A Nationwide Retrospective Study of Opioid Management Patterns in 2,468 Patients with Spinal Pain in Korea

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Study Design: Retrospective patient data collection and investigator survey.

Purpose: To investigate patterns of opioid treatment for pain caused by spinal disorders in Korea.

Overview of Literature: Opioid analgesic prescription and adequacy of consumption measures in Korea have markedly increased in the past decade, suggesting changing patterns in pain management practice; however, there is lack of integrated data specific to Korean population.

Methods: Patient data were collected from medical records at 34 university hospitals in Korea. Outpatients receiving opioids for pain caused by spinal disorders were included in the study. Treatment patterns, including opioid types, doses, treatment duration, outcomes, and adverse drug reactions (ADRs), were evaluated. Investigators were interviewed on their perceptions of opioid use for spinal disorders.

Results: Among 2,488 analyzed cases, spinal stenosis (42.8%) was the most common presentation, followed by disc herniation (24.2%) and vertebral fracture (17.5%). In addition, a greater proportion of patients experienced severe pain (73.9%) rather than moderate (19.9%) or mild (0.7%) pain. Oxycodone (51.9%) and fentanyl (50.8%) were the most frequently prescribed opioids; most patients...
**Introduction**

Spine and back pain are among the most common sources of chronic noncancer pain among adults. Low back pain is a globally prevalent concern, with an estimated lifetime prevalence of approximately 40% [1]. The UK National Institute for Health and Care Excellence and the American College of Physicians/American Pain Society (ACP/APS) guidelines provide recommendations for managing chronic low back pain through various pharmacological and nonpharmacological treatment modalities [2,3]. Despite the variety of treatment modalities in use, a considerable amount of needs in chronic pain management remain unmet. For example, pain-relieving medications were estimated to be the most commonly prescribed pharmacotherapy in ambulatory care in the United States (US) [4].

Pharmacotherapies recommended by the ACP/APS guidelines for subacute and chronic back pain include acetaminophen, benzodiazepine, tramadol, and opioids [2]. Opioids are considered effective for reducing nociceptive pain and are moderately effective for neuropathic pain; however, tolerability issues such as nausea and vomiting tend to limit their application in clinical practice. Despite these limitations, opioids can be both effective and safe, if appropriately used [3,5].

Long-term use of opioids for chronic noncancer pain remains controversial owing to concerns regarding analgesic tolerance and drug dependence [6-10]. The ratio of opioid to total analgesic use in Korea is still relatively low compared with Western countries. In a study evaluating the adequacy of opioid use at the national level with the Adequacy of Consumption Measure (ACM), Korea was listed with a 47.0% adequacy score for opioid consumption in 2010 [11]. This implies that less than half of the patients in Korea who required opioid treatment actually received it. In 2010, the adequacy scores of other countries were as follows: USA, 229.7%; Canada, 312.6%; France, 73.5%; UK, 66.4%; Japan, 15.5%; and China, 1.2% [11]. This indirectly indicates limited usage of opioids for management of spinal pain in Korea.

Nevertheless, opioid usage in Korea is growing rapidly. The adequacy level of opioid consumption, as indicated by the ACM, has increased by over six-fold during the 2006–2010 period [11,12]. Such a remarkable improvement suggests changing attitudes toward pain management [9]. Considering the lack of integrated data specific to the Korean population, we sought to better understand the effectiveness and safety of opioid use in the management of different types of spinal pain arising from multiple causes [5,13].

This retrospective study was designed to investigate the following: (1) patterns of opioid usage in patients with pain caused by spinal disorders; (2) physicians’ perceptions on opioid usage; and (3) opioid analgesic usage for spinal disorders.

**Materials and Methods**

1. Patients

Since this study was a retrospective study, the Institutional Review Boards of the 34 participating hospitals approved the study and granted waiver for collecting informed consent from patients. All information was anonymized in order to maintain patient confidentiality. Data were collected from medical records of 34 university hospitals in Korea. The list of patients was acquired from August 2011...
database, which included patients who visited hospitals due to spinal disorders in November 2010 or earlier, with an aim to collect data of more than 50 patients per investigator. In outpatient clinics with <50 patients in November 2010, patients from the preceding month were included until the number reached 50. The investigators reviewed patient medical records and extracted information including demographics, diagnoses, type and dose of the prescribed opioids, and comorbidities. Korean outpatients of both sexes, aged ≥20 years, who received opioids at least once to treat pain arising from spinal diseases in November 2010 or earlier were eligible for inclusion.

Exclusion criteria were used to eliminate cases wherein external factors may have influenced clinical decisions regarding opioid usage. Any patient participating in an interventional study during the study period was excluded. In addition, patients with cancer-related pain caused by primary or metastatic spinal cancer were excluded. In order to minimize selection bias, 50 consecutive cases were enrolled per investigator from the patients who met the selection criteria.

2. Definitions

Spinal disorders assessed in this study included, but were not limited to, spinal stenosis, disc herniation, vertebral fracture, persistent postoperative back pain, unspecified back pain, intervertebral disc disorders, spondylolisthesis, spinal cord injury, and spinal infection. Diagnosis was considered as a multiple-option item in the case report form because the medical records often described more than one spinal condition per patient.

Opioid analgesics included, but were not limited to, oxycodone (immediate release [IR], prolonged release [PR], and other composite formulations), fentanyl, hydromorphone, and codeine in combination with acetaminophen and ibuprofen. These commercially available medications are classified as “narcotics” by the Act on the Control of Narcotics, the Enforcement of Decree of the Act on the Control of Narcotics, and other relevant laws in Korea. A codeine combination is classified as a narcotic in Korea, but codeine is otherwise classified as a weak opioid according to the analgesic ladder published by the World Health Organization [14].

Pain intensity was recorded using a numeric rating scale (NRS [15,16]) where available. NRS scores were converted into following categories: “severe pain” for scores 7–10, “moderate pain” for scores 4–6, and “mild pain” for scores 1–3. In cases where no NRS values were recorded, pain intensity was assessed as severe, moderate, or mild according to the descriptions in the medical records. Pain intensity was examined at the initiation of opioid treatment and 1 and 2 months after treatment initiation. Moreover, adverse drug reactions (ADRs) after opioid administration were recorded.

3. Investigators’ questionnaire

Participating investigators and subinvestigators were interviewed to assess their perceptions regarding the usage of opioid analgesics. Investigators were also asked about their concerns regarding opioid dependency and their experiences with dependent patients. In addition, they were asked to suggest actions or measures that may improve opioid usage in Korea.

4. Statistical analyses

Descriptive statistics were used to summarize patient characteristics and opioid treatment patterns. Means and standard deviations or medians and ranges were used for continuous data. Categorical data were presented as numbers and percentages. The number of cases and the percentages of ADRs were presented as well. Results of the investigators’ questionnaire were descriptively summarized.

Pearson’s chi-square test was used to identify statistically significant relationships (1) between type of pain experienced and presence/absence of pain relief with opioid treatment and (2) between duration of opioid treatment and presence/absence of pain relief. All reported p-values were two sided; p-values <0.05 were considered significant. Statistical analyses were performed using SAS ver. 9.1 (SAS Institute, Cary, NC, USA).

Results

1. Baseline characteristics

In total, data regarding 2,483 cases were collected from 34 hospitals. Of these, 2,468 cases were analyzed after excluding 15 cases with protocol violations. Table 1 summarizes patient characteristics. The study population contained more female (60.0%) than male (40.0%) patients, and
the mean age was 64.2 years. Spinal stenosis (42.8%) was the most common diagnosis, followed by disc herniation (24.2%), vertebral fracture (17.5%), persistent postoperative back pain (13.0%), and unspecified back pain (10.7%).

Of the 2,468 patients analyzed, 694 (28.1%), 635 (25.7%), and 1,027 (41.6%) patients reported neuropathic, nociceptive, and mixed (both neuropathic and nociceptive) pain, respectively. Before initiating opioid therapy, 1,823 (73.9%) patients experienced severe pain, 490 (19.9%) experienced moderate pain, whereas 18 (0.7%) experienced mild pain. Only 593 (24.0%) patients underwent an NRS assessment of pain intensity; the mean pain score was 7.5. The results majorly indicated severe pain levels in the study population.

The duration of pain before initiating opioid treatment was <3 months in 865 (35.0%) patients, 3–12 months in 473 (19.2%) patients, and ≥12 months in 962 (39.0%) patients (Table 1).

### Table 1. Patient characteristics (n=2,468)

| Characteristic                                      | No. (%) |
|-----------------------------------------------------|---------|
| **Demographic information**                         |         |
| Age (mean±SD), yr                                   | 64.2±14.1|
| Sex                                                  |         |
| Male                                                 | 986 (40.0) |
| Female                                               | 1,482 (60.0) |
| **Diagnosis (multiple diagnoses possible)**          |         |
| Spinal stenosis                                      | 1,056 (42.8) |
| Disc herniation                                     | 597 (24.2) |
| Vertebral fracture                                   | 431 (17.5) |
| Persistent postoperative back pain                   | 320 (13.0) |
| Unspecified back pain                                | 264 (10.7) |
| Intervertebral disc disorders                        | 211 (8.6) |
| Spondylolisthesis                                    | 204 (8.3) |
| Spinal cord injury                                   | 100 (4.1) |
| Spinal infection                                     | 46 (1.9) |
| Others                                               | 457 (18.5) |
| **Type of pain**                                     |         |
| Neuropathic pain only                                | 694 (28.1) |
| Nociceptive pain only                                | 635 (25.7) |
| Both neuropathic and nociceptive pain                | 1,027 (41.6) |
| No information                                       | 112 (4.5) |
| **Pain intensity at the initiation of opioid treatment** |         |
| Severe                                               | 1,823 (73.9) |
| Moderate                                             | 490 (19.9) |
| Mild                                                 | 18 (0.7) |
| No information                                       | 137 (5.6) |
| **Duration of pain prior to the initiation of opioid treatment** |         |
| <3 mo                                                | 865 (35.0) |
| 3 to 12 mo                                           | 473 (19.2) |
| ≥12 mo                                               | 962 (39.0) |
| No information                                       | 168 (6.8) |

SD, standard deviation.

### 2. Nonopioid analgesia before initiation of opioid treatment

Over half of the patients (1,389/2,468; 56.3%) were treated with nonopioid analgesics before receiving opioids for spinal pain. Of these, 847 (34.3%) patients had received weak opioids (including tramadol), 639 (25.9%) patients had received nonsteroidal anti-inflammatory drugs (NSAIDs), and 264 (10.7%) patients had received anticonvulsants.

### 3. Opioid treatment patterns

Prescriptions were classified as regular or pro re nata (PRN). In 2,060 (83.5%) patients, opioid therapy was administered regularly, whereas in 408 (16.5%) patients, it was prescribed only when required. The opioid types prescribed, daily doses, and treatment duration for each opioid analgesic are summarized in Table 2. Oxycodone (PR, IR, and other composite drugs combined) was the most commonly prescribed drug (in 51.9% patients), followed by fentanyl (50.8%) and codeine combinations (20.0%). The median daily dose of fentanyl was 12.0 μg/hr (range, 10.0–75.0 μg/hr), while the median daily doses of oxycodone PR and IR were 20.0 mg (range, 5.0–200.0 mg) and 10.0 mg (range, 5.0–60.0 mg), respectively. The median daily dose of codeine combinations was 30.0 mg (range, 10.0–80.0 mg). The patients in this study had received relatively low-dose opioid prescriptions according to the recommendations of the Korean Ministry of Health and Welfare's 2012 Cancer Pain Treatment Guideline [17]. The median treatment duration of fentanyl, oxycodone PR, and codeine combinations was 67, 120, and 46 days, respectively.
4. Opioid treatment outcomes and relationships with pain type and treatment duration

Achievement of pain relief with opioid treatment was significantly related to the type of pain. The proportion of patients experiencing pain relief differed across the three types of pain, and the difference was significant ($p<0.0001$) (Table 3). The proportion of patients who experienced pain relief was highest in the group with nociceptive pain alone (63.3%), followed by that with neuropathic pain alone (56.5%) and that with mixed-type pain (47.0%) (Table 3).

Moreover, achievement of pain relief was significantly related to opioid treatment duration (<1 month, 1–2 months, and ≥2 months); statistically significant differences were noted across all three treatment duration categories ($p=0.0013$) (Table 4). In comparison with shorter treatment durations, treatment duration of ≥2 months resulted in a greater proportion of patients experiencing pain relief (Table 4).

5. Concomitant treatment for spinal pain management

Of the 2,468 patients, 1,467 (59.4%) patients received concomitant treatment with surgery, physical therapy, or nonsurgical interventions for pain control in addition to opioid therapy. Concomitant analgesics were prescribed in 1,513 (61.3%) patients. The most frequently prescribed concomitant drug was tramadol in 779 (31.6%) patients, followed by NSAIDs in 685 (27.8%) patients and anticon-
vulsants in 389 (15.8%) patients (Table 5).

6. Investigator survey results

Investigators’ perceptions regarding opioid treatment for spinal disorders are presented in Table 6. In total, 75 investigators and subinvestigators responded to the survey. Of these respondents, 30 (40.0%) had expertise in orthopedics, 25 (33.3%) in neurosurgery, 18 (24.0%) in anesthesiology and pain medicine, and 2 (2.7%) in rehabilitation medicine.

Among these, 72 (96.0%) respondents perceived “excellent analgesic effect” as the primary advantage of opioid analgesics in outpatient clinics; 50 (66.7%) investigators responded that “concern for early side effects” was a disadvantage of opioid analgesics. “Long-term safety concerns including drug dependence” were chosen by 34 (45.3%) respondents, and 60 (80.0%) investigators had experienced patients with opioid dependence; however, most (81.7%) investigators answered that true cases of
drug dependence were rarely observed.

For improved use of opioid analgesics, a majority of investigators suggested solutions such as “development of drugs with fewer side effects and easier titration” (76.0%) and “guidelines and clinical data applicable to the Korean population” (70.7%).

7. Adverse drug reactions

Of the 2,468 patients eligible for analysis, 211 patients (of 2,468 [8.6%] patients, 259 cases) experienced ADRs wherein opioid analgesic-related causality could not be ruled out. ADR severity was mild in 49.7% (157/259) cases, moderate in 21.2% (67/259) cases, and severe in 11.1% (35/259) cases. The three most frequently reported ADRs were vomiting, constipation, and dizziness (Table 7).

Discussion

This study aimed to provide an original integrated set of

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**Table 6. Investigators’ perceptions and suggestions regarding opioid analgesic use in Korea (n=75)**

| Category (details)                                                                 | No. (%) |
|-----------------------------------------------------------------------------------|---------|
| Perceived advantages of opioid analgesic prescription in outpatient clinics       |         |
| Excellent analgesic effect                                                        | 72 (96.0) |
| Useful for controlling persistent pain following surgery                          | 42 (56.0) |
| Useful for patients in whom surgery is prohibitively difficult                    | 36 (48.0) |
| Useful as a conservative preoperative treatment                                    | 20 (26.7) |
| Others                                                                            | 1 (1.3)  |
| Perceived drawbacks of opioid analgesic prescription in outpatient clinics        |         |
| Concerns for early side effects                                                   | 50 (66.7) |
| Long-term safety concerns, including drug dependence                             | 34 (45.3) |
| Ongoing side effect concerns                                                      | 33 (44.0) |
| Short reimbursement period                                                         | 21 (28.0) |
| Complex administrative processes including issuance of opioid prescription        | 19 (25.3) |
| Burdensome procedure required for explanation to patients                         | 18 (24.0) |
| Others                                                                            | 2 (2.7)  |
| Suggestions for better opioid analgesic use                                      |         |
| Development of drugs with fewer side effects and easier titration                 | 57 (76.0) |
| Development of guidelines and better clinical data applicable to Koreans         | 53 (70.7) |
| Better administrative conditions including reimbursement and regulations          | 38 (50.7) |
| Meetings for idea exchange and education regarding analgesic use                 | 28 (37.3) |
| Others                                                                            | 1 (1.3)  |

*Respondents comprised 75 principal investigators and sub-investigators participating in this study. Areas of expertise include Orthopaedics, Neurosurgery, Anaesthesiology and Pain Medicine, and Rehabilitation Medicine.

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**Table 7. Incidence of adverse drug reactions (n=2,468)**

| Adverse drug reaction (ADR) | No. (%) |
|-----------------------------|---------|
| Total number of patients with ADRs | 211 (8.6) |
| Vomiting                    | 85 (3.4) |
| Constipation                | 64 (2.6) |
| Dizziness                   | 30 (1.2) |
| Somnolence                  | 15 (0.6) |
| Pruritus                    | 12 (0.5) |
| Gastrointestinal disorder   | 7 (0.3)  |
| Dyspepsia                   | 5 (0.2)  |
| Abdominal discomfort        | 3 (0.1)  |
| Headache                    | 3 (0.1)  |
| Decreased appetite          | 3 (0.1)  |

*ADRs considered as possibly related to the administration of opioid analgesics are shown in the table above. Multiple ADRs could be recorded for individual patients. Only the 10 most frequently reported ADRs are listed.*
data on the issue of opioid treatment practice for spinal pain in Korea. Through a nationwide investigation to observe treatment patterns across the country, this study achieved its primary goals with a large cohort of 2468 patients.

The management of spinal pain requires active treatment plans and implementation. Recommended treatment modalities for spinal pain management can be classified into four categories: interventional pain therapies, complex medication (including opioids and neuropathic pain medications), high-intensity cognitive behavioral therapy-based programs, and spinal surgery [18]. Despite various treatment modalities, there has been very limited systematic research to guide and improve the use of opioid analgesics for managing spinal disorder-associated pain. This may be a reason for conservative opioid prescription practices. For example, an observational study that examined opioid use for spinal and radicular pain in 25,479 patients revealed that only 3.4% (867) patients were treated with opioids [6].

In a manual guiding the use of opioids for persistent pain, the British Pain Society (BPS) recommends strict restrictions on the use of strong opioids [19]. The guidelines state that (1) opioids should not be used as a first-line treatment, (2) patients should be adequately informed about the long-term effects of opioids, including the possibility of adverse events, (3) mental health history should be recorded before treatment to aid exclusion of patients with depression or substance misuse disorders, and (4) whenever possible, modified-release opioid formulations at regular intervals should be used. In addition, the BPS guidelines for low back pain recommend that the lowest dose possible should be used for the shortest time possible [18,19]. Other recent guidelines and physician resources for opioid prescription, such as guidelines from the Centers for Disease Control and Prevention and the UK Royal College of Anaesthetists, state that opioids are not effective for long-term use [20,21].

Our results indicate that the current prescribing practice in Korea is generally in alignment with the BPS guidelines in terms of opioid dosage. Most cases in our study were prescribed daily doses of opioids that were in the lowest range recommended in the Korean Ministry of Health and Welfare’s Cancer Pain Treatment Guidelines [17]; however, our data also revealed that 50% of patients had received opioid analgesics for >3 months, which may be attributed to the lack of adequate treatment options for chronic pain.

This study indicates that opioid analgesics are a more appropriate treatment option for nociceptive pain than for neuropathic or mixed-type pain. In general, opioids are known to be excellent pain relievers, particularly for nociceptive pain. In addition, higher opioid doses are needed more often for treatment of neuropathic pain than for nociceptive pain [22]. Therefore, the results from this study are in agreement with the existing knowledge; however, we note that our observations regarding the type of pain could be alternatively interpreted, that is, patients with neuropathic or mixed-type pain may generally not have had the opportunity to receive more optimal treatment with opioids or concomitant adjuvants to reach adequate levels of pain control.

To the best of our knowledge, there are no local reports dedicated to physician surveys investigating opioid usage for managing spinal pain. The results of our investigators’ survey suggest that Korean physicians adequately understand the efficacy parameters of opioid usage; however, they are concerned regarding the safety issues such as addiction although the ADRs from opioid usage in this study were limited to 8.6%, and there were no reports of actual addiction. These concerns may contribute to the modest opioid usage index in Korea, which is still below 50% [22]. Although the guidelines for use of opioids in cancer pain management are relatively well established [17] and adopted in clinical practice in Korea, use of opioids for noncancer pain treatment (including spinal disorders) is estimated to be much lower. As indicated by the investigators’ survey responses, there is need for more local clinical data and development of improved guidelines for use of opioids to treat spinal pain in Korea.

The NRS is a well-validated and preferred unidimensional self-report tool for pain assessment [23,24]; thus, it should be used more widely in clinical settings. Nevertheless, in this study, NRS pain assessments were only recorded for 24.0% of the 2,468 patients. Because the suitability of pain alleviation by opioid therapy cannot be fully supported or rejected unless appropriate, standardized methods for pain measurement are applied [5,13,15,16,25-27]. Our data imply that additional education is needed on regular assessment and documentation of pain in clinical practice.

We note several limitations inherent to the nature of the study. First, we only assessed patients who received opioid treatment for spinal disorders and did not examine the
entire spinal disorder population. Thus, it is difficult to analyze global factors that affect clinical decisions related to spinal pain management, for example, the data collected do not permit us to explain how clinical decisions were made on whether to prescribe opioid analgesics or to choose other treatment modalities. Second, certain patients were receiving ongoing opioid treatment at the time of data collection and had not yet completed the full treatment course. For such patients, data for the entire treatment duration and ultimate outcomes of opioid treatment were not available at the point of data collection. Third, reporting of adverse events or ADRs may have been incomplete owing to the retrospective nature of the study.

**Conclusions**

To the best of our knowledge, this is the first large-scale report on patterns of opioid treatment in 2468 patients with spinal disorders in university hospitals across Korea. The findings demonstrated an overall alignment of current practices in Korea with international guidelines for opioid-based management of spinal pain. In particular, the results may be a valuable local source of preliminary data for treatment guidelines on spinal disorders in Korea. The findings underscore the importance of objective measurements and appropriate documentation of pain to guide opioid usage for management of spinal pain in Korea.

**Conflict of Interest**

Hye-Jeong Park is an employee of Mundipharma Korea Ltd. All other authors have no relevant conflicts of interest to declare.

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