

CLINICAL INVESTIGATION

The relationship between life-sustaining treatment limitation and organ donation in Swedish intensive care: A nationwide register study

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Background: Life-sustaining treatment limitation (LSTL) on the intensive care unit (ICU) may affect the rate of organ donation after brain death (DBD). The primary aim of this study was to examine whether there is a relationship between LSTL and DBD. Furthermore, we aimed to determine the rate of LSTL involved in ICU deaths and to describe technical and procedural characteristics of LSTL on Swedish ICUs.

Methods: This was an observational cohort study on all ICU deaths ($n = 13\,156$) in Sweden between 2014 and 2017. We analysed differences in DBD rates between deaths in ICU with and those without LSTL, using descriptive statistics and logistic regression.

Results: After excluding 1084 deaths on specialised ICUs and units not registering goals of treatment, the study population comprised 12 072 deaths including 615 DBDs, of which 7865 had LSTL, 1706 had no LSTL and 2501 had no stated goals of treatment. The final cohort on which the relationship between DBD and LSTL was analysed comprised 9571 deaths including 419 DBDs. When no LSTL was documented, the rate of organ donation was 9.5% compared to 3.3% when LSTL was documented ($P < .001$). LSTL was associated with a lower DBD rate after adjusting for patient- and ICU-related factors (OR 0.41, 95% CI 0.31–0.53, $P < .001$).

Conclusion: There was an inverse relationship between LSTL and DBD amongst patients who died on the ICU. This relationship remained after adjusting for factors known to influence organ donation. The reason remains to be determined.

Editorial Comment

It has become common practise to always consider organ donation in end-of-life care on the ICU. In this retrospective analysis of all ICU deaths in a national cohort, lower donation rates, adjusted for factors that influence organ donation, were observed when death was preceded by life-sustaining treatment limitations.

Abbreviations: CNS, central nervous system; DBD, organ donation after brain death; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; ICU-LSTL, life-sustaining treatment limitations per ICU; LSTL, life-sustaining treatment limitations; SAPS3, Simplified Acute Physiology Score 3; SIR, The SIR; WD, withdrawal; WH, withholding.

Correction added on 10 June 2021, after first online publication: The Editorial Comment section was corrected.

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1 | INTRODUCTION

End-of-life decisions on the ICU, including withdrawal (WD) and withholding (WH) of life-sustaining treatment, have important consequences, one of which may be to reduce the rate of organ donation after brain death (DBD).^{1,2} Early withdrawal of life support in patients deemed to have irreversible brain injury with imminent death may be one possible cause of loss of potential donors.

Variation in the number of DBDs per million population varies considerably between countries.^{3,4} Many countries suffer from a chronic inability to meet the transplantation needs of its population.⁵ Sweden belongs to the group of nations with comparatively low brain dead organ donation rates per million population.³ Each year in Sweden, between 600 and 700, solid organs are transplanted from 140–170 deceased patients. At the same time there are around 800 people on the waiting list for a solid organ transplant, of which around 50 die each year waiting for a suitable organ.⁶ Yet according to the Eurobarometer survey, citizens in Sweden have the greatest will to donate organs in Europe.⁷

The discrepancy between willingness to donate and the low DBD rate indicates the urgent need to identify possible causes in current practise that may have led to loss of potential organ donors in Sweden.

Changes in the legal consent system is one cause that has been identified and remedies suggested.^{8–12} The current consent process for organ donation is a blend of opt-in (explicit consent given during lifetime) and opt-out (consent presumed provided the deceased did not explicitly oppose donation during his/her lifetime).¹³ When the will of the deceased is unknown, but only then, the next-of-kin has the right to deny donation. Moreover, if several next-of-kin cannot come to an agreement regarding the likely will of the deceased, organ donation is not allowed. There are three equally valid ways to state your will to donate organs, where the most recently dated statement is valid: (1) The National Donor Register (NDR), (2) donor card and (3) verbal statement. By law, the NDR must not be accessed by a transplant coordinator until a patient has been declared dead.⁸

2 | OBJECTIVES

We are unaware of any study examining the possible relationship between end-of-life decisions and DBD; such data could be helpful in improving organ donation after death. The primary aim of this study was to examine this relationship by testing the hypothesis that there is no relationship between life-sustaining treatment limitations (LSTL) and DBD. A second aim was to determine the rate and type of LSTL in patients who die. A third was to investigate those involved in LSTL decisions and the reasons for limiting end-of-life treatment.

3 | METHODS

3.1 | Study design

This was a population-based cohort study on all ICU deaths in Sweden 2014–2017 using data from the Swedish Intensive Care

Register (SIR). SIR collects data from intensive care admissions throughout Sweden and operates within the legal framework of the Swedish National Quality Registers.¹⁴ This framework does not require written informed consent from the patient, but a patient may withdraw data from the register. The study was approved by the Regional Ethics Review Board of Linköping University (no. 2014/117-31) as well as by the board of the SIR.

3.2 | Setting and participants

We examined all deaths that occurred on 65 Swedish ICUs between 1 January 2014 and 31 December 2017 ($n = 13\,156$). Study data were retrieved 28 February 2018. The ICUs were distributed as follows: local hospitals ($n = 25$), county hospitals ($n = 23$), and tertiary care regional hospitals ($n = 17$) (Table 1).

We excluded 12 ICUs that provided specialised care: 4 paediatric ICUs and 1 ECMO unit with missing registration of treatment goals, 5 cardiothoracic ICUs with low unit mortality (1.6%) and few organ donors ($n = 9$) and 2 burns units with no organ donors and few cases with LSTL. Deaths on units not affiliated to SIR (3 ICUs, 503 deaths) and 96 deaths with risk adjustment missing (Simplified Acute Physiology Score 3, SAPS3) were also excluded (Figure 1).

3.3 | Variables

Variables included basic demographic data and a broken down SAPS3-score that allowed separation of cancer cases from other serious comorbidities.¹⁵ Data on presence and timing of stated goals of treatment and reasons for LSTL,¹⁶ as well as diagnoses according to the International Classification of Diseases version 10 (ICD-10) were collected from SIR. The principal diagnosis, recorded by the attending intensive care physician for each admission, was grouped into one of the following five main ICD 10 diagnosis categories: central nervous system (CNS) disease, cerebrovascular disease, injury and poisoning, heart disease and other disease (Data S1). If there was clinical suspicion of new severe brain injury, this was entered into the

TABLE 1 ICU deaths, treatment limitations and organ donations by hospital type

Hospital type	Number hospitals	ICU deaths	LSTL	Organ donors
Local, n (% of ICU deaths)	25	1982	1672 (84.4)	37 (1.9)
County, n (% of ICU deaths)	23	4551	3857 (84.8)	172 (3.8)
Regional, n (% of ICU deaths)	17	3038	2336 (76.9)	210 (6.9)
Total, n	65	9571	7865 (82.2)	419 (4.4)

Abbreviations: ICU, intensive care unit; LSTL, life-sustaining treatment limitations.

Note that a case is less likely to have LSTL documented and more likely to proceed to organ donation in more centralised hospitals ICU.

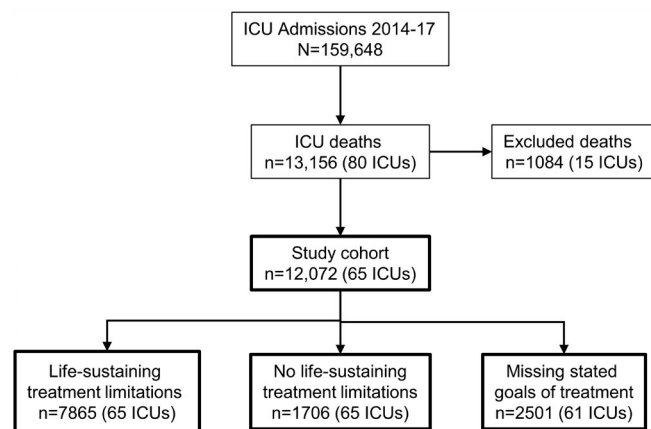


FIGURE 1 Exclusions are detailed in methods

patient records. Details of end-of-life decisions (timing, reason for decision, healthcare professionals involved and whether treatment withheld [WH] and/or withdrawn [WD]) were collected whenever available. LSTL decisions were grouped into no LSTL (no WH/WD) or LSTL (WH with details, WD with details, WH+WD with details and WH/WD without details). Details included one or more of the following: invasive mechanical ventilation, noninvasive mechanical ventilation, continuous or intermittent renal replacement therapy, vasoactive drugs, cardiopulmonary resuscitation and other (surgery, blood transfusion, antibiotic treatment or pacemaker). We collected basic data of the cases with no stated goals of treatment (a source of potential information or selection bias). Variables that described the consent process of organ donation such as the will of the deceased regarding organ donation (unknown, positive or negative) and the form of statement (verbal, donor card or recorded in the NDR) were included. Given the nature of this register-based study, a priori sample size calculation was not performed.

By using the Swedish personal identification number, SIR data were linked to data from a national protocol for follow-up of ICU deaths in order to identify DBD as well as potential, harvested and missed organ donors.¹⁷

3.4 | Calculations and statistical methods

We grouped the four LSTL categories (WH with details, WD with details, WH+WD with details and WH/WD without details) together since their association with DBD was similar (Data S2). The ICU-specific treatment limitation rate (ICU-LSTL) was expressed as the number of deaths with any treatment limitation as percentage of all deaths on the same ICU. Continuous variables were described using means (standard deviations, SD) or medians (interquartile ranges, IQR). Differences in proportions were analysed using the χ^2 -test. Changes over the years covered by the study were analysed using the nonparametric trend test. Logistic regression was used to examine associations between patient and ICU characteristics and DBD as dependent variable. Mixed-effects logistic regression clustered per ICU was used to assess the relationship between treatment

limitation and DBD after adjusting for patient age, sex, cancer and SAPS3 score,¹⁸ principal diagnostic category, presence of treatment limitation and type of hospital.

Although age and cancer are included in the SAPS3 model, they were included separately in our analysis since their SAPS3 weights may not adequately carry the associated risk in the current context. Sensitivity analyses were performed on two selected cohorts to investigate whether the main results were consistent: (1) those who died of presumed new severe brain injury defined as reduced cerebral responsiveness on admission (Glasgow Coma Score <5 or Reaction Level Scale Score >6) and clinical suspicion of new severe brain injury and (2) those who died during 2017. Significance was assumed if $P < .05$.

STATA/SE 16.0 (Stata Corp, College Station, TX, USA) was used for data handling and statistical analyses.

4 | RESULTS

Between 2014 and 2017, there were 13,156 deaths on Swedish ICUs including 615 DBDs corresponding to 17.9 organ donors per million population and year. The relationship between DBD and LSTL was analysed from 9571 deaths with 419 DBDs (Figure 1).

Selected characteristics of the study population, including patients without stated goals of treatment, are presented in Table 2. Numbers without stated goals of treatment varied over time and between ICUs, with fewer patients lacking documentation during the last year of the study period (Data S3). The mean ICU-specific treatment limitation rate (ICU-LSTL, number LSTLs/total deaths) was 82.0% (range 41.0% - 100%).

4.1 | Life-sustaining treatment limitations

LSTLs were documented in some detail in 7865 of 9571 deaths (median number of documented decisions per patient was 1, IQR 1-3) (applied limitation rates are shown in Data S4). LSTL was documented in 82.2% of deaths and in 61.6% of DBDs. The overall proportion of those dying with LSTL was lower in regional than in county and local hospital ICUs (76.9%, 84.8% and 84.3%, respectively; $P < .05$). The median time in ICU until first LSTL was 14.0 h, IQR 1.2-58.5 h (Data S5).

Documented reasons behind treatment limitation in ICU were as follows: patient autonomy ($n = 334$), poor prognosis of the acute illness ($n = 5158$), poor prognosis of simultaneous chronic illness ($n = 3126$), therapy failure ($n = 2111$) and other ($n = 92$). Multiple reasons were possible.

The intensive care physician responsible for the patient decided and documented LSTL and reason/s, in consultation with at least one other colleague. Patient involvement was documented in 334/5911 = 5.7% and next-of-kin involved in 2826/5911 = 47.8%. In 40.5% of the decisions, two physicians and a next-of-kin participated (for more details see Data S6).

4.2 | Deceased patient's will

When organ donation was discussed with the next-of-kin, the patient's will regarding organ donation was unknown in 50.5% ($n = 325$), positive in 38.5% ($n = 248$) and negative in 10.9% ($n = 70$). Of the deceased whose will was unknown, presumed consent was assumed with no family refusal in 199 (61.2%) cases (those nearest to the deceased were informed of intended organ donation and did not claim their right to deny donation). Despite patients having expressed their will to donate organs ($n = 248$), 28 (12.7%) did not progress to DBD for several reasons (Data S7).

The median survival time in ICU for the patients in this study was 34.3 h (IQR 11.0-100.2) and was somewhat shorter when DBD took place (30.5 h, IQR 18.8-52.5). The median survival time was longer for patients with treatment limitation compared to those with no treatment limitation (45.9 vs 18.6 h, $P < .001$, Data S5). In patients with no stated goals of treatment, the median survival time was 21.0 h (IQR 4.9-67.5).

4.3 | LSTLs related to DBD

When no LSTL was applied, the proportion of deaths going to DBD was 9.5%, whereas if LSTL was documented, the figure was 3.3% ($P < .001$). Patient- and ICU-related factors associated with DBD are presented in Table 3.

The results of multilevel logistic regression are presented in Table 4. Documented LSTL was associated with a lower rate of DBD after adjusting for patient- and ICU-related factors (OR 0.407, 95% CI 0.313-0.528, $P < .001$). The results were similar after exclusion of cancer patients ($n = 1907$ with 14 DBDs).

Identical analyses to test for sensitivity were performed on two selected cohorts (died with clinical suspicion of new severe brain injury as specified in the SIR protocol and deaths during 2017). These also revealed that the presence of LSTL was associated with a lower DBD rate (Data S8-9).

5 | DISCUSSION

The main finding of this study was an inverse relationship between LSTL and organ DBD amongst those dying on Swedish ICUs 2014-2017. The null hypothesis, no relationship between the two, was thus rejected. Possible confounders such as age, cancer, principal cause of death and type of hospital were addressed by multivariable analyses, showing no impact on the result.

Discussion around organ donation as a fundamental part of end-of-life care on the ICU is increasing.^{3,19,20} Our premise was that there is no relationship between LSTL and organ donation in Swedish ICUs. This proposal was based on our experience of a distinct separation of care of the critically ill and organ donation in clinical practise and the lack of studies on the impact of end-of-life care

	LSTL n = 7865	No LSTL n = 1706	Missing stated goals of treatment n = 2501
ICUs, n	65	65	61
Age, years, mean (SD)	71.1 (13.2)	64.8 (15.7)	67.9 (14.5)
SAPS3 score, mean (SD)	75.8 (14.6)	73.4 (13.6)	75.9 (14.1)
Female gender, %	41.5	41.0	41.6
Proportion with cancer ^a , %	20.9	16.4	18.7
Major diagnostic categories, n (%)			
CNS disease	124 (1.6%)	53 (3.1%)	51 (2.0%)
Cerebrovascular disease	650 (8.3%)	164 (9.6%)	239 (9.6%)
Injury or poisoning	375 (4.8%)	114 (6.7%)	169 (6.8%)
Heart disease	2003 (25.5%)	516 (30.2%)	764 (30.5%)
Other	4713 (59.9%)	859 (50.4%)	1278 (51.1%)
Hospital type, n (%)			
Local	1672 (21.3%)	310 (18.2%)	499 (20.0%)
County	3857 (49.0%)	694 (40.7%)	1242 (49.7%)
Regional	2336 (29.7%)	702 (41.1%)	760 (30.4%)
Organ donors, n (%)	258 (3.3%)	161 (9.4%)	158 (6.1%)

TABLE 2 Characteristics of study cohort (N = 12 072)

Abbreviations: CNS, central nervous system; LSTL, life-sustaining treatment limitation; SAPS3, Simplified Acute Physiology Score 3; SD, standard deviation.

^aCancer was defined as the presence of cancer plus/minus therapy or haematological cancer as defined in the SAPS3 model.

TABLE 3 Univariable analyses of factors associated with DBD (n = 9571)

	Odds ratio	95% CI	P-value
Age, per year	0.95	0.95-0.96	<.001
SAPS3 score, per point	0.99	0.98-1.00	<.01
Sex:			
Male	1		
Female	1.25	1.02-1.52	<.05
Cancer ^a			
No	1		
Yes	0.13	0.08-0.22	<.001
LSTL			
No	1		
Yes	0.33	0.27-0.40	<.001
Major diagnostic categories			
CNS diseases	1		
Cerebrovascular diseases	0.51	0.36-0.72	<.001
Injury or poisoning	0.32	0.21-0.47	<.001
Heart diseases	0.06	0.04-0.09	<.001
Other	0.003	0.001-0.006	<.001
ICU-LSTL, per 10%	0.86	0.80-0.92	<.001
Hospital type			
Local	1		
County	2.06	1.44-2.96	<.001
Regional	3.90	2.74-5.56	<.001

Abbreviations: CI, confidence interval; CNS, central nervous system; DBD, donation after brain death; ICU, intensive care unit; ICU-LSTL, the proportion of deceased with life-sustaining treatment limitations calculated per ICU; LSTL, life-sustaining treatment limitation; NS, not significant; SAPS3, Simplified Acute Physiology 3.

^aCancer was defined as cancer or cancer therapy or haematological cancer as defined in the SAPS3 model.

on DBD.¹ Since the results revealed an inverse relationship between LSTL and DBD, the null hypothesis was rejected. The results remained significant after adjustment for confounding factors, as well as restricting the analyses to those dying without cancer, those with presumed new severe brain injury and those dying during 2017. It is important to note that according to Swedish law, consent to DBD from the patient's next-of-kin or from the patient (by consulting the Swedish Donor Register after death) may only be sought after the patient's death. Hence, the results of this study cannot be explained by refused DBD consent leading to withdrawal or withholding of end-of-life care.

Restricted access to intensive care beds may influence LSTL and end-of-life decisions.^{21,22} Clinicians may need to prioritise to make beds available for other more critically ill patients, especially when ICU occupancy is high.²³ From the present results, it is possible that the high proportion of cases with LSTL could partly be explained by the shortage of ICU beds in Sweden. Sweden has about

TABLE 4 Multivariable analysis of factors associated with DBD (n = 9571)

	Adjusted odds ratio	95% CI	P-value
Age, per year	0.96	0.96-0.97	<.001
SAPS3 score, per point	1.01	1.00-1.02	<.01
Sex			
Male	1		
Female	1.33	1.06-1.68	<.05
Cancer ^a			
No	1		
Yes	0.20	0.11-0.36	<.001
LSTL			
No	1		
Yes	0.40	0.31-0.52	<.001
Major diagnostic categories			
CNS diseases	1		
Cerebrovascular diseases	0.71	0.47-1.07	NS
Injury or poisoning	0.32	0.20-0.50	<.001
Heart diseases	0.07	0.04-0.10	<.001
Other	0.01	0.00-0.01	<.001
Hospital type			
Local	1		
County	1.96	1.23-3.10	<.01
Regional	2.04	1.27-3.29	<.01

Abbreviations: CI, confidence interval; CNS, central nervous system; DBD, donation after brain death; LSTL, life-sustaining treatment limitation; NS, not significant; SAPS3, Simplified Acute Physiology 3. Note that the presence of treatment limitations was associated with a 60% reduced likelihood of DBD.

^aCancer was defined as cancer or cancer therapy or haematological cancer as defined in the SAPS3 model.

5 adult ICU beds per 100,000 citizens, which is in the lowest range in Western countries.²⁴ However, differences in the proportion of patients dying with treatment limitations (ICU-LSTL) between ICUs in Sweden were considerable, indicating that there may be other explanations. In agreement with the shortage of ICU beds, time to treatment limitation and length of stay in ICU were short (Table 2). Short length of stay and low mortality on the ICU appears to be characteristic of intensive care in Nordic countries. A substantial proportion of patients die after discharge from ICU resulting in overall hospital mortality of around 15%.²⁵ However, a detailed analysis of organisational features that could have contributed to the inverse relationship between LSTL and DBD was not within the scope of this study. A comprehensive analysis should include information on a wide range of factors that were not available such as actual workload, premature discharge related to treatment limitations, staffing, communication skills and attitudes, all of which should be the subject for further research.

5.1 | Strengths and limitations

During the period of this study, SIR had detailed guidelines and regular education on collection of data on ICU mortality, organ donation and LSTL. Guidelines were available on the Internet and launched stepwise 2009-2013. Data were captured at the bedside, submitted electronically and entered in the register after validation. Invalid entries were returned for correction before renewed validation. The carefully created register infrastructure has led to almost complete capture of ICU deaths and organ donors nationwide. Unfortunately, 20% of patients dying had no documentation of goals of treatment, a deficiency in documentation that has also been reported by other research groups.²⁶⁻²⁸ Documentation was incomplete for several ICUs, especially during the first year of the study but improved gradually as register guidelines were implemented. When restricting analysis to 2017 only, the proportion of completed register data sets had reached 89%. But even when assuming that all deaths with missing documentation were non-LSTL, the DBD rate in the non-LSTL group would still be significantly higher (7.6%, $P < .001$ compared to the LSTL-group).

It was assumed that LSTL documentation mirrored actual limitations. Whilst detailed documentation on treatment being withdrawn or withheld was found in most cases, we grouped the four categories of WH and WD together since their relationship to DBD was similar. The aggregate SAPS3 score was used in the multivariable analyses despite the complex relationship between components of the SAPS3 score and DBD. A higher score due to reduced cerebral responsiveness increased the likelihood of DBD, whereas a higher score due to comorbidity and age decreased the likelihood of DBD. However, when breaking down the SAPS3 into components, we found minimal impact on the principal results of the multivariable analyses (data not shown). We therefore decided to use the aggregate score. We analysed the relationship between LSTL and organ donation using a two-level model with deceased patients nested within ICUs. This was obviously a simplified model as suggested by recent work that showed considerable variability in provider (physicians and nurses) agreement with consensus statements on end-of-life care.²⁹ There are important geographical and cultural differences regarding end-of-life care and organ donation, underlining the fact that our results may not be valid in other settings.^{30,31} Inclusion of physicians and nurses in the model was impossible since data were unavailable. Furthermore, the relevance of including individual healthcare providers is questionable in the present context, since the number of providers involved in each case was probably large (Data S6). Future work is needed to shed light on the degree to which variability in ICU care provider attitude contributes to variation in the proportion of those dying with LSTL.

6 | CONCLUSION

Documentation of limitation of life-sustaining treatments increased during the study period, with 85% of deaths in ICU during 2017 having LSTL. Limitation of life-sustaining treatment was associated with

a reduced crude and adjusted likelihood of DBD. A key concern, therefore, is whether there are many cases of "lost" DBD hidden amongst ICU deaths with LSTL. The reasons for the high proportion LSTLs amongst patients dying in Swedish ICUs and the association with reduced likelihood of DBD remain to be determined.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests.

AUTHOR CONTRIBUTIONS

Both authors contributed to the study conception, design, acquisition of data, analysis and interpretation of data. Both authors participated in the drafting and writing of the manuscript. Both authors have read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Regional Ethics Review Board of Linköping University (no. 2014/117-31) as well as by the board of the Swedish Intensive Care Registry.

CONSENT FOR PUBLICATION

A signed Copyright Transfer Agreement is signed (see AAS_Copyright_Transfer_Agreement_Nolin_AAS-20-0674.pdf). SIR collects data from intensive care admissions in Sweden and operates within the legal framework of the Swedish National Quality Registers. This framework does not require written informed consent from the patients, but patients may withdraw their data from the register.

PROTOCOL REGISTRATION AND STROBE STATEMENT

The cohort study was assigned ID NCT04131140 17 October 2019 in ClinicalTrials.gov. Data S10 gives the STROBE reporting guidelines (the checklist of items that should be included in reports of cohort studies with reference to row and page in the manuscript).

DATA AVAILABILITY STATEMENT

The datasets generated and analysed in the present study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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