Risk assessment of the ICU patient

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Conflict of interest disclosure

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Overview

1. Clinical scenario
2. IC natural history (NNCIP)
3. S.A.T. modalities
4. IC prediction rules:
    - Colonization index; Ostrosky rule; Candida Score
5. Candida Score & clinical use
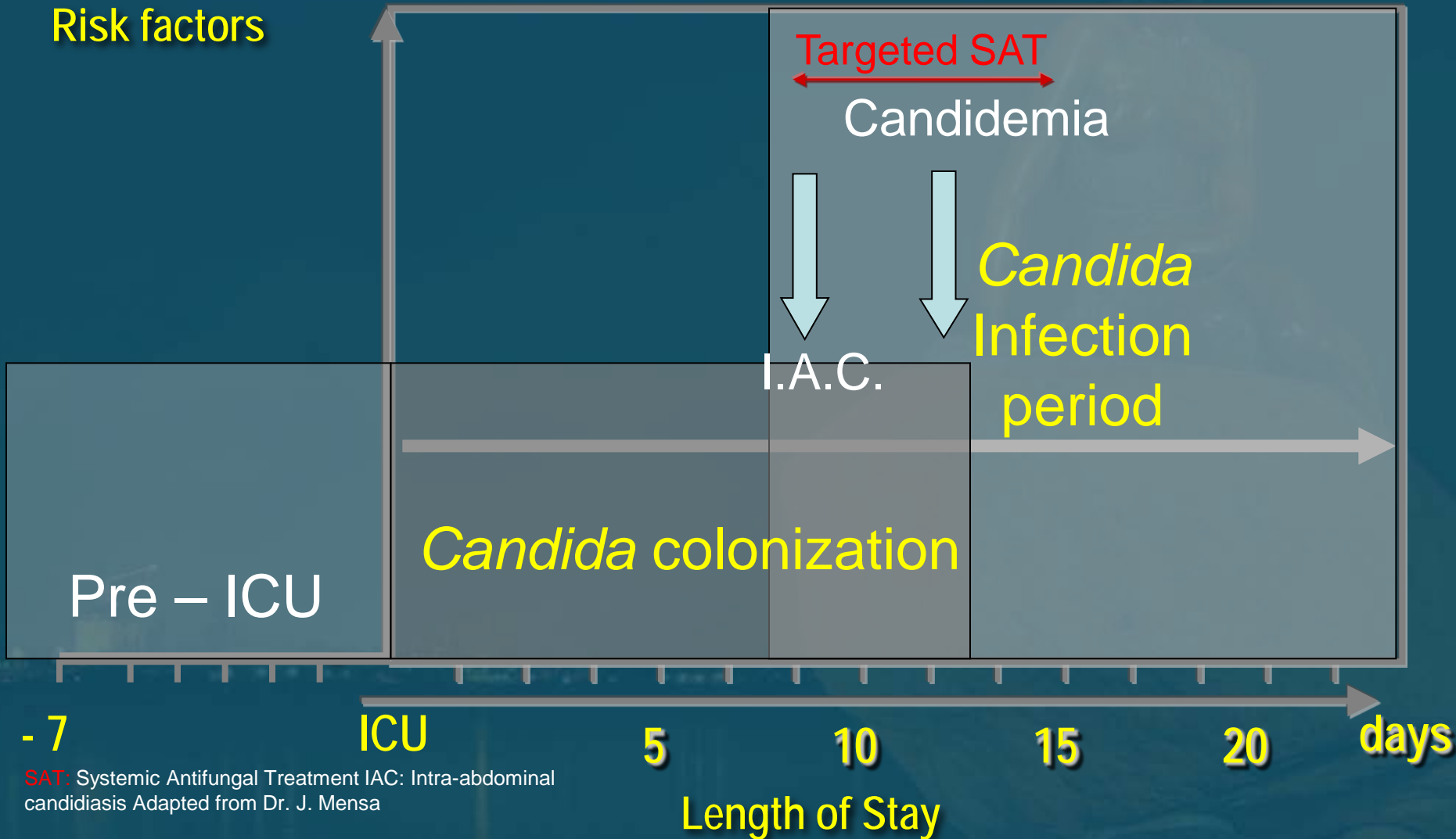6. Candida Score & biomarkers
7. Conclusions

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Clinical scenario

- Adults, medical / surgical critically ill patients
- ICU - L.O.S. ≥ 3-5 days, multiple *Candida* infection risk factors
- With w/o *Candida* unifocal / MF colonization
- With w/o clinical symptoms infection
- IC diagnosis delay
- *Candida* infection ➔ ↑morbi-mortality
- Non-IC targeted S.A.T.
- Prediction rule ➔ identify ICU patients high IC risk

S.A.T. = Systemic Antifungal Treatment

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IC natural history in NNCIP

Risk factors

Targeted SAT

Candidemia

Candida Infection period

I.A.C.

Candida colonization

Pre – ICU

- 7   ICU   5   10   15   20   days
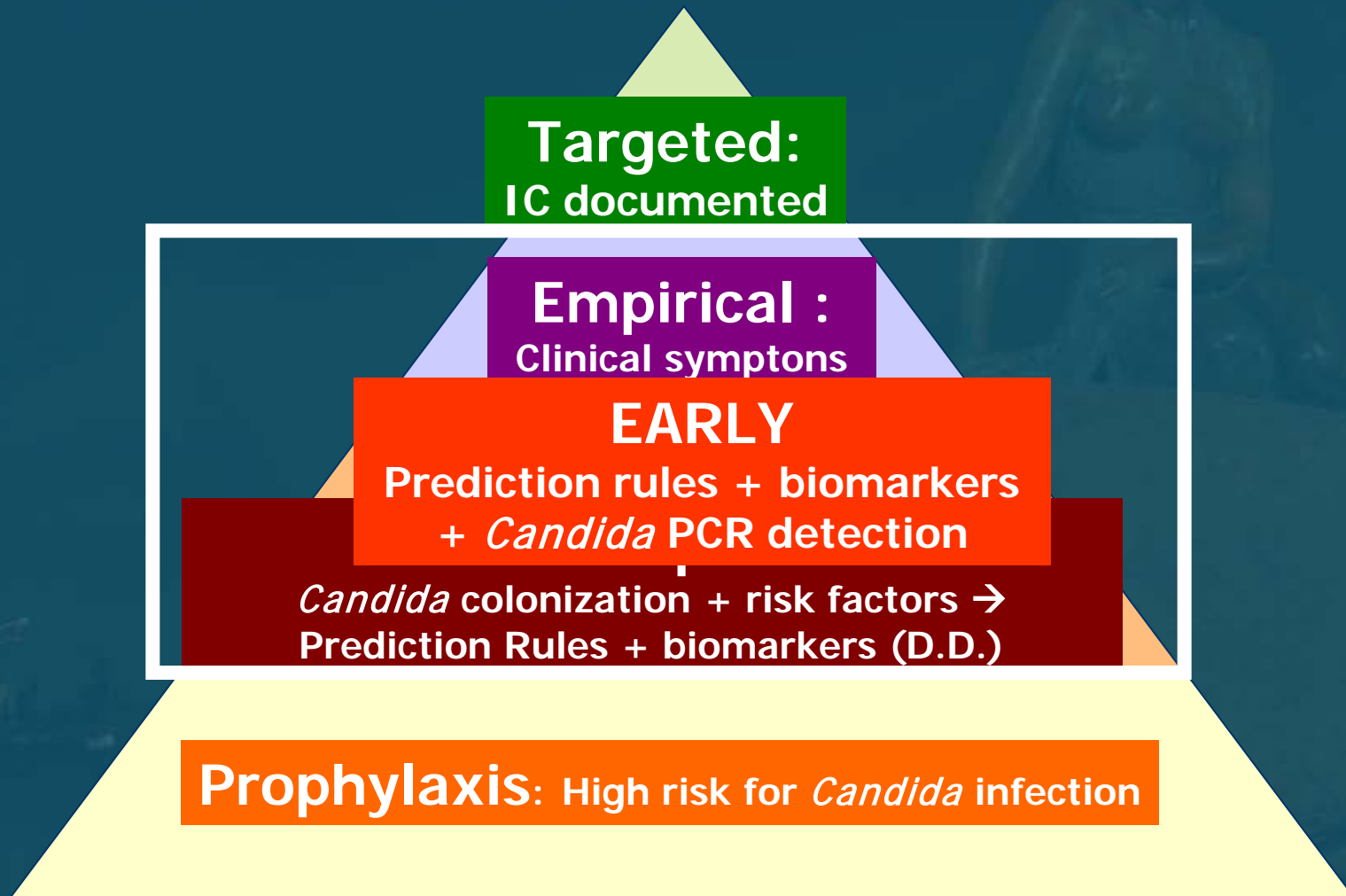
SAT: Systemic Antifungal Treatment IAC: Intra-abdominal candidiasis Adapted from Dr. J. Mensa

Length of Stay

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Systemic Antifungal Treatment Modalities

Targeted:
IC documented

Empirical :
Clinical symptons

EARLY
Prediction rules + biomarkers
+ *Candida* PCR detection

Candida colonization + risk factors →
Prediction Rules + biomarkers (D.D.)

Prophylaxis: High risk for *Candida* infection

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Prediction rules to identify ICU patients at high **IC** risk

Parameters included

Colonization Index [1]

nº sites / nº sites
screened
2 x weekly
> 0.5 or ≥ 0.4 corrected

Candida Score [2]

Surgery on ICU admission
TPN
Severe sepsis
Candida colonization
≥ 3 points

Ostrosky Rule [3]

ICU L.O.S. > 4 days
All of:
Broad Syst..Antib. + CVC + MV
+ **one of:**
TPN (day 1-3)
Dialysis (day 1-3)
Major surgery (- 7 -0)
Pancreatitis (- 7 -0)
Immunosupp. / steroids (- 7 -0)

1 Didier Pittet, M.D., M.S.,* Michel Monod, Ph.D.,‡ Peter M. Suter, Edgar Frenk, M.D.,‡ and Raymond Auckenthaler, M.D.* — ANNALS OF SURGERY Vol. 220, No. 6, 751–758 © 1994 J. B. Lippincott Company

2 Cristóbal León, MD; Sergio Ruiz-Santana, MD, PhD; Pedro Saavedra, PhD; Benito Almirante, MD, PhD; Juan Nolla-Salas, MD, PhD; Francisco Álvarez-Lerma, MD, PhD; José Garnacho-Montero, MD; María Ángeles León, MD, PhD; EPCAN Study Group — (Crit Care Med 2006; 34:730–737)

3 Luis Ostrosky-Zeichner,[1] Peter G. Pappas,[2] Shmuel Shoham,[3] Annette Reboli,[4] Michelle A. Barron,[5] Charles Sims;[1] Craig Wood[6] and Jack D. Sobel[7] — 2011 Blackwell Verlag GmbH • Mycoses 54, 46–51

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A bedside scoring system ("Candida score") for early antifungal treatment in nonneutropenic critically ill patients with *Candida* colonization*

Cristóbal León, MD; Sergio Ruiz-Santana, MD, PhD; Pedro Saavedra, PhD; Benito Almirante, MD, PhD;
Juan Nolla-Salas, MD, PhD; Francisco Álvarez-Lerma, MD, PhD; José Garnacho-Montero, MD;

Courtesy by J. Mensa

Variable	Proven Candidal Infection %	p Value	Crude Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio (95% Confidence Interval)
Surgery on ICU admission				
No				
Yes	1	<.001	2.69 (1.76–4.10)	2.71 (1.45–5.06)
Total parenteral nutrition				
No				
Yes	1			(1.16–5.31)
Severe sepsis				
No				
Yes	2			(4.14–14.22)
Candida species colonization				
No				
Yes	1	<.001	3.20 (1.85–5.53)	3.04 (1.45–6.39)

Score ≥ 2.5 — Sensitivity 81% Specificity 74%

Scores in blue box: Surgery on ICU admission = 1; Total parenteral nutrition = 1; Severe sepsis = 2; *Candida* species colonization = 1

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A bedside scoring system ("Candida score") for early antifungal treatment in nonneutropenic critically ill patients with *Candida* colonization*   Crit Care Med 2006 Vol. 34, No. 3 730

Cristóbal León, MD; Sergio Ruiz-Santana, MD, PhD; Pedro Saavedra, PhD; Benito Almirante, MD, PhD; Juan Nolla-Salas, MD, PhD; Francisco Álvarez-Lerma, MD, PhD; José Garnacho-Montero, MD;

Courtesy by J. Mensa

Variable	Proven Candidal Infection %	p Value	Crude Odds Ratio (95% Confidence Interval)	Adjusted Odds Ratio (95% Confidence Interval)
Surgery on ICU admission **1**				
No	6.9			
Yes	6.5	<.001	2.69 (1.76–4.10)	2.71 (1.45–5.06)
Total parenteral nutrition **1**				
No				
Yes				2.48 (1.16–5.31)
Severe sepsis **2**				
No				
Yes	8.8	<.001	8.63 (5.49–13.56)	7.68 (4.14–14.22)
Candida species colonization **1**				
No	4.2			
Yes	2.3	<.001	3.20 (1.85–5.53)	3.04 (1.45–6.39)

Score ≥ 2.5 } probability of *Candida* infection x 7.75

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Comparison IC prediction rules

Score, year	Patients (n)	ICUs	Sensit. (95%CI)	Specif. (95%CI)	PPV (95%CI)	NPV (95%CI)	Threshold
Colonization Index, 1994	29 prospective	1	100	66.6 (43-83)	64.7 (41-83)	100	≥ 0.5
Candida Score, 2006	1,699 retrospective	73	81 (69-89)	74 (70-77)	24.6 (19-31)	97.4 (95-98)	≥ 3
Candida Score, 2009	1,107 prospective	36	77.6 (65-86)	66.2 (63-69)	13.8 (10-17)	97.7 (96-98)	≥ 3
Ostrosky Rule, 2011	597 retrospective	6	90 (72-97)	48 (44-52)	6 (4-9)	99 (97-99)	MV+B.S.A + CVC + other

Rule concerns: 1. High sensitivity / Low specifcity **2**. No prospective validation **3**. Complicated use
B.S.A : broad spectrum antibiotics ; MV: Mechanical ventilation; CVC: Centrall venous catheter

Abdominal Surgery IC rates, according CS

Candida Score	< 3	= 3	> 3
IC rate medical / surgical patients (n = 1,107)	2.3 %	5.9 %	11.5 % (5.1 - 17.8)
IC rate Abdominal Surgery (n = 182)	2.3 %	12.5 %	30.3 % (19.2 - 41.4)

Values in parentheses: 95% CI

Usefulness of the "*Candida* score" for discriminating between
Candida colonization and invasive candidiasis in non-neutropenic
critically ill patients: A prospective multicenter study

Cristóbal León, MD; Sergio Ruiz-Santana, MD, PhD; Pedro Saavedra, PhD; Beatriz Galván, MD;
Armando Blanco, MD; Carmen Castro, MD; Carina Balasini, MD; Aránzazu Utande-Vázquez, MD;
Francisco J. González de Molina, MD; Miguel A. Blasco-Navalproto, MD; Maria J. López, MD;
Pierre Emmanuel Charles, MD, PhD; Estrella Martín, PhD; María Adela Hernández-Viera, MD; on behalf of
the Cava Study Group

Table 4. Rates of invasive candidiasis according to the *Candida* score

Cutoff Value	Incidence Rate (%) (95% CI)	Relative Risk (95% CI)
<3	2.3 (1.1–3.5)	1
3	8.5 (4.2–12.7)	3.7 (1.8–7.7)
4	16.8 (9.7–23.9)	7.3 (3.7–14.5)
5	23.6 (12.4–34.9)	10.3 (5.0–21.0)

CI, confidence interval.

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Crit Care Med 2009; 37:1624 –1633

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Evaluation of "*Candida* score" in critically ill patients: a prospective, multicenter, observational, cohort study

Guillaume Leroy[1], Fabien Lambiotte[2], Didier Thévenin[3], Christian Lemaire[4], Erika Parmentier[5], Patrick Devos[6] and Olivier Leroy[1*]

- To evaluate <u>CS performance</u> ICU patients developing hospital-acquired <u>severe sepsis or septic shock</u>.
- Prospective, multicenter (5 ICUs France), cohort study
- n = 94 recruited (IC = 5 → 5.3 %)
- IC rates: CS = 2 or 3 → 0%; CS = 4 → 17.6%; CS = 5 → 50% (p < 0.0001).
- CS > 3 → Benefit early S.A.T.

Table 2 Risk factors for invasive candidiasis, according to the value of "*Candida* score"

Risk factors	*Candida* score = 2 (n = 44)	*Candida* score = 3 (n = 29)	*Candida* score = 4 (n = 17)	*Candida* score = 5 (n = 4)
Severe sepsis or septic shock	44	29	17	4
Total parenteral nutrition	0	8	15	4
Surgery	0	10	17	4
Multifocal *Candida* colonization	0	11	2	4
Invasive mechanical ventilation	30	23	11	2
Central venous catheter	39	27	15	4
Urinary catheter	42	27	17	4
Antibiotherapy > 5 days within the past 2 weeks	39	25	14	4
Renal replacement therapy	8	10	4	1
Insulin-dependent diabetes mellitus	7	4	0	0
Immunosuppression	4	3	2	0

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Systemic antifungal therapy in critically ill patients without invasive fungal infection*

(Crit Care Med 2012; 40:813–822)

Elie Azoulay, MD, PhD; Hervé Dupont, MD, PhD; Alexis Tabah, MD; Olivier Lortholary, MD, PhD; Jean-Paul Stahl, MD; Adrien Francais; Claude Martin, MD; Bertand Guidet, MD, PhD; Jean-François Timsit, MD, PhD; on behalf of the French Society for Critical Care (SRLF) in Collaboration With the French Society for Infectious Diseases (SPILF) and the French Society for Anesthesia and Intensive Care (SFAR)

- To determine → nº patients, w /o documented IC, received S.A.T.

- 1-day cross-sectional cohort study; 169 ICUs France / Belgium

- n = 2,047 recruited

- n = 154 (7.5%) with SAT (only 54 with IC)

- Independent predictors SAT:
  - <u>Center-related factors:</u> Hospital < 800 beds (OR: 2.9); organ transplant activity (OR:2.6); use fluoroquinolones (OR:2.3); use SAT unresolved sepsis (OR:1.9 / 2.2/ 2.0)
  - <u>Patient related factors:</u> Candida colonization (OR: 12.4); severe sepsis and septic shock (OR:4.7); emergency surgery (OR: 2.4); hematologic malignancies (OR:7.1)

- <u>Trend greater impact SAT on survival</u> when CS = 4 or 5

S.A.T: Systemic Antifungal Treatment

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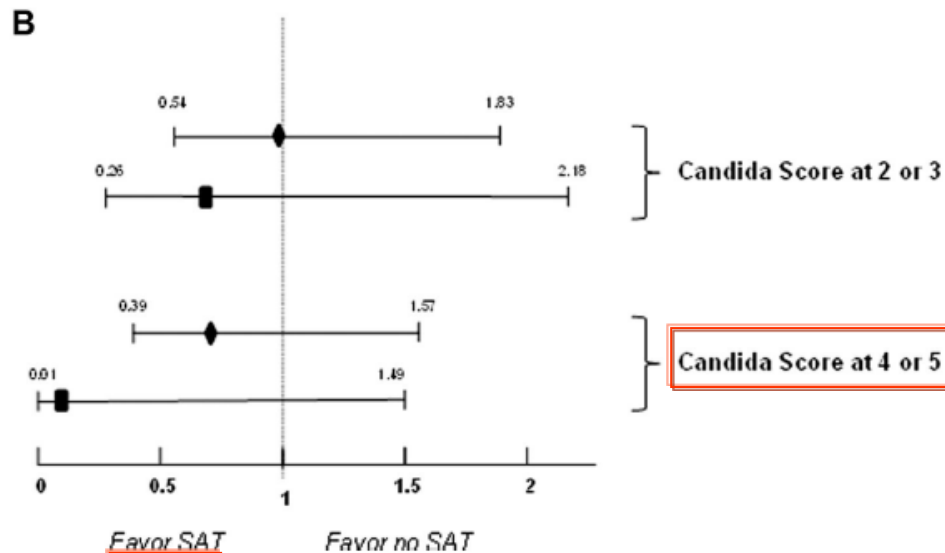# Impact SAT on 28-d mortality according CS

Figure 4. Impact of systemic antifungal treatment (*SAT*) on day 28 mortality according to *Candida* score. *A*, Impact of SAT on day 28 survival according to three classes of *Candida* score. ‡Adjusted hazard ratios were obtained by adjustment on propensity score for day 28 mortality and with stratification on the center. *B*, Unadjusted (lozenges) and adjusted (*squares*) hazard ratio (*HR*) and 95% confidence intervals depicting the impact of SAT on day 28 mortality in patients with *Candida* score at 2 or 3 or with *Candida* score at 4 or 5.

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Comparison of **BG** test findings
in <u>non-neutropenic critically ill patients</u>

Author, year	Patient´s type	Number Pts./ samples (mean)	IC Type	Cut-off	Sensit.(%) 95% CI	Specif.(%) 95% CI	PPV (%) 95% CI	NPV (%) 95% CI	Proven IC BG ** (median)
Tissot, 2013	Surgical Pancreatitis	89 / 921 (9)	IAC	≥ 80	65 * (46-82)	78 * (63-93)	68 * (52-88)	77 * 63-89)	253
León, 2012	Surgical Pancreatitis	176/ 766 (4.3)	C, IAC	≥ 80	51.6 (34-69)	86.9 (78-92)	59.3 (40-75)	83.0 (73-89)	259
Del Bono, 2011	Surgical	152 / 152 (1)	C	≥ 80	62	98	98.4	57.3	324
Posteraro, 2011	Med. / Surg.	95 / 130 (1.3)	C	≥ 80	92.9 (66-99)	93.7 (85-90)	72.2 (46-90)	98.7 (92-99)	500
Mohr, 2011	Med. / Surg.	57 / 239 (4.1)	C	≥ 80	100 *	59 *	NDA	NDA	171
Presterl, 2009	Med. / Surg.	197/ NDA	C, IAC, HC	≥ 40	52.2 (31-76)	75.9 (62-85)	46.2 27-66)	80 (66-89	44

* Two consecutive BG determinations
** pg / mL,

IC: Invasive Candidiasis, C: Candidemia, IAC: Intra-abdominal Candidiasis, HC: Hepatic Candidiasis NDA: No data available

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Early diagnosis of candidemia in intensive care unit patients with sepsis: a prospective comparison of (1→3)-β-D-glucan assay, *Candida* score, and colonization index

Brunella Posteraro[1], Gennaro De Pascale[2], Mario Tumbarello[3*], Riccardo Torelli[1], Mariano Alberto Pennisi[2], Giuseppe Bello[2], Riccardo Maviglia[2], Giovanni Fadda[1], Maurizio Sanguinetti[1] and Massimo Antonelli[2]

- Prospective, single center, observational study
- To compare diagnostic value BG, CS, CI ICU patients risk IC
- n = 95 (LOS > 5 days): clinical sepsis onset ➔ BG; blood cultures,
- Clinical data / surveillance cultures
- Of 14 IC patients:13 candidemias.
- Combination positive **BG and CS ≥3**
  improved IC diagnosis:
  Sensitivity [100% (95% CI, 76.8% to 100%)]
  NPV [100% (95% CI, 94.6% to 100%)]
- *vs.* 92.9% and 98.7% for BG test alone.
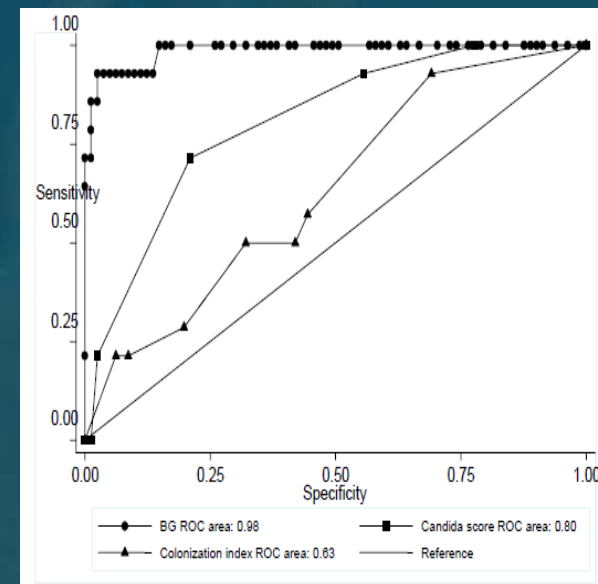
Table 3 Performances of (1→3)-β-D-glucan assay (BG), *Candida* score (CS), and colonization index for detection of invasive candidiasis in 95 patients

	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)	PLR (%) (95% CI)	NLR (%) (95% CI)
BG cut-off value, 80 pg/mL	92.9 (66.1 to 99.8)	93.7 (85.8 to 97.9)	72.2 (46.5 to 90.3)	98.7 (92.8 to 99.9)	14.74 (4.65 to 47.52)	0.07 (0.02 to 0.39)
CS ≥3	85.7 (57.2 to 98.2)	88.6 (79.5 to 94.7)	57.1 (34.0 to 78.2)	97.2 (90.3 to 99.7)	7.51 (2.79 to 18.29)	0.16 (0.02 to 0.54)
Colonization index ≥0.5	64.3 (35.1 to 87.2)	69.6 (58.2 to 79.5)	27.3 (13.3 to 45.5)	91.7 (81.6 to 97.2)	2.12 (0.84 to 4.25)	0.51 (0.16 to 1.11)

Beta-Glucan Antigenemia Anticipates Diagnosis of Blood Culture-Negative Intra-Abdominal Candidiasis
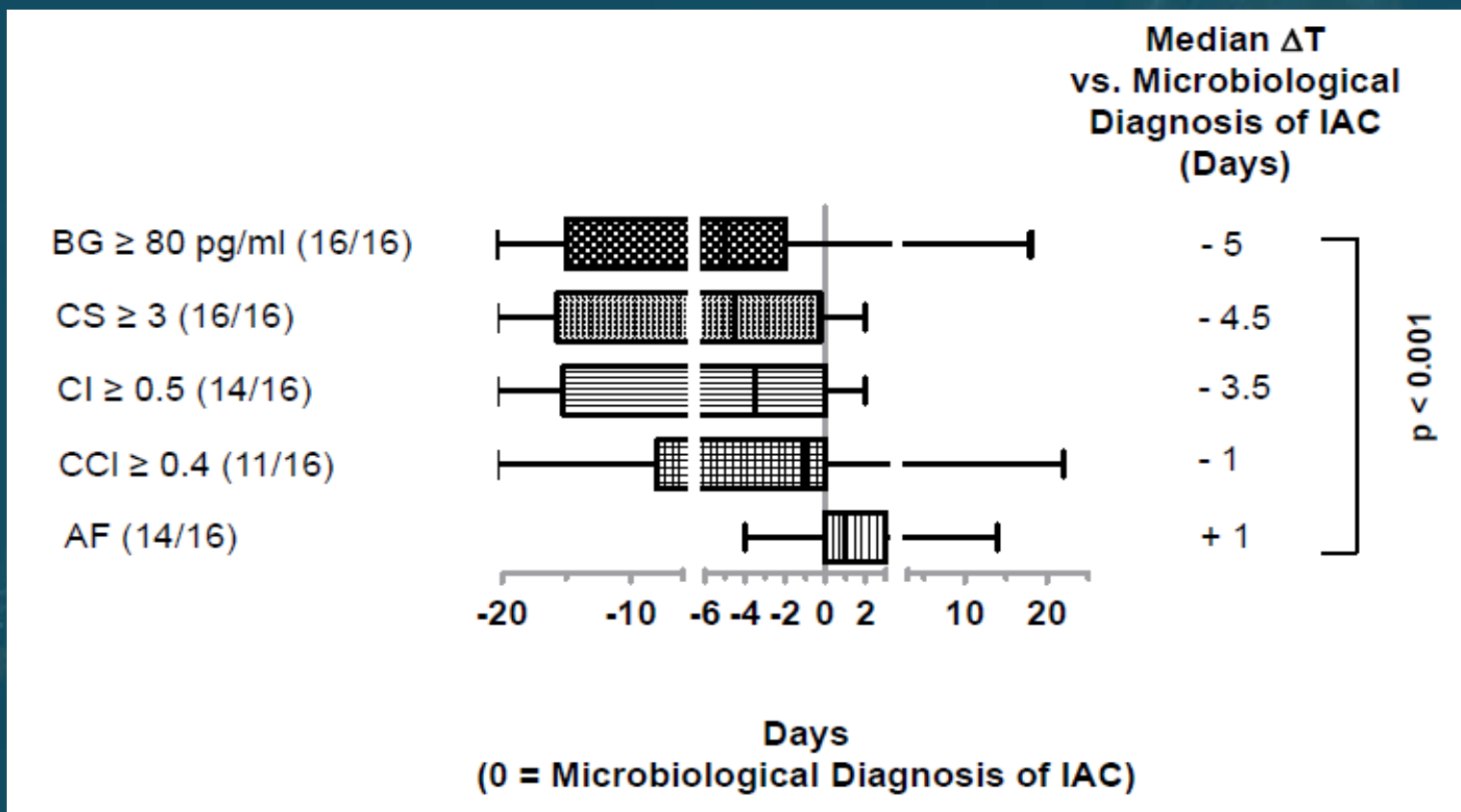
Tissot F, Lamoth F, Hauser PM, et al.

- Prospective, cohort study **(FUNGINOS)**
- 89 (20.5%) / 434 patients high-risk IAC studied (ICU stay ≥72h):→ 29 IAC + <u>negative blood culture (27/29).</u>
- BG <u>preceded</u> microbiological documentation IAC and start SAT by five / six days (median), respectively.
- <u>Conclusion:</u> BG is superior to cultures, CS, CI, CCI for anticipating diagnosis of blood-culture-negative post-surgical IAC.

	Sensit. (95%CI)	Specif. (95%CI)	PPV (95%CI)	NPV (95%CI)
BG ≥ 80 pg/ml 1 x	0.83 (0.64 -0.94)	0.40 (0.26-0.57)	0.49 (0.34-0.64)	0.77 (0.55-0.92)
BG ≥ 80 pg/ml 2 x	0.65 (0.46-0.62)	0.78 (0.63-0.90)	0.68 (0.48-0.84)	0.77 (0.61-0.68)
CS ≥ 3	0.86 (0.68-0.96)	0.38 (0.23-0.54)	0.49 (0.35-0.63)	0.80 (0.56-0.94)

Beta-Glucan Antigenemia Anticipates Diagnosis of Blood Culture-Negative Intra-Abdominal Candidiasis
Tissot F, Lamoth F, Hauser PM, et al.

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Value BG / CAGTA discriminating between *Candida* colonization / IC critically ill patients with S.A.C. (CAVA II study)

Multicenter, observational, prospective:
C. Score; biomarkers & IC
18 ICUs; n = 176 (S.A.C.); 4 wks. Study; 2009-10

3d   1st   2nd   3rd   4th

ICU*   > 7 days
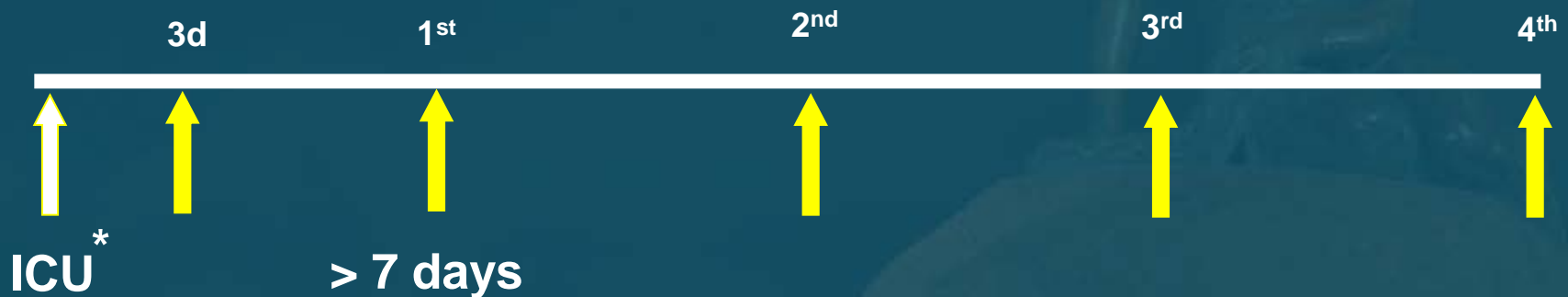
C Score, BG, CAGTA, others → Weekly (x 2) screening
Optional Samples   related clinical situation / follow up

Variables: demographics; APACHE II, SOFA (admission; weekly x 2, starting antifungals); comorbid diseases; risk factors; antifungal therapy and outcome.

*Adult patients, admitted ICU ≥ 7 days
S.A.C. = Severe Abdominal Conditions
CAGTA = *Candida albicans* germ-tube antibody

Leon C, Ruiz-Santana S, Saavedra P, et al.
Intensive Care Med 2012;38:1315–1325

CART predicition rule model

- Patients with *Candida* colonization ➜ A <u>model for IC prediction</u> was obtained using **C**lassification **A**nd **R**egression **T**rees (**CART**).

- Variables used ➜ maximum values biomarkers before / during development IC, or highest value when IC did not developed (Apache-II, BG, CAGTA).

- CART through a process of binary recursive spliting of the datasets based on rules of the form *if-then-else* ,identifies a set of predictors of IC estimating the probabilities of IC according to the values of predictors.

- The discriminate value of the probabilities of IC obtained by the CART was evaluated by the receiver characteristic operating (ROC) curve .

- Predictive rule ➜ identify patients have an IC risk, when probability to develop IC is ≥ 30%.(cut-off chosen by CART algorithm to minimize error measurement = deviance)

- Obtained rule: estimated ➜Sensitivity, Specificity, PPV, NPV.

- Data analysis ➜ carried out using R-package.

Breiman L. et al. (1984). Classfication and regression trees.
Belmont CA: Wadsworth International

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Prediction rule for IC diagnosis (NNCIP with SAC)
Each terminal node → Probability predicted event

Leon C, Ruiz-Santana S, Saavedra P, et al. Intensive Care Med 2012;38:1315–1325
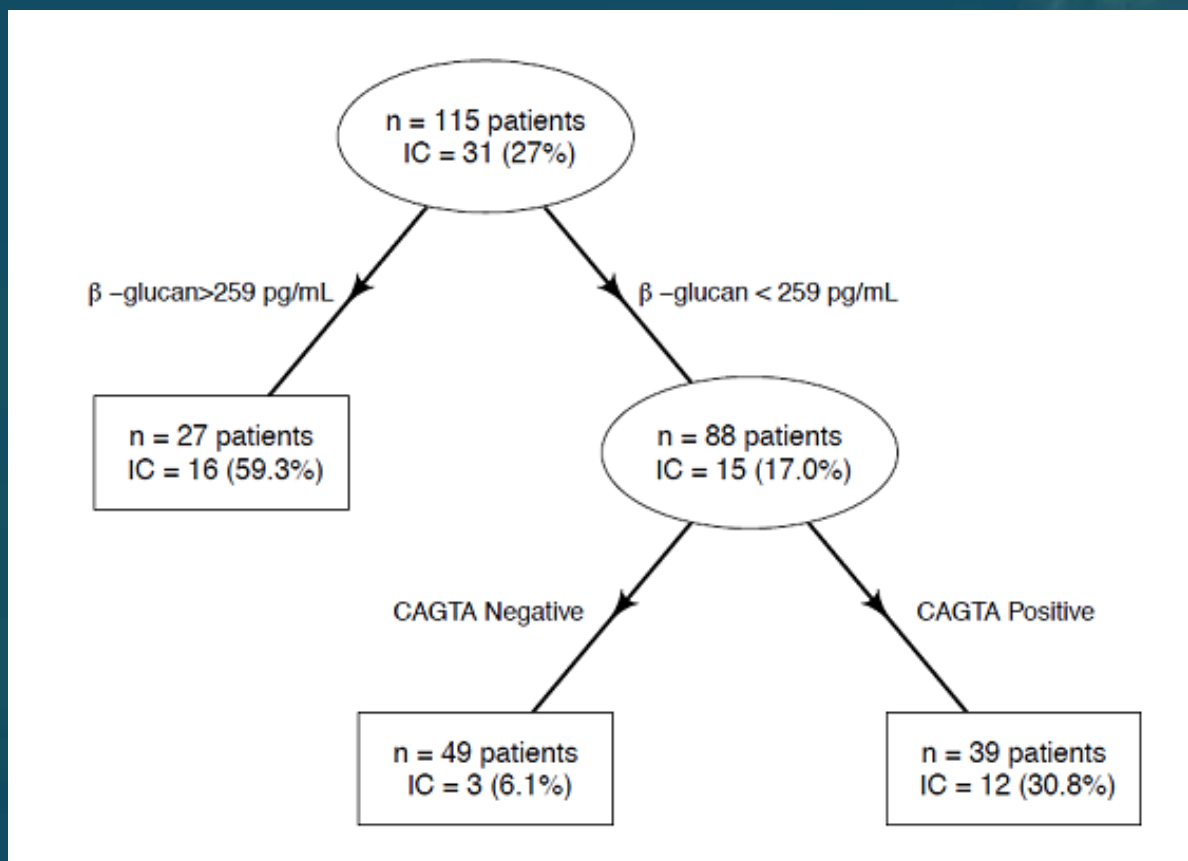
IC: invasive candidiasis. **BG:** [1→3]-β-D-glucan; **CAGTA:** *Candida albicans* Germ Tube Antibodies.
n= number of patients with IC. **SAC**: Severe Abdominal Conditions.

Diagnostic accuracy of _CART-derived prediction rule_, BG (cut-off: > 259 pg/mL), CAGTA (cutt-off: positive) and CS for IC diagnosis

	Area under ROC curve (95% CI)	Sensitivity % (95% CI)	Specificity % (95% CI)	Predictive value	
				Positive % (95% CI)	Negative % (95% CI)
CART analysis	0.78 (0.76-0.81)	90.3 (75.1-96.6)	54.7 (44.1-65.0)	42.4 (31.2-54.4)	93.9 (83.5-97.9)
BG	0.67 (0.59-0.74)	51.6 (34.8-68.0)	86.9 (78.0-92.5)	59.3 (40.7-75.5)	83.0 (73.8-89.4)
CAGTA	0.67 (0.63-0.70)	71.0 (53.4-83.9)	57.3 (46.5-67.5)	38.6 (27.1-51.6)	83.9 (72.2-91.3)
CS	0.62 (0.58-0.66)	93.5 (79.2-98.2)	18.1 (11.3-27.7)	29.9 (21.7-39.6)	88.2 (65-7-96.7)

CART: classification and regression tree analysis; BG: beta-D-glucan; CAGTA: _Candida albicans_ germ tube antibody. Total number of patients with Candida spp. colonization = 115.

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Conclusions

- IC diagnosis and S.A.T. delay : influences morbi-mortality.

- Non IC-targeted S.A.T. → not well established.

- Utility prediction rules & biomarkers to select patients benefit "early" S.A.T.

- Predictive (CART) rule → allow IC structured management.

- Candida PCR detection → would improve IC diagnosis.

- IC diagnosis → multifactorial process requires multidimensional markers.

Thank you for your attention !

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