

Implication of the Life-Sustaining Treatment Decisions Act on End-of-Life Care for Korean Terminal Patients

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Purpose

Life-sustaining treatment (LST) decisions for patients and caregivers at the end-of-life (EOL) process are supported by the “Act on Hospice and Palliative Care and Decisions on LST for Patients at the EOL,” enforced in February 2018. It remains unclear whether the act changes EOL decisions and LST implementation in clinical practice. For this study, we investigated patients’ decision-making regarding LSTs during the EOL process since the act’s enforcement.

Materials and Methods

Retrospective reviews were conducted on adult patients who were able to decide to terminate LST and died at Seoul National University Hospital between February 5, 2018, and February 5, 2019. We examined demographics, who made the decisions, the type and date of documentation confirming patient’s LST, and whether the LST was withheld or withdrawn.

Results

Of 809 patients who were enrolled, 29% (n=231) completed forms regarding LST themselves, and 71% (n=578) needed family members to decide. The median time from confirmation of the EOL process to death and from the Advance Statement to death were 2 and 5 days, respectively (both ranges, 0 to 244). In total, 90% (n=727) of patients withheld treatment, and 10% (n=82) withdrew it. We found a higher withdrawal rate when family members made the decisions (13.3% vs. 1.7%, $p < 0.001$).

Conclusion

After the act’s enforcement, withdrawing LSTs became lawful and self-determination rates increased. Family members still make 71% of decisions regarding LSTs, but these are often inconsistent with the patients’ wishes; thus, further efforts are needed to integrate the new act into clinical practice.

Key words

Withholding treatment, Palliative care, Advance directives

Introduction

As medical and technological advances are able to prolong life, patients and family members are often eager to receive aggressive treatment even if patients are close to inevitable death [1,2]. In Korea, over a 10-year period, terminal cancer patients have utilized an increasing amount of aggressive treatments with little curative effects at the end-of-life (EOL) process, including chemotherapy [3]. This trend deteriorates

patients’ and caregivers’ quality of life at the EOL process, but taking away dignity before death [4,5]. To achieve a dignified death, advance care planning (ACP), including EOL discussion, must be increased.

It is important for a person to prepare an EOL care plan aligning with one’s own wishes, values, and beliefs [6]. However, in Korea, several studies on terminal cancer patients show that EOL discussions commonly take place when death is imminent or even when cardiac arrest occurs and it is too late for the patient to have input [7-9], so the EOL discussions

mainly occur between physicians and family caregivers [7,8,10,11]. Therefore, patients' intents regarding life-sustaining treatment (LST) cannot be respected. Most do-not-resuscitate (DNR) orders only indicate that cardiopulmonary resuscitation (CPR) should not be performed in the event of cardiac arrest, which may not entirely reflect the patients' will. The "Act on Hospice and Palliative Care and Decisions on LST for Patients at the EOL" went into effect on February 4, 2018 in Korea, and its goal is to assure the best interest of the patients and to respect their self-determination rights [12].

However, it remains unclear whether the act changes EOL discussion process or influences decisions on LST in clinical practice. Therefore, we conducted this study to investigate the status of decision-making for LST during the EOL process, after the enforcement of the act.

Materials and Methods

1. Study design, patients, and data collection

We performed single-center, retrospective study of adult patients who legally terminated LST and died at Seoul National University Hospital (SNUH) between February 5, 2018, and February 5, 2019, the first year after the act was enforced. The SNUH is a 1,779-bed tertiary referral hospital in the Republic of Korea, where a total of 1,400 doctors work in mainly acute and specialized care. It does not have an inpatient hospice-palliative care unit.

We excluded patients who were younger than 19 years old, had incomplete legal forms, had previously signed DNR forms, or had no documentation in electronic medical records (EMR).

We reviewed the EMR of the final admission for patients in their EOL process for data including demographics (age, sex, and residence), comorbidities (using Charlson comorbidity index [CCI]), intensive care unit (ICU) admission, and status of critical care. We obtained data from the EMR and the database of Korea National Institute for Bioethics Policy concerning type of legal forms confirming patient's intent regarding LST, decision-makers, date of documentation, and whether the LST was withheld or withdrawn.

2. Definition and measurement

The act adopted two main concepts: "terminal phase" and "EOL process." The "terminal phase" is defined as the period when fundamental recovery is not possible despite aggressive treatment, and it is accompanied by a gradual worsening

of symptoms. The "EOL process" is when death is imminent with no possibility of recovery, and there is a rapid worsening of symptoms despite treatment. In general, the terminal phase is defined as the period of inexorable and irreversible decline in functional status before death [13]. However, in this study, we used the legal term mentioned in the act.

The LST refers to medical treatment that merely extend the duration of the EOL process without curative effect. The act defines LST as CPR, mechanical ventilation (MV), renal replacement therapy (RRT), and chemotherapy. It makes withholding and withdrawing LST possible with the legal determination form. For the patient at the EOL process, "withholding" means not performing LST at all, and "withdrawing" means terminating LST that the patient is already receiving. We defined "critical care" as CPR, MV, or RRT performed before confirmation of the EOL process.

To withhold or withdraw LST, three steps are required. First, two physicians (the primary physician and one medical specialist) must confirm that a patient is at the EOL process (form 9). Second, a patient should express his or her intention in person with an advance statement regarding LST or form 1 (LST plan). When the patient lacks "decision-making capacity," family members take on this role and must provide two or more identical statements regarding patient's intent to withhold or withdraw LST (form 11). When it is impossible to verify a patient's intent, "all" members of patient's family should show unanimous consensus on withholding or withdrawing LST (form 12). The "patient's family" herein refers to all of immediate family members who are 19 years of age or older. Finally, primary physician should write the execution form (form 13), clarifying which LST to withhold or withdraw, and implement any necessary action.

To investigate the current status of decision making for LST since the act was put into effect, we measured the number of days from (1) the date of form 9 and (2) the date of form 1 to death. We reviewed (3) how withholding or withdrawing LST was performed in practice, (4) whether or which critical care was performed, and (5) place of death within the hospital. Additionally, we examined the ICU admission rate for terminal cancer patients' final month.

3. Statistical analysis

We used descriptive data such as median, range of value, and the number of patients (expressed as a percent) to illustrate the demographics and clinical characteristics of patients. To analyze data between different decision-makers, we applied Student t test for continuous variables and chi-square test for categorical variables. For the analysis of critical care, among 809 patients, the rates of those who were given CPR, MV, and RRT before and after documentation of form 9 were separately calculated. We considered a p-value

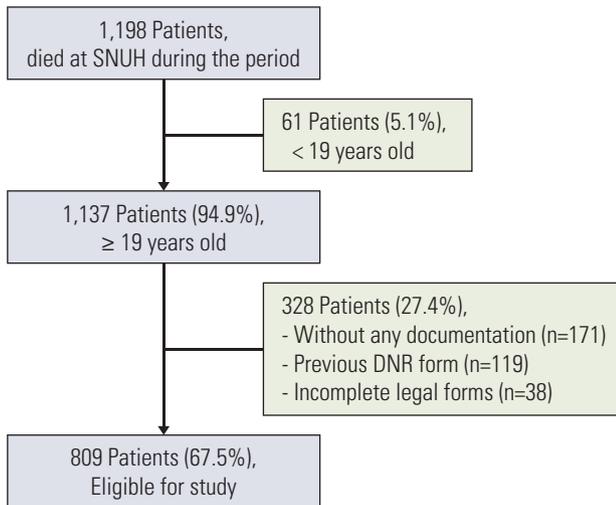


Fig. 1. Flow chart. SNUH, Seoul National University Hospital; DNR, do-not-resuscitate.

of less than 0.05 to be statistically significant. Statistical analysis was performed using STATA ver. 12.0 (StataCorp LP, College Station, TX).

4. Ethical statement

The study protocol was reviewed and approved by the institutional review board of the SNUH (No. H-1907-171-1050). We conducted the study in accordance with the Principles of the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.

Results

A total of 1,198 patients died at SNUH between February 5, 2018, and February 5, 2019. Among them, we excluded patients who were younger than 19 years old ($n=61$), had incomplete legal forms ($n=38$), had previously signed DNR forms ($n=119$), or had no documentation in EMR ($n=171$). To summarize, data from 809 adult patients who died at SNUH with complete legal forms during the period were reviewed (Fig. 1). Demographics and clinical characteristics of the patients are summarized in Table 1, in which the CCI score shows a marked burden of comorbid diseases [14]. The median number of comorbidities was 6, with metastatic solid tumors (45.4%) being the most common, followed by uncomplicated diabetes mellitus (19.4%), cerebral vascular disease (15.3%),

and moderate to severe chronic kidney disease (12.5%). Terminal cancer comprised 70.0% of the terminal diagnoses, which accurately represents our study population, consisting of 71.1% of the patients (575/809).

1. Documentation of the legal forms and decision-makers

Among 809 patients, 231 (29%) completed forms in person, and 578 (71%) had family members complete the forms. To evaluate the interval between documentation and death, we divided forms into ones that were documented during the EOL process and ones before then. With the former, it took a median of 2 days (range, 0 to 244 days) from documentation to death. The interval was longer when patients documented forms in person than when family members did (4 days vs. 1 day). From the time patients show their intent, the median amount of time was 5 days (range, 0 to 244 days) (Table 2).

2. Withholding or withdrawing LST

In practice, 727 patients (89.9%) withheld and 82 (10.1%) withdrew the LST. Regarding decision-makers, the rate of withholding LST was higher when the forms were signed by patients themselves rather than when family members were involved (98.3% vs. 86.5%) (Fig. 2A).

Among 82 patients who withdrew LST, three patients (3.7%) stopped CPR, 74 (90.2%) discontinued MV, four (4.9%) discontinued RRT, and four (4.9%) terminated other treatments including bilevel positive airway pressure and extracorporeal membrane oxygenation (Fig. 2B).

3. Status of "Critical Care"

We assessed how critical care was administered in "the last" admission, according to the documentation date of form 9. In total, CPR (12%), MV (37.8%), and RRT (21.9%) were performed before documentation of the cases, but after documentation, the execution rate of these LSTs dropped to 0.5%, 26.1%, and 15.5%, respectively. Overall, patients experienced critical care at a higher frequency when discussing LST with family members (Fig. 3A-C).

4. ICU admission in the last month of life in terminal cancer patients

From a previous study, it is known that cancer care near the EOL process is becoming increasingly aggressive [3]. To see how this was affected by the act, we analyzed the data of 575 terminal cancer patients. In their final month, 30.3% (174/575) of them admitted to the ICU. ICU admission rate was clearly lower when patients signed the legal forms themselves rather than when family members did (14% vs. 39%)

Table 1. Demographics and clinical characteristics

Characteristic	Total (n=1,198)	Complete legal forms (n=836)	Incomplete legal forms (n=39)	Previous DNR form (n=120)	Without any forms (n=203)
Age (yr)					
Median (range)	66 (0-102)	66 (0-98)	61 (0-80)	72 (0-102)	65 (0-98)
≥ 19	1,137 (94.9)	809 (96.8)	38 (97.4)	119 (99.2)	171 (84.2)
< 19	61 (5.1)	27 (3.2)	1 (2.6)	1 (0.8)	32 (15.8)
Sex					
Male	732 (62.0)	524 (62.7)	21 (53.8)	79 (65.8)	119 (58.6)
Female	455 (38.0)	312 (37.3)	18 (46.1)	41 (34.2)	84 (41.4)
Residence					
Seoul	709 (59.2)	469 (56.1)	24 (61.5)	85 (70.8)	131 (64.5)
Metropolitan	207 (17.3)	149 (17.8)	8 (20.5)	13 (10.8)	37 (18.2)
Suburban	282 (23.5)	218 (26.1)	7 (18.0)	22 (18.3)	35 (17.3)
Comorbidities					
Myocardial infarction	119 (9.9)	76 (9.1)	1 (2.6)	17 (14.2)	25 (12.3)
Congestive heart disease	90 (7.5)	59 (7.1)	1 (2.6)	8 (6.7)	22 (10.8)
Peripheral vascular disease	20 (1.7)	9 (1.1)	1 (2.6)	4 (3.3)	6 (3.0)
Cerebral vascular disease	183 (15.3)	121 (14.5)	2 (5.1)	37 (30.8)	23 (11.3)
Dementia	34 (2.8)	23 (2.8)	0	5 (4.2)	6 (3.0)
COPD	31 (2.6)	24 (2.9)	0	3 (2.5)	4 (2.0)
Rheumatic disease	1 (0.1)	1 (0.1)	0	0	0
Peptic ulcer disease	51 (4.3)	33 (3.9)	2 (5.1)	11 (9.2)	5 (2.5)
Liver disease					
Mild	70 (5.8)	54 (6.5)	1 (2.6)	7 (5.8)	8 (3.9)
Moderate to severe	130 (10.8)	92 (11.0)	3 (7.7)	17 (14.2)	18 (8.9)
Diabetes					
Uncomplicated	232 (19.4)	161 (19.3)	5 (12.8)	29 (24.2)	37 (18.2)
Complicated	49 (4.1)	30 (3.6)	0	9 (7.5)	10 (4.9)
Hemiplegia	7 (0.6)	4 (0.5)	0	1 (0.8)	2 (1.0)
Chronic kidney disease					
Moderate to severe	150 (12.5)	97 (11.6)	2 (5.1)	24 (20.0)	27 (13.3)
Malignancy					
Localized	117 (9.8)	82 (9.8)	1 (2.6)	19 (15.8)	15 (7.4)
Metastatic	544 (45.4)	450 (53.8)	32 (82.1)	31 (25.8)	31 (15.3)
Leukemia	66 (5.5)	57 (6.8)	2 (5.1)	2 (1.7)	5 (2.5)
Lymphoma	59 (4.9)	47 (5.6)	1 (2.6)	5 (4.2)	6 (3.0)
Human immunodeficiency virus	3 (0.3)	2 (0.2)	1 (2.6)	0	0
Charlson comorbidity index score					
Median (range)	6 (0-15)	6 (0-15)	6 (0-12)	4 (0-10)	1 (0-15)
Mean±SD	4.5±2.9	5.0±2.7	5.9±2.4	4.0±2.6	2.5±2.8
0-2	373 (31.1)	203 (24.3)	6 (15.4)	39 (32.5)	125 (61.6)
3-4	170 (14.2)	110 (13.2)	1 (2.6)	30 (25.0)	29 (14.3)
> 4	655 (54.7)	523 (62.6)	32 (82.0)	51 (42.5)	49 (24.1)
Terminal diagnosis					
Yes	771 (64.4)	624 (74.6)	35 (89.7)	53 (44.2)	59 (29.1)
Cancer	707 (59.0)	585 (70.0)	34 (87.2)	41 (34.2)	47 (23.2)
Liver cirrhosis	78 (6.5)	47 (5.6)	3 (7.7)	13 (10.8)	15 (7.4)
COPD	17 (1.4)	11 (1.3)	0	2 (1.7)	4 (2.0)
AIDS	1 (0.1)	1 (0.1)	0	0	0
No	427 (35.6)	212 (25.4)	4 (10.3)	67 (55.8)	144 (70.9)

Values are presented as number (%) unless otherwise indicated. DNR, do-not-resuscitate; COPD, chronic obstructive pulmonary disease; SD, standard deviation; AIDS, acquired immune deficiency syndrome.

Table 2. Intervals between documentation and death

Decision-makers	Type of the legal forms	No. (%)	Median (range)			
			Days between form 9 and death		Days between form 1 or advance statement and death	
Patient (n=231, 29%)	Form 1 (terminal phase)	31 (3.6)	1 (0-51)	4 (0-244)	17 (3-235)	5 (0-244)
	Form 1 (end-of-life process)	191 (23.3)	4 (0-244)		4 (0-244)	
	Form 10 (advance statement verification)	9 (1.0)	0 (0-20)		33 (2-220)	
Family members (n=578, 71%)	Form 11 (≥ 2 members)	349 (41.8)	2 (0-173)	1 (0-173)		
	Form 12 (all members)	229 (30.1)	1 (0-167)			
Total (n=809)			2 (0-244)			

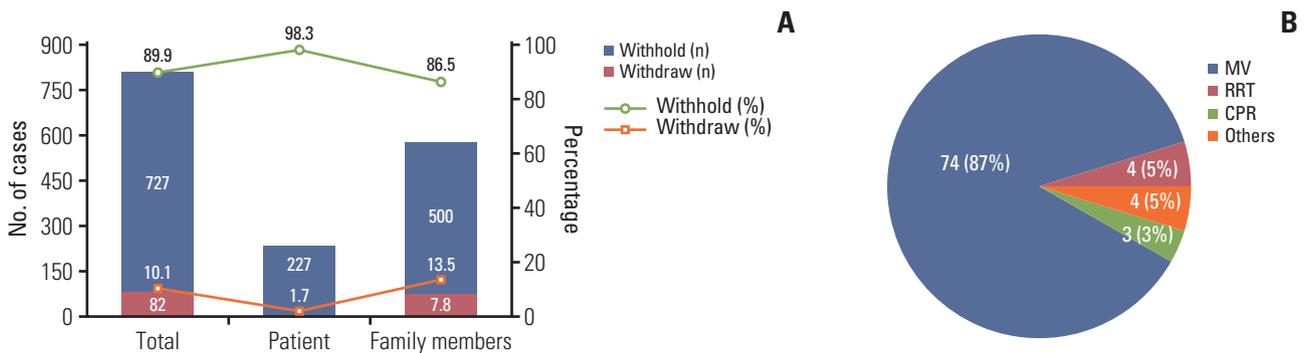


Fig. 2. Implementation status of life-sustaining treatment in the first year of the act's enforcement. (A) Withholding (n=727) or withdrawing (n=82) rate in total, and by decision-makers. (B) Proportions of the treatment which were withdrawn, such as cardiopulmonary resuscitation (CPR), mechanical ventilation (MV), renal replacement therapy (RRT), and others.

(Fig. 4). Additionally, more patients died in ICU (29.9% vs. 5%) when family members made the decisions.

Discussion

Our study found that self-determination rate on LST has increased by up to 29% since the enforcement of the act, which is higher than those from previous studies [3,7,10,11,15]. In Korea, physicians tend to avoid telling the truth to patients directly, concerned that they might be frightened or depressed, so family caregivers are frequently surrogate decision-makers, and do not always respect the patient's will [11]. However, patients want to know their disease status [16] and

discuss ACP in person [17]. Not considering patient's own values, wishes, and goals may result in unnecessary LSTs [18] and deteriorate quality of life for patients and caregivers [4,5]. Our finding implies that patients have been more likely to discuss ACP with their physicians and family caregivers since the act's enforcement. However, the self-determination rate from this study is lower than the rates from Western countries [19,20], so further efforts are needed to enable self-determination by patients themselves.

To date, many ethicists and judges have concurred that there is no moral difference between withholding and withdrawing LST [21,22]. Yet, in majority of Asian countries, the public, patients, and even some physicians tend to understand and treat the two concepts differently [23]. Before the act, withholding LST was accepted, but the first case of withdrawing LST for a person who has no chance of recovery was

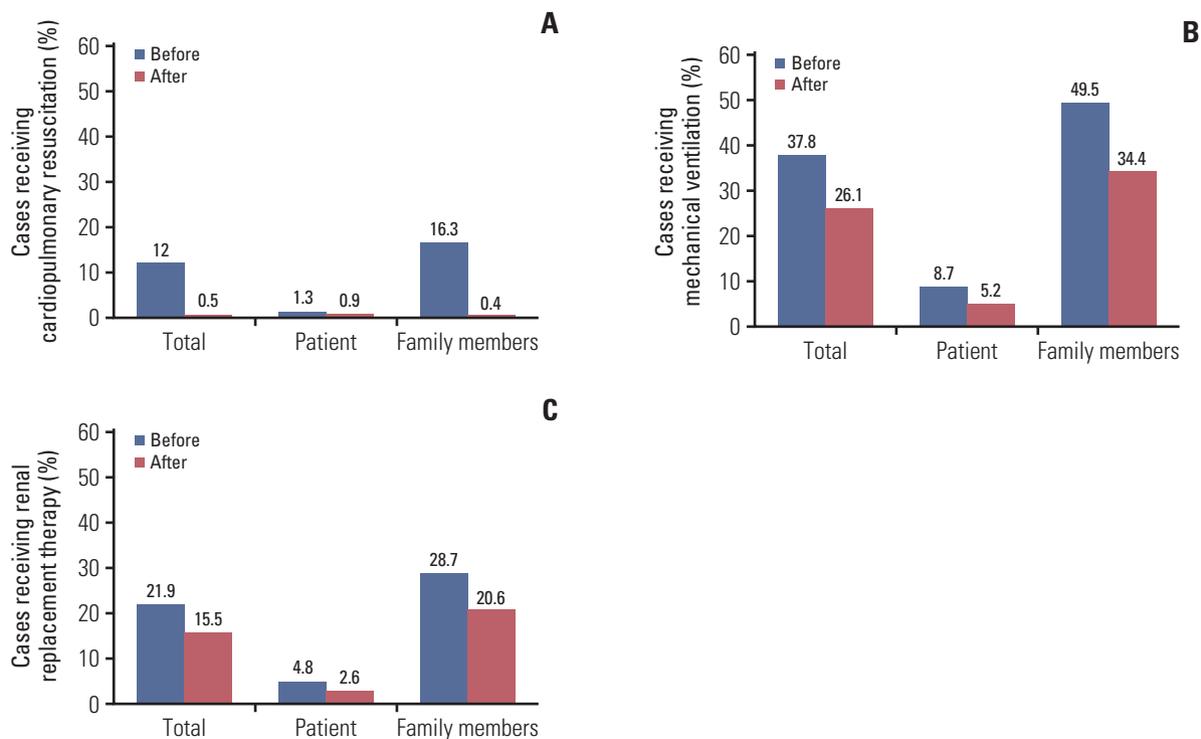


Fig. 3. Status of critical care (%) such as cardiopulmonary resuscitation (A), mechanical ventilation (B), and renal replacement therapy (C), before and after documentation of the legal form 9.

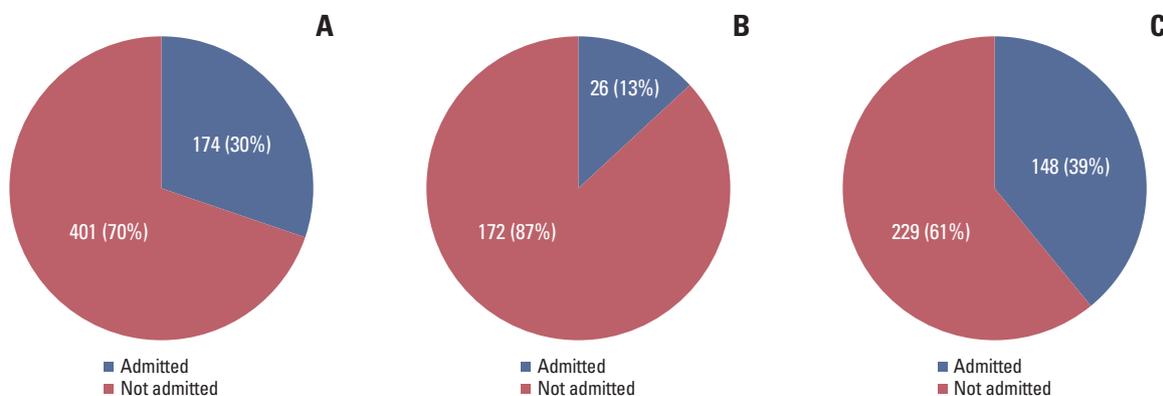


Fig. 4. Intensive care unit (ICU) utilization in the last month of life in terminal cancer patients. (A) ICU admission rate by decision-makers in the first year of the act's enforcement. Admission patterns when patients (B) or family (C) members made decisions.

a result of prolonged litigation in the so-called Grandma Kim case in 2009. After the legitimation following that “case,” patients were lawfully able to withdraw LST and 10% of self-determination led to termination in this study. Supposedly its justification would have alleviated physicians' guilty feelings.

From the aspect of “critical care,” however, patients underwent CPR, MV, and RRT in 12%, 38%, and 22%, respectively in their last admission. As critical care turns into LST after confirmation of the EOL process, decision to withhold means not starting additional LST rather than terminating ongoing treatments in a patient who is already on critical care. There-

fore, even in patients who decided to withhold LST, a considerable percentage actually experienced critical care.

High ICU admission rate (30.3%) within the last month before death in patients with terminal cancer was consistent with those from the previous study [3], even it seems to be on the rise. This reflects high level of aggressive care utilization at the EOL and implies pathetic practice in terminal cancer patients [3,18], the majority of the study population. DNR rather than legal form had been used in 2002 and 2012, and discussion for decision making on LST in those periods differed from 2018, so ICU admission rate could not be directly compared between 2018 and previous periods. However, we propose that ICU admission rate in terminal cancer patients is still high, even after enforcement of the act.

Our finding showed that decisions regarding LST made by family members are different from those made by patients in person. Decisions by family members were significantly associated with higher rates of withdrawal and critical care use, suggesting caregivers' obsession with LST. Cultural aspects including filial piety, the belief that doing everything possible is the best, and unease in accepting death could explain those situations. The difference in implementation of LST by decision-makers compared to patients raises the issue that patients could receive over-treatment not in line with their wishes. Patients' intent and best interest should be taken into consideration during EOL discussion, especially when the patient lacks the capacity for decision-making.

Although decision making occurs earlier than before [24,25] given that the interval from advance statement to death was median of 33 days, it does not seem sufficient enough for all the patients to be able to make decision themselves. Additionally, in Korea, DNR orders are usually written in a week before dying [7,9,15], which means that most of them are documented without proper ACP. To be more effective, we should consider initiating ACP discussion when a patient is diagnosed with critical or terminal illness [17,26]. However, short outpatient consultation time [27], communication difficulties [26], or patients' inaccurate understanding of illness [1,28] may hinder early initiation of ACP. Yet we

shall observe further progress since the results are based on 1-year data after the act's enforcement, consisting only 1% of study population.

In the act, since terminating LST is possible only after physicians confirm that a patient is at the EOL process, uncertainties could be hurdles for the implementation process. Our study demonstrates that the confirmation is done at a median of 2 days before death, but the wide range (0 to 244 days) implies difficulty in further prediction [26]. In order for physicians to make decisions with less struggle, a general consensus should be settled.

There are a few limitations in our study. First, it alone cannot represent the practice pattern of a whole country since it is a study from a single tertiary hospital with mainly cancer patients. Therefore, further studies should be conducted in various institutional settings. Hopefully, investigating a nationwide database would provide more information on strengths and limitations of the act. Second, since this study is based on retrospective data, we should be cautious when interpreting causal relationships. Prospective cohort studies are warranted to overcome this issue.

In conclusion, this study showed that terminating LST became possible, and the self-determination rate actually rose in the clinical practice after the act's enforcement. Considering that patterns of the implementation differed according to who made decisions regarding LST, further efforts are needed to assure best interest and self-determination rights of patients.

Conflicts of Interest

Conflict of interest relevant to this article was not reported.

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