ORIGINAL RESEARCH / *ÖZGÜN ARAŞTIRMA*

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Potentially Inappropriate Treatments in Intensive Care Units (INAPPT-ICU): Point Prevalence Study

Yoğun Bakım Ünitelerinde Potansiyel Yersiz Tedaviler (INAPPT-ICU): Nokta Prevalans Çalışması

ABSTRACT *Objective:* Technological advances increased prolonged life expectancy of the terminal patients, who had end-stage diseases. End-of-life care in intensive care units (ICU) has increased with the rise in admissions of terminal patients to ICU. Our aims in this study were to determine the prevalence of terminal patients, and to find the reasons for potentially inappropriate treatments in ICUs.

Materials and Methods: It was nationwide, multicenter, point prevalence and observational study. All adult patients, who stayed more than 48 h in the ICU, were enrolled. All patients were recorded on an electronic case record form, consisting of data on patient demographics, treatments, family participation and mini survey for physicians. The study was conducted on October 15, 2018 with a follow-up for 30 days.

Results: Of 1127 patients 286 (25%) ICU patients were diagnosed as terminal patients by ICU physicians depending on primary physician statement. Terminal patients relatives requests and physicians legal concerns reduced end-of-life care quality. Terminal patients had significantly increased usage of mechanical ventilation, inotropic drugs, and poor end-of-life care quality (p<0.001). Fifty-four percent of the terminal patients didn't have any end-of-life decisions at discharge. Half of the terminal patient relatives requested the full code. Without legal concerns, most of the physicians would apply do not resuscitate (86%), withhold (77%) and withdraw (53%) to terminal patients at the end-of-life.

Conclusion: Terminal patients occupy an important place in the ICU. To increase the quality of terminal patients' end-of-life care in the ICU, advanced care planning and legal arrangements should be conducted properly.

Keywords: Terminal care, inappropriate treatments, intensive care units, advanced care planning, patient care planning

ÖZ *Amaç:* Teknolojik gelişmeler, son dönem hastalıkları olan terminal hastaların yaşam sürelerinin uzamasına neden olmuştur. Yoğun bakım ünitelerinde (YBÜ) yaşam sonu bakım, terminal hastaların YBÜ'ye kabullerindeki yükselme ile artmıştır. Bu çalışmadaki amacımız, terminal hastaların YBÜ'deki prevalansını ve YBÜ'de potansiyel olarak yersiz tedavilerin nedenlerini incelemektir.

Gereç ve Yöntem: Çalışmamız ülke çapında, çok merkezli, nokta prevalans ve gözlemsel olarak yapıldı. YBÜ'de 48 saatten fazla kalan tüm yetişkin hastalar çalışmaya alındı. Tüm hastalar, hasta demografisi, tedaviler, aile katılımı ve hekimler için mini anket ile ilgili verilerden oluşan elektronik bir olgu kayıt formuna kaydedildi. Çalışma, 15 Ekim 2018'de 30 günlük bir takip ile gerçekleştirildi.

Bulgular: Kaydedilen tüm 1127 hastanın 286'sına (%25) primer hekimi beyanına göre YBÜ hekimleri tarafından terminal hasta tanısı konuldu. Terminal hasta yakınlarının talepleri ve hekimlerin yasal kaygılarının yaşam sonu bakım kalitesini düşürdüğü görüldü. Terminal hastalarda mekanik ventilasyon kullanımı, inotropik ilaçlar ve düşük yaşam sonu bakım kalitesi önemli ölçüde fazlaydı (p<0,001). Terminal hastaların yüzde %54'ü taburcu olurken herhangi bir yaşam sonu kararı verilmedi. Terminal hasta yakınlarının yarısı tam kod istedi. Yasal kaygılar olmaksızın, doktorların çoğu terminal hastalara yaşamlarının sonunda canlandırma girişiminde bulunmama (%86), tedaviyi durdurma (%77) ve tedaviyi geri çekme (%53) kararı vereceklerini açıkladılar.

Sonuç: Terminal hastalar yoğun bakımda önemli bir yer tutmaktadır. Terminal hastaların YBÜ'deki yaşam sonu bakımının kalitesinin artırılması için önceden yaşam sonu bakım planlaması ve yasal düzenlemelerin doğru yapılması gerekmektedir.

Anahtar Kelimeler: Terminal bakım, yersiz tedaviler, yoğun bakım üniteleri, yaşam sonu bakım planlaması, hasta bakım planlaması

Introduction

Intensive care units (ICU) are life-saving facilities for critically ill patients, using advanced technology and specialized personnel. Especially in high-income countries, increased ICU resources and technological advances resulted in an increase in prolonged life expectancy of the terminal patients (TP), who had end-stage diseases. End-of-life care in ICU has increased with the rise in admissions of TPs to ICU (1). Approximately 20% of deaths occur in ICU (2,3). Dying in ICU might be an advantage when end-of-life (EOL) decisions are regarded or disadvantage when inappropriate treatment is practiced.

The intensive care associations recommended the term "potentially inappropriate" should be used, rather than "futile" to describe treatments that have at least some chance of accomplishing the effect sought by the patient (4). Society of Critical Care Medicine (SCCM) defines inappropriate ICU treatments as "when there is no reasonable expectation that the patient will improve sufficiently to survive outside the acute care setting, or when there is no reasonable expectation that the patient's neurologic function will improve sufficiently to allow the patient to perceive the benefits of treatment" (5). As well as high costs of inappropriate treatments, they also delay other patients' care (6).

It is aimed to prevent long-term hospitalizations in ICU to meet the intensive care needs of more patients and to reduce the expenditures on intensive care. For this purpose, advance directives of TPs have become important issues (7). In the United States, the proportion of advance directives increased from 51% to 90% over the 5-year from 1988 to 1992 (8). To the best of our knowledge, there was no point prevalence study about the potentially inappropriate treatments of TPs in ICUs. Our first objective was to determine the prevalence of TP in ICU. Secondary objectives were to assess the reasons of potentially inappropriate treatments and the quality of EOL care in ICU.

Materials and Methods

Study Design

Inappropriate treatments in intensive care units was a nationwide, multicenter, prospective, observational, point prevalence study conducted on October 15, 2018. All adult patients, whose ICU stay was more than 48 hours, were included in the study. Patients younger than 18 years old and patients admitted for monitorization for less than 48 hours, were excluded. Informed consent was obtained from the family. The study was approved by the Instutional Ethics Committee of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine (decision no: 172227, date: 10.05.2018). The study was registered to the Clinical Trials, NCT03520270.

Procedures

The announcement of our study and protocol was made through a society website on August 8, 2018. Enrollments to the study were allowed until October 1, 2018. For the study, a password protected safe portal was created with this society. This portal required society membership to save the center information form and patient data. After all enrollments, the electronic case report forms (e-CRF) were sent to the physicians by portal link with the individual number for their ICUs.

Data Records and Definitions

The center information form included name, e-mail, cell phone of the participant, city, name and specialty of the individual responsible of the ICU, number of hospital and ICU beds, type and level of ICU, number of patients who were admitted to the ICU in 2017 and crude mortality of ICU in 2017.

The e-CRF was for all the included patients to use on the study date and follow up for 30 days. The form included demographics of patients, including age, sex, hospital admission date, ICU admission date, type, source and diagnosis of admission, comorbidities, metastasis, the Acute Physiology Chronic Health Evaluation-II (APACHE-II) score Sepsis-related Organ Failure Assessment (SOFA) score, presence of sepsis diagnosis and Glasgow coma score (GCS). Interventions include the use of mechanical ventilation, vasoactive agents, antibiotics, blood or blood product transfusions.

Care related features like defining the goals of care daily, family meeting, family visits, and spiritual support. The ICU physician's diagnose depending on primary doctor's statement, whether the patient is terminal, was asked on a five point Likert scale ranging from completely agree to completely disagree. Also the opinion of the physicians were asked if they would implement an EOL decision for the patient, who did not have any advance directives, if it would be possible legally. EOL decisions included "Do Not Resuscitate" (DNR, not to initiate or perform

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cardiopulmonary resuscitation), "Withhold" (not to initiate or escalate a life-sustaining treatment), "Withdraw" (cease or remove a life-sustaining intervention).

After 30 days of initial data collection, discharge date and status, and any EOL decision if implemented was recorded to complete the study. The e-CRFs were sent with detailed explanation of each question. The end date of the study was November 14, 2018, and the portal was allowed to record data until December 31, 2018.

Statistical Analysis

SPSS 15.0 for Windows program was used for statistical analysis. Descriptive statistics of the patients are given as number and percentage for categorical variables, mean (± standard deviation) or median (IQR 25 to 75) for continuous variables. The cohort was divided as terminal or non-terminal according to the intensive care physician's diagnose. TPs were the patients, which physicians agreed or completely agreed with the statement that the patient is terminal. The proportion of TPs was calculated as the prevalence on the study day. Normal distribution was analyzed using Kolmogorov-Smirnov test. Comparisons of terminal and non-TPs were made by Student t-test for independent groups for data showing normal distribution, and by Mann-Whitney U test for non-normally distributed data. Multiple comparisons in normally distributed data were made by ANOVA with Bonferoni post-hoc test. The ratios were compared with the chi-square analysis. In all statistical analyses, the level of significance was considered as two-sided $p < 0.05$.

Results

After the announcement in society website, 102 ICU were enrolled until the day of study on October 15, 2018. Eighty-nine of these ICUs (87%) completed the study within 30 days follow up until the end date of the study, November 14, 2018 (Figure 1). Characteristics of the ICUs are presented in Table 1. The total number of enrolled patients was 1127. Of all patients, 25% (n=286) were indicated as TP. Clinical characteristics of patients are presented in Table 2. Most of the admissions were due to medical reasons (73%), and nearly half of these patients had respiratory failure. Number of patients with comorbidities was significantly higher in the TP group, with heart failure being the most prevalent comorbidity. ($p < 0.001$) TP had significantly higher admission day APACHE-II, study day SOFA, and significantly lower study day GCS scores than non-TP patients ($p < 0.001$).

Oxygen treatment, invasive mechanical ventilation, central venous catheter, norepinephrine and dopamine use were significantly higher in TP ($p < 0.001$). In addition, the number of patients with sepsis was significantly higher in TP ($p = 0.001$), but there was no significant difference between antibiotic use (Table 2).

At the end of the study 34% of the all patients died in the ICU, 37% discharged and 28% were still in the ICU. Thirteen percent of the patients had EOL decisions at discharge.

In quality measures of EOL; daily goals of care determination were significantly low in TP ($p < 0.001$). Family meeting in 72 hours was performed in almost all the patients, but only 5% of the ICUs had an open visit. Most of the families (90%) were informed about the terminal state, and half (49.65%) of the families' decisions about EOL were full code (Table 3).

The mini survey was about physicians EOL decisions, if TP did not have any advance directives and it was legally possible. Most of them (86%) would apply DNR, 77% would apply withhold, and 53% would apply withdraw to TP (Table 4).

Table 1. Characteristics of intensive care units	
Characteristics of ICU	**Results**
Mean number of hospital beds	721.52±423.87
Mean number of ICU beds	20.97±20.44
ICU level	
1st level	1 (1.12)
2nd level	4 (4.49)
3rd level	84 (94.38)
ICU type	
Medical/surgical	75 (84)
Medical	11 (12.36)
Surgical	2 (2.25)
Neurology	1 (1.12)
ICU model	
Closed	74 (83.15)
Open	5 (5.62)
Mixed	10 (11.24)
ICU physician's specialty	
Intensive care specialist	60 (67.42)
Anesthesiologist	29 (33.58)
Mean number of patients admitted in 2017	853.38±781.58
Mean 2017 crude mortality	24.81 (15.37)
Data are presented as the mean ± standard deviation or absolute number (percentage). ICU: Intensive care unit	

Table 2. Demographic and clinical characteristics of patients				
Variables	Terminal (n=286)	Not terminal (n=841)	Total (n=1127)	p-value
Age	70.36±16.12	62.59±18.56	64.56±18.28	<0.0001
Sex				0.521
Male	157 (54.9)	480 (57.1)	637 (55.65)	
Hospital stay before ICU, median	0 (0 to 4)	0 (0 to 3)	0 (0 to 3)	0.399
Admission type				<0.0001
Medical	248 (86)	580 (69)	828 (73)	
Emergency surgery	27 (9.4)	123 (14.6)	150 (13)	
Elective surgery	7 (2.4)	61 (7.3)	68 (0.6)	
Trauma	4 (1.4)	77 (9.2)	81 (0.7)	
Admission reason				0.0014
Respiratory	112 (10.0)	291 (25.8)	403 (35.8)	
Cardiovascular	29 (2.6)	80 (7.1)	109 (9.7)	
Gastrointestinal	19 (1.7)	80 (7.1)	99 (8.8)	
Trauma	4 (0.4)	77 (6.8)	81 (7.2)	
Urogenital	14 (1.6)	35 (3.1)	49 (4.3)	
Metabolic	2 (0.2)	13 (1.1)	15 (1.3)	
Neurological	88 (7.8)	232 (20.6)	320 (28.4)	
Other	18 (1.6)	33 (2.9)	51 (4.5)	
Comorbidity				<0.0001
Yes	227 (79.4)	542 (64.4)	769 (68)	
Comorbidity type				
COPD	64 (22.4)	218 (25.9)	282 (25)	0.232
Chirosis	4 (1.4)	11 (1.3)	15 (0.1)	1.00
DM non-insulin	45 (15.7)	87 (10.3)	132 (11)	0.014
DM insulin	24 (8.4)	90 (10.7)	114 (10)	0.263
Heart failure	83 (29)	165 (19.6)	248 (22)	0.001
HIV	1 (0.3)	2 (0.2)	3 (0.2)	1.00
Renal failure	33 (11.5)	76 (9)	109 (0.9)	0.216
Immunosupresive treatment	13 (4.5)	41 (4.9)	54 (0.4)	0.882
Chemotheraphy	29 (10.1)	41 (4.9)	70 (0.6)	0.001
Solid tumor active	56 (19.6)	64 (7.6)	120 (10)	<0.0001
Hematologic cancer	5 (1.7)	17 (2)	22 (1)	0.773
Metastasis	53 (18.5)	45 (5.4)	98 (8)	<0.0001
APACHE-II - admission day	24.48±8.47	20 .67±8.32	21.94±9.72	<0.0001
SOFA - study day	7.97±3.87	5.62±3.41	6.21±3.67	<0.0001
Glasgow coma score	7.90±3.95	10.98±3.83	10.22±4.11	<0.0001
Initiatives				
Oxygene treatment	53 (18.5)	297 (35.3)	350 (31)	<0.0001
Nasal high flow oxygene	3 (1)	28 (3.3)	31 (2.7)	0.042
Noninvasive MV	22 (7.7)	97 (11.5)	119 (10.5)	0.068

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Table 2. Continued

Variables	Terminal (n=286)	Not terminal (n=841)	Total (n=1127)	p-value
Invazive MV	222 (77.6)	484 (57.6)	706 (62.6)	<0.0001
Tracheotomy	82 (28.7)	220 (26.2)	302 (26.7)	0.407
Central venous catheter	192 (67.1)	461 (54.8)	653 (57.9)	<0.0001
Other invazive monitorization	76 (26.6)	235 (27.9)	311 (27.5)	0.654
Renal replacement treatment	40 (14)	88 (10.5)	128 (11.3)	0.105
ECMO	1 (0.3)	3 (0.4)	4 (0.3)	1.00
Nasogastric tube	170 (59.4)	430 (51.1)	600 (53.2)	0.015
Percutaneous endoscopic gastrostomy	55 (19.2)	111 (13.2)	166 (14.7)	0.013
Total parenteral nutrition	36 (12.6)	105 (12.5)	141 (12.5)	0.964
Vasoactive agents	163 (57)	243 (28)	406 (36)	
Norepninephrine	114 (39.9)	188 (22.4)	302 (26)	<0.0001
Dopamine	24 (8.4)	21 (2.5)	45 (3)	<0.0001
Dobutamine	13 (4.5)	14 (1.7)	27 (2)	0.006
Epinephrine	10 (3.5)	17 (2)	27 (2)	0.159
Vasopressine	2 (0.7)	2 (0.2)	4 (0.3)	0.268
Other	0	1 (0.1)	1 (0.1)	1.00
Sepsis	112 (39.2)	244 (29)	356 (31.5)	0.001
Antibiotic	70 (75.5)	172 (79.5)	242 (21.4)	0.152
Blood transfusion <24 h	45 (15.7)	143 (17)	188 (16.6)	0.619

Data are presented as the mean ± standard deviation, median (interquartile range), or absolute number (percentage).
ICU: Intensive care unit, COPD: chronic obstructive pulmoner disease, DM: diabetes mellitus, HIV: human immunodeficiency virus, MV: mechanical ventilation, ECMO: extracorporeal membrane oxygenation, APACHE-II: Acute Physiology Chronic Health Evaluation-II, SOFA: Sepsis-related Organ Failure Assessment

Table 3. Quality measures of end-of-life care

Variables	Terminal (n=286)	Not terminal (n=841)	Total (n=1127)	p-value
Daily goals of care	267 (93.4)	822 (97.7)	1,089 (96.6)	0.001
Family meeting in 72 h	281 (98.3)	830 (98.7)	1,111 (98.5)	0.569
Family visit				0.227
Open visit	19 (6.6)	35 (4.2)	54 (4.7)	
1/day	250 (87.4)	736 (87.5)	986 (87.4)	
A few times/week	16 (5.6)	65 (7.7%)	81 (7.1)	
1/ week	1 (0.3)	5 (0.6)	6 (0.5)	
Spiritual support for patient/family	106 (37.1)	384 (45.7)	490 (43.4)	0.011
Family knowledge about terminal period	245 (90.4)	27 (31)	272 (24.1)	0.0001
Family decision about EOL care			363 (32.2)	0.0001
Not asked	96 (34.5)	57 (67.1)	153 (13.5)	
Everything	142 (51.1)	27 (31.8)	169 (14.9)	
Everything except CPR	29 (10.4)	0	29 (2.5)	
Withhold	6 (2.2)	0	6 (0.5)	
Withdraw	5 (1.8)	1 (1.2)	6 (0.5)	

Data are presented as the absolute number (percentage). EOL: End-of-life, CPR: cardiopulmoner resuscitation

| Table 4. Mini survey about clinician's end-of-life decisions and patients' discharge status				
	Terminal (n=286)	Not terminal (n=841)	Total (n=1127)	p-value
If you think patient is in EOL period, what would you do?				
Withhold			373 (33)	0.0001
I do	214 (77)	35 (36.8)	249 (22)	
Not sure	14 (5)	25 (26.3)	39 (3.4)	
I do not	50 (18)	35 (36.8)	85 (7.5)	
Withdraw			364 (32.2)	0.0001
I do	146 (53.9)	24 (25.9)	170 (15)	
Not sure	34 (12.5)	21 (22.6)	55 (4.8)	
I do not	91 (33.5)	48 (51.6)	139 (12.3)	
DNR			372 (33)	0.0001
I do	237 (86.2)	42 (43.3)	279 (24.7)	
Not sure	15 (5.5)	23 (23.7)	38 (3.3)	
I do not	23 (8.3)	32 (33)	55 (4.8)	
ICU LOS	30 (13 to 54)	29 (10 to 45)	30 (11 to 49)	0.134
Status after 30 days				0.0001
Discharged	46 (16.1)	375 (44.6)	421 (37.3)	
Death	172 (60.1)	212 (25.2)	384 (34)	
Still in ICU	68 (23.8)	254 (30.2)	322 (28.5)	
EOL decision at discharge			934	0.0001
N/A	148 (53.8)	632 (95.9)	780 (83)	
Withhold	17 (6.2)	2 (0.3)	19 (0.2)	
Withdraw	2 (0.7)	2 (0.3)	4 (0.4)	
DNR	108 (39.3)	23 (3.5)	131 (14)	
Standardized mortality rates	1.49	0.98		
Data are presented as the median (interquartile range) or absolute number (percentage). EOL: End-of-life, DNR: do not resuscitate, ICU: intensive care unit, LOS: length of stay				

Status after 30 days; 60% of TP died in the ICU, 16% discharged in the study period and 24% were still in the ICU at the end of the study (p<0.001). TP discharge status was significantly high in medical/surgical type ICU (84%, p<0.005) and third level ICU (92%, p<0.001). More than half of the TP did not have any EOL decisions, 40% had DNR, 6% had withhold, and 1% had withdraw order at discharge.

Discussion

In a large population of multicenter and point-prevalence study, we showed 25% prevalence of TP in the ICUs. In the literature there were surveys about TP prevalence in ICUs in other countries, and our data were consistent with them (4,9,10).

Second important finding of the current study was about the reason of potentially inappropriate treatments in ICU. Physicians legal concerns were the most important reason of avoiding EOL decisions of TPs, and accordingly as well high potentially inappropriate treatment administrations in ICU. Physicians were willing to implement EOL decisions in TP, who did not have any advance directives, if legally possible. But their daily practices were far away from their declaration. In our study EOL decision of TP, who died in ICU (4%), were lower than other studies (11-13). The rates of EOL decisions in Northern and Southern European countries were significantly different (47% vs. 18%) (7). EOL decisions were ranged from 10% in South Asia to 67% in Oceania. They determined that less frequent EOL decisions were made in countries with low-gross national income, and more
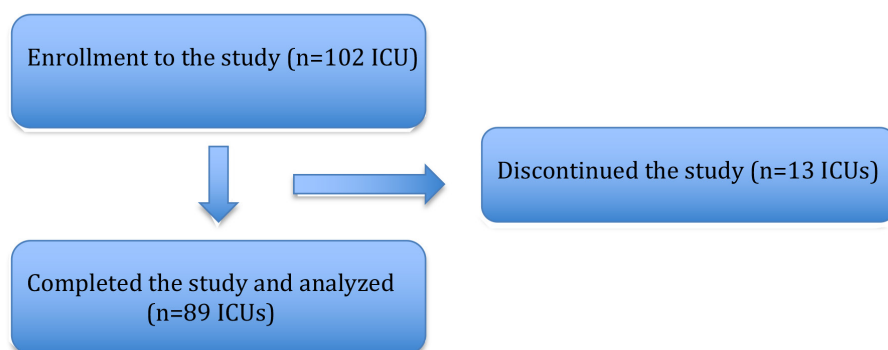
Figure 1. Flow chart
ICU: Intensive care unit

frequently in countries with high-gross national income (14,15). In addition, it was shown that making EOL decision increased 22% in 17 years in European ICUs. The reason for these differences was thought to be due to the changes in attitudes, laws, recommendations and guidelines in Europe regarding EOL practices and the support of European public support in making EOL decisions in the last decade (16).

Other reason of the potentially inappropriate treatments in ICUs was the request of the TPs relatives. Half of the TP relatives EOL decision was full code. Our findings were similar with Palda et al. (9), who showed the most frequent reasons for the potentially inappropriate treatments, were the request of the relatives of the patients (91%) and legal pressure (80%). Some studies showed the reason of the inappropriate treatments in ICUs was poor communication with the patients' families. In our study, we did not find a poor communication between physicians and families.

Other important result of our study was TP ICU length of stay, which was 30 days, was not significantly different from non-TP. Aygencel and Türkoğlu (17) study showed shorter TP ICU length of stay than our study 5 years ago. In the literature, there were studies on limiting the TP ICU length of stay, and avoiding inappropriate treatments, which can be used as a protocol in ICUs (5,18-20). Instead of aggressive treatments, which include ICU admission in the last 30 days of life, SCCM suggests treatments to relieve pain and suffering. Even if such analgesic treatments hasten death, this double effect should not hinder the comfort care (21,22).

Our other result was regarding to the important scoring systems. The most common scoring systems in ICU were APACHE-II, SOFA and GCS. In our study, admission day

APACHE and study day SOFA scores were significantly high, and study day GCS was significantly low in TP. Likewise Xia and Wang (23) study found high APACHE and SOFA scores as significant risk factors for poor ICU prognosis. In addition, Villa et al. (24) developed a scoring system including, length of ICU stays, days of mechanical ventilation, days of vasoactive drug use and sepsis, to find the probability of ICU death.

Our other result showed poor EOL care in ICUs. More than half of the TP died in ICU, and 24% was still in ICU after 30 days follow up. These results showed that more than half of the TP had aggressive care rather than comfort care in the last 30 days of their lifes. The best EOL quality of advanced cancer patients was related with avoiding hospitalization and ICU, remaining calm, praying and meditating (25). Patients and families are the gold standard sources for the evaluation of EOL care. According to patients and families, the most important things in the EOL care were; not admitting to ICU in last 30 days of life, communication with clinicians, patient focused decision making, comfort, dignity, personhood, privacy and family support (26,27). Although SCCM suggests family presence in the ICU, in our study most of the families were allowed to visit their patients once a day (28).

Conclusion

In conclusion, there was a high prevalence of TP in ICUs. In order to avoid inappropriate treatments, and to increase the quality of EOL care in ICUs, advance directives should be recorded in patients' files and legal arrangements should be done without delay.

Ethics

Ethics Committee Approval: The study was approved by the Instutional Ethics Committee of İstanbul University-Cerrahpaşa, Cerrahpaşa Faculty of Medicine (decision no: 172227, date: 10.05.2018). The study was registered to the Clinical Trials, NCT03520270.

Informed Consent: Informed consent was obtained from the family.

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Authorship Contributions

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