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A protocol of no sedation for critically ill patients receiving mechanical ventilation: a randomised trial

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*Standard practice is to sedate critically ill patients needing intubation and mechanical ventilation.

*Many memories have been shown that the daily interruption of sedation reduce the severity of post traumatic stress disorder and several complications-ventilator .

*the duration of
mechanical ventilation
could be reduce with a
protocol of no sedation?*

Outcomes:

- *the number of days without mechanical ventilation in 28-day period

- *the length of stay in the care unit and in hospital

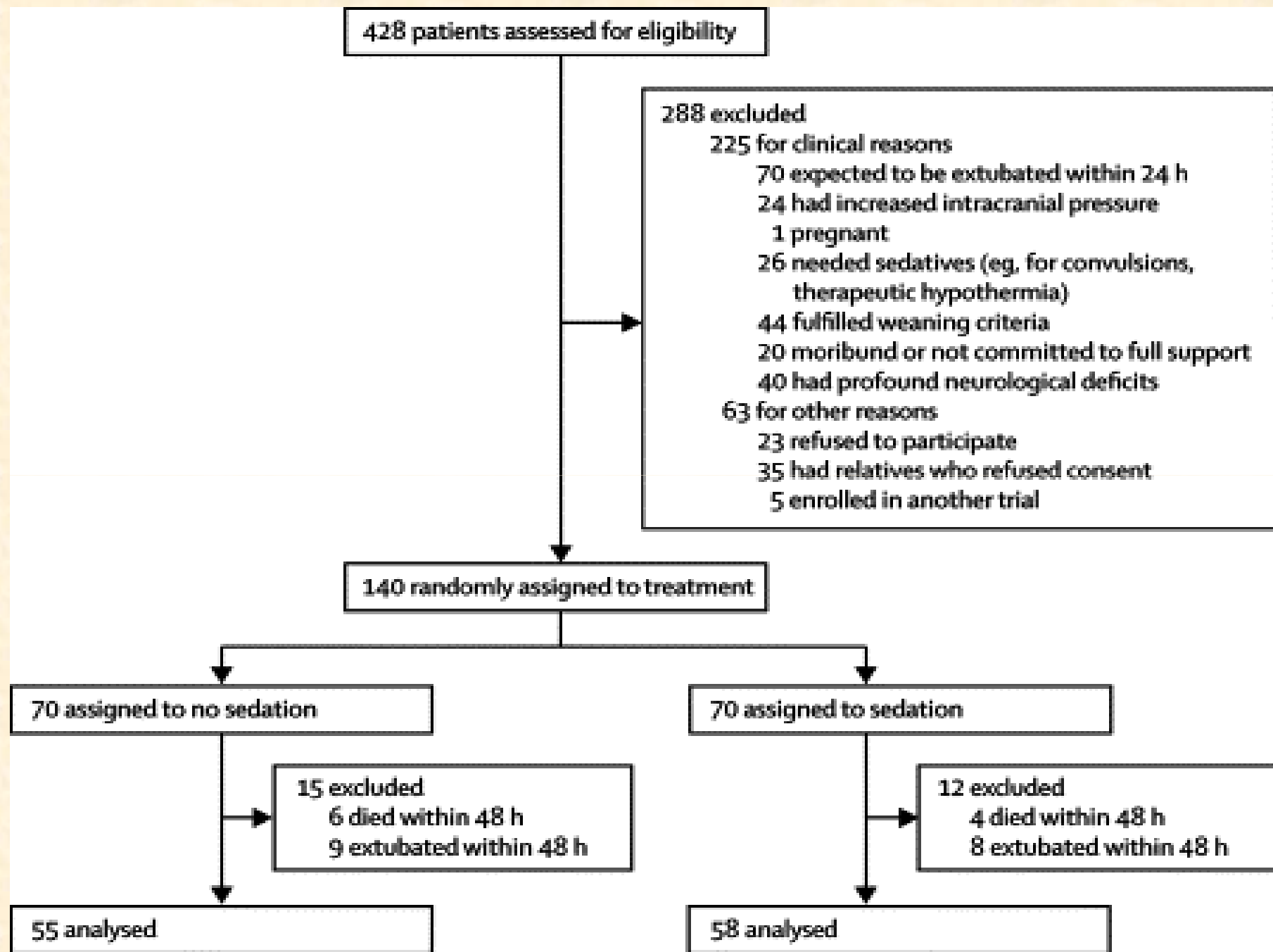
- *the occurrences of complications

*2 criteris of inclusions:

- age > 18
- patients need more than 24h of ventilation

* criteris of exclusions:

- increased PIC
- patient needed sedation: convulsions..
- $F_{iO_2} < 40\%$ and $P_{eep} < 5$
- No cerebral contact
- Relatives refuse to consent..



2 groupes:

*intervention group: no sedation

*control group: sedation

the 2 groups are comparables

	No sedation (n=55)	Sedation (n=58)
Age (years)	67 (54-74)	65 (54-74)
Women	13 (24%)	24 (41%)
Weight (kg)	80.0 (74.0-92.0)	78.5 (70.0-91.0)
APACHE II	26 (19-30)	26 (22-31)
SAPS II	46 (36-56)	50 (43-63)
SOFA (at day 1)	7.5 (5.0-11.0)	9.0 (5.5-11.0)
Diagnosis at admission to intensive care unit		
Respiratory disorder*	26 (47%)	27 (47%)
Sepsis	15 (27%)	19 (33%)
Pancreatitis	2 (4%)	3 (5%)
Peritonitis	0	1 (2%)
Gastro-intestinal bleeding	5 (9%)	0
Liver and biliary disease	2 (4%)	0
Trauma	2 (4%)	3 (5%)
Other	3 (5%)	5 (9%)

*both groups receive **iv morphine** in bolus doses: no difference of doses.

*the sedation of control group:

- infusion of **Propofol** (20 mg/ML) titrated to reach a Ramsay score 3-4 with daily interruption and neurologic testing, after 48 h, we change it with **Midazolam 1mg/ml**

*the indication of morphine is patient discomfort: pain

Results:

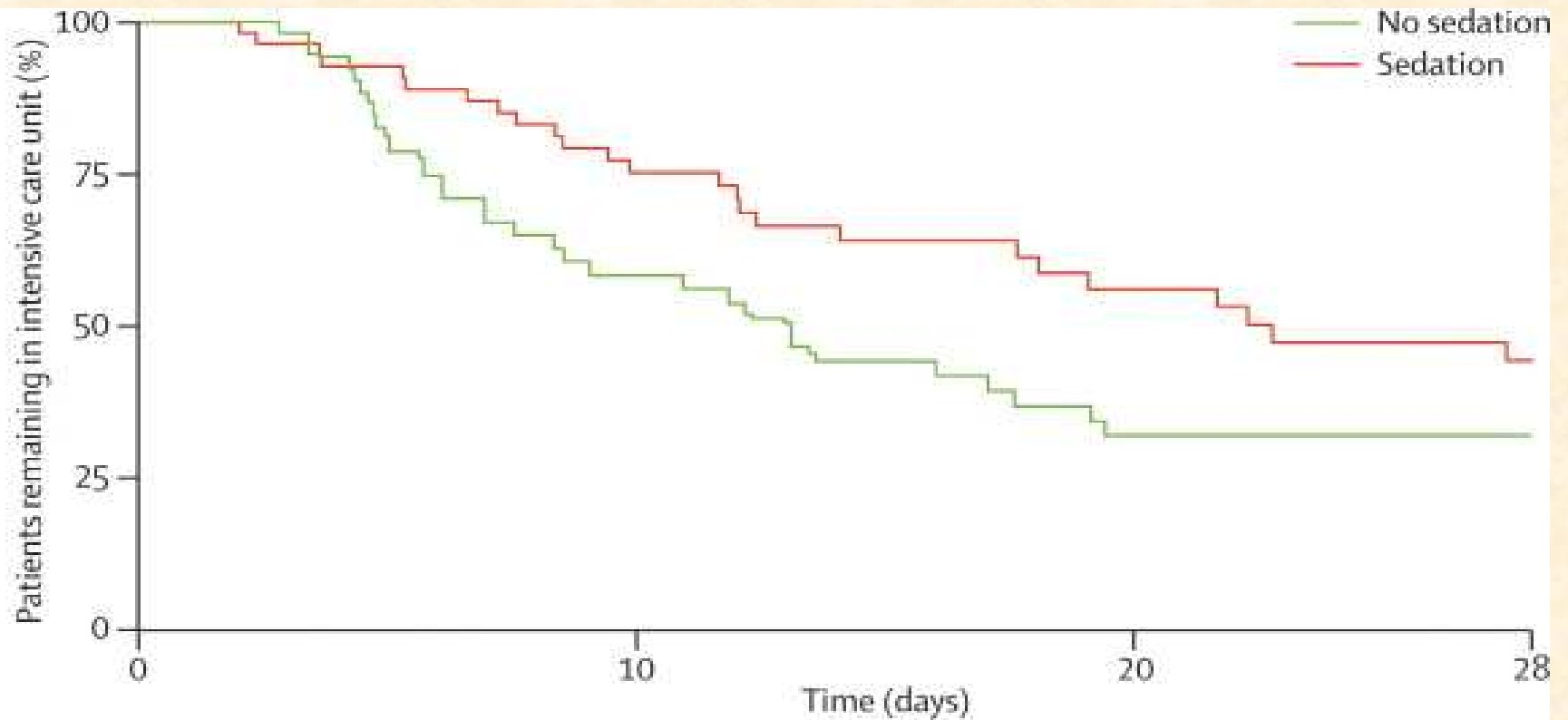
1-no sedation reduce the number of days without ventilation.

2-no sedation reduce the length of stay in the intensive care unit and in hospital

*no difference in the occurrences of accidental extubation, the need for TDM cérébral, or ventilator-associated pneumonia.

*agitated delirium was more frequent in the intervention group

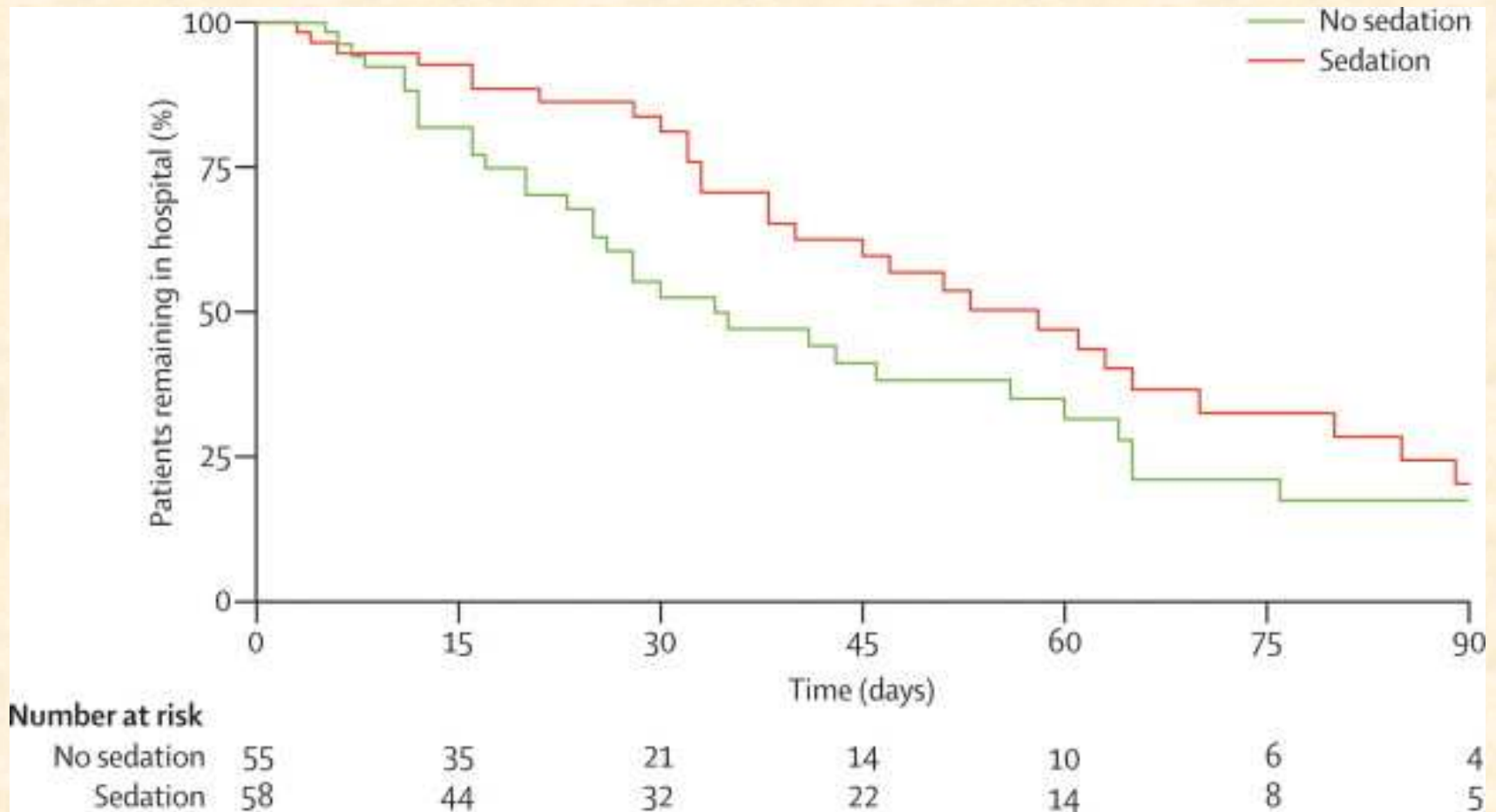
	No sedation (n=55)	Sedation (n=58)	p value
Days without mechanical ventilation (from intubation to day 28)	13.8 (11.0); 18.0 (0-24.1)	9.6 (10.0); 6.9 (0-20.5)	0.0191*†
Length of stay (days)			
Intensive care unit	13.1 (5.7--)	22.8 (11.7--)	0.0316*§
Hospital	34 (17-65)	58 (33-85)	0.0039*§¶
Mortality			
Intensive care unit	12 (22%)	22 (38%)	0.06
Hospital	20 (36%)	27 (47%)	0.27
Drug doses (mg/kg) 			
Propofol (per h of infusion)**	0 (0-0.515)	0.773 (0.154-1.648)	0.0001
Midazolam (per h of infusion)	0 (0-0)	0.0034 (0-0.0240)	<0.0001
Morphine (per h of mechanical ventilation)	0.0048 (0.0014-0.0111)	0.0045 (0.0020-0.0064)	0.39
Haloperidol (per day of mechanical ventilation)	0 (0-0.0145)	0 (0-0)	0.0140
Tracheostomy	16 (29%)	17 (29%)	0.98
Ventilator-associated pneumonia	6 (11%)	7 (12%)	0.85



Number at risk

No sedation	55	26	13	12
Sedation	58	38	20	15

Kaplan-Meier of length of stay in the intensive care unit and number at risk from admissions to 28 days



Kaplan-Meier plot of length of stay in hospital and number at risk from admission to 90 days

LIMITS:

*several ill patients were included who dependent on mechanical ventilation for more 2 weeks

*the use of Midazolam could increase the duration of mechanical ventilation

*we should follow-up the intervention group 1 year to detect deliriums

*the ratio nurse/patient=1/1

*it is a single-center study

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