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**Legal Defensiveness-Induced Life-Sustaining Treatment:
Results of a Natural Experiment**

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Legal Defensiveness-Induced Life-Sustaining Treatment:

Results of a Natural Experiment

A dissertation submitted to
the Department of Public Health, Yonsei University
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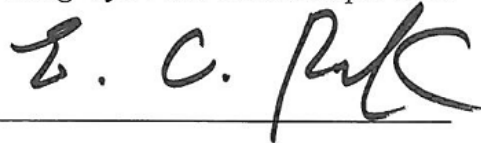
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“All citizens shall be assured of human worth and dignity and have the right to pursue happiness. It shall be the duty of the State to confirm and guarantee the fundamental and inviolable human rights of individuals.”

- Article 10 of the Constitution of the Republic of Korea

It is 20 years since I entered medical school to become a doctor full of love for human beings. After realizing that understanding human beings was not enough to become an excellent doctor, I entered law school and became a lawyer to study society. I realized that the path to learning is endless and I could not be a good doctor without a deep understanding of health policy. I had the good fortune to meet great mentors who showed me the right path to study public health as a whole.

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Abstract

Legal Defensiveness-Induced Life-Sustaining Treatment: Results of a Natural Experiment

Background: Although great attention has been paid to futile life-sustaining treatment (LST), little is known as to whether decreasing a physician's legal defensiveness could decrease LST. Focusing on the legally defensive attitude toward forgoing LST, whether a decrease in a physician's legal defensiveness could decrease the use of legally high-risk LST was examined through quasi-experimental quantitative analyses under the natural experimental circumstances brought about by two landmark court decisions.

Materials and Methods: After reviewing previous studies regarding defensiveness medicine and legal defensiveness, a conceptual framework for a legal defensiveness model was developed for this study and from the model, the study design for quantitative analyses was drawn. This study used the National Health Insurance Service Elderly Cohort (NHIS-NSEC) which consisted of 588,147 Korean participants older than 60 years in 2002. From the NHIS-NSEC, 73,096 decedents who died during 2003–2013 owing to cancer, circulatory, or respiratory diseases were selected as study subjects. Time series were constructed by time units of a quarter from 2003 to 2013 and divided into periods of

increasing, conflicting, and relieving periods according to the level of physicians' legal defensiveness toward forgoing LST. Within the time series, trends and changes in legally high-risk (physician-driven) LST including cardiopulmonary resuscitation (CPR) and mechanical ventilation (MV) provided during the last 30 days of life were measured and compared between three periods by interrupted time series with segmented regression. Admission to hospitals and per capita hospital days were used as control outcomes (patient-driven) for comparison. Annual increasing rate (AIR) of outcomes during each period and ratio of AIR and outcome level along with 95% confidence intervals were estimated with a generalized linear model with a Poisson distribution and robust standard error.

Results: During the study period, CPR and MV were administered to 7,809 (11.1%) and 11,863 (16.8%) decedents, respectively, during their last 30 days of life. The risk of receiving CPR during the last 30 days of life increased 11.9% per year (AIR 1.119, 95% CI 1.082–1.158), decreased 6.1% per year (AIR 0.939, 95% CI 0.899–0.981), and maintained the same level (RR 1.009, 95% CI 0.982–1.038) during the periods of increasing, conflicting, and relieving legal defensiveness, respectively. The risk of receiving MV during the last 30 days of life increased 8.3% per year (AIR 1.083, 95% CI 1.055–1.112) during the increasing period of legal defensiveness, then maintained the same level during the conflicting (AIR 1.017, 95% CI 0.982–1.053) and relieving (AIR 1.000, 95% CI 0.978–1.022) periods of

legal defensiveness. In contrast, although AIRs during the conflicting and relieving period were lower than the AIR of the increasing period, the risks of admission to hospitals (12.3%, 3.6%, and 1.1% per year) and per capita hospital days (20.5%, 4.9%, and 2.3% per year) increased during all three periods.

Conclusion: This study provides evidence that physicians' legal defensiveness toward forgoing LST contributes to administering LST and if a physician's legal defensiveness can be decreased then defensive LST can also be decreased. However, considerable legal defensiveness still remains and the level of LST needs to be decreased further. Policies that can reduce physician's legal instabilities should be implemented to reduce defensive LST.

Key words: Life-sustaining treatment, Death with dignity, Euthanasia, Legal instability, Legal defensiveness

I. Introduction

1. Study Background

In February 3, 2016, the Hospice-Palliative Care and Decision on Life-sustaining Treatment Care of Dying Patients Act (hereinafter referred to as “the LST Act”) was enacted and its enforcement begins on August 4, 2017¹. The LST Act permits the removal of only extraordinary treatments such as CPR (cardiopulmonary resuscitation), MV (mechanical ventilation), hemodialysis, and chemotherapeutic treatment and applies only to patients expected to die soon. However, it has significant implications for physicians as well as the general public in that the LST Act is the first legislation about the legality of forgoing life-sustaining treatment (LST) in South Korea. However, because the LST Act does not describe how to determine the legality of discontinuing LST when a patient has not reached the irrecoverable and imminent death stage, the right to refuse unwanted treatment is not guaranteed sufficiently.

Before the LST Act, there was no specific law governing forgoing LST in South Korea and hence there has been considerable uncertainty concerning the permission of removal of life-sustaining devices and punishments for such acts²⁻⁴. In the meantime, two landmark judicial judgments regarding removal of MV from incompetent patients affected physicians’ attitudes toward forgoing LST. The LST Act was enacted under the influence of judicial judgment and associated public debate.

This situation is very similar to the process of the enactment of the Patient Self Determination Act in the USA.^{2,4} Physicians' paternalistic decision-making changed considerably following the 1976 groundbreaking case of Karen Ann Quinlan, when the New Jersey Supreme Court announced that a patient's guardian had the right to refuse unwanted LST even if doing so resulted in death^{5,6}. In the 1990 Nancy Cruzan case, the USA Supreme Court declared a patient's comprehensive right to refuse unwanted treatments including LST^{5,6}. Following the Nancy Cruzan case, the Patient Self Determination Act was passed in 1990 to protect a patient's right to refuse unwanted LST⁷.

Although higher spending in the last year of life might not improve quality of end-of-life care⁸, the intensity of end-of-life care has been high and increasing worldwide⁹⁻¹³. Many researchers have reported the aggressiveness of end-of-life care in western countries and South Korea^{9-11,13-18}. However, there are substantial discrepancies between patient's desires and clinical practice. People do not want LST but physicians perform LST. A study of 3,840 Korean individuals showed that most of the general public and physicians supported withdrawal of futile life-sustaining treatment (87.1%–94.0%) and the use of active pain control (89.0%–98.4%). A slightly smaller majority (60.8%–76.0%) supported withholding life-sustaining treatment¹⁹.

In 2007, Korean dying patients in the ICU received LST including CPR (19.0–30.9%) and MV (42.9–61.5%)²⁰ during their last 30 days of life. In western countries, many dying patients utilize medical services within the last 30 days of life, including hospitalization in acute care hospitals (44.8–62.6%) and ICU

admission (3.5–27.2%)¹⁸.

It is not a general phenomenon that people determine their way of death and express their wishes about that decision. Advance directives or POLST (physician order for life-sustaining treatment) have not been satisfactorily used in western countries where the right to self-determine whether to receive LST was recognized socially several decades ago^{21,22}. Several surveys done in previous studies showed completion rates of advance directives are only around 30%^{23,24}. Although advance directives could decrease medically futile LST, it is hard to expect patients to provide such advance directives in South Korea²⁵. In the absence of advance directives, physicians usually have no choice but to administer LST such as CPR and MV during medically urgent states. Among many reasons for providing LST, physicians' fear of legal liability stemming from legal uncertainty might play a pivotal role in South Korea.

In spite of the importance of physician's legal defensiveness toward forgoing LST, there is limited literature investigating whether LST-related decisions of physicians could be affected by perceived legal defensiveness. Furthermore, the few quantitative analyses using nationally representative administrative claims data were conducted in mainly western countries. Therefore, there is little evidence of whether physician's legal defensiveness could affect LST-related decisions in East Asian countries.

2. Study Objectives

Under the peculiar legal circumstances regarding LST in South Korea, this study investigated physicians' defensive attitude toward forgoing LST through quantitative analyses measuring specific procedures or medical utilizations. This study takes the attitude that a patient has the right of self-determination to refuse medically futile LST based on human dignity and the right to pursue happiness as a human being under Article 10 of the Constitution²⁶. Just as physician-assisted suicide is illegal in most states in the USA²⁷, the right to die actively is not currently legal in South Korea in 2016²⁸. Even if a dying patient has the constitutional right to refuse LST and the result of refusal is death, the right to refuse LST and the right to die are not synonyms²⁹. The Korean Supreme Court and the LST Act did not say anything about the right to die just as in the Quinlan and the Cruzan cases^{28,29}. Forgoing LST in this study is limited to the exercise of the right to refuse unwanted treatments.

Therefore, the principal purpose of this study was to investigate whether physician's legal defensiveness could affect LST-related decisions. To achieve the principal purpose, trends of legally high-risk outcomes and control outcomes were measured and compared between periods of physicians' legal defensiveness. Additionally, a detailed analysis of data was performed to present descriptions of the level of LSTs in time series divided by periods of legal defensiveness. Focusing on the physician's legal defensiveness toward forgoing LST, specific hypotheses were examined:

First, LSTs would decrease if physicians' legal defensiveness was decreased.

Second, physician-driven legally high-risk LSTs could be decreased earlier than patient-driven medical utilization.

II . Theoretical Background

1. Two Landmark Court Decisions regarding LST

In the absence of a specific law to govern LST directly in South Korea, criminal law that punishes murder and murder upon request could be applied to physicians who terminate LST after a family's request³. Until 1998, there had been no judicial precedence that ruled whether withdrawal or withholding of LST was legal or illegal. However, Korean medical society has perceived that physicians in South Korea perform clinical practice in a context of legal ambiguity and under the fear of prosecution, even if what they do what is considered routine practice in many other countries worldwide³. Meanwhile, there were two important legal cases related to the legality of forgoing LST. One was a criminal case and the other was a civil case. Although the underlying facts and legal judgment were different from each other, withdrawing MV from incompetent patients at the request of family members was the starting point of both cases. In addition, the impact of the rulings on medical and legal community was so powerful that physicians and lawyers are quite familiar with them^{30,31}. The following describes the two cases, focusing on facts related to the doctor's legal uncertainty.

(1) The Boramae Hospital case

On December 4, 1997, a 58-year-old man developed an epidural hemorrhage in his house after falling while drunk. Admitted to the Boramae hospital, he was

transferred to the ICU after surgery. Because his spontaneous respiration was insufficient, he depended on MV. The next day, the patient, who had no response after surgery, returned to positive light reflex, Glasgow Coma Scale E3 and M5.

The wife insisted several times on the discharge of the patient for economic reasons, as there were ongoing medical costs for continued treatment. In addition, the patient was an unemployed alcohol abuser and perpetrator of family violence. The physicians tried to persuade the wife to not discharge the patient because of the possibility that he would die. Furthermore, they recommended she seek a safe refuge until the state of the patient could be stabilized. Because she did not accept this recommendation and persisted discharge of the patient, the physician in charge decided to permit discharge. Two days after the surgery, the patient was discharged to home and intubation tube was removed. The patient died within five minutes after removal of the intubation tube. On May 15, 1998, a lower court sentenced two physicians with murder³². In February 7, 2002, the Seoul High Court, an appellate court, sentenced them with aiding and abetting murder³³. In June 24, 2004, the Korean Supreme Court concluded that the doctors' action that allowed the patient to be discharged from hospital led to the patient's death and rejected a final appeal and the decision of the Seoul High Court was upheld³⁴. The physicians were declared murderers by the court.

The impact of this case was so great that even before the Supreme Court ruling came out, legal research papers were published based on the lower courts' decisions³⁵⁻³⁷. A well-known criminal law professor pointed out that the reaction of the medical community to the ruling was at the level of astonishment and they

expressed a reluctance to describe the physician's actions as murder³⁸.

In a survey study done in 1998, 100% of physicians were aware of the Boramae hospital case, and 98% of them considered the ruling to be unfair³⁰. The medical profession's emphasis on the unfairness of the decision by pointing out the reality of the clinical setting was ignored³¹. In particular, physicians raised questions about the basis of the fact-finding by the court, especially the possibility of the patient's recovery, which was the critical issue of the case³¹.

Before the Boramae Hospital Case, the topic of end-of-life medical decisions had been rarely discussed in Korea. However, after the Boramae Hospital Case in 1997, the issues surrounding end-of-life medical decisions have received the keen interest of the general public³.

This legal case was not a case of withdrawal of LST but rather a case of discharge against medical advice (DAMA)^{39,40}. The patient's surrogate decision maker, his wife, did not have any intention to act in his best interest⁴. There was no mention of the patient's explicit or presumptive willingness to forgoing LST. Before this case, physicians had often performed the withdrawal of futile LST for terminally ill patients and allowed for hopeless discharge^{31,40,41}. However, after this verdict, the majority of Korean medical society somewhat misunderstood that this case was about euthanasia or a hopeless discharge, which has been routinely done before^{3,30,42}.

After this judgment, medical professionals have generally interpreted that not only DAMA but also withdrawal of life-sustaining treatments for a terminally ill patient could be regarded as homicide^{2,3,40}. The Boramae Hospital case made

physicians worry about being convicted of murder⁴. Since then, they have taken a defensive attitude towards treating terminally ill patients and they have displayed a tendency to continue futile, often excessive, treatments⁴¹. Physicians have kept their patients alive for a long time even though they knew that medical treatments for their patients were futile and useless³.

(2) The Grandma Kim case

In February 16, 2008, while undergoing an endoscopic lung examination for pneumonia at Severance Hospital in Seoul, a 76-year-old patient, Grandma Kim, sustained massive hemorrhage and hypoxic brain damage, leaving her in a persistent vegetative state and dependent on a MV². In the absence of advance directives, the family members applied a provisional disposition on March 5, 2008 and filed a lawsuit on June 2, 2008. The family members wanted to not provide any medical treatment for her, including MV, medication, nutrition, hydration, and CPR⁴². During the trial, the plaintiff accepted the court's proposal to limiting the claims to not providing MV⁴². During the trial, several doctors testified that Ms. Kim had no reasonable chance of recovering from her vegetative state. The patient's children testified that their mother had always opposed keeping people alive when there was no hope of recovery. In November 28, 2008, the Seoul West District Court concluded that there was no hope for recovery and her inferred intention not to receive LST was assumed, and ruled that removing the MV was allowed⁴³. This was the first court judgment that allowed the withdrawal of LST.

In February 10, 2009, the Seoul High Court upheld the decision of the trial court⁴⁴.

In May 22, 2009, the Korean Supreme Court upheld the appellate court ruling²⁶.

As the first court decision regarding legal and bioethical issues relevant to LST in South Korea, there are several meaningful points to discuss^{2,4}. For the first time, the Supreme Court declared a constitutional right to refuse LST and provided requirements for withdrawal of LST. The Supreme Court said “LSTs carried out in cases where a patient has no medical possibility of recovering consciousness, has lost critical biological function, or has only a short time to live (hereinafter “the irrecoverable stage of death”) are not aimed at improving the patient’s condition, but merely at maintaining the patient’s current condition²⁶. Because in such an exceptional circumstance futile LST “can harm the patient’s human dignity and fundamental value as a human being”²⁶, “protecting the patient’s dignity, value, and right to pursue happiness as a human being is consistent with social norms, and respecting the patient’s decision to face death does not go against the constitutional spirit”²⁶. Related to procedural requirements, the Supreme Court recommended that “Unless the patient files a lawsuit directly in court, it is desirable for a committee composed of medical doctors, etc. to decide whether the patient has reached an irrecoverable stage of death”²⁶.

Legal uncertainty about decision making around LST was addressed in a statement of grounds in the final civil appeal^{2,42}. The defendant appealed that a general substantive and procedural guideline for forgoing LST is crucial and it is impossible for all cases to rely on a court’s decision. As for uncertainty about medical futility, it often cannot be predicted with certainty that the patient has

entered into an irrecoverable death stage. Decisions on whether the patient entered into an irrecoverable death stage is a very complicated process involving considerable uncertainty intrinsic to medical decision making³. This is further corroborated by the fact that Grandma Kim survived an additional 6 months after removal of the MV.

Although the Supreme Court limited the range of patients for whom forgoing LST is allowed, this ruling allowed physicians to recognize that forgoing LST is not illegal and they would not be prosecuted as murders. However, the general guideline composed of broad and ambiguous substantive requirements and insufficient procedural requirements could not eliminate the risk of legal disputes and physicians' defensive attitudes towards forgoing LST⁴².

2. Physicians' Psychological Burden of Legal Dispute

Physicians' legal liability related to forgoing LST is realized by civil liability for damages, involuntary manslaughter in criminal law, and licensure punishment by regulatory sanction. Because forgoing LST means physical death, in extreme cases criminal prosecutions charging homicide could be initiated^{34,45}. In the course of long-lasting litigation and trials, physicians incur damages to their professional reputation, criticism from family members, and experience considerable physical and psychological burdens regardless of the results of legal judgment^{45,46}. For some physicians, these burdens may be as large as their concern about winning or losing a case⁴⁵.

In the first legal case, the Grandma Kim case, permitting withdrawal of LST in South Korea, the concurrence of the majority opinion in the en banc decision of the Korean Supreme Court demonstrated incomplete resolution of legal uncertainty precisely and appropriately²⁶. The concurrence opinion worried about the effectiveness of the judgment permitting withdrawal of LST and expressed their view concerning appropriate legal procedures for determining whether discontinuing LST can be permitted as follows²⁶:

“Where a patient who has already reached the irrecoverable stage of death without issuing a prior medical instruction, there are two possibilities as to discontinuing life-sustaining treatment: (i) The patient seeks to discontinue life-sustaining treatment and the medical practitioner infers that the patient would consent to discontinue treatment since the patient has reached the irrecoverable stage of death as determined by a committee composed of expert doctors, etc. ... In case (i), the medical practitioner can discontinue life-sustaining treatment by accepting the patient’s request after going through procedures and considering expert opinions as stated in the Majority. Thus, interference by a court is likely unnecessary when the patient’s request clearly satisfies the element for discontinuing life-sustaining treatment. However, the problem is that the medical practitioner, even in case of (i), cannot be completely immune from legal liability regarding the discontinuance of life-sustaining treatment. Since no legislation has been enacted stipulating the legal procedure governing the discontinuation of life-sustaining treatment, to exempt the medical practitioner from responsibility solely because the medical practitioner performed such treatment based on careful

procedure leads to the issue of protecting the patient's right to life being left entirely to the medical practitioner. Consequently, even though the medical practitioner discontinued life-sustaining treatment after going through necessary procedures, we cannot exclude the possibility that the medical practitioner may face civil and criminal liability because it may subsequently be determined that the patient had not reached the irrecoverable stage of death or that the patient's inferred intent was unclear. As the possibility of criminal liability based on ex post facto judicial evaluation cannot be excluded, the medical practitioner cannot help but adopt a defensive attitude towards the patient's request, and if there is any doubt, he/she would hesitate to discontinue life-sustaining treatment. In this context, it is understandable that the medical profession is currently taking a passive approach towards discontinuing life-sustaining treatment despite the patient's request. Furthermore, the uncertainty as to the possibility of legal liability based on decision after the fact cannot be fundamentally alleviated by suggesting substantial elements without procedural elements established. Thus, allowing case (i) to also go through a procedure to obtain the court's decision would considerably help in stabilizing legal relations concerning the discontinuance of life-sustaining treatment."

It is difficult for a physician to accurately determine whether a patient has entered an unrecoverable death stage, and it is even more difficult to determine the presumptive willingness of a dying patient regarding LST unless there is a living will. Furthermore, in addition to the patient factors, physicians should consider not only the relationship and consistency of the decision made by the

family members but also underlying legal problems surrounding family members such as the inheritance. Decision making for LST needs substantial effort and time and since the consequence of the decision is death of a patient, substantial psychological burden is imposed on physicians in practice. Even if a physician's decision was completely legal, it does not eliminate the risk of getting involved in a litigation process. Even if the decision is proven to be free from legal liability by ex post court judgment, physical and psychological burdens during the course of the proceedings are inevitable.

3. Defensive Medicine

Legal instability and legal defensiveness have been described as defensive medicine in the medical and economic literature for many years. Previous studies suggested that the majority of adverse clinical events do not result in malpractice claims, and a substantial proportion of claims involve no medical error, both of which suggest substantial idiosyncrasy in malpractice⁴⁷⁻⁴⁹. The primary determinant of whether an injury will receive compensation is not the extent of negligence but the extent of the injury^{49,50}. For LST-related decisions, the injury is death, the most serious adverse event. In addition, empirical evidence suggests that the incentives produced by the tort-based legal system for malpractice claims leads doctors to practice defensive medicine—to administer precautionary treatment with minimal expected medical benefit out of fear of legal liability⁵⁰⁻⁵³.

Defined as medical practice based on fear of legal liability rather than on patients' best interests, the concept of defensive medicine describes physicians' distorted behaviors in response to potential threats stemming from malpractice litigation^{46,54,55}. In other words, defensive medicine can be defined as medical practice decisions predicated on a desire to avoid malpractice liability, rather than a consideration of medical risk-benefit analysis⁵⁰. Explanations for physicians' defensive behaviors, however, vary⁵⁴. Many studies, especially those based in the US context, attribute defensive medicine to medical malpractice litigation systems whereas others have sought to explain it from physicians' internal emotional mechanisms rather than from external modifiers of behaviors⁵⁴. In addition to the

economic burden of legal disputes, the likelihood of a claim that takes many years to resolve or that involves a large amount of conflict or hassle has a substantial effect on defensive treatment behavior^{52,56}.

Physicians report defensive medicine as a major contributor to healthcare costs, and commonly argue that they must practice defensively to reduce malpractice liability⁴⁸. For instance, among physicians practicing in high risk specialties in Pennsylvania during a malpractice crisis, more than 90% reported sometimes or often practicing defensive medicine^{48,56}. These assurance behaviors of physicians can also be found in a study that reported that within specialty and after adjustment for patient characteristics, higher resource use by physicians is associated with fewer malpractice claims⁴⁸.

In a simple model of medical decision-making, the legal system would induce doctors and patients to balance the costs of liability against the costs of precautions and the health benefits of care⁴⁶. Unfortunately, operation of the countries' health-care and liability systems deviates substantially from this simple model⁴⁶. In practice, however, these systems can lead doctors to take insufficient precautions against medical injuries, or might lead to defensive medicine⁴⁶.

The practice of defensive medicine can take two forms: positive and negative⁴⁶. Positive defensive medicine, also called assurance behavior, includes the supply of care that is unproductive for patients; negative defensive medicine, also called avoidance behavior, takes place when providers decline to supply care that is productive for patients^{46,56}. In other words, positive defensive medicine is expressed by an increased use of resources, both to reduce the risk of receiving a

further complaint and to increase doctors' ability to defend one, and negative defensive medicine refers to withdrawal of medical services. Doctors may cease providing care if they believe particular types of patients or diseases place them at greater risk of receiving a complaint⁵⁷.

Positive defensive medicine can arise from two sources⁴⁶. First, because doctors bear substantial uninsured, non-monetary costs of liability, including the value of lost time, the matter of reputational damage, and the expenditure of emotional energy in responding to a malpractice claim, they might view the cost of negligence to be greater than the burden that negligence imposes on patients⁴⁶. Second, because neither patients nor doctors bear the full cost of care in any particular case, they might perceive the cost of precautions to be less than it actually is. Even if tort law allocated the burden of medical injuries perfectly and inexpensively, the fact that the costs of precautionary services are largely financed through health insurance or government reimbursement can lead doctors and their patients to take socially excessive care against injuries⁴⁶.

Negative defensive medicine also can arise from two sources. The same uninsured non-monetary costs of liability that create the incentive for positive defensive medicine can also drive doctors out of practice. Furthermore, to the extent patients reap substantial surplus from medical care for which they cannot compensate providers, doctors might weigh the malpractice downside of a course of care against only a fraction of the upside, leading them to withhold treatments that can be in their patients' best interests⁴⁶.

The fact that physicians tend to have defensive attitudes against certain types of

medical services is well known in western countries and South Korea^{56,58-60}. Previous empirical evidence suggests that patients from areas with the greatest malpractice pressure experience more defensive medical practice^{46,50,61,62}. In a series of studies, Kessler and McClellan used longitudinal data for almost all elderly patients admitted to hospital with serious cardiac illness, matched with information on the existence of law reforms from the US state in which the patient was treated. They reported that reforms that directly limited liability—such as caps on damages—reduced hospital expenditures by 5–9% in the late 1980s, with effects that are greater for ischemic heart disease than for acute myocardial infarction patients. In contrast, reforms that limit liability only indirectly were not associated with any substantial expenditure effects. Thus, treatment of elderly patients with heart disease does include defensive medical practices, and reductions in liability can reduce this costly behavior^{52,63}. Although the effect size was small, the presence of defensive medicine among physicians was supported by data suggesting the rate of childbirth by cesarean section has increased due to defensive medicine against malpractice disputes regarding childbirth⁶⁴.

Findings of two studies in the USA identified the mechanism by which direct reforms affect doctors' behavior, to help predict whether new and untried types of reforms will have similar effects. Kessler and McClellan reported that although reforms directly limiting liability improve medical productivity mainly by reducing malpractice claims rates and compensation conditional on a claim, other policies that reduce the time spent and the amount of conflict associated in defending against a claim can also reduce defensive practices substantially⁵³. In

addition, the level of malpractice pressure may be too high or misdirected, leading doctors to take socially excessive precautions, such that the marginal social benefit of the additional treatments provided are greater than their marginal social cost. In this case, malpractice pressure would induce doctors to practice defensive medicine⁵⁰.

Reforms in tort law are designed to influence patient decisions about bringing and resolving liability claims. In turn, law reforms may affect the incentives the liability system gives to health care providers to undertake precautionary care or malpractice pressure⁵⁰. The authors of one article, taking a legal and psychological basis, argued that a shame response from malpractice drives the observable changes in physicians' attitudes towards patients and changes in practicing behavior⁵⁷. Research from the USA, the UK, and Australia indicate that positive defensive medicine such as increased referrals, test ordering, and prescribing are all responses to litigation. These common findings from disparate cultures (with respect to complaint and litigation procedures) suggest that doctors' responses arise more from internalized mechanisms, rather than from an externalized modifier of behavior⁶⁵.

Although the direct costs of lawsuits and settlements account for a very small fraction of total health spending—in the USA, less than 1%—the costs of defensive medicine might be far greater. Almost one in four healthcare dollars is spent on legally, not medically-indicated medicine, in the USA⁶⁶.

Because doctors might not take into account all of the costs and benefits of treatment decisions, small increases in the costs of lawsuits might lead to large

changes in the intensity and volume of care^{46,55}.

4. Legal Defensiveness

Defensive medicine in the medical literature represents only part of a complex constellation of factors that comprise physicians' reluctance to terminate treatment. This phenomenon encompasses medical, ethical, legal, social, psychological, and spiritual factors interacting in ways that are not fully understood. For the purposes of this study, however, we have chosen to focus on the legal and psychological aspects of physicians' reluctance to terminate treatment and the corresponding ethical implications⁶⁷. For integration of factors associated with physicians' perceived legal risk about LST-related decisions, McCrary and Swanson proposed the concept of legal defensiveness with tools for measuring the intensity of legal defensiveness⁶⁷. They defined legal defensiveness as the aggregate of legal factors encompassing physicians' perceptions and practices regarding the abatement of life-sustaining treatment. Thus, legal defensiveness includes physicians' reported practice of defensive medicine, but the phrase also includes physicians' attitudes and perceptions about potential civil and criminal liability, physicians' perceptions of a general obligation to continue prescribing life-sustaining treatments, and physicians' responses to multi-factorial hypothetical cases containing legal issues⁶⁷.

Based on evidence from their pioneering studies, McCrary and Swanson suggested phenomena regarding physician's legal defensiveness: 1) a significant proportion of physicians manifest extreme legal defensiveness surrounding end-of-life treatment; 2) inaccurate information often circulates among physicians

regarding their risk of litigation and/or prosecution for terminating LST; 3) physicians' exaggerated concerns about their legal risk can infuse unnecessary conflict into relationships between physicians, terminally-ill patients, and/or their surrogate decision makers; and 4) better knowledge of relevant medical law might correct misinformation and mitigate these attitudes held by some physicians⁶⁷⁻⁶⁹.

Physicians who use other physicians as a source of knowledge of laws regarding withdrawal of treatment performed significantly worse on the legal knowledge instrument than their colleagues who do not rely on physicians for such information. This suggests that many physicians currently obtain much of their information on the law from a clearly inappropriate source—other physicians also lacking sufficient knowledge⁶⁷. If physicians make treatment decisions for dying patients primarily in reliance on perceived constraints from the legal system, then incorrect information about the law may have severe consequences for patients—most likely in the form of overtreatment⁶⁷. The intensity of legal defensiveness could be affected by physician factors such as specialty and clinical experience⁶⁷. For example, legal defensiveness tends to be high among non-oncologists and less-experienced physicians⁶⁷.

Legal defensiveness among South Korean physicians was reported consistently in several studies. In 2011, a survey of Korean critical care medicine specialists revealed that the biggest obstacle to the application of the guidelines was the lack of legal support⁶⁰. The preferred method for dispute resolution when there is a dispute about forgoing LST could provide evidence of legal defensiveness. A study in 2009 to sample the public consensus on foregoing of LST found that 75%

of the general population wanted to resolve dispute with physicians directly, while 55% of physicians preferred to resolve disputes by way of the hospital ethics committee and only 34% wanted direct resolution with the patient side²⁰. In other studies, physicians reported that legal risk is a major barrier to forego LST⁷⁰ and the Korean Supreme Court recognized physicians' hesitation to withdraw LST²⁶. Due to the fear of legal disputes, physicians highly preferred to resolve LST-related disputes with the aid of the hospital ethics committee⁷⁰.

Ⅲ. Conceptual Framework of Legal Defensiveness Model

1. The need for a legal defensiveness model

There is scarce literature suggesting a comprehensive model or conceptual framework for LST-related decision making. Although not focusing on the decision making process, one study proposed a conceptual framework to guide research and policy aimed at enhancing healthcare efficiency and promoting goal-directed care of patients with serious illnesses. Kelley et al. proposed a model that provides a conceptual framework for more inclusive and comprehensive studies by describing the simultaneous interactions and effects of region, physician, patient, and family determinants on treatment intensity⁸. Kelley's model consists of patient and family determinants, and region and physician determinants. After a rigorous literature review, the authors included factors influencing treatment intensity for patients with serious illness. Although the authors indicated that significant interactions between constructs might exist, legal aspects were not considered in the model. Among the constructs, although the individual physician practice pattern could be affected by perceived legal instability, the authors did not include perceived legal instability as extrinsic or intrinsic characteristics of physicians. Only decisions on medical futility were considered as a benefit from treatment that composed patient and family determinants.

However, as described in explanations for defensive medicine, legal

defensiveness as an extrinsic factor plays a key role in decision making as to whether to perform LST^{67,69}. There is a significant difference between the present laws about LST and the actual practice of physicians. A major explanation for the persistent gap between medical-legal principle and the reality of medical practice is ignorance and misunderstanding of the law. Liability is on the minds of physicians, who tend to overestimate the risk of malpractice lawsuits^{27,47}. In the clinical setting "myths about the law often overshadow reality"⁷¹. The most efficacious social facts in the actual hospital situation are physicians' perceptions about themselves, not the objective risks⁷². Often, clinicians' perceptions are that legal risks are far greater than they actually are⁷³. This is the cause of much defensive medicine. This is particularly true with respect to end-of-life care⁷⁴

In order to investigate the impact of legal uncertainty on LST-related decisions, the conceptual framework of Kelly et al. could not be used in this study. Therefore, a new conceptual framework was proposed in this study based on the literature about defensive medicine and legal defensiveness.

2. Legal defensiveness-induced LST

Although refusal must be made ahead-of-time, many decisions about life-sustaining treatment concern patients who have lost their decision-making capacity²¹. These patients cannot personally and legally refuse treatment at the time its use becomes necessary. In this circumstance, a surrogate makes an LST-related decision. If the surrogate is a family member of a dying patient, an LST-favoring decision would be made under the ethical burden to actively hasten the death of a dying patient. In conjunction with patient side source, under the nonexistence or unavailability of an advance directive, physicians generally prefer to provide LST.

In his brilliant study, legal scholar Pope suggested two factors produce this preference²¹. First, when the patient has not declared the treatment to be unwanted, it is presumed that it is wanted⁷⁵. End-of-life medicine is like a train that will proceed to the final stop, unless the patient has a valid ticket to disembark at an earlier station. Second, as a result of inertia instead of a deliberate choice, most patients have failed to rebut that presumption. In addition to the factors suggested by Pope, the situations when CPR, MV, and ICU care are needed are typically urgent emergency states. There is no time to get informed consent from the patient. Physicians have no option but to provide LST to the dying patient.

Importantly, with respect to administering LST without consent, physicians' perception is that the legal risks are lower than they actually are²¹. The general view from the medical front is that you cannot be sued for doing too much, you

can only be sued for doing too little^{45,76-78}. Indeed, a 2012 survey found that a majority of physicians agree that there is less liability risk for "maintaining someone alive against their will than mistakenly allowing them to die"⁵. Attorneys often advise health care institutions and physicians to "play it safe" when in doubt and just administer treatment⁷⁹. This advice seems consistent with the literature. Legal commentators have generally agreed that "there are few, if any, effective incentives for physicians and other healthcare providers to be scrupulous in their adherence to advance directives"⁸⁰. Neither judges nor lawmakers have yet formulated coherent or effective remedies for physicians' failures to comply with the instructions patients have provided^{80,81}.

Yet another situation in which clinicians often provide unwanted life-sustaining treatment is at the demand of the patient's own surrogate. Even if a patient has an advance directive refusing treatment, advance directives are rarely self-executing. Clinicians usually turn to the patient's surrogate for direction. But, notwithstanding the patient's clear intent in the advance directive to refuse treatment, the surrogate often wants to continue treatment²¹. Physician's fear of the family as a potential plaintiff means that the family member's demand for LST virtually always controls the situation regardless of medical futility^{45,82}. "Dead patient don't sue, but live families do" is veritable mantra among physicians⁴⁵.

In such conflict situations, clinicians are overwhelmingly prepared to override the patient's advance directive at the surrogate's request. A choice between the liability risk posed by an emotionally distraught family and that posed by a vegetative patient who will never regain consciousness is not much of a choice. In

addition, liability is not the clinician's only concern. Even prevailing parties pay transaction costs. An angry surrogate's action, "even if frivolous will cost the provider in legal fees, stress, and perhaps even professional reputation." When the patient's potential surrogates cannot agree on a decision or plan, the clinician may be hesitant to stop life-sustaining treatment. Clinicians err on the side of continuing treatment when surrogates provide no clear direction, preferring to wait until consensus develops²¹

If a physician have a vitalistic philosophy of medicine, things get worse. There remains a significant amount of physician paternalism. Many physicians are not ready to give up. In general, many physicians still consider it their responsibility to make treatment decisions that they believe are in the patient's best interest and that patient preferences should be ignored if they are inconsistent with the physician's view of the patient's best interests⁸³. Even when physicians know a patient's preference, they may disregard it as not in the patient's best interests^{84,85}.

Clinicians may object to complying with patient wishes not only on professional or paternalistic grounds, but also on personal grounds²¹. For example, "a healthcare provider may have a powerful personal moral bias that all life is worth saving and that everything possible should be done for every patient."

Another reason that clinicians administer unwanted life-sustaining treatment is that overtreatment is well-reimbursed^{86,87}. Clinicians are often paid more for doing more⁸⁸. The current fee-for-service reimbursement model incentivizes clinicians to provide more treatment and to deploy more technology, even more than the patient desires⁸⁹.

In East Asia, cultural influence strongly affects physicians' LST-related decision^{70,90}. Although physicians in East Asian countries face ethical problems similar to those of their western counterparts, they are different from those of western countries in cultural traditions, customs, religious beliefs, and ethnic backgrounds. Although advance directives are essential for communicating intentions before death, it is almost impossible for the majority of Korean patients to provide such an advance directive²⁵. In East Asian countries where family-oriented values are shared (i.e., Confucius values), most decision making, even medical decisions, are made by families. The truth with regard to the seriousness of a patient's illness is generally kept hidden by the family members from the patient to prevent any negative emotional influence^{3,91}.

Confucianism does not advocate forgoing of life sustaining treatment for patients⁹². In addition, physicians may encounter severe social criticism if a terminally ill older patient is allowed to die or denied a life-saving intervention⁷⁰. Similarly, the patient's family members might be blamed by other members of society for violating the principle of filial piety or criticized for being anti-humanitarians^{3,70}. In East Asian countries, the social idea and norm of the Confucian value of filial piety is commonly shared, and there is an expectation that children should work to save their parents with all their strength regardless of the costs⁷⁰. The lasting influence of Confucianism is apparent in these family-centered Asian societies as reflected by the importance that is placed on ancestor-worship, patriarchy, and filial piety⁹³. In the US setting, minority populations such as Asian Americans are less likely to access hospice care

compared with white Americans^{87,94,95}.

3. Legal defensiveness model used in this study

Prior studies regarding defensive medicine in general and legal defensiveness specific to forgoing LST altogether contributed to developing the conceptual framework for the legal defensiveness model in this study. In particular, the legal defensiveness model integrates and reconstructs determinants proposed by Kelley et al.⁸ into the model focusing on physicians' legal defensiveness toward LST-related decisions. The theoretical background from legal defensiveness proposed by McCrary and Swanson⁶⁷ played a pivotal role in incorporating perceived legal uncertainty or ambiguity stemming from misunderstanding laws. Pioneering research of Pope²¹ about legal aspects of LST and physicians' inertia toward administering LST provided significant implications for psychological and legal burdens or fears of physicians.

Nevertheless, literature describes mechanisms from which legal defensiveness stemmed and how legal defensiveness could influence LST-related decisions listed associated factors in parallel^{21,45,67,73,96}. Therefore, in order to advance the progress of the study objectives, the following conceptual framework for a legal defensiveness model provides for a possible mechanism to explain the association between physicians' legal defensiveness and forgoing LST.

If there are laws or judicial precedents governing LST, they set the range of allowed and prohibited behaviors toward physicians. On the other hand, the legal system could clarify legal disadvantages that will be incurred if those behaviors are recognized as illegal. Above the range and disadvantages constructs an

objective legal stability, which is the objective in terms of its irrelevance to perceptions of individual physicians. On the contrary, if there are not laws or judicial precedents governing LST, then considerable objective legal ambiguity or instability occur and debates on legality of forgoing LST can arise among the judicial world.

Regardless of objective legal ambiguity, individual physicians might perceive objective legal ambiguity differently, and even misunderstand the law as in the Boramae case. In other words, physicians' perception of legality is subjective and could conflict with objective legality in the present legal system. Individual perceptions of subjective legal instability or ambiguity finally constructs legal defensiveness toward forgoing LST.

In this study, physicians' legal defensiveness was defined as the attitude formed accumulatively by influences and interactions of various factors such as physicians' knowledge of law, level of fear for liability, prior experience of legal disputes, intrinsic characteristics such as age and sex, practice patterns of doctor-patient relationships, and individual values about life and religion. The legal defensiveness ensconced deeply in physicians' minds is expressed by the preference for LST in individual cases. The preference for LST depends on the factors such as presence of advance directives and patient's age within that individual case. Experiences during formation of preferences for individual cases can affect legal defensiveness. Behaviors incorporated into the legal system including informed consent, advance directives, and POST can affect the doctor-patient relationship, and changes in the doctor-patient relationship can influence

general legal defensiveness and specific preference for LST in an individual case. Again, legal defensiveness and preference influence the doctor-patient relationship and determine the level of participation of the patient side in LST-related decision making.

Although many factors could affect a physician's preference for LST in an individual case, legal defensiveness toward LST plays a major role. Legal defensiveness-induced preferences determine the decisions about LST in an individual case. The level of force differs according to the medical urgency and legal risk. Legally high-risk LST such as CPR, MV, and ICU care are administered primarily by physician-driven decisions and are medically urgent in terms of high risk of immediate death. In contrast, legally low-risk LST such as ED visits and acute hospital admission are utilized by patient-driven decisions as well as physicians' decisions in terms of low risk about the immediate decision. The higher the legal risk, the less likely it is that decision to forego LST be made.

The conceptual framework for a legal defensiveness model is presented as a flow chart focusing on legal aspects (Figure 1).

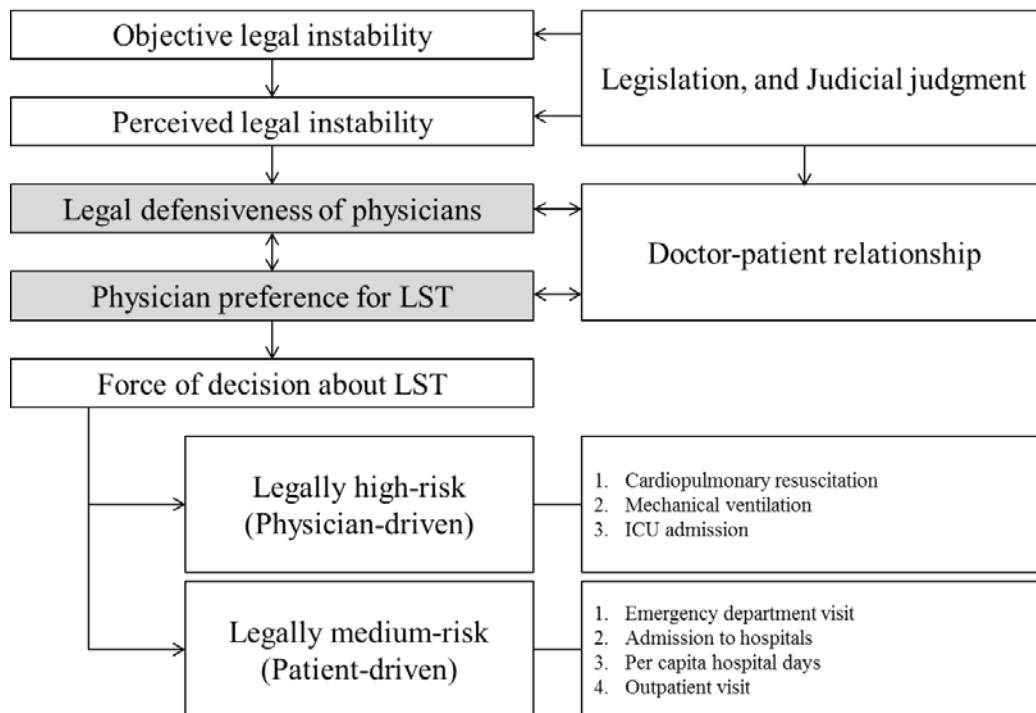


Figure 1 Conceptual framework of legal defensiveness model in this study

IV. Materials and Methods

1. Study subjects and data source

The study population was decedents aged 70–89 with cancer, circulatory, or respiratory diseases between 2003 and 2013 in South Korea. Inference about the study population was performed through analyses of a 10% simple random sample from the study population. The random sample of the study population was obtained from the National Health Insurance Service–Elderly Cohort (NHIS-NSEC)⁹⁷. The NHIS-NSEC was constructed for the purpose of providing public health researchers and policy makers with representative, useful information regarding citizens’ utilization of health insurance and health examinations⁹⁷. Data and a manual can be accessed through the NHIS’ National Health Insurance Data Sharing Service website [<https://nhiss.nhis.or.kr/bd/ab/bdaba008cv.do>].

The target population of NHIS-NSEC was people older than 60 years in 2002 in South Korea. From the target population consisting of about 0.5 million enrollees in the National Health Insurance (NHI) and medical aid beneficiaries, 588,147 participants of the HNIS-NSEC were randomly selected through 10% simple random sampling. Therefore, the NHIS-NSEC can represent the South Korean population older than 60 years in 2002. The participants were followed for 12 years until 2013 unless participants’ eligibility was disqualified due to death or emigration. Since initial enrollment in 2002, additional enrollment of a new

subject was not permitted in the NHIS-NSEC. Therefore, the study population's representativeness is not guaranteed during the follow-up period, because during the follow-up period, participants were getting older and dying and the remaining participants could not represent the South Korean population older than 60 years.

To maintain the representativeness of the data and control for a changing age distribution, study participants were limited to decedents aged 70–79 at death. The information in the data set included all inpatient and outpatient medical claims data, including personal information, prescription drugs, diagnostic test and treatment procedure codes, and primary and secondary diagnosis codes. In addition, each patient's unique de-identified number was linked to mortality information from the Korean National Statistical Office. To protect participants' privacy, the Resident Registration Number that was initially used to construct the cohort was replaced with a newly-assigned eight-digit personal identification number.

Under the retrospective framework, decedents were identified between 2003 and 2013 by a death certificate with the unique identification number and the cause of death. Initially 108,548 decedents with cancer, circulatory, or respiratory diseases were selected (Figure 2). To preserve representativeness of data, 23,664 decedents aged less than 70 or more than 89 were excluded. Until 2008, claims information about medical aid beneficiaries was not reliable, and therefore 12,391 decedents who were beneficiaries of the medical aid program were excluded. Under the assumption that decedents without any health care utilization might not have exact death certificates, 1,972 decedents with that condition were excluded.

Finally, study decedents consisted of a total of 70,521 decedents who were 70–89 years old at the time of death.

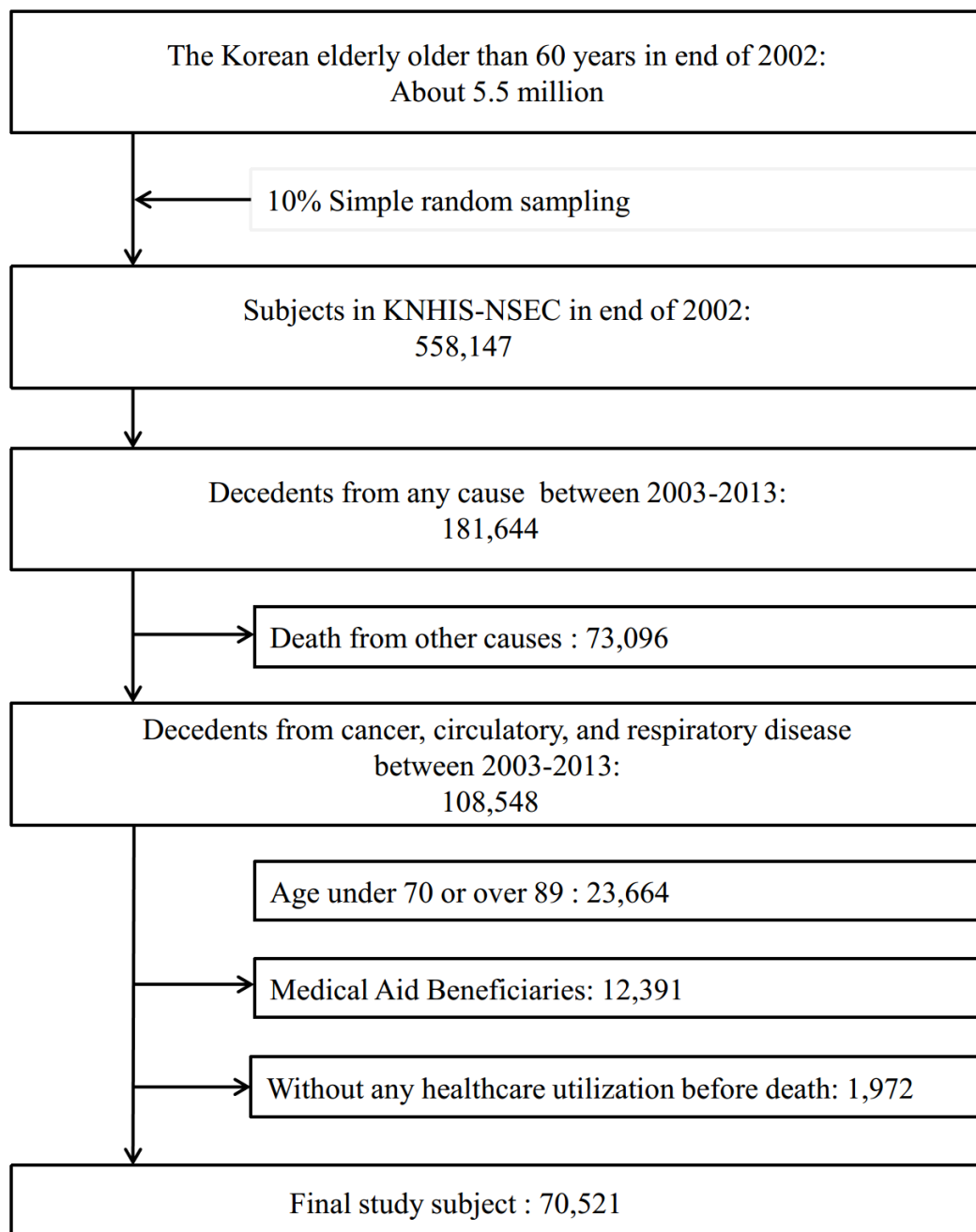


Figure 2 Description of the process to construct the KNHIS-NSEC and the selection of dying patients from the KNHIS-NSEC

2. Study Design

(1) Retrospective observation study

A retrospective observation study of decedents with cancer, circulatory, and respiratory diseases was conducted in this study. Time series were constructed by time unit of a quarter from 2003 to 2013. During 44 quarters, decedents were classified to corresponding quarters according to their dates of deaths. Outcomes were identified retrospectively since the date of death to the last 30 and 180 days of life. The time series were interrupted at the specific break points that divided study periods into segments according to the legal defensiveness toward LST-related decisions. Within the time series, trends and its changes of outcomes were measured and compared between these segments.

In this study, the exact time of entering the dying end-of-life phase could not be identified easily due to the nature of administrative claims data. The attempt to identify dying end-of-life phase patients and conduct a prospective study was not feasible under the limitation of administrative claims data. By conducting a retrospective study, the selection of cases is not dependent on inaccurate investigator prognostication of survival⁹⁸. Therefore, a retrospective observational study was selected as the optimal study design for this study.

(2) Division of period on the basis of physician's legal defensiveness

The study period 2003–2013 was divided into distinct periods according to the physicians' legal defensiveness based on legal circumstances and the social atmosphere.

First, through qualitative and empirical analysis, two attorneys at law with medical doctor qualifications listed and reviewed meaningful events related to LST in chronological order (Table 1). After a discussion, the Boramae hospital case during 1998–2004 and the Grandma Kim Case during 2008–2009 were chosen as the landmark events that influenced physicians' legal defensiveness toward LST-related decisions. Whereas the break point in the first quarter of 2010 was a relatively clear point where the time series was interrupted by a major event such as the Supreme Court judgment for Grandma Kim's case and death of Gramma Kim, the break point in the first quarter of 2007 was a relatively vague point where publically sensational events were absent. However, in addition to the two monumental court decisions, some important LST-related news items were reported through mass media and medical media in the second quarter of 2007, and so they could not be neglected. The first case reported that physicians who had removed MV from a terminal cirrhosis patient were approved to be free from suspicion by the prosecution^{99,100}. The KBS's Tracking 60 Minutes, the high-profile investigative TV program on public service broadcasting, covered a murder case in which a father removed MV from his son in vegetative state¹⁰¹. Although these not widely known events might not influence the general medical community, specialists engaged in LST who are very sensitive to the LST-related news could be affected considerably.

Summarizing the events listed above, two possible divisions of time series were suggested. One was three distinct periods of increasing (2003–2006), conflicting (2007–2009), and relieving (2010–2013), the other was increasing (2003–2009) and relieving (2010–2013).

Second, the basis for supporting the above qualitative division was provided by the quantitative analysis of attention to LST among the general public and physicians. In order to measure the degree of attention of the South Korean people, a Google trend analytics search was carried out using Korean terms meaning Boramae hospital case, life-sustaining treatment, death with dignity, and related terms in South Korea, which tracked the popularity of peak searching for this term from 2004 (Appendix 1). The Google trend analytics was used in a previous study to find a time point when the general public was interested in specific subject broadcasted through mass media¹⁰². The analysis found increased public attention to LST-related terms during the conflicting period (2007–2009) of legal defensiveness followed by decreasing attention during end of the increasing period.

To measure the degree of attention of physicians, the number of news items mentioning the Boramae hospital case, life-sustaining treatment, death with dignity, and related terms from the Newspapers of the Korea Medical Association were measured (Appendix 2). Similar to the general public, the analysis found that physician's attention to LST-related terms had increased during the conflicting period (2007–2009) of legal instability followed by decreasing attention during the end of the increasing period. Based on the analyses of degree of attention paid

to LST, the division of time series into three periods seemed to be more reasonable than division into two periods.

Third, in order to assist in selecting break points of the time series, descriptive statistics of outcome measures over time were used as supplementary and empirical information (Figure 3 and 4). Although there were variations among outcome measures, the first quarter of 2007 and 2010 were selected as break points to divide the time series into three periods of legal defensiveness in this study.

Table 1 Major events concerning life-sustaining treatment

Time series	Major events
1998. May.	The first trial judgment of the Boramae Hospital case
2002. Feb.	The appellate court's judgment of the Boramae Hospital case
2004. Jun	The Supreme Court's judgment of the Boramae Hospital case
2005. Mar.	Media coverage of Terry Schiavo case
2007. Jun.	Media coverage of Jack Kevorkian's release and Korean broadcasting's interview with him ¹⁰³
2007. Jul.	Media coverage that physicians who had removed MV from terminal cirrhosis patient approved free from suspicion by the prosecution
2007. Aug.	Media coverage of the murder case in which a father removed MV from his son in vegetative state
2008. May.	The first media coverage of the Grandma Kim case
2008. Nov.	The first trial judgment of the Grandma Kim case
2009. Feb.	The appellate court's judgment of the Grandma Kim case
2009. May.	The Supreme Court's en banc judgment of the Grandma Kim case
2009. Dec.	The pilot project for hospice palliative care
2010. Jan.	Death of the Grandma Kim after 6 months from removal of MV ¹⁰⁴
2016. Feb.	Enactment of the Hospice-Palliative Care and Decision on Life-sustaining Treatment Care of Dying Patients Act (enacted by Act No. 14013, Feb.34, 2016)

1) The first period: increasing legal defensiveness (2003–2006)

The first period was when physicians became aware of the legal burden of aid and abetment of murder around the Boramae Hospital case that progressed 1998–2004⁴. In this period many physicians recognized that forgoing LST was illegal or at least legally very risky^{2,3,30,40,42}. Although there was no specific law governing LST, physicians' legal defensiveness toward LST-related decisions was so high that physicians were reluctant not only to withdraw or withhold LST but also to agree with hopeless discharge from hospitals^{31,40,41}. The perceived legal uncertainty or ambiguity was excessively high compared with the objective legal uncertainty or ambiguity. Under the high burden of legal risk, physicians had a diminished need to ask the patient side about the willingness to receive LST. It was a safe decision to delay the time of death by providing LST until the patient entered the natural dying process^{3,41}.

Characteristics in this period were: 1) it was difficult to expect shared decision making in the patient-doctor relationship with regard to discontinuation of LST; and 2) the physicians played a leading role (paternalism) in LST-related decision making, and actively initiated LST such as CPR and MV if a patient experienced life-threatening conditions such as cardiopulmonary arrest.

2) The second period: conflicting legal defensiveness (2007–2009)

The second period is when public needs for forgoing LST had increased and

cases favorable to forgoing LST were covered by mass media. In the process of the long-running Boramae Hospital case, there was a great deal of controversy and debate among the general public as well as in the academic world. In the meantime, changes and conflicts of legal defensiveness arose among physicians. In the process of the Grandma Kim case, a favorable atmosphere toward foregoing LST had developed among the general public as well as in the academic world. In the meantime, social consensus on the need to introduce hospice care had been developing since the Boramae Hospital case.

This period was characterized by physicians becoming more willing to initiate discussions about LST with the patient side (shared decision making), so the chance to make decisions in advance of an emergency situation requiring CPR or MV increased.

3) The third period: Relieving legal instability (2010–2013)

In the third period, under the influence of the Grandma Kim case, physicians' legal defensiveness was considerably relieved. In the circumstance that a specific law governing LST had not been enacted, the judicial precedent of the Grandma Kim case guaranteed the legality of forgoing LST to physicians. Under the intrinsic limitation of the judiciary in relation to the legislature, because detailed substantive and especially procedural requirements for forgoing LST was insufficient for physicians to be immune from litigation, considerable legal defensiveness has remained. In the meanwhile, a movement for enacting a specific

law governing LST progressed during this period and finally the LST Act was enacted in February 3, 2016.

This period was characterized by physicians perceiving that forgoing LST is not illegal and hence were more actively able to decide to not administer LST for a dying patient than in the prior two periods. However, legal uncertainty or ambiguity for procedural requirements for legal immunity did remain among physicians.

(3) Natural experimental characteristics

The three periods of legal defensiveness simulates an experimental design occurring in real world settings. Because legal defensiveness sharply increased during the first period and decreased during the second period, it looks like two policy interventions were implemented nationally (Table 2)¹⁰⁵.

Table 2 Characteristics as a natural experiment

	Increasing legal defensiveness	Conflicting legal defensiveness	Relieving legal defensiveness
Duration	1998-2006	2007-2009	2010 and later
Influencing event	Boramae hospital case	Cirrhosis case, Boramae hospital case, and Grandma Kim's case	Grandma Kim's case
Perceived legal uncertainty	Illegal for forgoing LST	Change from Illegal to legal for forgoing LST	Legal for forgoing LST
Legal defensiveness	High	Change from high to medium	Medium
Force of initiating LST	High	Change from high to medium	Medium

3. Outcomes

(1) Legally high-risk LSTs and control outcomes

There is no previous study suggesting LST-related outcomes according to the level of legal risk. However, Earle et al. proposed indicators of the quality of end-of-life cancer care from administrative data after reviewing literature, focus group interviews, and Delphi methods^{106,107}. These indicators have been used in many articles investigating quality of care at end-of-life^{9,108,109}. Focusing on treatment intensity, Barnato et al. proposed indicators including CPR and MV to measure hospital end-of-life treatment intensity¹¹⁰. Another review article summarized outcome measures in end-of-life cancer care but the outcomes were classified as aggressive or palliative care⁸⁷. Because legal aspects were not incorporated into the above quality or intensity indicators of end-of-life care, new classifications according to the level of legal risk were needed in this study.

Two attorney-at-laws with medical doctor qualifications including the author selected LST-related outcomes according to the level of legal risk under the legal defensiveness model. Legally high-risk outcomes included CPR and MV. In most legal cases for LST, removing MV has taken the center of controversy. If CPR and MV are not provided during an urgent crisis of life, patients die quickly. If there were not advanced directives or POLST available, legally high-risk outcomes tend to occur immediately. Typically done under an urgent emergency state, the decision whether to do or not to do is driven mainly by physicians. Hospital

admission and per capita hospital days among entire study decedents were selected as control outcomes. Decisions as to whether to do or not to do for these outcomes are made mainly by the patient side as well as physicians and these control outcomes generally are not closely related to immediate death risk.

(2) Outcome measurement

Taking into account the strength and limitations of the NHIS-NSEC, LST-related outcomes were measured by appropriate methods. In South Korea, most of the reimbursement by the NHIS was provided mainly based on fee-for-service and reimbursement to physicians and hospitals are not separated. Thus, for reimbursement, medical institutions should claim all individual services to the NHIS. These claims are first reviewed by the Health Insurance Review and Assessment Service, and if there are false claims then economic and administrative sanctions could be imposed on that medical institution. Although a small portion of reimbursement for inpatient care is provided by diagnosis-related groups, those diseases are not related to LST. Healthcare utilization of dental and traditional Korean (or Chinese) medicine was not included in this study.

Outcomes were measured individually with corresponding information including the date and unique patient and hospital identification numbers. In South Korea, hospitals are classified into four categories according to the Medical Law. Classification into clinic, acute care, and long-term care hospitals were

based on the medical care institution database containing information regarding the type of institution, establishment, location, number of beds, facilities, and physicians. Because tertiary hospitals were not identified directly from the NHIS-EC, admission fees for tertiary hospitals were used for identifying tertiary hospitals¹¹¹.

Providing CPR and MV according to institution types were identified by the presence of corresponding treatment procedure codes. MV included artificial ventilation through trans-tracheal and intra-tracheal catheter insertion. If MV was provided during anesthesia for surgery then it was excluded. Providing CPR and MV were considered to be present if the claims bill had a starting date during the decedent's last 30 days of life.

An admission to hospitals according to institution types were identified by claims bills that provides whether that claim was based on outpatient or inpatient care. Because the date of discharge was calculated by adding length-of-stay (LOS) to the date of admission, depending on the exact time of admission and discharge date, the calculated date of discharge could be one day later or earlier than the actual date of discharge. If the date of admission or discharge was within the last 30 days of life then the patient was considered to be admitted to hospital. Per capital hospital days according to institution types were calculated based on admission and discharge dates. Hospital days belonging to each admission were distributed to hospital days corresponding to the last 30 days of life.

4. Covariates

Sex and age in years at death were included as demographic variables^{9,12,112}. According to type of health insurance, decedents were classified into employees or self-employed individuals and their dependents. Residential area was divided into 1) a metropolitan area that included Seoul and six metropolitan cities or 2) a nonmetropolitan area otherwise. Household income level was identified from the 10 levels of the NHI premium. The premium level was categorized into low, middle, and high tertiles among the study decedents. The decedent's level of comorbidities was assessed by diagnostic codes during the 720 days before death using the Quan's International Statistical Classification of Disease and Related Health Problems, 10th Revision (ICD-10) coding algorithm of the Charlson Comorbidity Score (CCS)^{113,114}. The presence of disease constituting disease categories of the CCS was defined by at least two outpatient visits or one admission upon the primary or the first secondary diagnosis. Diseases corresponding to causes of death were not excluded during calculation of the CCS. Presence of registered disability was identified by the insurance eligibility database of the NHI. In order to control for seasonality and therefore autocorrelation, four quarters of a year were included as a covariate¹¹⁵. Causes of death were identified through death certificates provided by the National Statistical Office in Korea⁹⁷. According to the ICD-10, causes of death were classified into cancer (C00-C97), circulatory diseases (I00-I99), or respiratory diseases (J00-J99).

5. Subgroup and sensitivity analyses

The study decedents consisted of patients with cancer, circulatory, or respiratory diseases. These three causes of death have different characteristics of clinical progress. Hence, three separate analyses corresponding to the causes of death were performed and the results were compared under the assumption that if the preexisting level of LST is high then the magnitude of decrease would be high.

In the main analysis, the effect of increased medical resources such as hospital beds could have increased LSTs⁸. Such mixture of effects makes it hard to interpret the main results. Therefore, a sensitivity analysis was conducted with the decedents who were admitted to hospitals during their last 180 days of life. In addition to the covariates included in the main analysis, the type of medical institution where the decedents were last admitted was added to the multivariable-adjusted regression model.

Regarding the division of three periods according to the level of physicians' legal defensiveness, a sensitivity analysis using two periods was done. The first period started in the first quarter of 2003 and ended in the second quarter of 2009 when the Supreme Court Decision of the Grandma Kim case was announced.

6. Statistical analysis

In order to analyze time trend and its changes of LST-related outcomes, interrupted time series (ITS) with segmented regression was conducted. A time series is defined as a continuous sequence of observations on a population, taken repeatedly over time¹¹⁵. In an ITS with segmented regression, an underlying or baseline trend is constructed by using a time series of an outcome variable. This baseline trend is interrupted by an intervention or event at the break point¹¹⁵.

The hypothetical scenario called the counterfactual is the expected trend in the absence of the intervention. Had it not been for the intervention, the underlying trend would continue. Comparison of the counterfactual and observed outcomes in post-intervention could provide a way for investigating the effect of the intervention. An ITS study is generally robust to typical confounding variables which remain fairly constant, such as population age distribution or socioeconomic status, as these only change relatively slowly over time and are normally taken into account when modeling the underlying long-term trend¹¹⁵.

In a simple form, ITS is modeled using a linear regression model that includes three time-related variables, whose regression coefficients estimate the pre-intervention slope, the change in level at the time of intervention, and the change in slope from pre-intervention to post-intervention¹⁰⁵. The pre-intervention slope represents the baseline trend for the outcome prior to the intervention¹⁰⁵. The change in slope quantifies the difference between the pre-intervention and post-intervention slopes. The level change represents the absolute change of

outcome level at the time of the intervention, which measures the immediate effect of intervention between the time point immediately before and immediately after the break point¹⁰⁵.

In this study, the time series of LST-related outcomes of decedents was interrupted by two break points. The first break point was the first quarter of 2007 where the periods of increasing and conflicting legal defensiveness were divided. The second break point was the first quarter of 2010 where the periods of conflicting and relieving legal defensiveness were divided.

A generalized linear model (GLM) with a Poisson distribution and logarithmic link function was used in segmented regression. If a Poisson regression is applied to binomial data, the error for the estimated relative risk will be overestimated^{116,117}. To avoid overestimating the standard errors of the parameter estimates, a generalized estimating equation using a robust standard error was employed^{116,118,119}. Because this model used a logarithmic link function, model coefficients needed to be transformed into exponentials to present the trend and change of outcomes in the original scale. Additive interpretation of the model coefficients for $\text{Log}[E(Y_i)]$ were transformed to multiplicative interpretations for the original scale, $E(Y_i) = \mu_i$.

First, coefficients were estimated through the GLM described above:

$$\begin{aligned}\log(\mu_i) = & \beta_0 + \beta_1(Time_{before}) + \beta_2(Time_{during}) + \beta_3(Time_{after}) \\ & + \beta_4(Intervention1_{during}) + \beta_5(Intervention2_{after}) \\ & + \sum \gamma_k X_{ki}\end{aligned}$$

$Time_{before}$: a continuous time variable range from 0 to 43 starting in the first quarter of 2003

$Time_{during}$: a continuous time variable range from 0 to 27 during the second and third period, starting in the first quarter of 2007

$Time_{after}$: a continuous time variable range from 0 to 15 during the third period, starting in the first quarter of 2010

$Intervention1_{during}$: an indicator variable set to 1 during the second and third period

$Intervention2_{after}$: an indicator variable set to 1 during the third period

X_{ki} : a covariate vector of the i th individual

In the logarithmic scale of μ_i , β_1 is the time fixed effects representing the underlying baseline trend during the entire period, β_2 represents the slope change of the second period compared to the first period, and β_3 represents the slope change of the third period compared to the second period. β_4 represents the level change at the time of the first break point in the first quarter of 2007 and β_5 represents the level change at the time of the second break point in the first quarter

of 2010. γ_k is the fixed covariate effects.

Second, the coefficients of GLM were transformed to exponentials for interpretation of the original scale of outcomes.

$$\mu_i = e^{\beta_0 + \beta_1(Time_{before}) + \beta_2(Time_{during}) + \beta_3(Time_{after}) + \beta_4(Intervention1_{during}) + \beta_5(Intervention2_{after}) + \sum \beta_k X_{ki}}$$

Interpretation of β_1 is that the expected value of outcome Y increases e^{β_1} times per quarter during the first period. In other words, the average increasing rate during the first period was e^{β_1} per quarter or $(e^{\beta_1} - 1) \times 100\%$ per quarter. During the second period, the quarterly increasing rate is $e^{\beta_1 + \beta_2}$, and this rate is e^{β_2} times higher than that of the first period. During the third period, the quarterly increasing rate is $e^{\beta_1 + \beta_2 + \beta_3}$, and this rate is $e^{\beta_1 + \beta_2}$ times and e^{β_3} times higher than that of the first period and second period, respectively. Interpretation of β_4 and β_5 is that the expected value of outcome Y increased immediately e^{β_4} and e^{β_5} times at the time of the first and second break points.

Third, quarterly increasing rates were converted to annual increasing rates (AIR).

$$AIR_{before} = e^{4\beta_1}$$

$$AIR_{during} = e^{4\beta_1 + 4\beta_2}$$

$$AIR_{after} = e^{4\beta_1 + 4\beta_2 + 4\beta_3}$$

Rate ratios between the three periods were calculated through dividing the AIR of second and third period by the AIR of the first period.

All statistical analyses were conducted using SAS (Version 9.4, SAS Institute Inc., Cary, NC). A P value < 0.05 was considered statistically significant.

7. Ethics statements

This study was approved by the Institutional Review Board of the Graduate School of Public Health, Yonsei University. [IRB number 2-1040939-AB-N-01-2016-412-01]

V. Results

1. Characteristics of study decedents

Among 71,702 decedents during 2003–2013, 30,173 cancer patients, 30,336 circulatory disease patients, and 10,012 respiratory disease patients died (Table 3). Male decedents made up 53.7% and the mean age was 78.9. Distributions of age and sex between the three periods were statistically different but the differences were not large. The Charlson comorbidity score increased from 3.6 to 5.1 during study period. Decedents with cancer decreased from 40.3% to 44.3% and decedents with circulatory disease decreased from 46.3% to 40.4% during the study period. Seasonality across quarters of a year was not prominent.

Table 3 General characteristics of elderly decedents according to the period of physicians' legal defensiveness toward life-sustaining treatment (continued)

Characteristics	Physicians' legal defensiveness								P value
	Entire period (2003–2013)		Increasing period (2003–2006)		Conflicting period (2007–2009)		Relieving period (2010–2013)		
Decedents	70,521		22,032		19,135		29,354		
Sex									<0.001 ^a
Male	37,982	(53.9)	11,595	(52.6)	10,375	(54.2)	16,012	(54.5)	
Female	32,539	(46.1)	10,437	(47.4)	8,760	(45.8)	13,342	(45.5)	
Age (years)									
70–74	18,289	(25.9)	6,209	(28.2)	5,220	(27.3)	6,860	(23.4)	<0.001 ^a
75–79	20,516	(29.1)	6,596	(29.9)	5,395	(28.2)	8,525	(29.0)	
80–84	18,765	(26.6)	5,834	(26.5)	4,947	(25.9)	7,984	(27.2)	
85–89	12,951	(18.4)	3,393	(15.4)	3,573	(18.7)	5,985	(20.4)	
Mean (SD)	78.8	(5.4)	78.4	(5.3)	78.7	(5.4)	79.2	(5.4)	<0.001 ^b
Median (IQR)	79.0	(9.0)	78.0	(9.0)	79.0	(9.0)	79.0	(9.0)	<0.001 ^c
Type of national health insurance									<0.001 ^a
Self-employed	10,992	(15.6)	4,241	(19.2)	2,506	(13.1)	4,245	(14.5)	
Dependent of self-employed	14,043	(19.9)	4,746	(21.5)	4,111	(21.5)	5,186	(17.7)	
Employee	491	(0.7)	160	(0.7)	128	(0.7)	203	(0.7)	
Dependent of employee	44,995	(63.8)	12,885	(58.5)	12,390	(64.8)	19,720	(67.2)	
Residential area									0.653 ^a
Metropolitan	26,974	(38.2)	8,443	(38.3)	7,359	(38.5)	11,172	(38.1)	
Non-metropolitan	43,547	(61.8)	13,589	(61.7)	11,776	(61.5)	18,182	(61.9)	

Characteristics	Physicians' legal defensiveness								P value
	Entire period (2003–2013)		Increasing period (2003–2006)		Conflicting period (2007–2009)		Relieving period (2010–2013)		
Household income level									<0.001 ^a
Low	19,652	(27.9)	6,421	(29.1)	5,335	(27.9)	7,896	(26.9)	
Middle	23,430	(33.2)	7,304	(33.2)	6,337	(33.1)	9,789	(33.3)	
High	27,439	(38.9)	8,307	(37.7)	7,463	(39.0)	11,669	(39.8)	
Charlson Comorbidity Score									<0.001 ^a
0–1	13,276	(18.8)	6,873	(31.2)	2,942	(15.4)	3,461	(11.8)	
2–5	21,415	(30.4)	7,268	(33.0)	5,894	(30.8)	8,253	(28.1)	
6–7	19,639	(27.8)	3,790	(17.2)	5,595	(29.2)	10,254	(34.9)	
≥8	16,191	(23.0)	4,101	(18.6)	4,704	(24.6)	7,386	(25.2)	
Mean (SD)	4.5	(3.4)	3.6	(3.2)	4.8	(3.4)	5.1	(3.4)	<0.001 ^b
Median (IQR)	4.0	(5.0)	3.0	(4.0)	4.0	(5.0)	4.0	(5.0)	<0.001 ^c
Disability									<0.001 ^a
No	69,221	(98.2)	21,762	(98.8)	18,710	(97.8)	28,749	(97.9)	
Yes	1,300	(1.8)	270	(1.2)	425	(2.2)	605	(2.1)	
Quarter of Year at death									0.003 ^a
First	18,428	(26.1)	5,836	(26.5)	4,923	(25.7)	7,669	(26.1)	
Second	17,289	(24.5)	5,516	(25.0)	4,728	(24.7)	7,045	(24.0)	
Third	16,448	(23.3)	5,157	(23.4)	4,425	(23.1)	6,866	(23.4)	
Fourth	18,356	(26.0)	5,523	(25.1)	5,059	(26.4)	7,774	(26.5)	

Characteristics	Physicians' legal defensiveness								P value
	Entire period (2003–2013)		Increasing period (2003–2006)		Conflicting period (2007–2009)		Relieving period (2010–2013)		
Cause of death ^d									<0.001 ^a
Cancer	30,173	(42.8)	8,879	(40.3)	8,295	(43.3)	12,999	(44.3)	
Bronchus and lung	7,643	(10.8)	2,202	(10.0)	2,072	(10.8)	3,369	(11.5)	
Stomach	4,677	(6.6)	1,631	(7.4)	1,344	(7.0)	1,702	(5.8)	
Liver and intrahepatic bile ducts	3,390	(4.8)	944	(4.3)	933	(4.9)	1,513	(5.2)	
Colon and rectum	3,355	(4.8)	907	(4.1)	915	(4.8)	1,533	(5.2)	
Lymphoid, hematopoietic	1,323	(1.9)	340	(1.5)	352	(1.8)	631	(2.1)	
Other	9,785	(13.9)	2,855	(13.0)	2,679	(14.0)	4,251	(14.5)	
Circulatory disease	30,336	(43.0)	10,200	(46.3)	8,289	(43.3)	11,847	(40.4)	
Cardiovascular	13,858	(19.7)	4,039	(18.3)	3,874	(20.2)	5,945	(20.3)	
Cerebrovascular	15,798	(22.4)	5,959	(27.0)	4,214	(22.0)	5,625	(19.2)	
Other	680	(1.0)	202	(0.9)	201	(1.1)	277	(0.9)	
Respiratory disease	10,012	(14.2)	2,953	(13.4)	2,551	(13.3)	4,508	(15.4)	
CLRD	4,623	(6.6)	1,770	(8.0)	1,214	(6.3)	1,639	(5.6)	
Pneumonia	3,556	(5.0)	756	(3.4)	845	(4.4)	1,955	(6.7)	
Other	1,833	(2.6)	427	(1.9)	492	(2.6)	914	(3.1)	

Abbreviation: SD, standard deviation; IQR, interquartile range; CLRD, chronic lower respiratory disease

a Chi-square test

b Analysis of variance test

c Kruskal-Wallis Test

d Causes of death prepared by Statistics Korea was linked to KNHIS database

2. Legally high-risk LST

During the study period, 7,809 (11.1%) and 8,479 (12.0%) decedents were provided with CPR within their last 30 and 180 days of life, respectively (Table 4). The proportions of decedents who were provided MV were 16.8% and 20.9% within their last 30 and 180 days of life, respectively. Both CPR and MV were most likely to be administered to the study decedents during the conflicting period of physicians' legal defensiveness.

During the study period, 50,129 (71.1%) and 56,822 (80.6%) decedents were admitted to hospitals and 13.7% of the decedents were admitted within their last 30 and 180 days of life, respectively (Table 4). The average hospital days of the study decedents were 13.7 and 43.3 days during their last 30 and 180 days of life, respectively. Unlike CPR and MV, both the risk of hospital admission and per capita hospital days were highest during the relieving period.

Table 4 LST-related outcomes for elderly decedents according to the period of physician's legal instability on life-sustaining treatment

Outcomes	Entire period (2003-2013)		Physicians' legal defensiveness						P value
			Increasing period (2003–2006)		Conflicting period (2007–2009)		Relieving period (2010–2013)		
Decedents	70,521		22,032		19,135		29,354		
Legally high-risk LST									
Cardiopulmonary resuscitation									
Last 30 days of life (A)	7,809	(11.1)	2,202	(10.0)	2,314	(12.1)	3,293	(11.2)	<0.001 ^a
Last 180 days of life (B)	8,470	(12.0)	2,434	(11.0)	2,503	(13.1)	3,533	(12.0)	<0.001 ^a
Mechanical ventilation									
Last 30 days of life (A)	11,863	(16.8)	3,515	(16.0)	3,445	(18.0)	4,903	(16.7)	<0.001 ^a
Last 180 days of life (B)	14,734	(20.9)	4,402	(20.0)	4,211	(22.0)	6,121	(20.9)	<0.001 ^a
Outcome control									
Hospital admission									
Last 30 days of life (A)	50,129	(71.1)	12,342	(56.0)	14,365	(75.1)	23,422	(79.8)	<0.001 ^a
Last 180 days of life (B)	56,822	(80.6)	15,302	(69.5)	16,064	(84.0)	25,456	(86.7)	<0.001 ^a
Per capita hospital days [mean, (SD)]									
Last 30 days of life (A)	13.7	(13.1)	9.1	(11.4)	14.8	(13.1)	16.5	(13.3)	<0.001 ^{bc}
Last 180 days of life (B)	43.3	(53.9)	25.9	(38.9)	46.8	(54.9)	54.1	(59.4)	<0.001 ^{bc}

Abbreviation: LST, life-sustaining treatment; SD, standard deviation;

Unit: number (percent)

a Chi-square test

b Analysis of variance test

c Kruskal-Wallis Test

Figure 3 shows the trends in level of legally high-risk CPR and MV, and control outcome hospital admission and per capital hospital days. In these unadjusted and descriptive time series, all four outcomes had been increasing during the increasing period of physicians' legal defensiveness. However, during the conflicting period, the trends of outcomes showed different patterns between the four study outcomes. During the conflicting period, the risks of receiving CPR and MV did not increase but did maintain their levels. Following the conflicting period, during the relieving period, the risk of receiving CPR has maintained its level. In particular, the risk of receiving MV showed a slightly decreasing pattern during the relieving period.

In contrast, the risk of hospital admission and per capita hospital days increased during the conflicting period. This increasing pattern continued during the relieving period.

In summary, while the level of control outcomes increased during the entire study period, legally high-risk LSTs stopped increasing during the conflicting period and remained steady or decreased during the relieving period.

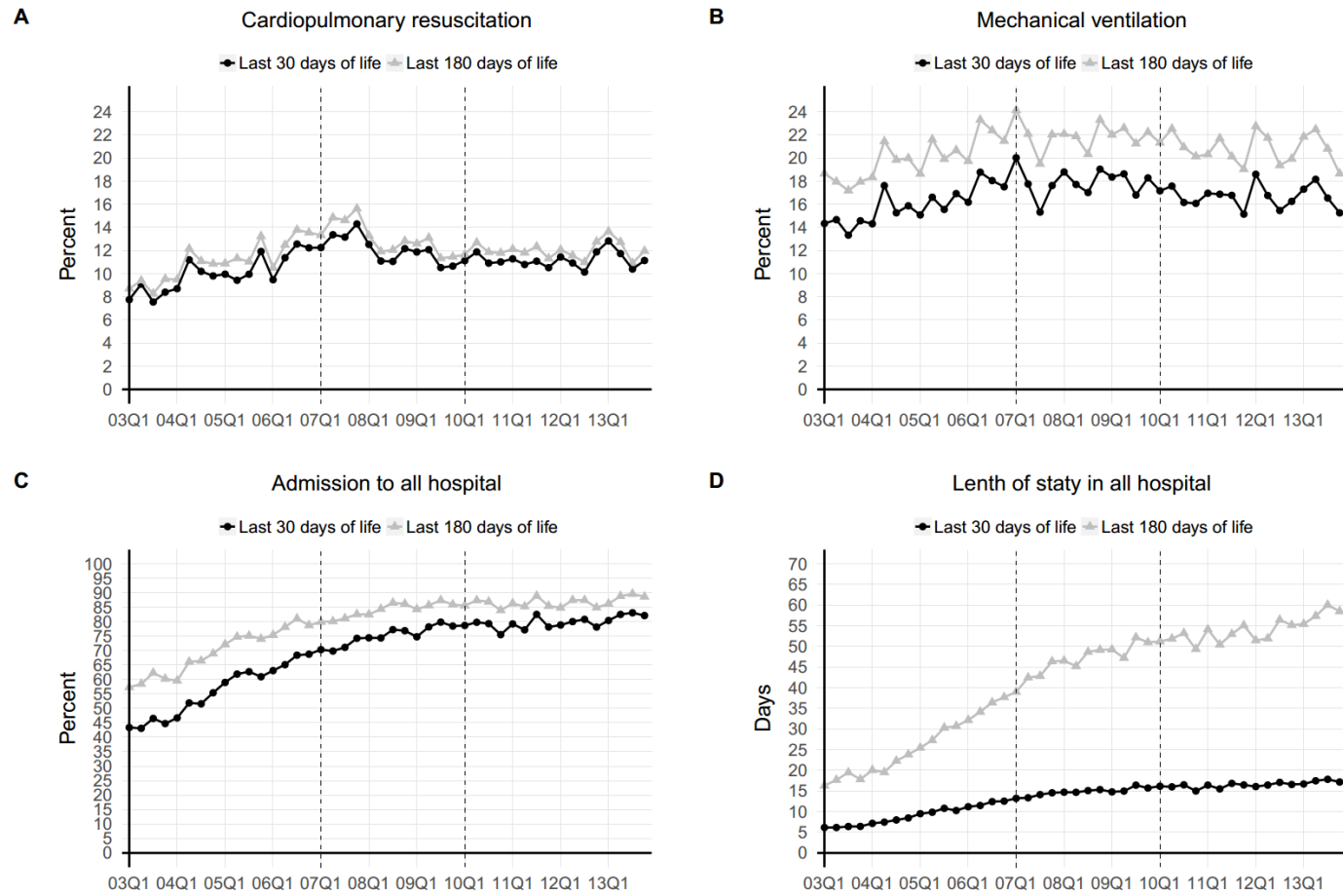


Figure 3 Trends in level of outcomes for elderly decedents with cancer, circulatory, and respiratory diseases

Table 5 shows the multivariable adjusted trends and changes in outcomes during the last 30 days of life for decedents with cancer, circulatory, or respiratory diseases according to the period of physicians' legal defensiveness toward LST.

The risk of receiving CPR during last 30 days of life increased 11.9% per year (AIR 1.119, 95% CI 1.082-1.158) during the period of increasing legal defensiveness. At the time of the first break point in the first quarter of 2007, the risk of receiving CPR during the last 30 days of life showed no statistically significant change (RR [rate ratio] 1.058, 95% CI 0.953–1.174) and thereafter had decreased 6.1% per year (AIR 0.939, 95% CI 0.899–0.981) during the conflicting period. At the time of the second break point in the first quarter of 2010, the risk of receiving MV during the last 30 days of life showed no statistically significant change (RR 1.031, 95% CI 0.931–1.143) and maintained its level (AIR 1.009, 95% CI 0.982–1.038) during the relieving period.

The risk of receiving MV during the last 30 days of life increased 8.3% per year (AIR 1.083, 95% CI 1.055–1.112) during the period of increasing legal defensiveness. At the time of the first break point in the first quarter of 2007, the risk of receiving MV during the last 30 days of life showed no statistically significant change (RR [rate ratio] 0.961, 95% CI 0.884–1.044) and maintained its level (AIR 1.017, 95% CI 0.982–1.053) during the conflicting period. At the time of the second break point in the first quarter of 2010, the risk of receiving MV during the last 30 days of life decreased 8.7% (RR [rate ratio] 0.913, 95% CI 0.843–0.990) and maintained its level (AIR 1.000, 95% CI 0.978–1.022) during the relieving period.

In contrast to the observed patterns in legally high-risk LSTs, the outcome controls showed continuously increasing patterns. The risk of hospital admission during the last 30 days of life increased 12.3% (AIR 1.123, 95% CI 1.111–1.134), 3.6% (AIR 1.036, 95% CI 1.027–1.046), and 1.1% (AIR 1.011, 95% CI 1.006–1.016) during the first, second, and last period, respectively. The risk of hospital admission decreased 2.9% (RR 0.971, 95% CI 0.946–0.997) and 3.3% (RR 0.967, 95% CI 0.948–0.986) at the time of the first and the second breakpoints.

Per capita hospital days during last 30 days of life increased 20.5% (AIR 1.205, 95% CI 1.188–1.223), 4.9% (AIR 1.049, 95% CI 1.034–1.065), and 12.3% (AIR 1.023, 95% CI 1.015–1.032) during the first, second, and last period, respectively. Per capita hospital days did not change (RR 1.002, 95% CI 0.964–1.041) and decreased 2.9% (RR 0.971, 95% CI 0.941–1.002) at the time of the first and the second breakpoints.

Table 6 shows the trends and changes in outcomes during last 180 days of life. The trends and changes of outcomes were similar during the last 30 and 180 days of life. However, unlike the statistically significant decrease in the risk of receiving MV during the last 30 days of life at the time of the second break point, the risk of receiving MV during the last 180 days of life decreased 5.5% but the change was not statistically significant (RR 0.945, 95% CI 0.881–1.014, P=0.117).

Table 5 Trend and changes in outcomes during last 30 days of life for elderly decedents according to the period of physicians' legal defensiveness toward life-sustaining treatment

Outcomes (During last 30 days of life)	Annual increasing rate (AIR)				Ratio of AIR				Level change at break points			
	AIR	95% CI	P value	RR ^a	95% CI	P value	LR ^b	95% CI	P value			
Legally high-risk LST												
Cardiopulmonary resuscitation												
Increasing period	1.119	1.082	1.158	<0.001	1.000				1.000			
Conflicting period	0.939	0.899	0.981	0.005	0.839	0.795	0.886	<0.001	1.058	0.953	1.174	0.292
Relieving period	1.009	0.982	1.038	0.520	0.902	0.863	0.942	<0.001	1.031	0.931	1.143	0.554
Mechanical ventilation												
Increasing period	1.083	1.055	1.112	<0.001	1.000				1.000			
Conflicting period	1.017	0.982	1.053	0.338	0.939	0.900	0.980	0.004	0.961	0.884	1.044	0.342
Relieving period	1.000	0.978	1.022	0.980	0.923	0.892	0.955	<0.001	0.913	0.843	0.990	0.027
Outcome control												
Hospital admission												
Increasing period	1.123	1.111	1.134	<0.001	1.000				1.000			
Conflicting period	1.036	1.027	1.046	<0.001	0.923	0.911	0.936	<0.001	0.971	0.946	0.997	0.027
Relieving period	1.011	1.006	1.016	<0.001	0.901	0.891	0.911	<0.001	0.967	0.948	0.986	<0.001
Per capita hospital days												
Increasing period	1.205	1.188	1.223	<0.001	1.000				1.000			
Second period	1.049	1.034	1.065	<0.001	0.871	0.853	0.889	<0.001	1.002	0.964	1.041	0.927
Relieving period	1.023	1.015	1.032	<0.001	0.849	0.836	0.863	<0.001	0.971	0.941	1.002	0.064

Abbreviations: LST, life-sustaining treatment; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death.

Table 6 Trend and changes in outcomes during last 180 days of life for elderly decedents according to the period of physicians' legal defensiveness toward life-sustaining treatment

Outcomes (During last 180 days of life)	Annual increasing rate (AIR)				Ratio of AIR				Level change at break points			
	AIR	95% CI	P value	RR ^a	95% CI		P value	LR ^b	95% CI		P value	
Legally high-risk LST												
Cardiopulmonary resuscitation												
Increasing period	1.122	1.086	1.159	<0.001	1.000				1.000			
Conflicting period	0.927	0.889	0.966	<0.001	0.826	0.784	0.870	<0.001	1.047	0.949	1.156	0.361
Relieving period	1.007	0.980	1.034	0.625	0.897	0.861	0.935	<0.001	1.048	0.950	1.157	0.349
Mechanical ventilation												
Increasing period	1.070	1.046	1.095	<0.001	1.000				1.000			
Conflicting period	1.013	0.982	1.044	0.425	0.947	0.912	0.983	0.004	0.960	0.892	1.032	0.267
Relieving period	0.995	0.976	1.015	0.628	0.930	0.903	0.958	<0.001	0.945	0.881	1.014	0.117
Outcome control												
Hospital admission												
Increasing period	1.080	1.072	1.088	<0.001	1.000				1.000			
Conflicting period	1.022	1.015	1.029	<0.001	0.946	0.937	0.956	<0.001	0.967	0.948	0.986	<0.001
Relieving period	1.006	1.002	1.010	0.003	0.931	0.924	0.939	<0.001	0.973	0.959	0.988	<0.001
Per capita hospital days												
Increasing period	1.225	1.204	1.247	<0.001	1.000				1.000			
Conflicting period	1.074	1.053	1.094	<0.001	0.876	0.854	0.899	<0.001	1.043	0.993	1.096	0.093
Relieving period	1.036	1.025	1.047	<0.001	0.845	0.828	0.863	<0.001	0.952	0.912	0.993	0.021

Abbreviations: LST, life-sustaining treatment; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death.

3. Subgroup analyses

During the study period, 1,599 (5.3%) decedents with cancer, 4,910 (16.2%) decedents with circulatory disease, and 1,300 (13.0%) with respiratory disease received CPR within their last 30 days of life (Table 7). The risk of receiving MV during their last 30 days of life were 8.7%, 22.2%, and 25.0% among decedents with cancer, circulatory, and respiratory diseases, respectively. Similar to the results in the main analysis, among all three causes of death, both CPR and MV were most likely to be administered to the study decedents during the conflicting period of physicians' legal defensiveness.

During the study period, 24,129 (80.0%) decedents with cancer, 18,629 (61.4%) decedents with circulatory disease, and 7,371 (73.6%) decedents with respiratory disease were admitted to hospitals (Table 7). The per capita hospital days were 15.7 days, 11.6 days, and 14.2 days among decedents with cancer, circulatory, and respiratory diseases, respectively. Similar to the results of the main analysis, among all the three causes of death, unlike CPR and MV, both the risk of hospital admission and per capita hospital days were highest during the relieving period.

Table 7 Level of outcomes during last 30 days of life for elderly decedents according to the causes of death and the period of physicians' legal defensiveness toward life-sustaining treatment

Outcomes			Physicians' legal defensiveness						P value
(During last 30 days of life)	Entire period (2003-2013)		Increasing period (2003–2006)		Conflicting period (2007–2009)		Relieving period (2010–2013)		
Legally high-risk LST									
Cardiopulmonary resuscitation									
Cancer	1,599	(5.3)	460	(5.2)	476	(5.7)	663	(5.1)	0.108
Circulatory disease	4,910	(16.2)	1,380	(13.5)	1,452	(17.5)	2,078	(17.5)	<0.001 ^a
Respiratory disease	1,300	(13.0)	362	(12.3)	386	(15.1)	552	(12.2)	0.001
Mechanical ventilation									
Cancer	2,629	(8.7)	788	(8.9)	752	(9.1)	1,089	(8.4)	0.180
Circulatory disease	6,734	(22.2)	2,088	(20.5)	1,983	(23.9)	2,663	(22.5)	<0.001 ^a
Respiratory disease	2,500	(25.0)	639	(21.6)	710	(27.8)	1,151	(25.5)	<0.001 ^a
Outcome control									
Hospital admission									
Cancer	24,129	(80.0)	5,877	(66.2)	6,855	(82.6)	11,397	(87.7)	<0.001 ^a
Circulatory disease	18,629	(61.4)	4,826	(47.3)	5,491	(66.2)	8,312	(70.2)	<0.001 ^a
Respiratory disease	7,371	(73.6)	1,639	(55.5)	2,019	(79.1)	3,713	(82.4)	<0.001 ^a
Per capita hospital days [mean, (SD)]									
Cancer	15.7	(12.2)	11.3	(11.6)	16.3	(11.9)	18.3	(11.9)	<0.001 ^{bc}
Circulatory disease	11.6	(13.4)	7.2	(10.8)	13.0	(13.8)	14.5	(14.1)	<0.001 ^{bc}
Respiratory disease	14.2	(13.6)	9.0	(11.5)	15.5	(13.5)	16.9	(13.9)	<0.001 ^{bc}

Abbreviation: LST, life-sustaining treatment; SD, standard deviation

Unit: number (percent)

a Chi-square test; b Analysis of variance test; c Kruskal-Wallis Test

Figures 6, 7, and 8 represent the unadjusted and descriptive time series trends in the level of outcomes during the last 30 days of life among decedents with cancer, circulatory, and respiratory diseases, respectively. Although the patterns of time series were similar to the main results, each cause of death showed somewhat different trends and changes. The levels of control outcomes among all three causes of death had been increasing during the entire study period.

The risk of receiving CPR and MV had been increasing during the increasing period of physicians' legal defensiveness regardless of the cause of death, although the magnitude of increase was relatively low among the decedents with cancer. During the conflicting period, the risks of receiving CPR and MV did not increase but instead maintained their levels. In particular, among decedents with cancer, noticeably decreased levels of CPR and MV were observed around the time of the Grandma Kim case in 2009. Moreover, the level of CPR and MV seems to start to decrease in the conflicting period.

In particular, the risk of receiving MV showed a marked decrease during the relieving period. Among decedents with cancer, the level seemed to be lowered from the time of the Grandma Kim case but thereafter remained constant. During the relieving period, a decreasing trend of the risk of receiving MV was observed among decedents with respiratory disease.

In summary, among decedents with all three causes of death, while the level of control outcomes has been increasing during the entire study period, legally high-risk LSTs stopped increasing during the conflicting period and remained steady or decreased during the relieving period.

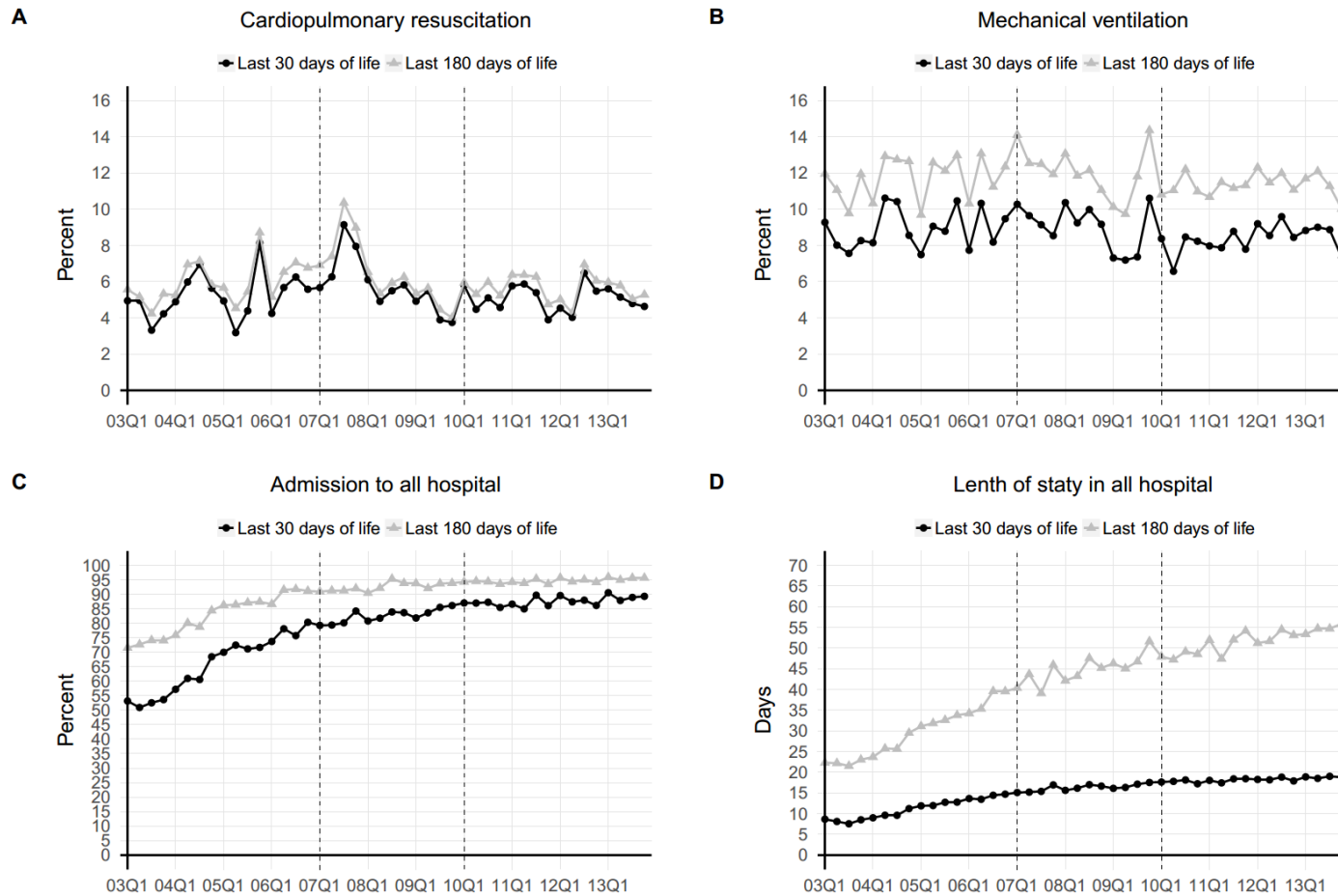


Figure 4 Trends in level of outcomes for elderly decedents with cancer

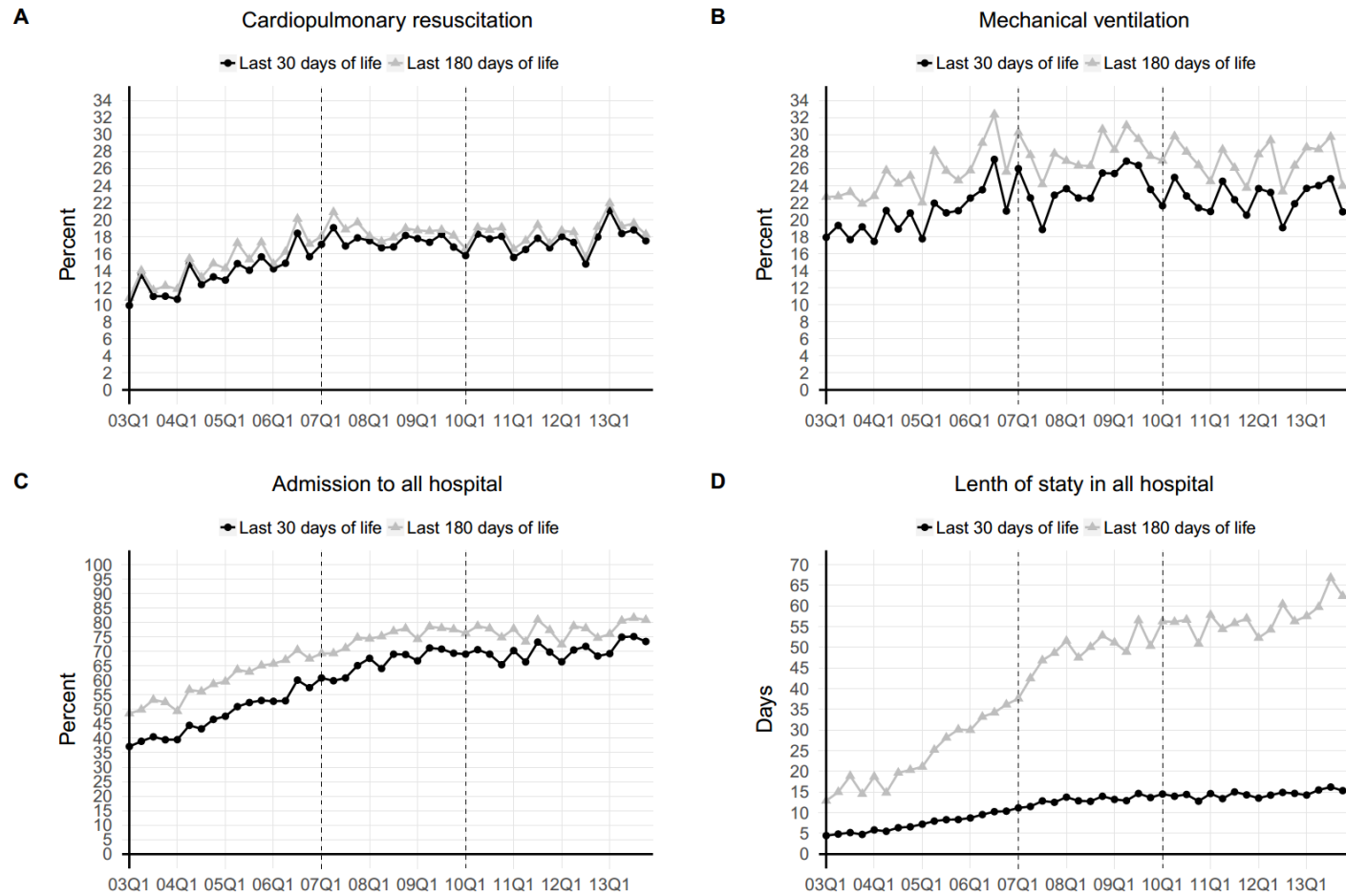


Figure 5 Trends in level of outcomes for elderly decedents with circulatory disease

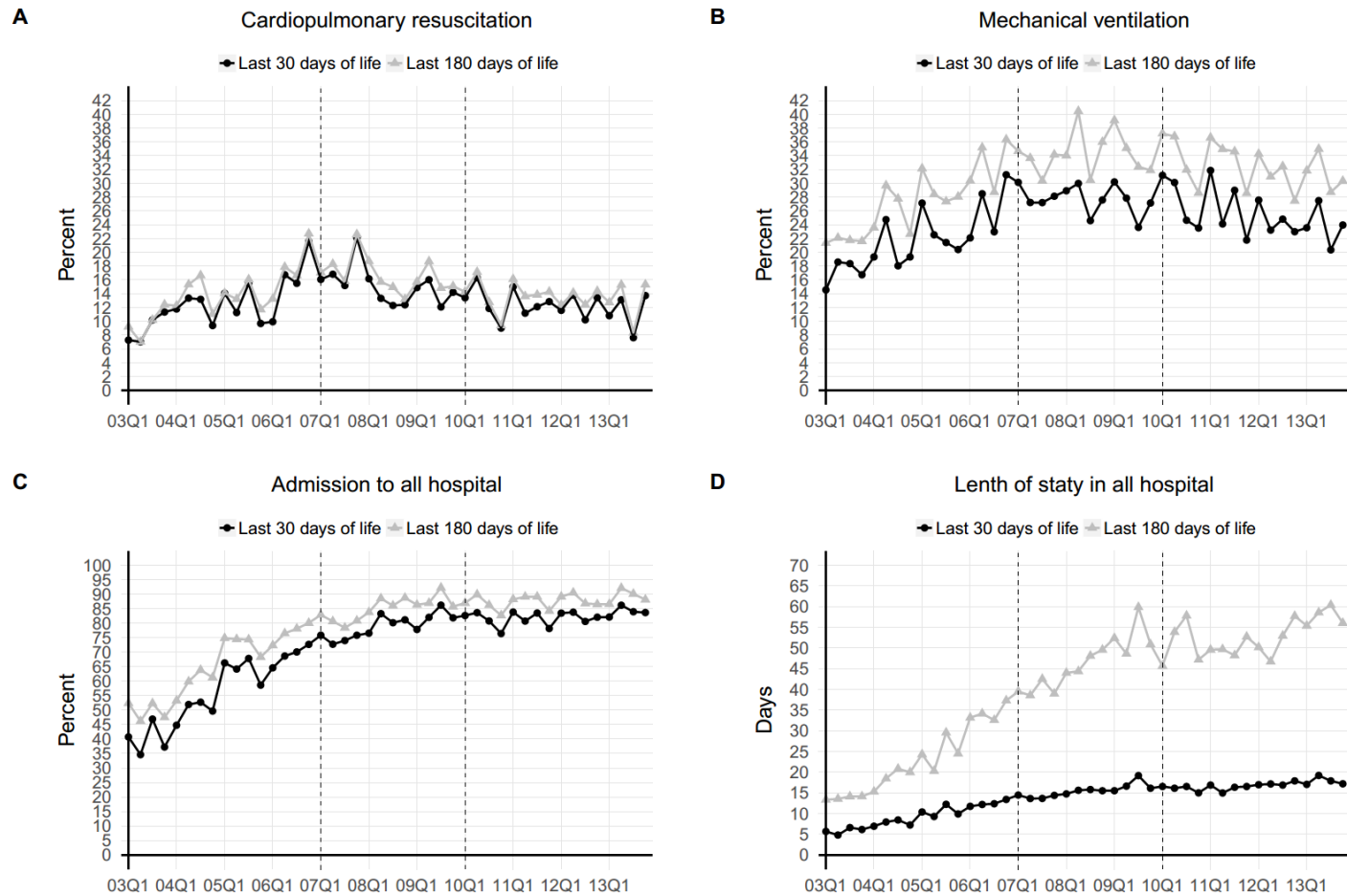


Figure 6 Trends in level of outcomes for elderly decedents with respiratory disease

Tables 8, 9, and 10 represent the multivariable adjusted trends in outcomes during the last 30 days of life among decedents with cancer, circulatory, and respiratory diseases, respectively, according to the period of physicians' legal defensiveness towards LST. Although the patterns of time series were similar to the main results, each cause of death showed somewhat different trends and changes.

Among decedents with cancer, although not statistically significant, the risk of receiving CPR had increased 6.8% per year (AIR 1.068, 95% CI 0.988–1.155) during the period of increasing legal defensiveness (Table 8). The risk of receiving MV showed no statistically significant change during the entire study period. The level of control outcomes showed similar patterns to the main results.

Among decedents with circulatory disease, except for MV which had increased during the conflicting period (AIR 1.055, 95% CI 1.009–1.104), the trends of outcomes were similar to the results of the main analysis (Table 9). A noteworthy feature was that at the second breakpoint the risk of receiving MV decreased 14.1% (RR 0.859, 95% CI 0.773–0.954) and thereafter the level was maintained during the relieving period.

Among decedents with respiratory disease, the risk of receiving MV had decreased 5.3% per year (AIR 0.947, 95% CI 0.906–0.990) during the relieving period (Table 10). Other results were similar to the main analysis.

Table 8 Trend and changes in outcomes during last 30 days of life for decedents with cancer according to the period of physicians' legal defensiveness toward life-sustaining treatment

Decedents with cancer (During last 30 days of life)	Annual increasing rate (AIR)			Ratio of AIR			Level change at break points		
	AIR	95% CI	P value	RR ^a	95% CI	P value	LR ^b	95% CI	P value
Legally high-risk LST									
Cardiopulmonary resuscitation									
Increasing period	1.068	0.988	1.155	0.100	1.000		1.000		
Conflicting period	0.810	0.732	0.896	<0.001	0.759	0.669	0.861	<0.001	1.326 1.046 1.682 0.020
Relieving period	0.989	0.926	1.056	0.736	0.926	0.837	1.025	0.136	1.296 1.013 1.656 0.039
Mechanical ventilation									
Increasing period	1.032	0.973	1.094	0.292	1.000		1.000		
Conflicting period	0.952	0.879	1.031	0.225	0.922	0.836	1.017	0.106	1.063 0.881 1.283 0.521
Relieving period	1.027	0.978	1.080	0.289	0.996	0.923	1.074	0.907	0.959 0.796 1.155 0.657
Outcome control									
Hospital admission									
Increasing period	1.116	1.102	1.131	<0.001	1.000		1.000		
Conflicting period	1.023	1.011	1.035	<0.001	0.917	0.901	0.933	<0.001	0.951 0.921 0.982 0.002
Relieving period	1.009	1.004	1.015	<0.001	0.904	0.892	0.917	<0.001	1.000 0.976 1.024 0.987
Per capita hospital days									
Increasing period	1.173	1.151	1.195	<0.001	1.000		1.000		
Conflicting period	1.037	1.018	1.056	<0.001	0.884	0.861	0.908	<0.001	0.980 0.933 1.030 0.435
Relieving period	1.019	1.009	1.029	<0.001	0.869	0.851	0.888	<0.001	1.012 0.973 1.052 0.561

Abbreviations: LST, life-sustaining treatment; RR, rate ratio; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death.

Table 9 Trend and changes in outcomes during last 30 days of life for decedents with circulatory diseases according to the period of physicians' legal defensiveness toward life-sustaining treatment

Decedents with circulatory diseases (During last 30 days of life)	Annual increasing rate (AIR)				Ratio of AIR				Level change at break points			
	AIR	95% CI	P value	RR ^a	95% CI	P value	LR ^b	95% CI	P value			
Legally high-risk LST												
Cardiopulmonary resuscitation												
Increasing period	1.113	1.067	1.161	<0.001	1.000				1.000			
Conflicting period	0.991	0.939	1.045	0.737	0.890	0.833	0.952	<0.001	0.997	0.876	1.134	0.960
Relieving period	1.024	0.990	1.060	0.163	0.920	0.873	0.971	0.002	0.971	0.856	1.100	0.641
Mechanical ventilation												
Increasing period	1.083	1.047	1.120	<0.001	1.000				1.000			
Conflicting period	1.055	1.009	1.104	0.019	0.975	0.922	1.031	0.371	0.906	0.814	1.008	0.070
Relieving period	1.008	0.979	1.038	0.586	0.931	0.891	0.973	0.002	0.859	0.773	0.954	0.004
Outcome control												
Hospital admission												
Increasing period	1.100	1.081	1.120	<0.001	1.000				1.000			
Conflicting period	1.050	1.031	1.069	<0.001	0.954	0.931	0.978	<0.001	1.004	0.956	1.054	0.879
Relieving period	1.015	1.005	1.026	0.003	0.923	0.905	0.942	<0.001	0.929	0.893	0.966	<0.001
Per capita hospital days												
Increasing period	1.214	1.184	1.245	<0.001	1.000				1.000			
Conflicting period	1.052	1.025	1.080	<0.001	0.867	0.836	0.898	<0.001	1.044	0.975	1.119	0.220
Relieving period	1.025	1.010	1.041	0.001	0.845	0.820	0.869	<0.001	0.945	0.892	1.001	0.055

Abbreviations: LST, life-sustaining treatment; RR, rate ratio; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death.

Table 10 Trend and changes in outcomes during last 30 days of life for decedents with respiratory diseases according to the period of physicians' legal defensiveness toward life-sustaining treatment

Decedents with respiratory diseases (During last 30 days of life)	Annual increasing rate (AIR)				Ratio of AIR				Level change at break points			
	AIR	95% CI		P value	RR ^a	95% CI		P value	LR ^b	95% CI		P value
Legally high-risk LST												
Cardiopulmonary resuscitation												
Increasing period	1.199	1.100	1.307	<0.001	1.000				1.000			
Conflicting period	0.910	0.815	1.016	0.095	0.759	0.662	0.871	<0.001	0.989	0.763	1.282	0.932
Relieving period	0.972	0.906	1.043	0.428	0.811	0.726	0.905	<0.001	0.997	0.771	1.290	0.984
Mechanical ventilation												
Increasing period	1.127	1.061	1.197	<0.001	1.000				1.000			
Conflicting period	0.974	0.905	1.048	0.479	0.864	0.787	0.949	0.002	1.006	0.839	1.207	0.948
Relieving period	0.947	0.906	0.990	0.016	0.840	0.780	0.905	<0.001	1.029	0.873	1.214	0.731
Outcome control												
Hospital admission												
Increasing period	1.178	1.145	1.212	<0.001	1.000				1.000			
Conflicting period	1.038	1.013	1.063	0.003	0.881	0.849	0.913	<0.001	0.932	0.869	1.000	0.050
Relieving period	1.004	0.992	1.016	0.529	0.852	0.826	0.878	<0.001	0.947	0.902	0.995	0.031
Per capita hospital days												
Increasing period	1.252	1.203	1.304	<0.001	1.000				1.000			
Conflicting period	1.070	1.028	1.115	0.001	0.855	0.808	0.905	<0.001	0.937	0.840	1.046	0.245
Relieving period	1.028	1.006	1.050	0.011	0.821	0.785	0.859	<0.001	0.896	0.823	0.975	0.011

Abbreviations: LST, life-sustaining treatment; RR, rate ratio; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death.

4. Sensitivity analyses

(1) Restriction to decedents who were admitted to hospitals

Table 14 represents the results of the sensitivity analysis that was conducted to control for the effect of increased medical resources during the study period. The study subjects were restricted to the 56,822 decedents who were admitted to hospitals during their last 180 days of life. During the study period, 6,199 (10.9%) and 6,857 (12.1%) decedents were provided CPR within their last 30 and 180 days of life, respectively (Table 14). The proportions of decedents who were provided MV were 18.9% and 23.9% within their last 30 and 180 days of life, respectively. Unlike the main analysis, both CPR and MV were most likely to be administered to the study decedents during the increasing period and then decreased during the conflicting and relieving period.

The number of decedents who had admitted to hospitals was the same as those of the main results, but the proportions changed to 88.2% and 100% during the last 30 and 180 days of life, respectively (Table 14). The average hospital stay days of the study decedents were 17.0 and 53.7 days during their last 30 and 180 days of life, respectively. Unlike CPR and MV, both the risk of hospital admission and per capita hospital days were highest during the relieving period.

Table 11 Level of outcomes for elderly decedents who admitted to hospitals during last 180 days of life according to the period of physicians' legal defensiveness toward life-sustaining treatment

Outcomes (Decedents who had admitted to hospitals during last 180 days of life)	Entire period (2003-2013)		Physicians' legal defensiveness						P value
			Increasing period (2003–2006)		Conflicting period (2007–2009)		Relieving period (2010–2013)		
Decedents	56,822		15,302		16,064		25,456		
Legally high-risk LST									
Cardiopulmonary resuscitation									
Last 30 days of life (A)	6,199	(10.9)	1,777	(11.6)	1,900	(11.8)	2,522	(9.9)	<0.001 ^a
Last 180 days of life (B)	6,857	(12.1)	2,007	(13.1)	2,089	(13.0)	2,761	(10.8)	<0.001 ^a
Mechanical ventilation									
Last 30 days of life (A)	10,720	(18.9)	3,144	(20.5)	3,142	(19.6)	4,434	(17.4)	<0.001 ^a
Last 180 days of life (B)	13,584	(23.9)	4,026	(26.3)	3,908	(24.3)	5,650	(22.2)	<0.001 ^a
Outcome control									
Hospital admission									
Last 30 days of life (A)	50,129	(88.2)	12,342	(80.7)	14,365	(89.4)	23,422	(92.0)	<0.001 ^a
Last 180 days of life (B)	56,822	(100.0)	15,302	(100.0)	16,064	(100.0)	25,456	(100.0)	
Per capita hospital days [mean, (SD)]									
Last 30 days of life (A)	17.0	(12.5)	13.1	(11.6)	17.6	(12.4)	19.1	(12.4)	<0.001 ^{bc}
Last 180 days of life (B)	53.7	(55.2)	37.2	(41.9)	55.7	(55.6)	62.4	(59.6)	<0.001 ^{bc}

Abbreviation: LST, life-sustaining treatment; SD, standard deviation;

Unit: number (percent)

a Chi-square test

b Analysis of variance test

c Kruskal-Wallis Test

Figure 3 shows unadjusted and descriptive time trends in levels of outcomes among the decedents who were admitted to hospitals during their last 180 days of life. Similar to the main analysis, the level of hospital admissions and the per capita hospital days seemed to have increased during the entire study period. However, the risks of receiving CPR and MV showed different patterns. Graphically, the risks of receiving CPR and MV seemed to have not increased during the increasing period of legal defensiveness. However, the level of CPR and MV seemed to decrease during the conflicting and relieving periods. In particular, a decreasing trend of MV was observed during the relieving period.

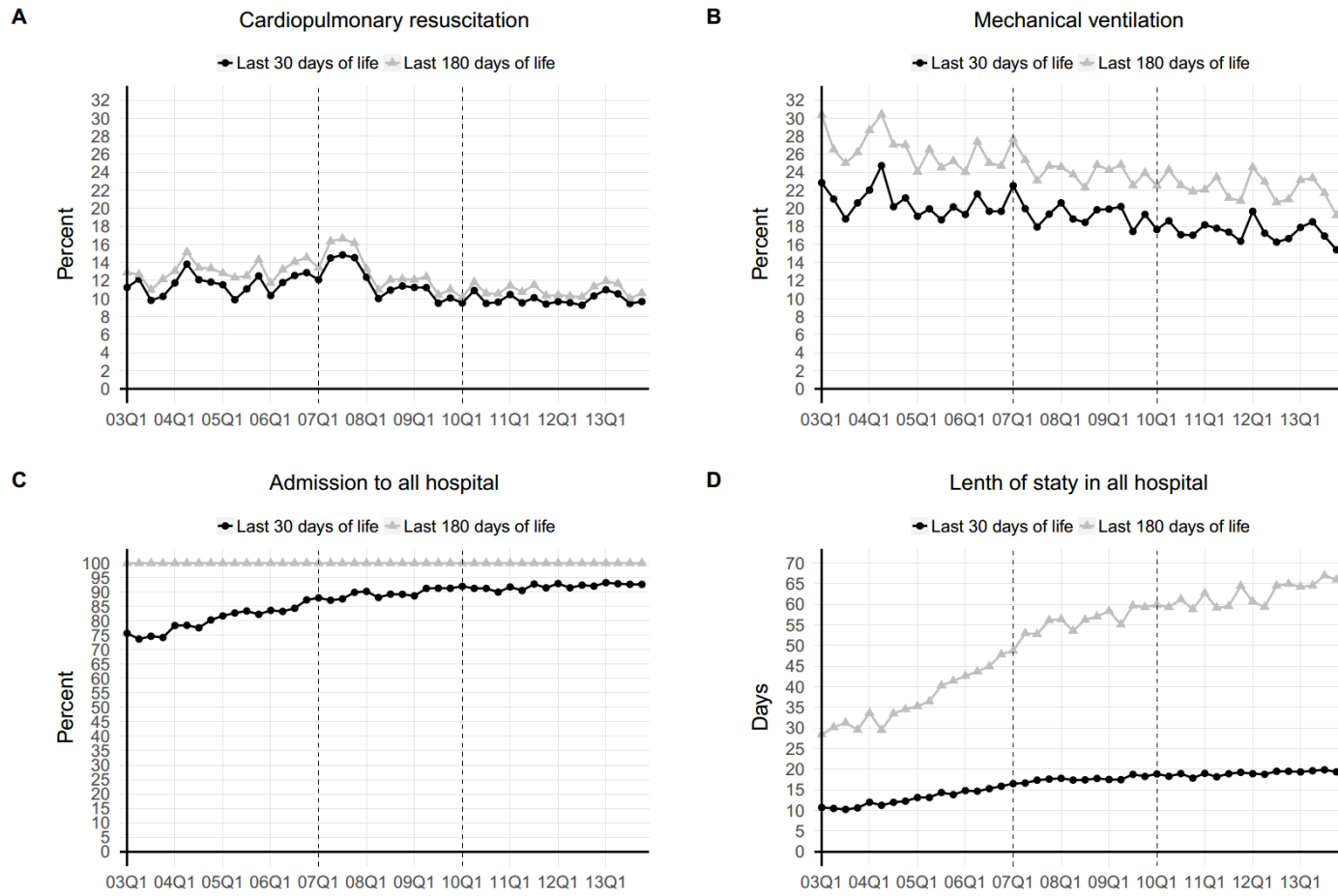


Figure 7 Trends in level of outcomes for elderly decedents who had admitted to hospitals during last 180 days of life

Table 5 shows the multivariable adjusted trends and changes in outcomes during the last 30 days of life for decedents who were admitted to hospitals during their last 180 days of life. In addition to the covariates included in the main analysis, the type of medical institution where the decedents were last admitted was added to the multivariate Poisson regression model. Unlike the descriptive patterns in Figure 7, the risk of receiving CPR and MV during the increasing period of legal defensiveness had increased 6.0% (AIR 1.060, 95% CI 1.021–1.101) and 5.3% (AIR 1.053, 95% CI 1.026–1.082), respectively. The results of this segmented regression were similar to the main results although the magnitude of the AIRs was smaller.

Table 12 Trend and changes in outcomes during last 30 days of life for elderly decedents who admitted to hospitals during last 180 days of life according to the period of physicians' legal defensiveness toward life-sustaining treatment

Decedents admitted to hospitals (During last 30 days of life)	Annual increasing rate (AIR)				Ratio of AIR				Level change at break points			
	AIR	95% CI	P value	RR ^a	95% CI	P value	LR ^b	95% CI	P value			
Legally high-risk LST												
Cardiopulmonary resuscitation												
Increasing period	1.060	1.021	1.101	0.003	1.000				1.000			
Conflicting period	0.891	0.849	0.935	<0.001	0.840	0.791	0.892	<0.001	1.177	1.049	1.321	0.006
Relieving period	1.007	0.976	1.039	0.679	0.950	0.904	0.997	0.037	1.045	0.932	1.173	0.450
Mechanical ventilation												
Increasing period	1.053	1.026	1.082	<0.001	1.000				1.000			
Conflicting period	1.001	0.967	1.035	0.971	0.950	0.910	0.991	0.018	1.053	0.969	1.144	0.226
Relieving period	0.996	0.975	1.018	0.715	0.946	0.914	0.978	0.001	0.946	0.875	1.024	0.168
Outcome control												
Hospital admission												
Increasing period	1.033	1.026	1.041	<0.001	1.000				1.000			
Conflicting period	1.012	1.006	1.019	<0.001	0.980	0.971	0.989	<0.001	0.999	0.982	1.017	0.924
Relieving period	1.004	1.001	1.008	<0.001	0.972	0.965	0.980	<0.001	0.992	0.979	1.006	0.254
Per capita hospital days [mean, (SD)]												
Increasing period	1.085	1.072	1.099	<0.001	1.000				1.000			
Conflicting period	1.017	1.004	1.029	0.008	0.937	0.921	0.953	<0.001	1.005	0.973	1.038	0.760
Relieving period	1.012	1.006	1.019	<0.001	0.933	0.920	0.946	<0.001	0.995	0.969	1.022	0.724

Abbreviations: LST, life-sustaining treatment; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death, type of lastly admitted hospital.

(2) Division of the study period into two periods

Table 16 shows the results of the sensitivity analysis in which the study period was divided into two distinct periods of the increasing and relieving period at the time of the third quarter of 2009. The multivariate adjusted AIRs showed similar results to the main analysis across the three periods. The risk of receiving CPR and MV had increased during the increasing period of legal defensiveness and then maintained their levels during the relieving period. In contrast to the legally high-risk LSTs, the risk of hospital admission and per capita hospital days had increased during both increasing and relieving periods.

Table 13 Trend and changes in outcomes during last 30 days of life for elderly decedents according to the period of physicians' legal defensiveness toward life-sustaining treatment

Outcomes (During last 30 days of life)	Annual increasing rate (AIR)			Ratio of AIR			Level change at break points		
	AIR	95% CI	P value	RR ^a	95% CI	P value	LR ^b	95% CI	P value
Legally high-risk LST									
Cardiopulmonary resuscitation									
Increasing period ^c	1.071	1.055	1.087	<.0001	1.000		1.000		
Relieving period	1.013	0.990	1.037	0.276	0.946	0.921	0.972	<.0001	0.819 0.757 0.886 <.0001
Mechanical ventilation									
Increasing period ^a	1.050	1.037	1.062	<.0001	1.000		1.000		
Relieving period	0.988	0.969	1.006	0.186	0.941	0.921	0.962	<.0001	0.909 0.854 0.968 0.003
Outcome control									
Hospital admission									
Increasing period ^c	1.085	1.080	1.089	<.0001	1.000		1.000		
Relieving period	1.008	1.004	1.012	<.0001	0.930	0.924	0.935	<.0001	0.920 0.906 0.935 <.0001
Per capita hospital days [mean, (SD)]									
Increasing period ^c	1.145	1.138	1.152	<.0001	1.000		1.000		
Relieving period	1.020	1.014	1.027	<.0001	0.891	0.883	0.899	<.0001	0.882 0.860 0.904 <.0001

Abbreviations: LST, life-sustaining treatment; CI, confidence interval; RR^a, rate ratio; LR^b, level ratio

Adjusted for age in years as continuous variable, sex, type of national health insurance, residential area, household income level, the Charlson Comorbidity Score as continuous variable, disability, quarter of year at death, cause of death.

^c Ended in the second quarter of 2009 when the Supreme Court decision on the Grandma Kim case was made

VI. Discussion

1. Study methods

In this study, LST-related outcomes during the last 30 days of life were assessed retrospectively. There have been debates about study design regarding prospective and retrospective approaches in the literature^{98,120-122}. Many studies have retrospectively assessed the care received by patients in the period leading up to death, whereas others have identified patients entering the terminal phase of disease and prospectively observed their care forward in time. Each of these approaches has its theoretical and practical advantages and disadvantages. In prospective studies of end-of-life care, investigators traditionally identify a group of subjects who are known to be “dying,” as evidenced by a sentinel event—for instance, subjects diagnosed with metastatic cancer, transferred to a long-term acute care facility, or admitted to a hospice¹²¹. Investigators then observe the care that these “dying” subjects receive, usually up to the point of their death. Studies that follow this design are termed “cohort studies” because they focus on the events that occur after an individual has acquired a particular characteristic that makes him or her eligible for the study. Incomplete enrollment of patients is an important potential limitation of prospective cohort studies¹²². In retrospective studies of end-of-life care, the cohort consists of decedents. Investigators then look back over the time leading up to death to observe end-of-life care¹²⁰. In accordance with epidemiologic principles, these studies are called “case series.” Case series focus on events that occur prior to an individual acquiring a particular

characteristic that makes him or her eligible for the study¹²¹.

Retrospective designs have several advantages over prospective designs¹²⁰. First, they allow for easy identification of cohorts of relevant patients. In contrast, prospectively identifying patients who are approaching the end of life is often not feasible, especially from administrative data sources. Second, a retrospective approach allows all patients who come to the end of life to be studied, not just a nonrandom subset defined by a disease characteristic or event that identifies them as dying. The prospective design is best used for research questions about the care given to patients who can readily be identified as having a terminal illness. The retrospective approach is optimal for asking, “what happens to patients who die shortly before death?” Retrospective designs are convenient, generalizable, and efficient for evaluating and implementing performance indicators related to end-of-life care¹²⁰.

In this study, under the inevitable limitations of administrative claims data, exact prognostication of dying patients was not feasible. Furthermore, unlike other studies investigated end-of-life care among patients with chronic diseases, especially cancer, patients with acute diseases such as myocardial infarction and bacterial pneumonia were included in this study. Inclusion of patients with acute diseases made prognostication more difficult than in other studies. Considering the tradeoff between the strengths and limitations of retrospective and prospective designs, retrospective observation was chosen as the study design.

Under the retrospective design, this study could include all decedents including those who were not admitted to hospitals, who had not utilized medical services

for a long time before death, and those who died in a very short time after disease onset. Thus, this study represents all decedents in South Korea. CPR, MV, and ICU care could be provided to patients who had not been prognosticated as dying. In some patients, these efforts could be not LST but meaningful usual treatment. If CPR, MV, and ICU care had been provided as usual treatment but the results were death within 30 days, those decedents were included as study subjects. However, because the proportion of misclassifications were thought to be fairly constant throughout the study period, the effect of a relatively slow change of misclassification could be absorbed into the slope change in the segmented regression model¹¹⁵.

2. Study results

In this study a conceptual framework for legal defensiveness model was developed. Based on the conceptual model, whether the decrease of legal defensiveness could decrease legally high-risk LSTs (CPR and MV) and whether legally high-risk LSTs could decrease earlier than patient-driven control outcomes (hospital admission and per capita hospital days) were examined through quasi-experimental quantitative analyses under the natural experimental circumstances. This mixed approach with legal and medical aspects revealed that in general legally high-risk LSTs had increased during the period of increasing legal defensiveness, then had decreased during the period of conflicting legal defensiveness, and then showed a plateau or decreasing pattern during the period of relieving legal defensiveness. In general, control outcomes had increased sharply during the period of increasing legal defensiveness, but AIR decreased and then the level increased during the period of conflicting legal defensiveness, and then AIR were decreased further but the level was increased during the period of relieving legal defensiveness. These patterns were repeated in cancer, circulatory, and respiratory diseases. In particular, the decrease of LST was prominent among decedents with respiratory diseases.

Although the risk of admission to hospitals and per capita hospital days increased throughout the entire study period, the risk of CPR and MV decreased or was maintained during the second and third period. Supply-sensitive care such as admission to hospitals and per capita hospital days was affected by an increased

supply of medical resources such as hospital beds but emergent medical procedures such as CPR and MV did not show a similar effect^{8,123,124}. This could be interpreted to mean that in spite of the increased supply of medical resources the risk of receiving CPR and MV decreased, and this means there would be an underestimation of effect size regarding CPR and MV.

Unfortunately, there is no previous study to compare this study's results with. Some studies reported that tort-law reform limiting physician's liability decreased malpractice pressure among physicians^{46,52}. Other studies reported survey results among physicians that defensive medicine is highly prevalent among physicians who pay the most for liability insurance^{53,56}. A low level of specific defensive cesarean section was reported after comparing rates among counties with different liability burdens⁶⁴. As for East Asian countries, using cross-sectional surveys of physicians, it was suggested that over-prescription in Chinese hospitals was driven not only by hard economic incentives, but also by physician's motive of avoiding disputes with patients⁵⁴. On reviewing the above articles, it seems that policies limiting legal liability against malpractice dispute could decrease legal defensiveness toward general medical treatment. Because the consequence of an LST-related decision is death of the patient, the defensive attitude of previous studies might be lower than that of this study. In the course of LST-related decisions, family members of a dying patient play important roles than other general medical decisions dealt with in previous studies. Therefore, physicians should consider more factors associated with LST-related decisions than with other medical decisions. From the fact that the consequence of LST-related death

is more serious and family members play a more important role than in other general medical decisions, previous studies reporting the low liability of physicians associated with low malpractice pressure supports the results of this study.

3. Limitations and strengths

(1) Limitations

There are several limitations in this study. First, the selection of the point at which the time series is divided into three periods is subjective. Whereas the break point in the first quarter of 2010 was a relatively clear point where the time series was interrupted by a major event such as the Supreme Court judgment for Grandma Kim's case and the death of Gramm Kim, the break point in the first quarter of 2007 was a relatively vague point where publically sensational events were absent. However, a cirrhosis case which was reported as the first case allowed by the prosecution, and debates about death with dignity reported by KBS's Tracking 60 Minutes took place in the second quarter of 2007. The events during the second quarter of 2007 were supported by quantitative analysis of attention among South Korean people and physicians. To measure the attention of South Korean people, a Google trend analytics search was carried out using Korean terms meaning the Boramae hospital case, life-sustaining treatment, death with dignity, and related terms in South Korea, which tracks the popularity of peak searching for this term from 2004 (Appendix 1). We found increasing public attention on LST-related terms during the conflicting period of legal instability followed by decreasing attention. To measure the attention of physicians, the number of news items dealing with the Boramae hospital case, life-sustaining treatment, death with dignity, and related terms from the Newspapers of Korea

Medical Association were evaluated (Appendix 2). We found increasing physician's attention on LST-related terms during the conflicting period of legal instability followed by decreasing attention. In particular, physicians conducting withholding or withdrawal of LST are small in number and they are very sensitive to news items related to LST. Because the division was based on physician's perceived legal instability, the first quarter of 2007 could be an appropriate break point in the time series. Furthermore, two attorney-at-laws with medical doctor qualification reviewed LST-related events during the study period and selected the two break points as the point where the time series were interrupted.

Second, there are intrinsic limitations of administrative claims data. Disease codes listed in the cohort may not represent participant's true disease status because the code was created to claim health insurance serviced to participants, an inherent limitation of insurance databases⁹⁷. Non-insurance benefits have not been included such as cosmetic surgeries and over-the-counter drugs. However, LST related benefits have been covered by the NHI and opioid analgesics are not over-the-counter drugs in South Korea. Evaluating details of a participant's specific medical treatment is difficult if patients' insurance claims were made under the diagnosis-related-group (DRG) policy. However, in Korea, nearly all types of healthcare providers follow the fee-for-service system and the DRG is applied only to seven disease groups⁹⁷ unrelated to LST. Furthermore, the sole purpose of constructing the cohort was to provide public health researchers and policy makers with representative, useful information regarding citizens' utilization of health insurance and health examinations⁹⁷.

Third, in September 2005 and December 2009 there were benefit expansion policies to lower copayments for serious diseases including cancer, cardiac, and cerebrovascular diseases¹²⁵. These two events could give patient side incentives for increasing health care utilization by reducing their economic burden. However, when focusing on LST and health care utilization of dying patients, the increasing trends had existed before the policy and the trend changes near the policy were not observed, and thus the effect of benefit expansion policy did not considerably influence the validity of this study. Rather, the results of this study might be underestimated considering the decreasing trends despite a decreased economic burden. Furthermore, many diseased or dying patients were not included in the benefit expansion policy.

Fourth, public discussion about the implementation of a hospice care system and palliative care units had been gradually increased after the Boramae hospital case and the National Cancer Control Act, and The Ministry of Health and Welfare had managed a demonstration project to develop a national health insurance service policy for hospice and palliative care from 2009 to 2015¹²⁶. However, during the study period, the recipients of hospice care were limited to terminal cancer patients and the number of hospice beds has been remained substantially small compared to the number of terminal cancer patients. The utilization rate of hospice care has increased 7.3% in 2008 to 12.7% in 2013^{126,127}. Because the number of dying patients with cancer is small, and most dying patients were not the recipients of hospice care, the effect of hospice care might be expected to be small in this study. Furthermore, because accepting hospice care

could affect the active LST-related decisions of physicians, a possible decrease of LST due to hospice care should be included in decreased LST by reducing the legal defensiveness of physicians.

Fifth, during the study period, the proportion of decedents who died in long-term care hospitals has increased approximately coinciding with the increase in the numbers of long-term care hospital beds. Moreover, beginning in 2008, reimbursement for long-term care hospitals changed from fee-for-service to a per diem fixed payment system. Except for admission and ICU care, exact identification of specific procedures such as CPR and MV conducted during long-term care hospital care could be difficult since 2008. However, fee-for-service reimbursement has been applied to patients discharged within 6 days, pneumonia patients, septicemia patients, patients in the ICU, and patients within the post-operation period¹¹¹. CPR and MV reimbursed by fee-for-service could be detected and these procedures are provided to seriously ill patients included with the exception of cases of per diem reimbursement, and therefore the effect of per diem reimbursement on the identification of MV could be minimalized. Because transfer of dying patients from acute care hospitals to long-term care hospitals could be actively correlated with LST-related decisions to not perform LST, the increasing numbers of deaths in long-term care hospitals should be interpreted as active LST-related decisions. In addition, legal instability is also present among physicians in long-term care hospitals. Legal anxieties during end-of-life care in nursing homes in the US have been reported in articles with a legal perspective⁴⁵.

Whereas the proportion of decedents in extra-hospital place has decreased continuously, the proportion of decedents in long-term care hospitals has increased during the study period. This opposing trend might suggest a transition of death place from decedents who might have died extra-hospital to long-term hospitals. Death in extra-hospital means no LST, and the considerable proportion of deaths in long-term care hospitals should be interpreted as the results of active LST-related decisions of physicians. Recall that a death after discharge from a hospital was the reason for the Boramae hospital case.

Sixth, the measured outcomes were mainly withholding of LST. Due to the absence of medical chart information, differentiation between withholding and withdrawal of LST was not feasible. Outcome variables measured by the presence within last 30 days of life are a surrogate for withholding of LST. Although some dying patients receiving LST might experience withdrawal of LST at some point before death, withdrawal of LST in South Korea has been extremely rare since the Boramae hospital case. Future studies should investigate withdrawal of LST using clinical data from patients receiving LST.

Seventh, the roles of the patient side during LST-related decision making were not considered thoroughly. In the legal defensive model, the effect of patient side factors was incorporated into the doctor-patient relationship and their influence on physician's legal defensiveness and preference for LST. Characteristics of family members were not considered due to absence of information. However, factors such as sex, age, and cause of death that were reported to be associated with patient's preference for LST were adjusted in multivariate regression

models^{15,19,128-130}.

(2) Strengths

Despite the above limitations, this study has some strengths. First, the NHIS-NSEC database contains representative population-based cohort data, which is a major strength as it ensures its applicability in research when evaluating the effects of medical practice on health outcomes. Moreover, the data are large-scale, extensive, and stable because it was constructed based on nationwide health insurance data generated by a monopolistic national health insurer. The NHIS-NSEC was constructed by the method of 10% simple random sampling from Korean people aged 60 or over in 2002. Therefore, dying patients not admitted to hospitals were also included in this study.

Second, a quasi-experimental study design was used as a quantitative analysis method. The interrupted time series design is a strong, quasi-experimental approach for evaluating longitudinal effects of interventions, and this design is robust despite the lack of randomization, because multiple pre- and post-intervention observations allow the detection of and accounting for time trends that are unrelated to the intervention^{131,132}. Its main advantage over alternative approaches is that it can make full use of the longitudinal nature of the data and account for pre-intervention trends¹⁰⁵. This design is particularly useful when “natural experiments” in real word settings occur—for example, when a health policy change comes into effect¹⁰⁵. The nature of the natural experiment of

this study comes from fact that the period of rising legal instability was the first intervention and the period of conflicting legal instability was the second intervention in this study. Several previous studies have used a difference-in-difference study design comparing only 2 time points to investigate net policy impacts on outcomes or used segmented regression with less than 10 time points^{52,63}. The time points were too small to capture baseline trends and their changes in those previous studies. Using 44 time points, this study captured trend changes more robustly.

Third, to the author's best knowledge, this study is the first study in many aspects. First, this is the first study that investigated the effect of legal defensiveness on the LST-related decision by quantitative analysis using nationally representative claims data. There are several studies that investigated the effect of tort-law reform on malpractice claims or costs^{48,52}. Studies investigating specific medical procedure such as cesarean section are very scarce⁶⁴. However, none of previous studies directly investigated LST-related procedures and defensive medicine. Instead of surveys^{56,133} or interviews⁶⁵ of physicians, this study used claims data to identify specific clinical procedures and health care utilization. Second, this is the first study to provide descriptive statistics for the level of LST-related outcomes serially in South Korea. Third, this is the first study that divided a time series into three periods according to a conceptual framework of legal defensiveness model in South Korea. Fourth, this is the first study that integrated a legal conceptual approach and medical quantitative approach into one study design in South Korea.

VII. Conclusion and Policy Implication

This study provides evidence that physicians' legal defensiveness toward forgoing LST contributes to administering LST and if physician's legal defensiveness is decreased, then defensive LST is also decreased. However, legal defensiveness is still considerable and the level of LST could be decreased further.

There are some policy implications to alleviate physicians' legal defensiveness in terms of a physician-side approach. First, the scope of target patients in the LST Act should be broadened to diminish medical uncertainty in the process of determining medical futility of LST. Currently, only patients in the irrecoverable death stage can exercise their constitutional right to refuse unwanted LST. A patient's constitutional right to refuse LST should be protected more comprehensively. Second, a procedural requirement for a legal immunity of physicians should be concretized. Clauses regarding physicians' legal immunity were not provided in the LST Act. Physicians should be able to discontinue futile LST with procedural legitimacy from patients who met the substantive requirement. The hospital ethics committee could play an important role by reducing medical and legal uncertainty. Third, physicians should be informed of legal knowledge related to forgoing LST. Ignorance or misunderstanding of the law should be avoided.

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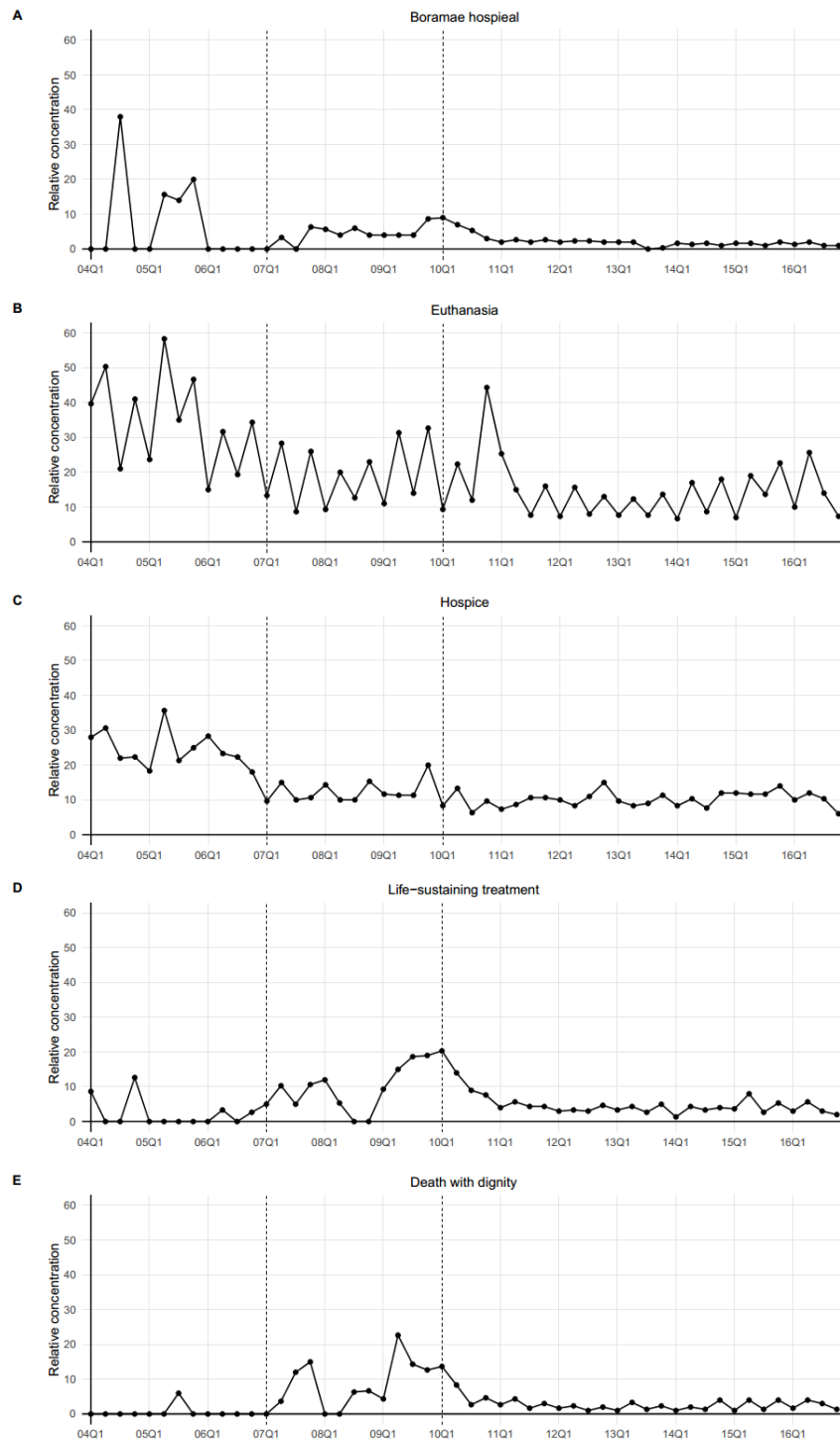
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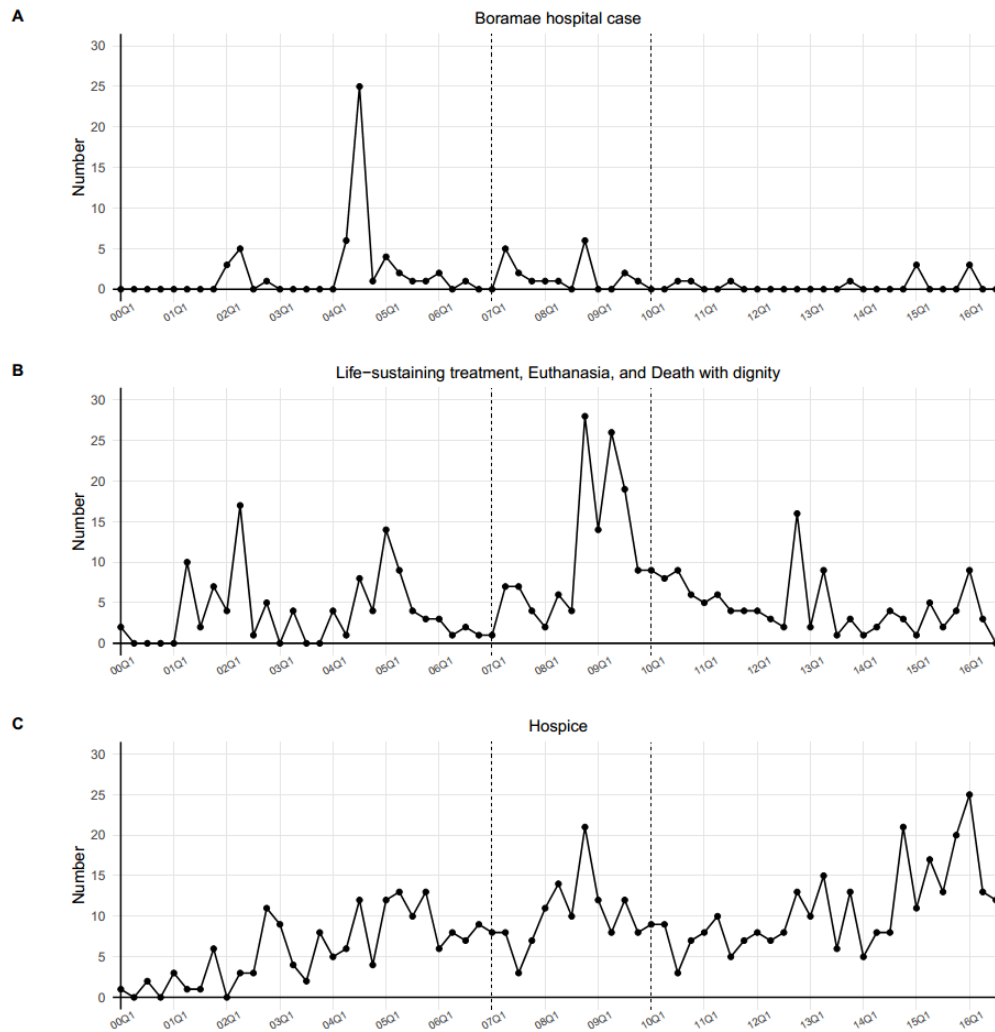
Appendix A

Appendix 1. Results of Google Trend Analytics

Appendix 2. Number of new items in the newspaper of the Korean Medical Association



Appendix 1 Results of Google Trend Analytics



Appendix 2 Number of new items in the newspaper of the Korean Medical Association

국문초록

법방어적 태도에 의하여 유도된 연명치료: 자연유사실험 결과

배경: 무의미한 연명치료에 대한 지대한 관심에도 불구하고 의사의 법적 불안정성의 감소가 연명치료의 감소로 이어질 수 있는지에 관하여 알려진 바가 거의 없다. 연명치료 중단 및 보류에 대한 법방어적 태도를 중심으로, 의사의 법방어적 태도가 감소할 경우 연명치료의 시행이 감소하는지를 두 개의 판결에 의하여 형성된 자연실험적 상황에 대한 유사실험적 연구설계를 통하여 분석하였다.

대상 및 방법: 방어의료 및 법방어적 태도에 관한 선행연구를 종합하여 법방어적 태도 모형을 위한 개념적 틀을 제시하고, 이로부터 계량적 분석을 위한 연구설계를 도출하였다. 연구자료는 2002년에 60세 이상이었던 노인 588,147명으로 구성된 국민건강보험공단 노인코호트를 사용하였다. 노인코호트로부터 2003년부터 2013년 사이에 암, 순환기 및 호흡기 질환으로 사망한 70세에서 89세까지의 노인 73,096명을 연구대상자로 선정하였다. 2003년부터 2013년까지 4분기로 나누어 시계열을 구축하였으며 연구기간은 의사의 연명치료 중단 및 보류에 대한 법방어적 태도의 수준에 따라 상승기, 갈등기, 완화기의 세 시기로 구분하였다. 주로 의사에 의하여 시행여부가 결정되는 법적 고위험 연명치료(심폐소생술, 기계환기)의 사망 전 30일 내 시행수준 및 변화를 분기별로 산출하여 세 시기 사이에 비교하였다. 환자측의 의사결정이 큰 역할을 하는 병원입원 여부 및 재원일수를 대조를 위한 결과변수로 사용하였다. 분절적 회귀모형을 통한 중도절단 시계열분석을 위하여 포아송 분포 및 강건표준오차를 사용한 일반화선형모델을 사용하였다. 시기별로 연증가율을 추정하고 각 시기

사이의 연증가율의 비를 95퍼센트 신뢰구간과 함께 추정하였다.

결과: 사망 전 30일 내에 7,809명(11.1%)의 대상자가 심폐소생술을, 11,863명(16.8%)의 대상자가 기계환기를 시행 받았다. 사망 전 30일 내에 심폐소생술을 시행 받을 위험은 법방어적 태도의 상승기에 연평균 11.9%(AIR 1.119, 95% CI 1.082-1.158) 증가하다가 갈등기에는 매년 6.1%(AIR 0.939, 95% CI 0.899-0.981) 감소하였으며 완화기에는 그 수준을 유지하였다(RR 1.009, 95% CI 0.982-1.038). 사망 전 30일 내에 기계환기를 시행 받을 위험은 상승기에 연평균 8.3%(AIR 1.083, 95% CI 1.055-1.112) 증가하다가 갈등기(AIR 1.017, 95% CI 0.982-1.053)와 완화기 (AIR 1.000, 95% CI 0.978-1.022)에는 그 수준을 유지하였다. 이에 비하여, 비록 갈등기와 완화기의 연증가율이 상승기보다 작을지라도 병원에 입원할 위험(12.3%, 3.6%, 1.1%) 및 재원기간(20.5%, 4.9%, 2.3%)은 세 시기 모두에서 증가하였다.

결론: 대한민국에서 의사의 연명치료 중단에 대한 법방어적 태도가 연명치료의 제공에 기여하고 있으며, 의사의 법방어적 태도가 완화될 경우 방어적 연명치료가 감소할 수 있다. 법방어적 태도는 상당 정도 남아 있으며 연명치료의 시행이 더욱 감소할 필요가 있다. 이를 위하여 의사의 법적 불안정성을 감소시킬 수 있는 정책이 시행되어야 한다.

핵심어: 연명치료, 존엄사, 안락사, 법적 불안정성, 법방어적 태도