

Original

**Integrating Cancer Patients' Satisfaction with
Rescue Medication in Pain Assessments**

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Abstract: A patient's pain intensity rating alone is insufficient grounds for determining the pain medication and dosage to administer daily. This study aimed to investigate whether a convenient assessment method could be developed that would reflect the effectiveness of an opioid analgesic on cancer patients' pain management. We investigated pain intensity (worst, least, average, current) and the effectiveness of the opioid rescue medication in terms of patient satisfaction. This study used Spearman's rank correlation coefficients to evaluate the relationships between patient satisfaction with rescue medication and both pain intensity and the medication's perceived effectiveness. Data from 60 participants with a mean age of 60.5 ± 11.4 years (range: 31-79 years) were analyzed. Thirty-eight (63.3%) participants were male, and 22 (36.7%) were female. The correlations found between rescue medication satisfaction and both the worst numerical rating scale (NRS) rating ($r = -0.15$, $P = 0.16$) and the average NRS rating ($r = -0.13$, $P = 0.13$) were not statistically significant. A significant positive correlation was observed between rescue medication satisfaction and the medication's perceived effectiveness ($r = 0.79$, $P < 0.0001$). Patient satisfaction with their rescue medication can be routinely assessed without imposing a significant burden on the patient. A new assessment method incorporating rescue medication satisfaction and pain intensity measures could allow routine pain assessments to reflect both pain intensity and the effectiveness of opioid analgesics. This new assessment method is potentially preferable to self-reported pain intensity and can identify patients for whom treatment is a priority. It also facilitates rapid dose adjustments and reduces the side effects of overdose due to unnecessary increases in opioid analgesics.

Key words: pain management, cancer, satisfaction, patient-reported outcomes, survey

Introduction

Pain is the most frequent complication related to cancer. Approximately 40% of cancer patients experience moderate-to-severe pain at the time of diagnosis, which increases to 70%

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toward the end of life. Cancer pain control is frequently suboptimal despite the availability of generic effective pain treatments. Factors including the underreporting of pain by cancer patients, inadequate communication regarding pain between patients and medical staff, and inadequate assessment of pain by professionals are known to contribute to poor pain control¹⁾. The development of new guidelines for treatment and the increased worldwide consumption of opioid analgesics is expected to reduce cancer patients' levels of pain. However, effective pain management has not been implemented, and knowledge concerning the evaluation and management of cancer pain by medical staff remains inadequate²⁾.

The effective treatment of cancer-related pain increases the efficacy of cancer treatment³⁾. Basing pain assessment on patient-reported outcomes (PROs)⁴⁾ is considered to be best practice when assessing cancer-related pain management outcomes. Numerous studies of such assessment methods have been conducted^{5, 6)}, such as the 1993 European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core Module 30 (EORTC QLQ-C30)⁷⁾. In Japan, studies have been performed using the Japanese versions of the Brief Pain Inventory (BPI-J)⁸⁾ and the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core Module 15-Palliative Care (EORTC QLQ-C15-PAL)⁹⁾. These measures have also been used to assess the effects of different pain intensity levels on patient pain management satisfaction and daily living¹⁰⁾. Both instruments comprise a lengthy series of questions, which, although suitable for patients participating in clinical trials or for those receiving outpatient treatment, could be burdensome for staff attempting to use them frequently in clinical settings.

Pain management is complex for patients with cancer-related pain. It requires a comprehensive evaluation of the potential causes (physical examinations, imaging scans, and blood tests) and the effects of the pain (impact on everyday life, patterns, intensity, location, history, type, aggravating or mitigating factors, and response to treatment)^{11, 12)}. Moreover, methodologies differ in their details. For example, numerous rating scales are used to assess pain intensity alone, including the visual analog scale, the numerical rating scale (NRS), and the faces pain scale.

At the Showa University Hospital, pain intensity is continually assessed for most patients. However, a patient's pain intensity rating alone is insufficient grounds for determining the pain medication and dosage to administer daily. Therefore, in this study, we examined other factors that may be less adequately monitored. Although including patient pain management satisfaction could potentially improve assessment utility, satisfaction with overall treatment for pain also reflects the effects of other factors, such as the efficacy of the patient's overall cancer treatment. To address this issue, we examined patient satisfaction with an opioid analgesic that was taken as a rescue medication when the patient experienced severe pain.

This study aimed to investigate whether a convenient assessment method could be developed that would reflect the effectiveness of an opioid analgesic for cancer patients' pain management. To that end, this study examined whether patient satisfaction with their rescue medication was correlated with pain intensity and perceived medication effectiveness. The reasons underlying high patient satisfaction levels were also evaluated, and data collected related to rescue medication selection were considered in relation to the findings.

Methods

Participants and Procedure

This was a cross-sectional study. The sample population for the study consisted of cancer patients admitted to Showa University Hospital between April and November of 2019 who were assessed for cancer-related pain as part of the palliative care team's interventions. Participants who had been on an opioid analgesic for at least one week and had a pain assessment performed were selected for participation in the study. Of this group, consenting patients aged 20–79 years old who had an Eastern Cooperative Oncology Group performance status (ECOG-PS) score of 3 or less were asked to complete a pain assessment survey questionnaire in conjunction with their regular pain assessments. The surveys were completed at minimum intervals of six days; therefore, a specific patient could potentially complete multiple surveys. The self-administered survey consisted of eight items. Data for the first item (patient characteristics) were obtained from the patient's electronic health record. The remainder of the items were completed by the patient unless they were unable to do so. In such cases, medical staff members were permitted to assist them. Patients were excluded from the study if they were at risk for respiratory depression due to a head injury or enlarged brain tumor, or if the physician leading the research project determined them to be unfit to participate for any reason.

Survey Content

The survey collected the following content using demographic variables, the NRS scores, and assessments of satisfaction:

1. Participant characteristics: age, gender, type of cancer, whether they were receiving cancer treatment, ECOG-PS score, regularly prescribed opioid analgesic, opioid analgesic dosage, and opioid analgesic dosage form
2. Most intense pain during the past 24 hours (worst NRS)
3. Least intense pain during the past 24 hours (least NRS)
4. Average pain intensity over the past 24 hours (average NRS)
5. Pain intensity when completing the survey (current NRS)
6. Effectiveness of the rescue medication
7. Satisfaction with the rescue medication
8. Reasons for the satisfaction rating

The pain assessment survey questionnaire was developed based on the BPI-J, for which the validity and reliability have already been confirmed as sufficient. The BPI-J is frequently used in research to assess cancer-related pain. For items 2–5, an 11-point NRS was used ranging from 0 (no pain) to 10 (worst pain ever experienced). For item 6, an 11-point scale was used ranging from 0 (no effect) to 10 (extremely effective). For item 7, an 11-point scale was used, ranging from 0 (extremely dissatisfied) to 10 (extremely satisfied). Item 8 examined the reasons the patient was satisfied or dissatisfied with their rescue medication; multiple responses were possible: i) it is fast-acting; ii) it is

slow-acting; iii) it lasts a long time; iv) it lasts a short time; v) the side effects are bad; vi) it has no side effects; vii) it is convenient; viii) the preparation time is too long; ix) it does not have to be drunk; and x) other (a space was provided for patients to provide more details).

The study's primary analyses examined how rescue medication satisfaction might correlate with pain intensity (worst and average NRS ratings) and with medication effectiveness. Secondary analyses compared medication satisfaction ratings for differences in pain intensity level based on the worst NRS rating and differences in dosage forms. In addition, we divided the sample into satisfied (satisfaction ratings of 5 or higher) and dissatisfied (ratings of less than 5) groups and identified the reasons why patients in the group with higher ratings were more satisfied.

Statistical Analyses

The correlations between rescue medication satisfaction and worst/average NRS ratings and the correlations with medication effectiveness were evaluated using Spearman's rank correlation coefficient. Additionally, the sample was divided by the patients' worst NRS ratings into mild (0-3), moderate (4-6), and severe (7-10) groups to compare rescue medication satisfaction by pain intensity level using the Kruskal-Wallis test by ranks. To compare medication satisfaction with difference dosage forms, the sample was divided into injection and oral/sublingual groups. The Mann-Whitney U test was used to identify significant differences between the two groups. The significance level was set at 5% (two-tailed). Statistical analyses were performed using JMP Pro 14.0.

Ethical Considerations

This study was conducted with the approval of the School of Medicine, Showa University Ethical Committee (approval no. 2852). All participants provided written informed consent. It should be noted that when the palliative care team began intervening in patient treatment, the patients received a thorough explanation about opioids.

Results

Participant Characteristics

Apart from some participant descriptive characteristics, analyses were performed on the responses to 100 surveys completed by the 60 study participants. The mean age (range) was 60.5 ± 11.4 years (31-79 years); 38 (63.3%) of the participants were male and 22 (36.7%) were female. Forty-one (75.9%) of the participants were undergoing cancer treatment. The most frequent primary cancer sites were the digestive system, followed by the lung/mediastinum. According to the ECOG-PS, 5 (5.0%) patients were Grade 1, 58 (58.0%) were Grade 2, and 37 (37.0%) were Grade 3. The median (interquartile range) for the dosage of regularly taken opioid analgesics in oral morphine equivalents was 45 mg/day (24-72 mg/day) (Table 1).

Pain Control Indicators

The medians and interquartile ranges of the worst NRS, least NRS, average NRS, and current

NRS ratings were 5 (4-8), 1 (0-2), 3 (2-4.25), and 2 (1-4), respectively (Table 2).

Rescue Medication: Satisfaction and Effectiveness

The median (interquartile range) for rescue medication effectiveness was 8 (5-10) whereas that for rescue medication satisfaction was 7 (5-10). A strong positive correlation ($r=0.79$, $P<0.0001$) was identified between rescue medication satisfaction and effectiveness. The correlations for medication satisfaction with worst NRS ($r=-0.15$, $P=0.16$) and with average NRS ($r=-0.13$, $P=0.13$) were not statistically significant (Figure 1).

Comparisons of rescue medication satisfaction with pain intensity level using the worst NRS

Table 1. Patient characteristics (n=60)

	n (%)
Age (years) (Mean±SD)	60.5±11.4
Male/Female	38 (63.3) / 22 (36.7)
Cancer site	
Head and neck	8 (13.3)
Breast	3 (5.0)
Lung/mediastinum	10 (16.7)
Digestive system	19 (31.7)
Hepatobiliary/pancreatic	5 (8.3)
Blood/lymphoma	1 (1.7)
Gynecologic/genitourinary	9 (15.0)
Other	5 (8.3)
Cancer treatment: Y/N	41 (68.3) / 19 (31.7)
Stage: II/III/IV	1 (1.7) / 5 (8.3) / 54 (90.0)
ECOG-PS: 1/2/3*	5 (5.0) / 58 (58.0) / 37 (37.0)
Regularly prescribed opioid dosage (mg/day)* in oral morphine equivalents [Median (interquartile range)]	45 (24-72)

*PS and opioid dosages are calculated for n=100
(the number of surveys in the analysis)

ECOG-PS, Eastern Cooperative Oncology Group Performance Status

Table 2. Pain control indicators (n=100)

	Median (interquartile range)
Pain worst (worst NRS)	5 (4-8)
Pain least (least NRS)	1 (0-2)
Pain average (average NRS)	3 (2-4.25)
Pain current (current NRS)	2 (1-4)
Rescue effect	8 (5-10)
Rescue satisfaction	7 (5-10)

NRS, numerical rating scale

and mild (n=24), moderate (n=45), and severe (n=31) pain satisfaction did not demonstrate significant between-group differences in pain intensity levels (Figure 2). The most frequent reasons for higher rescue medication satisfaction were that the medications were fast-acting and convenient (Figure 3).

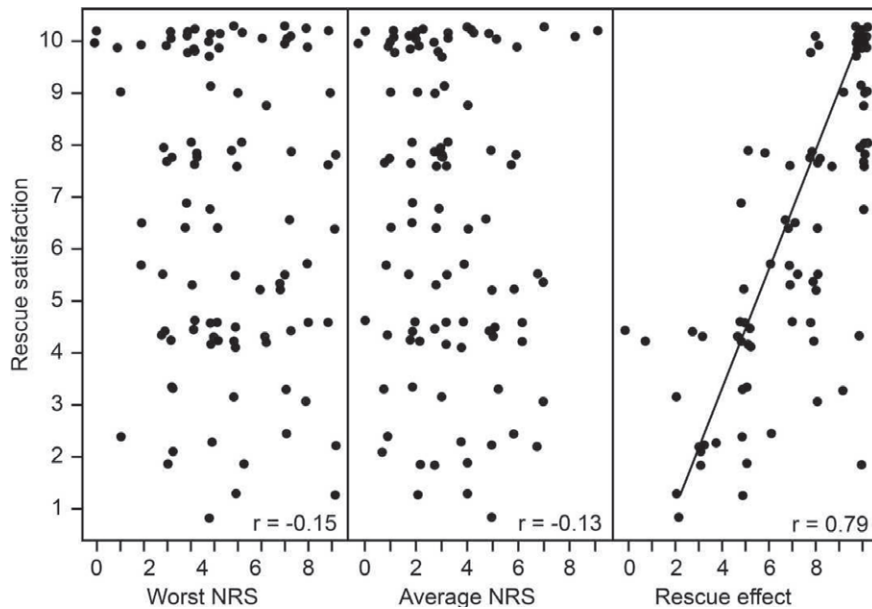


Fig. 1. Correlations between rescue medication satisfaction and worst NRS, average NRS, and rescue medication effectiveness
NRS, numerical rating scale

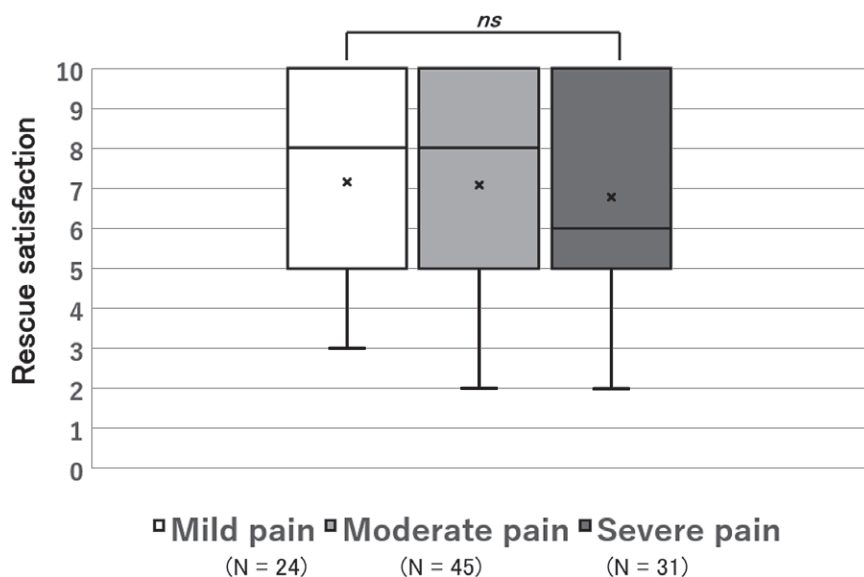


Fig. 2. Rescue medication satisfaction by pain intensity level NRS, numerical rating scale; Mild pain: NRS 0-3 (n=24), moderate pain: NRS 4-6 (n=45), severe pain: NRS 7-10 (n=31)
Kruskal-Wallis test, $P < 0.05$

No significant between-group differences were found when rescue medication satisfaction was compared by grouping the responses according to injection (n=30) and oral/sublingual (n=70) dosage forms (Figure 4). In addition, there were no significant differences in rescue medication satisfaction between males and females.

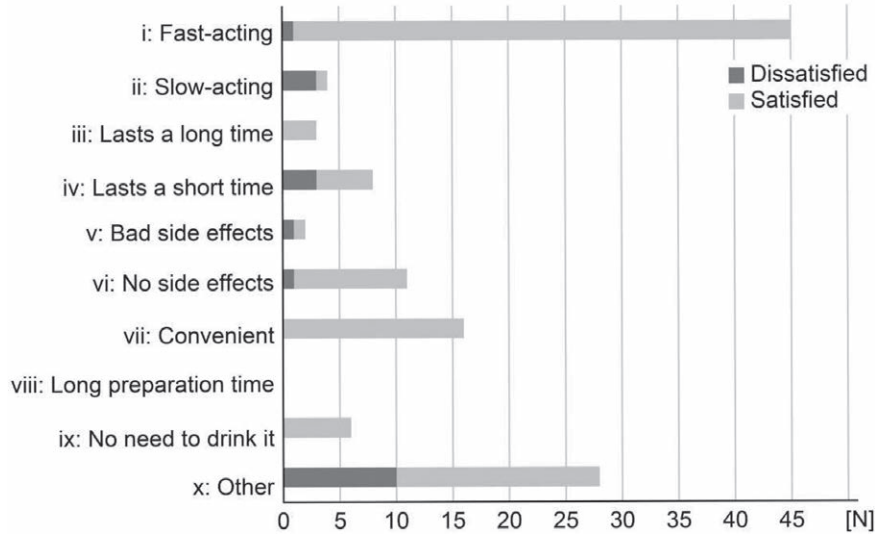


Fig. 3. Reasons for rescue medication satisfaction/dissatisfaction ratings stratified by the satisfied (≥ 5) and dissatisfied (< 5) groups (multiple responses possible) Notes: The patients most frequently reported higher rescue medication satisfaction because of fast-acting and convenient medications.

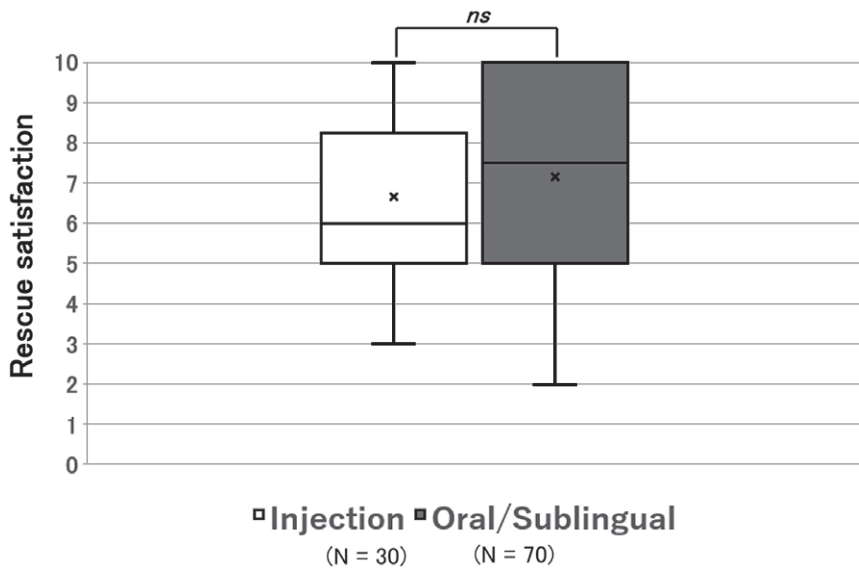


Fig. 4. Rescue medication satisfaction by dosage form NRS, numerical rating scale; injection group (n=30), oral/sublingual group (n=70); Mann-Whitney U test, $P < 0.05$

Discussion

In this study, satisfaction with rescue medication was not significantly correlated with worst and average NRS pain intensity ratings. However, satisfaction was strongly correlated with rescue medication effectiveness. Furthermore, there were no significant differences in the comparisons of rescue medication satisfaction by pain intensity level and dosage form. These findings suggest that performing a pain assessment consisting of only an NRS rating after administering opioid analgesics may be inappropriate because some patients appeared to be satisfied with their rescue medication despite having high worst and average NRS pain ratings. Instead, satisfaction with rescue medication was shown to better reflect medication effectiveness. This finding suggests that integrating rescue medication satisfaction into daily patient pain assessments could better indicate whether the opioid analgesic used was effective.

Fast-acting, convenient rescue medications were the most satisfactory forms of medication. Although we expected satisfaction to be higher for injections that take little time to prepare and are fast-acting, the results showed there was no significant difference in satisfaction between rescue medications in the injection and oral/sublingual forms. This finding suggests that patient satisfaction depends more on medication being fast-acting than on being convenient. Despite the need for convenience, hospitals frequently keep rescue medications for patients in narcotics cabinets to control their usage. To increase patient satisfaction, it is necessary to devise ways to select a dosage form for each patient and to otherwise promote rescue medication self-management so that they can be used immediately when necessary. It is also important to select drugs according to the cause of pain and to communicate with the patient.

Reducing or eliminating cancer-related pain is essential to improve the quality of life (QOL) of cancer patients. To achieve this, pain management must be initiated quickly, and side-effects should be comprehensively managed to ensure patient satisfaction. Although suggestions and guidelines¹³⁻¹⁸⁾ have been proposed in this regard, it remains extremely difficult to control cancer-related pain, which is usually experienced throughout the body and is influenced by multiple factors. As a result, pain assessments must be very detailed, and assessments of patient satisfaction with overall pain management are generally required to be multidimensional¹⁹⁾. Pain management assessment can also be complex because the relationship between pain severity and its interference with function is non-linear²⁰⁾. Furthermore, there is frequently disagreement between a patient's self-reported pain and the physician's clinical assessment of that pain^{21, 22)}. Adequate, effective pain assessment is significantly affected by regional and institutional differences in medical provider perceptions and the extent to which opioid analgesics are used, among other factors^{23, 24)}. In addition, interventions may be performed inappropriately with the aim of quantifying a patient's pain, leading to frequent or repetitive questioning, which adds to the distress of patients undergoing cancer treatment. As a result, complicated pain assessments may be difficult for providers to perform, and evaluations may sometimes rely entirely on self-reported pain intensity levels.

This study demonstrated that a new assessment method incorporating rescue medication

satisfaction and pain intensity measures could allow routine pain assessment to reflect both pain intensity and the effectiveness of the opioid analgesic. This is potentially a preferable assessment method to self-reported pain intensity. For example, a patient reporting intense pain and high satisfaction with their rescue medication may only require an increase in the dosage of the prescribed opioid analgesic. For patients reporting intense pain and low satisfaction with their rescue medication, a review of the current treatment approach and the drug being administered may be required. This method would help avoid cases of side effects due to overdosage. For patients reporting dissatisfaction with their pain medication, despite reporting low pain intensity, non-opioid drug therapies and other methods of providing care might be necessary.

This study has some limitations, including issues with several methodological factors and the risk of bias inherent to surveys. The small sample size resulted in a potential for selection bias, which occurred because all the patients sampled were from a single hospital. Thus, the results cannot be generalized to other populations. Further, the cross-sectional design limits the results of the analysis to a specific time point.

Recently, facilities have begun to assess the pain levels of cancer patients at admission, which results in quick identification of patients struggling with pain²⁵). An important role of medical providers is to provide adequate pain management during hospitalization. As a component of this role, it is useful to periodically perform a QOL assessment for whole-body pain using the EORTC QLQ-C30 and the BPI. Patient satisfaction with their overall pain management fosters advance care planning and decision-making for patients. Conversely, a patient's distress and anxiety may increase if pain control adjustments are inadequate due to inadequate daily pain assessments. In this regard, one benefit of multidisciplinary assessment and intervention is that the causes for patient distress and anxiety can quickly be identified. Integrating measures of rescue medication satisfaction into daily pain assessments can be implemented without imposing a significant burden on the patient. By doing so, the assessments can be used as a criterion to quickly evaluate whether to increase the dosage of the patient's opioid analgesic and to avoid the risk of increasing the dosage too much. In addition, to prevent any distress that the assessments may cause patients, providers could inform the patients about the importance of pain assessments and the benefits thereof. Moreover, providers should perform appropriate pain assessments based on information shared with patients.

This study's findings suggest that patient satisfaction with their rescue medication can be routinely assessed without imposing a significant burden on the patient. Moreover, the results indicated that patient satisfaction reflected the effectiveness of their rescue medication. Integrating rescue medication satisfaction with pain intensity measurements into a daily pain assessment should result in a convenient pain assessment that reflects the effectiveness of the patient's rescue medication. This assessment approach would be useful for patients taking an opioid analgesic because it would allow medical professionals to adjust dosages quickly and avoid side effects due to overdosage.

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Declaration of conflicting interests

The authors declare that there are no conflicts of interest.

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