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ORIGINAL

Withholding or withdrawing of life-sustaining therapy in older adults (≥ 80 years) admitted to the intensive care unit

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Abstract

Purpose: To document and analyse the decision to withhold or withdraw life-sustaining treatment (LST) in a population of very old patients admitted to the ICU.

Methods: This prospective study included intensive care patients aged ≥ 80 years in 309 ICUs from 21 European countries with 30-day mortality follow-up.

Results: LST limitation was identified in 1356/5021 (27.2%) of patients: 15% had a withholding decision and 12.2% a withdrawal decision (including those with a previous withholding decision). Patients with LST limitation were older, more frail, more severely ill and less frequently electively admitted. Patients with withdrawal of LST were more frequently male and had a longer ICU length of stay. The ICU and 30-day mortality were, respectively, 29.1 and 53.1% in the withholding group and 82.2% and 93.1% in the withdrawal group. LST was less frequently limited in eastern and southern European countries than in northern Europe. The patient-independent factors associated with LST limitation were: acute ICU admission (OR 5.77, 95% CI 4.32–7.7), Clinical Frailty Scale (CFS) score (OR 2.08, 95% CI 1.78–2.42), increased age (each 5 years of increase in age had a OR of 1.22 (95% CI 1.12–1.34) and SOFA score [OR of 1.07 (95% CI 1.05–1.09 per point)]. The frequency of LST limitation was higher in countries with high GDP and was lower in religious countries.

Conclusions: The most important patient variables associated with the instigation of LST limitation were acute admission, frailty, age, admission SOFA score and country.

Trial registration: ClinicalTrials.gov (ID: NTC03134807).

Keywords: Elderly, Intensive care, Ethics, Life sustaining treatment, Withholding, Withdrawal

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Introduction

Life expectancy in many countries is steadily increasing. As a result, patients admitted to hospital and ultimately to the ICU will be older. At present, > 10% of the patients admitted to the ICU are ≥ 80 years old [1]. The proportion of older adults is estimated to increase to 30% by 2050, with a huge impact on total hospital expenditures [2]. As a consequence, many ICUs across the globe must adapt their policies to these increased demands. Some estimate that the need for ICU beds will increase by 50% owing to these developments [3]. However, once an older adult has been admitted to the ICU for an acute medical reason, his/her risk of dying within 30 days is high. For frail patients the 30-day mortality is 40.7% [4].

As a result, ICU physicians are increasingly faced with difficult decisions on continuation of life sustaining treatment (LST) in older adults. In these situations, decisions are being made to withhold LST if patients deteriorate or even to withdraw already instigated LST if the short-term prognosis is poor. Differences in ethics, religion, culture and predictive capacity add to the difficulty of formulating a consistent approach to treatment limitation in critical illness. Previous publications have highlighted the huge variation in admission policies for older adults in Europe [1, 5, 6]. At present, there is a strong consensus that age should not be considered as a sole decision-making criterion [7–9]. Older adults (like any other patients) should be admitted to the ICU only with a predefined, reasonable goal of care. Finally, considering their inherent frailty, all older adults should undergo systematic reassessment a few days after ICU admission to evaluate the appropriateness of their level of care. This concept of an "ICU trial" is attractive and has been proposed for cancer patients requiring mechanical ventilation [11]. However, this should be well organised, explicit, and shared with all ICU staff and the patients' relatives. In most cases, important information is lacking when deciding to admit an older patient in ICU: no living will, incomplete information, and no clarity concerning life expectancy.

Differences in admission policies and health care systems, together with insufficient information from the patients or their relatives (i.e. advanced directives), result in huge variability in end-of-life (EOL) care in the ICU [12]. In addition, there is considerable variation in the proportion of deaths that occur after a decision to limit life support and this cannot be explained solely by patient characteristics [13, 14] or patients' preferences [15]. In the present study we aim to examine the incidence and determinants of LST limitation decisions (withholding and withdrawal) in patients older than 80 years admitted to ICUs in European countries.

Take-home message

Among 5021 very old (≥ 80 years) patients admitted to 309 ICUs in 21 European countries, the most important patient variables associated with the instigation of life-sustaining treatment (LST) limitation were acute admission, frailty, age and SOFA score. The frequency of LST limitation was higher in countries with high GDP and lower where more inhabitants considered their religion's deity very important. For patients with only a withholding decision, ICU and 30-day mortality were respectively 29.1 and 53.1%.

Methods

Study design and setting

The methods and patients have been described in a previous publication [4]. Briefly, VIP1 is a prospective European multicentre study. Each participating ICU could choose to include either consecutive patients throughout a 3-month period or the first 20 consecutive patients within this period. Individual ICUs started data collection between October 2016 and February 2017, depending on the speed of local ethics committee approval. A website was set up to facilitate sharing of information about the study and to allow data entry using an electronic case report form (CRF). The study was registered on ClinicalTrials.gov (ID: NTC03134807).

Participants

All patients aged 80 years or older admitted to the participating ICUs were eligible. Patients were followed until death or for 30 days after ICU admission.

Variables

The study collected a consistent set of data: age, gender, reason for ICU admission from a predefined list of 12 categories, length of stay (LOS) prior to ICU admission, Clinical Frailty Scale (CFS) score [16], admission SOFA score [17], any period of non-invasive or invasive ventilation with endotracheal intubation or tracheostomy during the ICU stay, use of vasoactive drugs, and renal replacement therapy. Severity scores such as SAPS2 were optional. ICU outcome (death or survival) and survival at day 30 after ICU discharge were collected for all included patients. All decisions to withhold and/or withdraw therapy were at the discretion of the treating physician(s) but were documented according to international recommendations [18]. However, we did not collect information on the timing of such a decision relative to ICU admission and/or commencement of organ support.

The CRF and database ran on a secure server at Aarhus University, Denmark.

Country's characteristics

Gross domestic product (GDP) and health expenditure from individual countries were extracted from EUROSTAT (http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics). Proportions of elderly patients per country were extracted from Health at a Glance 2013: OECD Indicators. Numbers of ICU beds per inhabitants were extracted from data derived from Rhodes et al. [37].

Data on religious beliefs were extracted from the European Values Study (http://www.europeanvaluesstudy.eu/).

Bias and study size

The participating ICUs included consecutive patients, and decisions to withhold or withdraw LST were documented. The relationship with 30-day outcome was assessed retrospectively after closure of the database. No formal sample-size calculation was performed for this observational study.

Statistical analysis

Baseline patient characteristics, treatment and outcomes were compared among three LST groups: (1) no limitations, (2) withholding alone and (3) withdrawal, whether or not preceded by a withholding decision. Continuous variables were compared among the groups using the Mann–Whitney U test, categorical variables using the Chi squared test. Normally distributed continuous data were described as medians with 25th to 75th percentiles (interquartile range, IQR). Associations between variables and treatment limitation—i.e. withholding or withdrawal of LST—were estimated using a logistic regression model. To account for the clustering of patients within countries, a multilevel logistic regression model was used. Two models were built to estimate (a) the effect of patient characteristics on treatment limitation and (b) the effect of patient and country characteristics on treatment limitation. In order to quantify the country effect, we used intraclass coefficient correlation (ICC) and median odds ratio (MOR). The ICC represents the proportion of the total observed individual variation in the outcome (treatment limitation, i.e. withholding or withdrawal) that is attributable to between-country variation. The higher this proportion, the higher is the general contextual effect. If one were to repeatedly sample at random two subjects with the same covariates from different countries, then the MOR is the ratio between the subject at higher risk of the outcome and the subject at the lower risk of the outcome (differences in risk are entirely quantified by the country-specific random effects).

Standardized treatment limitation ratios were estimated for each country, defined as the ratio of the observed number of treatment limitations in a country and the sum of the predicted individual probabilities of treatment limitation (estimated from model 1) in the same country. The 95% confidence intervals of the ratios were estimated using Byar's approximation.

Associations between variables and survival at 30 days after ICU admission were estimated using a Cox proportional hazard regression model. All patients were censored at 30 days. Adjusted survival curves were produced using inverse probability weighting. The weights were estimated using frailty, age, gender, type of admission and SOFA score. Mid-point imputations were used for patients discharged from ICU and dead at day 30. A p value less than 0.05 was considered to show a statistically significant difference.

All analyses were performed with R software, version 3.2.2 (R Foundation for Statistical Computing).

Ethics

Institutional research ethics board approval was obtained from each study site. No specific funding was received, but the study was endorsed by ESICM.

Results

In total, 309 ICUs from 21 European countries participated and included 5132 patients. Follow-up at 30 days was completed in 98% (5021/5132) of the patients. The median recruited number of patients per country was 114 and the median number of patients per ICU was 16. The median age of all patients was 84 years (IQR 81–86); 52.1% were male. See Table 1 for more baseline characteristics.

Patients with no LST limitation accounted for 3656/5021 (72.8%) patients with only withholding comprised 15.0% and patients with withdrawal (including those with previous withholding) made up 12.2% of the total. Patients with LST limitation were older, more frail, more severely ill and less frequently electively admitted (Table 1). Patients with withdrawal of LST were more frequently male and had a longer ICU LOS. The proportion of LST limitations varied according to diagnostic category (ESM3), with a very low frequency for patients admitted after elective surgery. Among the non-survivors at day 30, 24.3% had a withholding and 34.6% had a withdrawing LST decision (ESM5). The ICU and 30-day mortality were respectively 29.1 and 53.1% in the withholding group and 82.2 and 93.1% in the withdrawal group. The unadjusted and adjusted survival curves are depicted in Fig. 1.

Provision of organ support also differed according to LST decision, with more instances of organ supports in the withdrawal group (Table 2).

LST limitation was less frequent in eastern and southern European countries than in other parts of Europe (ESM6). The ICUs located in northern Europe had higher rates of LST limitation (up to 45.2%).

Country was found to have a significant effect on the decision whether or not to limit LST. The multivariate analysis identified independent factors for LST limitation decision (Table 3). The most important patient factors associated with LST limitation were: acute ICU admission, CFS score, higher age and admission SOFA score. A sensitivity analysis focusing only on urgent admission, thus excluding scheduled surgery, found similar results. Among the different country characteristics (ESM1) and patient characteristics (ESM2), high GDP was associated with a higher rate of LST limitation, while religiosity, defined as the proportion of inhabitants agreeing with the statement "God is important", was associated with low rates of LST limitation (Table 3) (Fig. 2). The number of ICU beds and the age distribution of the population had no impact on LST limitation.

The ICC was 0.14 (empty model), 0.23 (model with individual patient characteristics) and 0.08 (model with individual patient and country level characteristics). In this last model, 8% of the total variation in patients' treatment limitation is due to country.

The MOR was 2.06 (empty model), 2.57 (model with individual patient characteristics) and 1.66 (model with individual patient and country level characteristics). When comparing two patients with the same frailty level, age, gender, SOFA score and type of admission from randomly selected countries, the MOR for the patient from the country with the higher risk of treatment limitation relative to the patient from the country with the lower risk of treatment limitation was 1.66. Thus, in half such comparisons, the odds of treatment limitation would be less than 1.66 for a patient in the country of higher risk relative to an "identical" patient in the country of lower risk.

Among patients with withdrawal, invasive mechanical ventilation was highly associated with LST limitation decisions (ESM6).

Discussion

Our prospective European study included 5021 patients aged 80 years or older. Limitation of LST was instigated in 27.2% of these patients. Such limitations were associated with 30-day mortality of 54.8% in the withholding group and 94.2% in the withdrawal group. In this very old patient population, several factors other than chronological age are associated with limitations in LST, such as country, urgent admission, frailty and severity of illness (SOFA score).

Our findings are potentially important for policy makers. There was considerable geographical variation in preparedness to instigate limitations in LST in older adult patients. Using the MOR, we have shown that country effects (i.e. 'culture') are as important as, or in some instances more important than, patient characteristics in terms of the association with decisions to withhold or withdraw treatment. An advantage to use of the MOR for quantifying the contextual effect is that the MOR is on the same scale as that used for estimating measures of association when quantifying the effect of subject-level (and country-level) covariates on the odds of the outcome. Thus, one can compare the magnitude of the MOR with that of the association between characteristics of the subject and the outcome. In examining the odds ratios for the model including patient and country characteristics, we observed that only two of the six patient characteristics had an odds ratio above 1.66. Thus, the magnitude of the effect of clustering (the contextual effect) was higher than that of four of the six patient characteristics.

High GDP was associated with higher standardized treatment limitation ratio, while religiosity had the opposite effect. This may seem paradoxical, with more resources used in countries with lower GDP. From an ethical point of view, countries with low GDP potentially jeopardize the allocation of resources by postponing (or not formalizing) EOL decision making.

Such differences have been noted previously. For example, there is lower prevalence of withdrawal of life support in Asia than in the USA or in Europe [15, 19]. Regional variations have also been reported in the UK [20]. These studies suggest that although some variability is driven by ICU bed availability, much of the variability is driven by the views of individual physicians (culture, religion, profile) [21]. This indirectly indicates potential violation of the patients' autonomy (besides inappropriate allocation of resources) and suggests physician- or culture-centred care instead of patient-centred care. In northern European countries intensivists are apparently more willing to withhold or withdraw LST than in eastern and southern European countries. In our study, this difference was even more striking for decisions to withdraw treatment: 5.5% in eastern Europe vs 17.7% in northern Europe. Religion may play a part: the European ETHICUS study reported that withholding occurred more often than withdrawal if the physician was Jewish (81%), Greek Orthodox (78%) or Moslem (63%) [22].

The rate of LST limitation in our study is higher than previously reported in the general ICU population. For example, LST was limited in 11.0% of patients in France [23] and 9.8% in Europe [22]. Several factors may explain these differences: a much younger population (the median age was 57 and 66, respectively, in the French and

Table 1 Patient and ICU stay characteristics according to LST limitation

	All	No treatment limitation	Withholding alone	Withdrawing +/− withholding	p value
N	5021	3656	753	612	
%	100	72.8	15.0	12.2	
Age					
Median (range) (IQR)	84 (range 80–102) (IQR: 81–86)	83 (range 80–102) (IQR 81–86)	85 (range 80–99) (IQR 82–87)	84 (range 80–96) (IQR 82–87)	< 0.0001
Clinical frailty score					
Median (range) (IQR)	4 (range 1–9) (IQR: 3–6)	4 (range 1–9) (IQR 3–5)	5 (range 1–9) (IQR 4–6)	5 (range 1–9) (IQR 3–6)	< 0.0001
Hospital length of stay prior ICU admission (days)					
Median (range) (IQR)	1 (range 0–168) (IQR: 0–3)	1 (range 0–168) (IQR 0–3)	1 (range 0–151) (IQR 0–3)	0 (range 0–108) (IQR 0–3)	0.0016
SOFA score					
Median (range) (IQR)	7 (range 0–24) (IQR: 4–10)	6 (range 0–24) (IQR 3–9)	7 (range 0–22) (IQR 4–10)	10 (range 0–20) (IQR 7–13)	< 0.0001
ICU length of stay (days)					
Median (range) (IQR)	2.33 (range 0–145.58) (IQR: 1–5.92)	2.29 (range 0–145.58) (IQR 1–5.66)	2.12 (range 0–125.38) (IQR 0.92–6)	2.92 (range 0.02–75) (IQR 1–7.03)	0.0406
Patient's sex					
Female	2404 (47.9%)	1737 (47.5%)	395 (52.5%)	272 (44.4%)	0.009
Male	2617 (52.1%)	1919 (52.5%)	358 (47.5%)	340 (55.6%)	
Main reason for ICU admission	Missing: 114/ available: 4907	Missing: 97/ available: 3559	Missing: 12/available: 741	Missing: 5/ available: 607	
Resp failure	965 (19.7%)	627 (17.6%)	207 (27.9%)	131 (21.6%)	< 0.0001
Circ failure	569 (11.6%)	372 (10.5%)	96 (13%)	101 (16.6%)	
Resp + Circ fail	484 (9.9%)	300 (8.4%)	84 (11.3%)	100 (16.5%)	
Sepsis	502 (10.2%)	315 (8.9%)	111 (15%)	76 (12.5%)	
Multi trauma without head injury	63 (1.3%)	43 (1.2%)	9 (1.2%)	11 (1.8%)	
Multi trauma with head injury	66 (1.3%)	44 (1.2%)	5 (0.7%)	17 (2.8%)	
Isolated head injury	124 (2.5%)	78 (2.2%)	23 (3.1%)	23 (3.8%)	
Post elective surgery	906 (18.5%)	853 (24%)	38 (5.1%)	15 (2.5%)	
Intoxication	14 (0.3%)	12 (0.3%)	2 (0.3%)	0 (0%)	
Non trauma CNS causes	315 (6.4%)	196 (5.5%)	56 (7.6%)	63 (10.4%)	
Emergency surgery	403 (8.2%)	327 (9.2%)	45 (6.1%)	31 (5.1%)	
Other	496 (10.1%)	392 (11%)	65 (8.8%)	39 (6.4%)	
Type of ICU admission					
Elective	906 (18%)	853 (23.3%)	38 (5%)	15 (2.5%)	< 0.0001
Acute	4115 (82%)	2803 (76.7%)	715 (95%)	597 (97.5%)	

European studies); less severely ill patients (lower SAPS II scores, lower overall mortality); or the time when the study was conducted, with changes in the perceptions of society in general and ICU physicians in particular as the population ages.

Several studies have documented higher rates of treatment limitation in aged patients compared with their younger counterparts [18, 24–26]. In the SUPPORT study, older age was associated with higher rates of withholding ventilator support and dialysis in adjusted analyses [24, 25]. In a study by Hakim et al. in the USA, the rate of do-not-resuscitate orders increased with age (from 21% in patients < 54 years to 55% in patients > 84 years) [26]. In a study by Hoel et al. in Norway, medical and unscheduled surgical patients with LST limitation were older [27]. Other factors besides age have been associated with increased odds of decisions to forgo LST in US ICUs: female sex, white race, poor baseline functional status [13] and the treatments given to such patients [24].

In our study, the decision to limit LST was associated with increased 30-day mortality (54.8% in the withholding group and 94.2% in the withdrawal group). The same result was found in a recent multicentre observational study in France, in which withdrawing or withholding

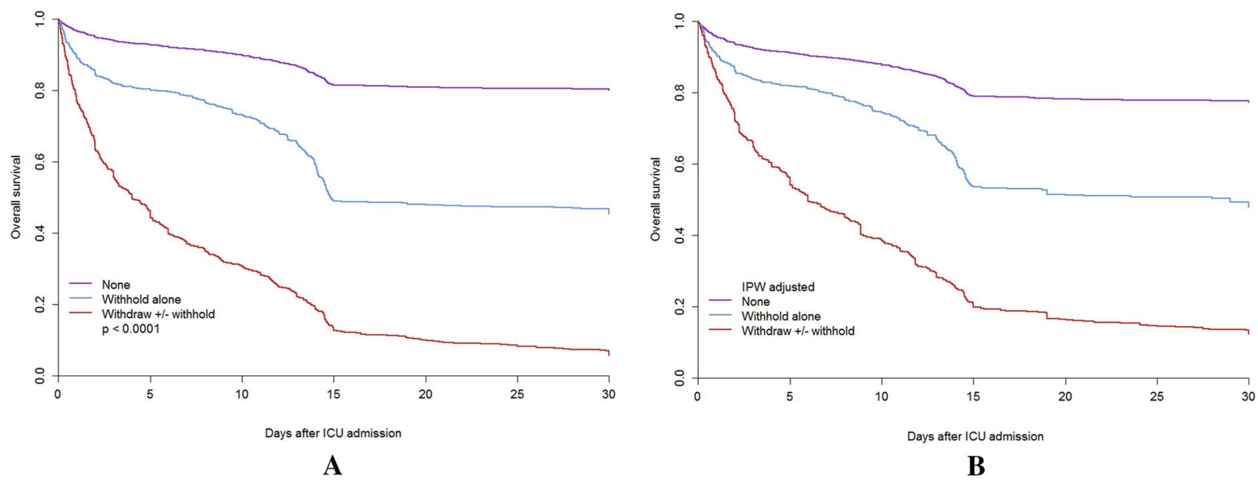

Fig. 1 Survival curves according to LST limitation: **a** unadjusted; **b** adjusted

Table 2 Treatments, frailty level and outcomes

	All 5021	No treatment limitation 3656	Withholding alone 753	Withdrawing +/— withholding 612	p value
Non invasive mechanical ventilation					
No	3872 (77.1%)	2910 (79.6%)	509 (67.6%)	453 (74%)	< 0.0001
Yes	1149 (22.9%)	746 (20.4%)	244 (32.4%)	159 (26%)	
Invasive mechanical ventilation					
No	2501 (49.8%)	1892 (51.8%)	460 (61.1%)	149 (24.3%)	< 0.0001
Yes	2520 (50.2%)	1764 (48.2%)	293 (38.9%)	463 (75.7%)	
Vasoactive drugs					
No	2408 (48%)	1894 (51.8%)	360 (47.8%)	154 (25.2%)	< 0.0001
Yes	2613 (52%)	1762 (48.2%)	393 (52.2%)	458 (74.8%)	
Renal replacement therapy					
No	4559 (90.8%)	3355 (91.8%)	682 (90.6%)	522 (85.3%)	< 0.0001
Yes	462 (9.2%)	301 (8.2%)	71 (9.4%)	90 (14.7%)	
Frailty level					
Fit	1893 (37.7%)	1545 (42.3%)	161 (21.4%)	187 (30.6%)	< 0.0001
Vulnerable	972 (19.4%)	726 (19.9%)	140 (18.6%)	106 (17.3%)	
Frail	2156 (42.9%)	1385 (37.9%)	452 (60%)	319(52.1%)	
Death in ICU					
No	3911 (77.9%)	3268 (89.4%)	534 (70.9%)	109 (17.8%)	< 0.0001
Yes	1110(22.1%)	388 (10.6%)	219 (29.1%)	503 (82.2%)	
Death at day 30					
No	3373 (67.2%)	2978 (81.5%)	353 (46.9%)	42 (6.9%)	< 0.0001
Yes	1648 (32.8%)	678 (18.5%)	400 (53.1%)	570(93.1%)	

care accounted for half of all deaths [28]. In Italy, withdrawal or withholding preceded 62% of deaths [29]. In our study, among the elderly patients dead at day 30, 41.1% had no LST decision, 24.3% withholding and 34.6% withdrawal. However, it should be emphasised that a LST limitation decision is not equal to an EOL decision. In fact, among the elderly patients with a decision to withhold care, the ICU mortality and 30-day mortality were only 29.1 and 53.1%, respectively. For patients in whom LST was withdrawn, ICU mortality and 30-day mortality were 82 and 94.2%. Clearly, not all LST limitations are EOL decisions, since the mortality rate is low for patients

Table 3 Multilevel logistic regression for withholding or withdrawing vs no LST limitation (level 1 = patient/level 2 = country)

	Empty model	Patients characteristics		Patients and countries characteristics	
		OR (95% CI)	p value	OR (95% CI)	p value
Frailty 4 vs 1–3		1.59 (1.3–1.95)	< 0.0001	1.59 (1.3–1.95)	< 0.0001
Frailty 5–9 vs 1–3		2.33 (1.98–2.75)	< 0.0001	2.33 (1.98–2.74)	< 0.0001
Age (5 years increase)		1.23 (1.11–1.35)	< 0.0001	1.22 (1.11–1.35)	< 0.0001
Male vs female patient		1.02 (0.89–1.18)	0.754	1.03 (0.89–1.18)	0.7305
Acute vs elective admission		5.61 (4.13–7.62)	< 0.0001	5.59 (4.12–7.59)	< 0.0001
Sofa score (one point increase)		1.12 (1.1–1.14)	< 0.0001	1.12 (1.1–1.14)	< 0.0001
GDP per capita (one point increase)				1 (1–1)	0.01976
Religiosity (one point increase)				0.96 (0.94–0.99)	0.00498
Country effect	Point estimate	Point estimate		Point estimate	
MOR	2.06	2.57		1.66	
ICC	0.14	0.23		0.08	

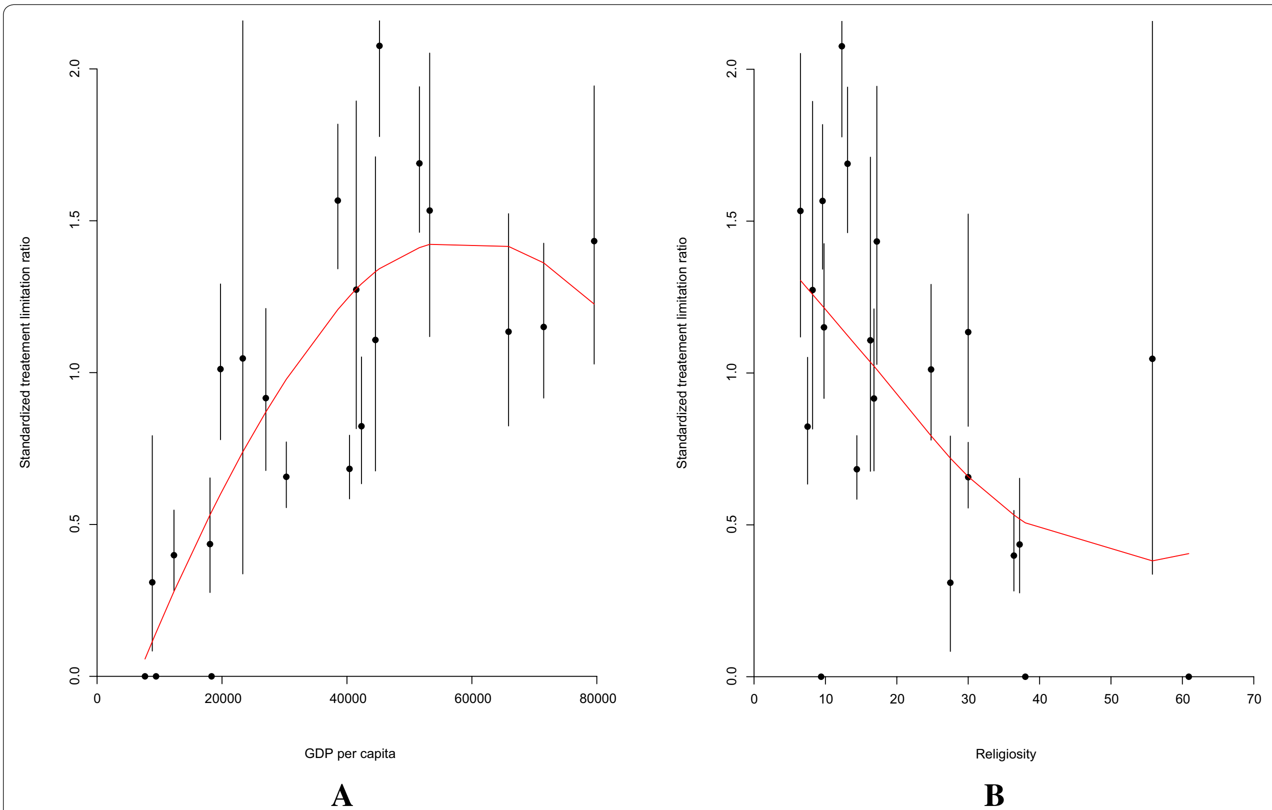

Fig. 2 Standardized treatment limitation ratio. The range lines are 95% confidence intervals. **a** According to the volume index of GDP per capita; **b** according to religiosity, defined as the proportion of the population considering God as very important

with only withholding of treatment and not 100% at 30 days for patients with withdrawal of LST. Apparently, LST limitation is proposed when such LST is considered disproportionate to the patient's chances of survival with a good quality of life [27, 30]. The impact of LST limitation on mortality is greatest in the first week of ICU treatment [31], depending on what kind of treatment is withdrawn and the number of organs failing at the time of LST limitation [31, 32]. We found that the impact of LST limitation on survival was discernible until 2 weeks after ICU admission (Fig. 1).

In our study, the ICU LOS of patients with LST withdrawal was a little longer than the other patients but was still below 3 days, suggesting an early decision to limit LST. In a study from Australia and New Zealand, the LOS of older adults was 3.9 days in non-survivors and 2.5 days in survivors, suggesting that EOL decisions were made later in patients older than 80 years [33]. On the other hand, data from Scandinavia show shorter LOS for non-survivors than survivors in the ICU, particularly for older patients [34].

Our study has several strengths: the focus on patients older than 80 years, the large number of participating ICUs from 21 European countries, the separate documentation of withholding and/or withdrawal of LST and the 30-day follow-up. However, it also has limitations. We have no documentation of the timing of the LST limitation decision, which could bias the results; patient inclusion was mostly during the winter, which may have contributed to the high rate of LST limitation; and the participating ICUs cannot necessarily be considered as representative of their countries. In order to combat these weaknesses, we grouped countries into five European regions; we did not document any possible influence of advance directives or patients' and/or relatives' preferences in the decision; and included no health economic data or bed access/pressure data that could help to develop a resource-based argument for deciding on LST limitation.

In the older adult population, LST limitation occurs frequently. The best criteria for the appropriateness of such decision include post-discharge functional capacity, mortality and quality of life [35]. A dialogue with family members (or care givers) about the possibilities and potential outcomes should take place within 72 h of a patient being admitted to the ICU [10, 21, 36].

Conclusion

Given the limited survival chances of very old patients and the cost and scarcity of ICU resources, an active policy for limiting life-sustaining therapy should be advocated for patients who are not responding to treatment or not willing to continue ICU treatment. This should be accompanied by a campaign encouraging patients to express their preferences and wishes before they become ill. Better definition of which elderly patients will benefit from ICU procedures, rather than drawing up exclusion criteria, is a challenge for future studies.

Electronic supplementary material

The online version of this article (https://doi.org/10.1007/s00134-018-5196-7) contains supplementary material, which is available to authorized users.

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All listed authors have (1) made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) drafted the article or revised it critically for important intellectual content; and (3) given final approval of the version submitted for publication.

Compliance with ethical standards

Conflicts of interest

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