National Cancer Institute of Thailand has estimated that there will be over 120,000 new cancer cases in 2008, reflecting an approximately 50% increment rate per decade[3].

Pain is the most common patient-reported outcome in clinical practice. It is strongly associated with Quality Of Life (QOL) and has been suggested as an important indicator for QOL of patients with cancer[4]. Nevertheless, the assessment of pain often captures only limited aspects of the patients' life making it an unsuitable comprehensive evaluation of

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cancer care. Few data are currently available on the magnitude of pain that has a clinically significant impact on patients' QOL. While studies in pain have suggested at least 50% pain relief from baseline as an indicator for effective pain treatment in clinical trials[5], its effect on patients' QOL is unknown.

QOL assessment has emerged as a more comprehensive evaluation of cancer treatment outcomes. Its multidimensional construct reflects a person's physical, emotional and social well-being resulting from disease and its treatment[6]. An increasing number of published studies have indicated QOL outcomes as responsive endpoints in clinical trials[7], facilitating clinical decision-making[8] and of good predictive value in oncology[9]. Aggregated QOL scores appear less meaningful to clinicians than the magnitude of changes in scores to reflect a patient's condition has been previously studied.

There are increasing volumes of literature currently focused on the clinical significance of QOL data. *Clinical important* change is based on anchoring QOL score differences to clinically familiar events (e.g. response of treatment) and/or patient-status indicators (e.g. performance status)[10]. One of the terms often referred to is the M*inimal* I*mportant* D*ifference* (MID). This is defined as the smallest difference in score that patients perceive as beneficial[11]. This magnitude is likely to be meaningful and lead the clinician to consider a change in the patient's management.

Numerous validated QOL assessment tools are now available[12,13]. One of the commonly used QOL tools in oncology is the Functional Assessment of Cancer Therapy-General Version (FACT-G)[14,15]. Its psychometric properties have been repeatedly reported in numerous studies worldwide. The tool has been cross-validated in Thai population with acceptable results of its reliability and validity[16,17]. A MID of 5-6 points for FACT-G scores has also been established. This indicates that these changes in QOL scores are clinically meaningful to physicians and patients[10].

The purpose of the present study was to identify the association between the QOL and pain intensity in a Thai population. The magnitude of change of pain scores that have a clinically significant impact on patients' QOL was also evaluated.

Material and Method

Study design

The present study was part of a multi-center, prospective cohort, conducted during a one-year period from February 2001 to January 2002. Participating centers included three departments (pain clinic, radiology and medical oncology) from seven university hospitals; Siriraj, Chulalongkorn, Ramathibodi, Pramongkutklao, Chiang Mai, Prince of Songkla, Khon Kaen and three tertiary care centers; National Cancer institute, Rajvithi, Bhumibol Adulyadej, located throughout Thailand. A cohort of patients with cancer pain was followed weekly for two weeks. Upon recruitment, demographic data, relevant medical history and previous analgesic therapy were all recorded. No effort was made to alter or modify the course of treatment. During the 2-week period, patients received medical treatment as judged necessary by responsible physicians.

Patients

Patients were recruited at each participating center. The ethics committee approval of the protocol was granted prior to data collection. Inclusion criteria were 1) patients aged more than 14 years old, 2) suffered from cancer pain (pain intensity > 3 on numeric rating scale: NRS 0-10, during the 24-hour period before interviewing) and 3) expected survival more than 3 months. Those who suffered from confusion or reduced level of consciousness and unable to communicate efficiently were excluded. Patients giving written informed consent to participate in the present study were interviewed by trained nurses in each center at study entry and two more follow-ups at one and two weeks after the recruitment.

Outcome measurement

The FACT-G version 4 (Validated Thai-version) was used for assessing QOL[14]. The instrument consists of 27 items. The item scales range from 0 to 4 (not at all - very much) and can be aggregated into four domains: physical, emotional, social and functional well-being. The FACT-G total scores range from 0 -108 with higher scores corresponding to better QOL. The Thai version shows good reliability with Cronbach's alpha coefficient ranging from 0.75-0.90. Many known groups and factor analysis have confirmed the construct validity of the questionnaire[16].

The Brief Pain Inventory (BPI: short form) was used for cancer pain assessment[18]. It assesses the intensity and impact of pain on daily functioning. Items were rated using a numeric rating system, ranging from 0-10. The single item on "describe your pain at its worst in the last 24 hours" was used for this analysis. The patient scores were also classified into four pain categories as none (score = 0), mild (score 1-3), moderate (score 4-6) and severe (score 7-10)[19].

Statistics

Data were analyzed using SPSS 11.5 software. Data at the study entry and two-week follow-up were used for this analysis. Descriptive statistics were used for demographic characteristic and pain scores. QOL data were checked and recorded according to the scoring guideline of FACT-G. The difference of pain and QOL scores at baseline and two weeks was analyzed using dependent t-test. The Pearson correlation coefficient was used to analyze the association between the mean changes in pain levels and mean changes in QOL scores. A p-value < 0.001 was regarded statistically significant to allow for the effect of multiple comparisons.

To determine the magnitude of change of pain scores that has clinically significant impact of patients' QOL, changes of pain scores at baseline and follow-up were compared against the change of QOL scores at respective period by analysis of variance. The MID of FACT-G, which is a change of scores of six points, was used as the cut-point to help determining clinically meaningful change of pain scores. This FACT-G score difference corresponds to an effect size of between 0.20 and 0.60, indicating small-to-medium effects[10].

Results

A total of 520 patients were recruited, 226 from pain clinics, 170 from medical oncology departments and 124 from radiology departments. The patients' mean age was 52 years (SD = 13.8), ranging from 14 to 88 years, and 299 patients (58%) were female. The majority (76%) reported two sites of pain and most patients (70%) were being treated at either step 2 or step 3 based on WHO guidelines of pain management (Table 1).

The percentage of patients classified by severity of pain at study entry and at the 2-week follow-up is shown in Table 2. Only one third of patients (32.9%) reported severe pain at two weeks, compared with 55% at baseline. The average level of maximum pain at the study entry was 6.6 (SD = 2.6). After two weeks, the average level of maximum pain was reduced to 4.8 (SD = 3.1) (mean difference = -1.8, SD = 3.2, $p < 0.001$). (The main result of the BPI will be reported elsewhere)

The FACT-G scale shows high internal consistency reliability with Cronbach's alpha above 0.7 (defined as acceptable level) in all domains (range 0.70-0.82). Reliability of the scale (27 items) was 0.86. The average level of FACT-G total scores of patients at the study entry was 58.6 (SD = 14.3). The QOL of patients marginally improved after two weeks (mean difference = 2.4, SD = 13.7, $p < 0.001$) (Table 2).

Of 514 patients with QOL scores at the two-week follow-up, 331 reported less pain, 92 had unchanged pain, and 91 had worsened pain scores. There was a high correlation between the average change of pain severity and FACT-G total scores ($rs = -0.42$, $p < 0.001$). All domains of FACT-G showed moderate to strong correlation with change of pain score (range $rs = -0.31$ to -0.42, $p < 0.001$), except for social well-being ($rs = -0.10$, $p = 0.02$).

Overall, a reduction of pain results in statistically significant improvement in QOL (Table 3, Fig. 1). Using the MID of FACT-G as the cut-point, most

Table 1. Patient characteristics at the study entry (N = 520)

Characteristics	Number of Patients	%
Sex		
Male	221	42.5
Female	299	57.5
Location of pain		
One site	121	23.3
Two sites	397	76.3
Three or more sites	2	0.4
Current treatment based on WHO guideline		
No treatment	187	3.4
Step 1 ladder	82	15.8
Step 2 ladder	168	32.4
Step 3 ladder	195	37.5
Others	57	10.9

Data are number and percent

Table 2. Severity of pain and QOL scores at baseline and 2-week follow-up

	Study entry		2-week follow-up	
Severity of pain	N	%	N	%
No pain	1	0.2	53	10.2
Mild	76	14.6	147	28.3
Moderate	158	30.4	149	28.6
Severe	285	54.8	171	32.9
Quality of life	mean (SD)	median (range)	mean (SD)	median (range)
Physical well-being	14.6 (4.4)	15.0 (1-24)	15.4 (5.0)	16.0 (2-32)
Social well-being	18.1 (5.0)	18.1 (2-28)	18.5 (5.0)	18.7 (0-28)
Emotional well-being	15.0 (5.3)	16.0 (0-24)	15.8 (5.4)	17.0 (0-24)
Functional well-being	10.9 (5.6)	11.0 (0-28)	11.3 (5.5)	11.0 (0-28)
Total FACT-G score	58.6 (14.3)	58.0 (23-94)	61.0 (15.0)	61.1 (18-98)

Data are number, percent, mean (SD) and median (range)

Table 3. Average change (SD) of QOL at all levels of change of pain scores reported at two weeks compared with baseline (N = 514)

Change of pain score*	Mean difference (SD) of QOL scores**,***				
	Physical well-being	Social well-being	Emotional well-being	Functional well-being	FACT-G total scores
-10 (less pain)	3.2 (3.8)	1.2 (2.5)	3.4 (6.8)	7.8 (3.6)	15.6 (11.4)
-8	4.1 (3.8)	1.6 (2.9)	4.2 (6.9)	4.6 (5.1)	14.5 (14.2)
-7	4.4 (2.3	0.2 (3.3)	4.0 (4.6)	3.2 (3.9)	11.8 (10.4)
-6	2.9 (3.4	-9.6 (2.9)	2.9 (4.8)	2.6 (4.2)	8.2 (10.2)
-5	3.2 (4.3	0.8 (3.7)	1.9 (6.5)	1.3 (4.6)	7.2 (12.7)
-4	1.3 (3.7)	1.3 (2.6)	2.0 (4.6)	1.3 (3.4)	6.2 (9.6)
-3	2.3 (5.5)	1.3 (2.7)	1.8 (4.4)	2.0 (4.6)	7.6 (11.9)
-2	1.0 (3.4)	0.1 (4.0)	1.6 (4.6)	0.6 (4.5)	3.3 (10.3)
-1	-0.1 (3.6)	0.4 (3.6)	-0.9 (4.5)	-0.5 (4.7)	-1.0 (12.7)
0 (unchanged)	-0.6 (4.0)	0.05 (4.2)	-0.05 (6.0)	-0.8 (4.6)	-1.4 (13.3)
1	-0.8 (4.3)	1.2 (5.1)	1.2 (4.4)	-1.2 (6.4)	0.8 (16.4)
2	-1.3 (3.6)	1.6 (5.8)	-1.0 (4.3)	0.7 (4.6)	0.02 (12.5)
3	-1.8 (4.6)	-0.7 (5.5)	-3.3 (4.0)	-4.5 (4.9)	-10.3 (11.8)
4	-0.2 (4.7)	-4.6 (5.5)	-1.7 (5.3)	-0.8 (6.2)	-7.2 (14.5)
5	-4.6 (4.0)	-1.3 (2.9)	-2.4 (4.2)	-4.2 (6.5)	-12.6 (14.4)
6	-2.8 (2.7)	0.8 (3.5)	-3.2 (4.8)	-5.5 (3.9)	-10.7 (10.3)
7	-9.0 (8.5)	0.5 (0.7)	-6.5 (2.1)	-8.0 (8.5)	-23.0 (18.4)
8 (more pain)	-2.5 (12.0)	-9.4 (14.7)	-5.0 (12.7)	-5.0 (18.4)	-21.9 (57.9)

* BPI: Higher scores mean worsened pain

** FACT-G: Higher scores mean improved QOL

*** ANOVA test resulted in p value < 0.001 in all domains, except SWB (p = 0.025), at different level of pain classified as no change, little (- 1 to -3), moderate (- 4 to -6), and much (> -7) reduction and little (1 to 3), moderate (4 to 6) and much (> 7) increase

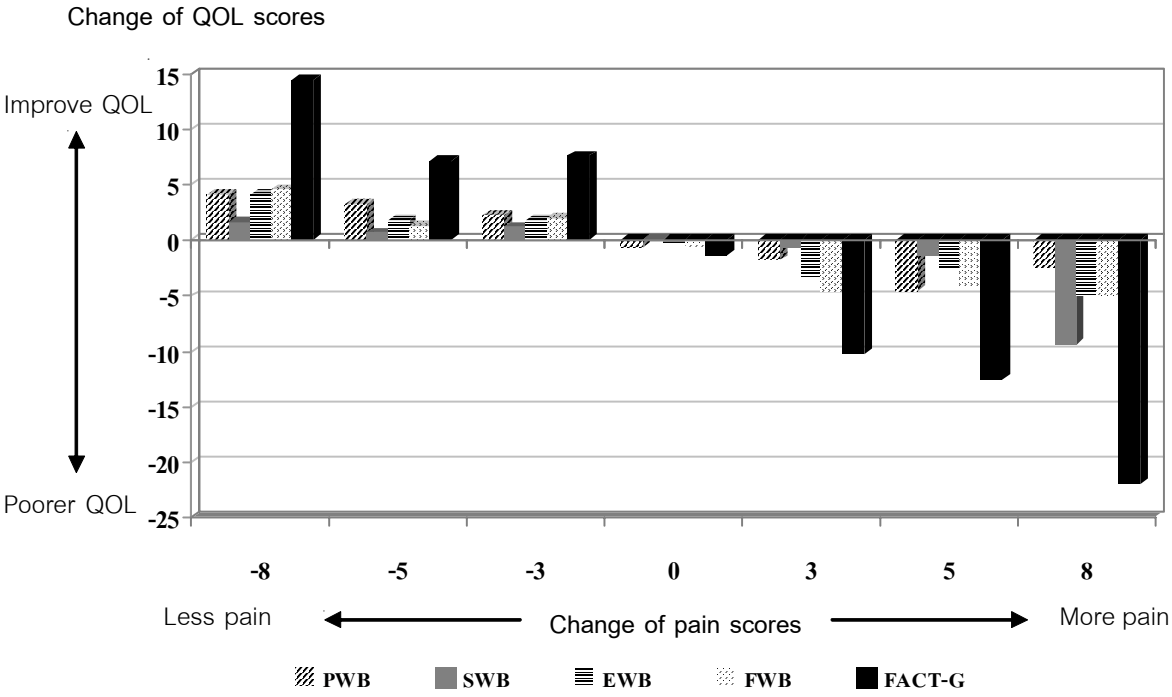

Fig. 1 Average change of QOL scores at different levels of average change of pain scores from baseline
PWB: physical well-being, SWB: social well-being, EWB: emotional well-being,
FWB: functional well-being, FACT-G: total FACT-G scores

changes in pain severity resulted in changes of QOL score of more than six points. In addition, a change of pain score of at least three points achieved the MID of FACT-G scores, indicating that such a change has a clinical impact on patients' QOL. Pain deterioration had slightly more impact on QOL than pain improvement; a 3-point pain deterioration impaired QOL 10.3 points while 3-point pain reduction increased QOL only 7.6 points.

Discussion

The findings show a strong correlation between pain deterioration and reduction of QOL. The worsening of pain by more than three points has a significant impact on the patients' QOL. A previous study had indicated the importance of the reduction of patients' pain scores by more than 50%[5]. The present study is the first attempting to define the magnitude of change of pain severity based on patients' QOL. It has emphasized that only a 30% change of pain scores already leads to a significant change meaningful to patients.

It should be noted that pain severity used in the present study is based on 'pain at its worst' in the last 24 hours. This is believed to better reflect its impact on patients' QOL and independent of the timing for data collection. Further analysis of the present study using 'current pain', one of the items in the BPI, also shows similar results (data not shown).

Eton et al[10] have suggested that a change of FACT-G total score of six points is the minimal important difference. This not only helps in determining the effect size of the intervention, but also makes the interpretation of QOL more meaningful for clinicians. The present study helps fine-tuning current knowledge on the importance of change of pain scores upon patients' QOL. A meaningful interpretation should, therefore, encourage a wider use of pain scores in clinical practice.

Although pain has been recognized as a key symptom in cancer patients[20], different types of cancer can result in varied pain intensities and characteristics. It is a limitation of the study that the origin of cancer was not verified. Therefore, the differentiation of pain and QOL scores for different types of cancer could not be analyzed.

The present study recruited patients mainly from specific centers for cancer treatment in Thailand. Being specialists in the area may have lead to better

outcome of pain management in the present study compared with those in the previous report[21]. It should be noted that the results of the present study may not represent overall cancer pain management in regional hospitals throughout Thailand.

Conclusion

This prospective, cohort, multicenter study shows that patients' QOL is associated with cancer pain. The findings suggest the importance of pain management. Changes of pain score of at least three points (out of 10) have statistical and clinical significance to a patient's QOL ($p < 0.001$).

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อาการปวดกับคุณภาพชีวิตของผู้ป่วยมะเร็ง: การศึกษาแบบสหสถาบันในประเทศไทย

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วัตถุประสงค์*: เพื่อศึกษาความสัมพันธ์ระหว่างระดับความปวดกับคุณภาพชีวิตของผู้ป่วยมะเร็ง และประเมินระดับการเปลี่ยนแปลงความปวดที่ส่งผลกระทบต่อคุณภาพชีวิตของผู้ป่วย*

รูปแบบการวิจัย*: การศึกษาแบบ cohort ร่วมกันระหว่างสหสถาบัน*

วัสดุและวิธีการ*: ศึกษาในผู้ป่วยมะเร็งที่มีอาการปวดในโรงเรียนแพทย์ 7 แห่ง และโรงพยาบาลศูนย์อีก 3 แห่งในประเทศไทย ระดับอาการปวดของผู้ป่วยประเมินด้วยเครื่องมือ Brief Pain Inventory ส่วนคุณภาพชีวิตประเมินด้วยเครื่องมือ FACT-G การประเมินความปวดและคุณภาพชีวิตทำครั้งแรกเมื่อเริ่มการศึกษาและทำการประเมินซ้ำอีกใน 2 สัปดาห์ต่อมา*

ผลการศึกษา*: มีผู้ป่วยที่ร่วมในการศึกษาทั้งหมด 520 ราย (อายุเฉลี่ย 52 ปี) ผู้ป่วยส่วนใหญ่ (76%) มีอาการปวดตามร่างกาย 2 แห่ง และร้อยละ 80 ของผู้ป่วยได้รับการรักษาอาการปวดตามบันไดขั้นที่ 2 หรือที่ 3 ของแนวทางการระงับปวดของ WHO การประเมินที่เวลา 2 สัปดาห์ต่อมาพบว่า ระดับความปวดสูงสุดลดลงจาก 6.6 เป็น 4.8 (mean difference = -1.8, $p < 0.001$) และผู้ป่วยมีคุณภาพชีวิตที่ดีขึ้นจาก 58.6 เป็น 61.0 (mean difference = 2.4, $p < 0.001$) โดยที่ระดับความปวดสูงสุดที่ลดลงมีความสัมพันธ์กับคุณภาพชีวิตที่ดีขึ้น ($rs = -0.42$, $p < 0.001$) ทั้งนี้พบว่าค่าคะแนนความปวดที่เปลี่ยนแปลงอย่างน้อย 3 คะแนน (3 ใน 10 คะแนน) จะส่งผลทำให้ค่าคะแนนของ FACT-G มีการเปลี่ยนแปลงในระดับที่เริ่มบ่งบอกได้ว่าส่งผลกระทบต่อคุณภาพชีวิตของผู้ป่วยอย่างมีนัยสำคัญทางคลินิก โดยอาการปวดที่เพิ่มขึ้นมีผลต่อการเปลี่ยนคุณภาพชีวิตมากกว่าอาการปวดที่ลดลง คืออาการปวดเพิ่มขึ้น 3 คะแนนทำให้คุณภาพชีวิตลดลง 10.3 คะแนน ในขณะที่อาการปวดลดลง 3 คะแนนทำให้คุณภาพชีวิตเพิ่มขึ้น 7.6 คะแนน*

สรุป*: การวิจัยนี้แสดงให้เห็นความสำคัญของการระงับปวด โดยระดับความปวดที่เพิ่มขึ้นหรือลดลงอย่างน้อย 3 คะแนน (จาก 10 คะแนน) จะส่งผลให้มีการเปลี่ยนแปลงคุณภาพชีวิตของผู้ป่วยได้อย่างมีนัยสำคัญทั้งทางสถิติและทางคลินิก*