# 学位論文の要旨

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学 位 論 文 名 Factors and Impact of Physicians' Diagnostic Errors in Malpractice
Claims in Japan

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# 論文内容の要旨

# **INTRODUCTION**

According to the landmark report titled Improving Diagnosis in Health Care, cases of diagnostic errors are common, but it is difficult to measure them; thus, they are frequently overlooked. Several studies have revealed a substantial incidence and economic burden associated with diagnostic error. One study estimated the outpatient diagnostic error rate in the US as 5.08%, which translates to approximately 12 million adults per year. Another study estimated that 40,000 to 80,000 patient deaths that occur each year in the US are due to diagnostic errors.

Diagnostic errors can be studied using several means, including data from: 1) malpractice claims, 2) autopsies, 3) questionnaire surveys, 4) case reviews, 5) hospital incident reports, 6) patient surveys, and 7) secondary reviews. Diagnostic errors are a common reason for malpractice claims, and claims data could provide vital information from patients' viewpoints. For instance, Tokuda and colleagues summarized the findings from 274 malpractice claims filed at two local district courts in Tokyo and Osaka, and found that cognitive errors were the most common errors associated with these medical claims. However, little is known regarding diagnostic error-related malpractice claims at the national level in Japan. Thus, the objective of the present study was to better characterize the negative impact of diagnostic errors reported in malpractice claims, including the magnitude of indemnity payment and severity of patient outcomes. An additional objective was to compare these effects and the underlying factors of physicians' diagnostic errors between diagnostic error-related claims (DERC) and non-diagnostic error-related claims (non-DERC). Certain background factors, such as clinical specialty or work settings, would be more likely related to DERC cases. Finally, we explored the most frequent initial diagnoses in cases of

#### **MATERIALS AND METHODS**

We conducted a retrospective review of claims data related to medical malpractice cases closed between 1961 and 2017 from the largest database in Japan (Westlaw Japan K.K.), a publicuse data file that includes 223,218 Japanese lawsuit cases. This database was used to identify the reported claims, outcomes, and payments for closed claims. While the malpractice claims were anonymous, we were able to extract detailed medical information for each case. All claims cases were merged into a single tabular list (3,430 cases). Before extracting the data, the primary investigator and a senior medical student who was also a qualified lawyer set the exclusion criteria: duplications of cases, intentional crimes, robbery, money troubles, and veterinary claims. We excluded 751 cases that were duplicates, 707 cases based on the other exclusion criteria, 34 cases that constituted an "unfair suit," and 136 cases with a non-physician defendant (nurse = 51 cases, paramedic = 47 cases, "other" = 36 cases). This left us with 1,802 cases to analyze. All of the targeted cases were labeled as DERC or non-DERC by the three co-investigators and confirmed by the primary investigator. Ethical approval was not required, as this study did not involve human subjects or any Ethical approval was not required, as this study did not involve human subjects and any personally identifiable information.

# **RESULTS AND DISCUSSION**

All 1,802 malpractice claims were included in the analysis. The median patient age was 33 years (interquartile range = 10-54), and 54.2% were men. Deaths were the most common outcome of claims (939/1747; 53.8%). In total, 709 (39.3%, 95% CI: 37.0%-41.6%) DERC cases were observed. The adjusted total billing amount, acceptance rate, adjusted median claims payments, and proportion of deaths were significantly higher in DERC than non-DERC cases. Departments of internal medicine and surgery were 1.42 and 1.55 times more likely, respectively, to have DERC cases than others. Claims involving the emergency room (adjusted odds ratio [OR] = 5.88) and outpatient office (adjusted OR = 2.87) were more likely to be DERC than other cases. The initial diagnoses most likely to lead to diagnostic error were upper respiratory tract infection, nonbleeding digestive tract disease, and "no abnormality." Our results, based on 1,802 malpractice claims over a 56-year period in Japan, showed that about 40% of the claims involved allegations of a diagnostic error, that the most frequent outcome was death, and that the magnitude of indemnity payment was variable but its median value was expensive. The initial diagnoses most commonly associated with allegations of diagnostic errors in malpractice claims were upper respiratory tract infection (mainly the common cold), non-bleeding digestive tract disease (mainly gastroenteritis), and "no abnormality." Thus, it is important to improve diagnostic skills to

differentiate between life-threatening conditions and an innocuous upper respiratory tract infection or common gastrointestinal disease. Although several studies have examined final diagnoses involving malpractice claims within each clinical specialty, few have examined initial inaccurate diagnoses that were later identified as incorrect diagnoses. Our results from comparisons between DERC and non-DERC cases were similar to those from a study by Gupta et al. indicating that DERC cases are more likely to be associated with death and greater compensation costs, although in other claims studies that focused on errors in limited settings such as emergency department, pediatrics, and inpatient-outpatient settings in the US, death was reported less frequently (36%, 28.2%, and 30.4%, respectively). In a 25-year summary of DERC malpractice cases in the US, death was the most common outcome. To the best of our knowledge, however, this is the first study investigating diagnostic error-related malpractice claims in Japan, and it utilized the largest internet claims database available. Despite these limitations, the present database remains the most complete source of malpractice data available in the past half century in Japan. Further research on diagnostic errors is needed to better understand the mechanisms underlying diagnostic failures and translate this knowledge into clinical education and patient safety policies.

# **CONCLUSION**

In our study, diagnostic errors were a common allegation in malpractice claims and tended to involve allegations of relatively severe patient outcomes compared to other types of malpractice claims. They were also associated with more final court judgments in favor of the claimants, and increased indemnity amounts. To reduce the risk of diagnostic errors, physicians should take care when making diagnoses for potentially serious conditions during general examinations or emergency department visits. A better understanding of malpractice claims might help reduce both patient harm and risk related to physicians' liability.