



Prescribing patterns of the four most commonly used sedatives in endoscopic examination in Korea: Propofol, midazolam, diazepam, and lorazepam



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ABSTRACT

As the sedative use increases due to the effectiveness and relatively safe profile, the abuse potential is also increasing. This study was conducted to examine the usage of four sedative agents in endoscopic examination and to compare the propofol use with the other three sedatives. Using National Health Insurance claims data from 2008 to 2012, we identified the number of cases of conscious sedation during endoscopy using one or more of the following agents: propofol, midazolam, diazepam, and lorazepam. The general characteristics of patients and medical service providers were analyzed, and the regional and annual distributions of frequency of use were compared. We also identified patient cases with excessive number of endoscopic examinations. Among the total of 3,156,231 sedatives users, midazolam was the most commonly used agent ($n = 2,845,250$, 90.1%). However, the largest increase in patient number, which increased from 11,410 in 2008 to 28,170 in 2012, was observed with propofol. While the majority of patients received an annual endoscopy, we identified several suspected abuse cases of patients receiving endoscopies repetitively as many as 114 times in five years. The rise of sedative use in endoscopic examinations and several patient cases of repeated sedative administration suggest a potential risk for abuse. Medical service providers should be cautious when using sedatives and carefully review each patient's medical history prior to the procedure.

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1. Introduction

Recently, conscious sedation has been widely utilized to reduce patients' anxiety and pain during endoscopic examination. It is well known that both patients and physicians generally prefer sedated over unsedated endoscopy (Brandt, 2001). According to a survey conducted in the United States, the interest in propofol use for endoscopy is growing rapidly (Faulx et al., 2005). Liu showed that the proportion of sedated endoscopic procedures has more than doubled, from approximately 14% in 2003 to 30% in 2009 (Liu et al., 2012). In another study, the percentage of sedated endoscopy was expected to increase by 53% in 2015 (Inadomi et al., 2010).

Generally, periodic surveillance endoscopy is recommended for various conditions and risk factors, varying from every

three months to every 2–3 years (Hirota et al., 2006). For example, in Korea, the National Cancer Screening Program provides biannual gastrointestinal (GI) endoscopy for cancer screening (National Cancer Information Center). Propofol (2,6-diisopropylphenol) is an intravenously administered sedative that was first introduced to clinical practice in 1989. Recently, many clinical trials demonstrated intravenous sedation with propofol to be more effective than sedation with other sedative agents (Koshy et al., 2000; Carlsson and Grattidge, 1995; Seifert et al., 2000). With its rapid onset of action and recovery time and good quality of recovery after sedation (Vargo, 2004; Riphhaus et al., 2006), propofol is widely used for induction and maintenance of sedation in endoscopy.

However, since the first report of propofol abuse in 1992 (Follette and Farley, 1992), several other reports have been published that expand on propofol's potential for abuse using molecular and clinical evidence (Pain et al., 2002; Weerts et al., 1999; Zacny et al., 1993). Recently, abuse and misuse of propofol has been a social problem in Korea, particularly when used in endoscopy. Roh et al. described a patient who visited a number

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of endoscopists with the sole aim of receiving propofol until he was admitted to a closed psychiatric facility for treatment of his propofol addiction (Roh et al., 2011). Kim et al. examined the degree of abuse liability among those of the general population who had gastric endoscopic examination and used propofol as a sedative (Kim et al., 2013). Not only is there the potential for dependence on the drug and serious accompanying social problems, but its overuse can easily lead to death caused by respiratory suppression.

In this study, we investigated the usage of four commonly used sedatives in endoscopic examination, including propofol, midazolam, diazepam, and lorazepam, using the Korean National Health Insurance claims database. By comparing the prescribing patterns of the four drugs, we examined if the extent of propofol use changed over the study period more than the other three sedatives.

2. Methods

2.1. Data source

We analyzed National Health Insurance claims data retrieved from the Health Insurance Review and Assessment Service (HIRA). In Korea, the National Health Insurance system provides coverage to the entire Korean population. All medical services provided to a beneficiary must be reported to HIRA by the medical service provider, which are then reviewed for reimbursement of the expenses. Therefore, the HIRA database contains all information on claims submitted, including medical services and prescribed medications. The database contains anonymized patient identifiers, demographics, including age and gender, medical diagnoses (according to the International Classification of Disease, Tenth Revision (ICD-10)), dispensed medications (drug code, date dispensed and number of doses supplied), medical procedures performed, and details of medical service providers (identifier, type and region). The database was retrieved from HIRA with de-identified codes that enabled sorting and linking only for research purposes.

2.2. Study subjects

We included subjects who received sedated endoscopy with one of the following intravenous sedatives from 2008 to 2012: propofol, midazolam, diazepam, or lorazepam. Patients who were aged 12 years and younger, cases of sedation during surgery, and sedation for inpatients were excluded. Sedation performed for inpatients in the operating room involves a more complicated rationale for use that requires a clinical review, which was not appropriate for our analysis. Endoscopy was defined by procedure codes, which were confirmed by a practitioner. An endoscopy patient was defined as a patient who received sedation at least once for a non-operative outpatient endoscopy with propofol, midazolam, diazepam, or lorazepam. In cases of a patient receiving two or more sedatives per procedure or having more than one procedure performed during the study period, each sedative received by the patient was counted.

2.3. Gender, age and type of medical service provider

Descriptive statistics, including frequencies, proportions, and means (\pm SD), were used to characterize study subjects by gender and age. We categorized age into groups of ten years (i.e., 13–19, 20–29, 30–39, 40–49, 50–59, 60–69, 70–79, and \geq 80). The type of medical service provider was analyzed by frequency and proportion and was categorized into three groups according to the level of medical care: tertiary hospitals, secondary hospitals, and primary care clinics. The escalating levels of care indicate the degree of size

and specialty. Primary care clinics generally provide basic health services, which are the most accessible to the patients. Based on the condition, the patient who initially visited a primary care clinic may be referred to a specialist in secondary hospitals for a higher level of care. Tertiary hospitals provide the most advanced care for patients who were referred from a primary or secondary healthcare professional. In general, the bed capacities in primary, secondary, and tertiary hospitals are a minimum of 30, 100, and 500 respectively.

2.4. Trends of sedative use over time and regional distribution

We presented the total number of patients from 2008 to 2012 receiving each sedative to show the changes in yearly usage. We also indicated the frequencies and proportions by visit year. The regions were categorized into three groups, metropolitan area, major city, and rural area, according to the number of population. The metropolitan area included Seoul, the capital city of Korea, Gyeonggi, and Incheon. The major cities included Busan, Daegu, Gwangju, Daejeon, and Ulsan. The rural area was the rest of regions, which included Gangwon, Chungcheong, Jeolla, Gyeongang, and Jeju. The proportion of sedative use for each region was calculated for propofol and midazolam, which was shown in maps.

2.5. Distributions of visit frequency of endoscopy and cases of suspected abuse patients

For each sedative, the frequency of sedated endoscopy per patient was calculated. The number of patients for different visit frequencies are calculated and presented by year from 2008 to 2012. And we identified suspected abuse patients who received sedation endoscopies with sedatives repeatedly during study period. Then we showed the safety profile of several cases about the general characteristics of patients and medical service providers in sequence of date of visit.

2.6. Statistical analysis

Categorical variables, including gender and categorized age, are presented as numbers and percentages. Means and standard deviations (SD) of age were also calculated. The regional distribution and frequency of receiving endoscopies were visualized by Quantum Geographic Information Systems (QGIS) (OSGeo, Beaverton, OR, USA). This geographic software effectively presents the nationwide drug use pattern. *P*-values were calculated by the chi-squared test for discrete variables, and *P*-values of less than 0.05 were considered to be statistically significant for all analyses. All statistical analyses were performed using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA).

2.7. Ethics statement

The study protocol was approved by the Institutional Review Board of the Korea Institute of Drug Safety and Risk Management. The requirement for informed consent from the study population was waived by the board.

3. Results

The total number of upper gastrointestinal endoscopic procedures in each year during the study period is shown in Fig. 1. This number increased from 3,723,460 in 2008 to 4,234,539 in 2010, and decreased to 3,940,443 in 2012. Despite the decrease in the number of endoscopies from 2010 to 2012, there was a sharp

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