

Prezentarea statisticii intr-un articol medical

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- partea de statistică este cea mai ușoară într-o cercetare
 - cel mai greu este sa reușești o cercetare validă
 - **erorile sistematice și factorii de confuzie eventuali**
 - eliminare prin design
 - Măsurare și introducere în baza de date
- o statistică se poate face și reface oricând, pe cand dacă designul nu este valid, sau nu ai măsurat eventuali factori de confuzie, totul este pierdut...

- Unde în articol este prezentă statistica?
- Rezumarea datelor (statistica descriptivă)
și testele statistice (statistica analitică)
- p vs interval de încredere

Unde în articol este prezentă statistica?

- Abstract (Rezultate)
- Material si metoda (Analiza statistica)
- Rezultate

Protocol / Grant / clinicaltrials.gov

Acces baza de date

- citită secțiunea de la Info pt autori din revista respectivă
- majoritatea nu au mare lucru pt statistică, dar cele mari = BMJ, Annals of Internal Med etc au, și sunt f pretențioase;
- dacă vrei să faci o statistică corectă, poți lua instrucțiunile pt autori din BMJ sau Annals

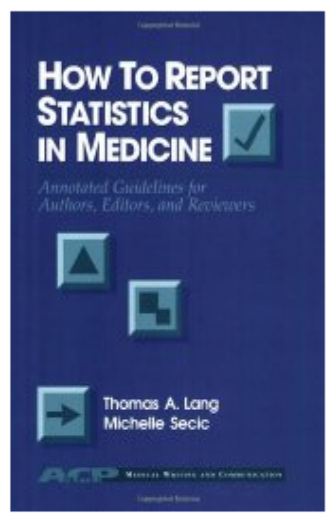
Annals of Internal Medicine

- www.annals.org

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ISBN is **978-0-943126-44-9 / 0943126444**

[How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors and Reviewers \(Acp Information Technology Series\)](#)

by **Lang, Thomas A.**

Publisher: American College of Physicians
Edition: Softcover
Language: English

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About the book:
 Detailing information needed to understand statistical... covers all aspects of statistical presentation and ana... biomedical literature. Common errors in methodology... identified, allowing readers to verify completeness of... Descriptions of more than 350 statistical terms and t...

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Guidelines for Statistical Reporting in Articles for Medical Journals

Amplifications and Explanations

JOHN C. BAILAR III, M.D., Ph.D.; and FREDERICK MOSTELLER, Ph.D.; Boston, Massachusetts

The 1988 edition of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals* includes guidelines for presenting statistical aspects of scientific research. The guidelines are intended to aid authors in reporting the statistical aspects of their work in ways that are clear and helpful to readers. We examine these guidelines for statistics using 15 numbered statements. Although the information presented relates to manuscript preparation, it will also help investigators in earlier stages make critical decisions about research approaches and protocols.

[MeSH terms: clinical protocols; clinical trials; eligibility determination; manuscripts, medical; probability; random allocation; statistics. Other indexing terms: blinding; blocking; confidence intervals; International Committee of Medical Journal Editors; matching; *P* values; software; statistical methods; stratification; study design; treatment complications; Uniform Requirements for Manuscripts]

IN 1979, the group now known as the International Committee of Medical Journal Editors first published a set of uniform requirements for preparing manuscripts to be submitted to their own journals. These uniform requirements have been revised several times (1), and have been

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid sole reliance on statistical hypothesis testing, such as the use of *P* values, which fails to convey important quantitative information. Discuss eligibility of experimental subjects. Give details about randomization. Describe the methods for, and success of, any blinding of observations. Report treatment complications. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for study design and statistical methods should be to standard works (with pages stated) when possible, rather than to papers where designs or methods were originally reported. Specify any general-use computer programs used.

Put general descriptions of methods in the Methods section. When data are summarized in the Results section specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant,"

tions; however, we have tried to present the spirit of the Committee's discussions as well as our own views.

The International Committee's statistical guidelines are as follows:

► From the Department of Health Policy and Management, School of Public Health, Harvard University; Boston, Massachusetts; Office of Disease Prevention and Health Promotion, U.S. Dept. of Health and Human Services, Washington, D.C.; Department of Epidemiology and Biostatistics, McGill University; Montreal, Quebec, Canada.

- Descrieti procedeele statistice a.î. să poată fi reproduse de oricine ar avea acces la date
- Prezentați rezultatele cu măsurile adecvate ale erorii sau incertitudinii (CI)
- Nu dați numai p-urile (CI)
- Dați nr observațiilor (pacienților)

- Raportați pierderile din observație
- Specificați softul statistic utilizat
- Tabele sau figuri numai cât e necesar pt argumentarea rezultatelor/concluziilor
- Evitați utilizările netehnice ale termenilor tehnici:
normală, semnificativă, corelație, eșantion

- Placebo: supraviețuire: 10 ani
- Tratament: supraviețuire 10 ani + 1h
- $p = 0,0001$.

- Tratatamentul îmbunătățește semnificativ supraviețuirea ($p = 0,0001$)

1. Uitați-vă întotdeauna după mărimea efectului!

- Tratatamentul îmbunătățește *semnificativ* supraviețuirea ($p=0,0001$)
 - CI dau mai multe informații decât p, așadar sunt de preferat
 - p-urile amestecă mărimea efectului cu mărimea eșantionului
 - p-urile nu au ce căuta în medicină
 - Schulz, Grimes. The Lancet Handbook of Clinical Research, 2006
 - 1986: Ken Rothman a interzis p-urile în *Epidemiology* cat a fost editor șef

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Statistical analyses must explain the methods used.

[Guidelines on presenting statistics >>](#)

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The key reporting guidelines are:

- Randomised controlled trials (RCTs): [CONSORT guidelines](#)
- Systematic reviews and meta-analyses: [PRISMA guidelines](#) and [MOOSE guidelines](#)
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- Diagnostic accuracy studies: [STARD guidelines](#)
- Quality improvement studies: [SQUIRE guidelines](#)

Research checklists should be uploaded using the File Designation "Research Checklist".

Pre-submission checklist

Statistics at Square One

Ninth Edition

T D V Swinscow

Revised by M J Campbell, University of Southampton

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Contents

[Preface](#)

[1 Data display and summary](#)

[2 Mean and standard deviation](#)

[3 Populations and samples](#)

[4 Statements of probability and confidence intervals](#)

[5 Differences between means: type I and type II errors and power](#)

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Metode

Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy
		(e) Describe any sensitivity analyses



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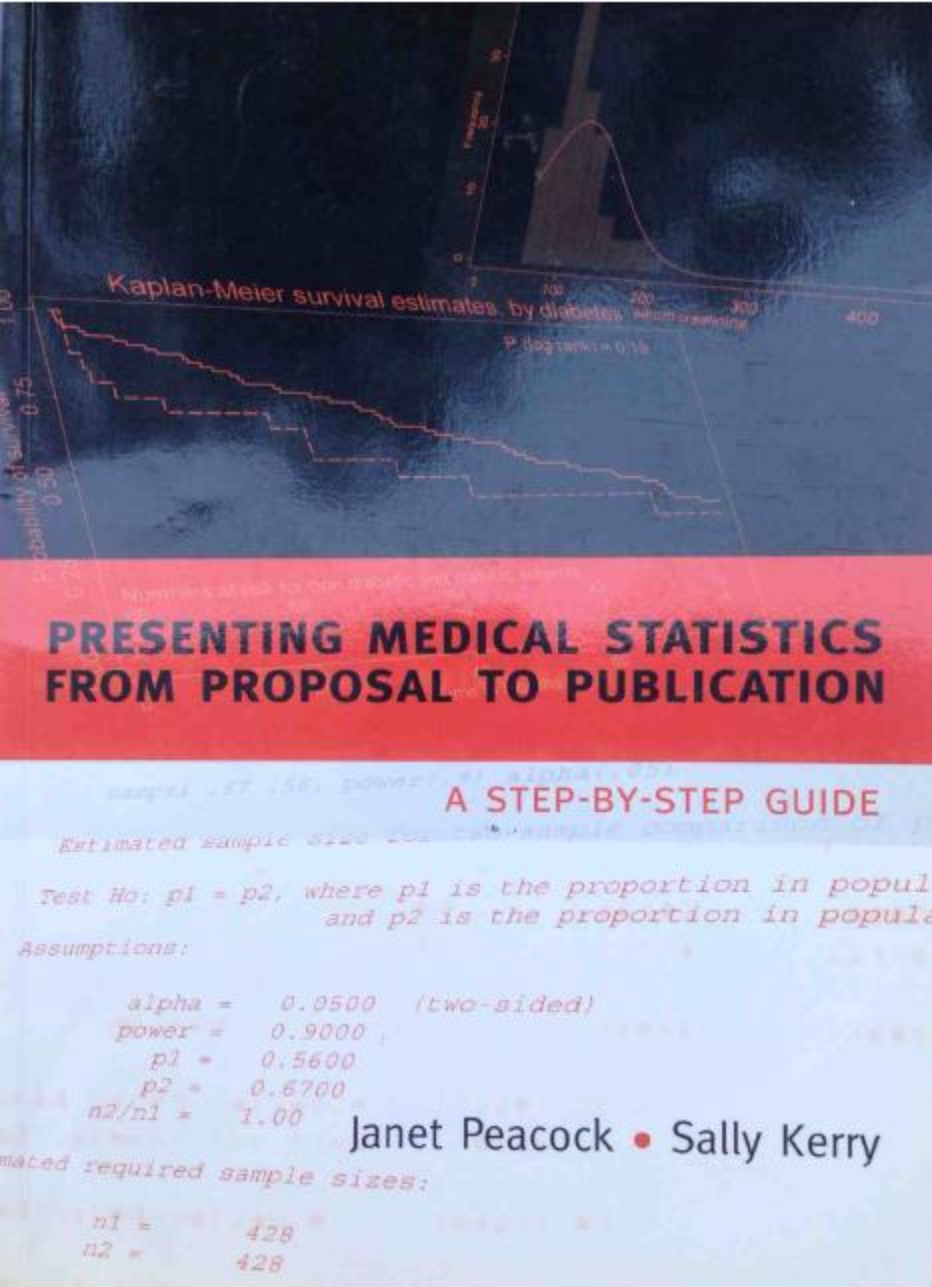
Metode

		(retrospective study):	
<i>Test methods</i>	7	The reference standard and its rationale.	
	8	Technical specifications of material and methods involved including how and when measurements were taken, and/or cite references for index tests and reference standard.	
	9	Definition of and rationale for the units, cut-offs and/or categories of the results of the index tests and the reference standard.	
	10	The number, training and expertise of the persons executing and reading the index tests and the reference standard.	
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test and describe any other clinical information available to the readers.	
<i>Statistical methods</i>	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g. 95% confidence intervals).	
	13	Methods for calculating test reproducibility, if done.	

Mărimea eşantionului

Rezultate

		standard.	
<i>Estimates</i>	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g. 95% confidence intervals).	
	22	How indeterminate results, missing data and outliers of the index tests were handled.	
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers or centers, if done.	
	24	Estimates of test reproducibility, if done.	
DISCUSSION	25	Discuss the clinical applicability of the study findings.	



Mărimea eşantionului

- Din protocol / grant
- StatMate, GPower, WinPepi, EpilInfo
- $p(\alpha) \leq 0.05$
- Puterea $(1-\beta) \geq 0.80$
- Mărimea efectului:
 - RR, OR, RA
 - Δ medii
- Variabilitate = SD

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RESEARCH ARTICLE


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VIEWS

1

SAVE

Cancer and Involuntary Weight Loss: Failure to Validate a Prediction Score

Cristian Baicus , Mihai Rimbasi, Anda Baicus, Simona Caraiola, Grupul de Studiu al Scaderii Ponderale Involuntare

Published: April 24, 2014 • DOI: 10.1371/journal.pone.0095286

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Abstract

Background

Many patients who have involuntary weight loss have cancer. The Hernandez prediction rule includes 5 variables (elevated levels of alkaline phosphatase and lactate dehydrogenase, low albumin, high white blood cell count, and age >80 years). The purpose of this study was to

 CrossMark

Subject Areas

Albumins

Blood count

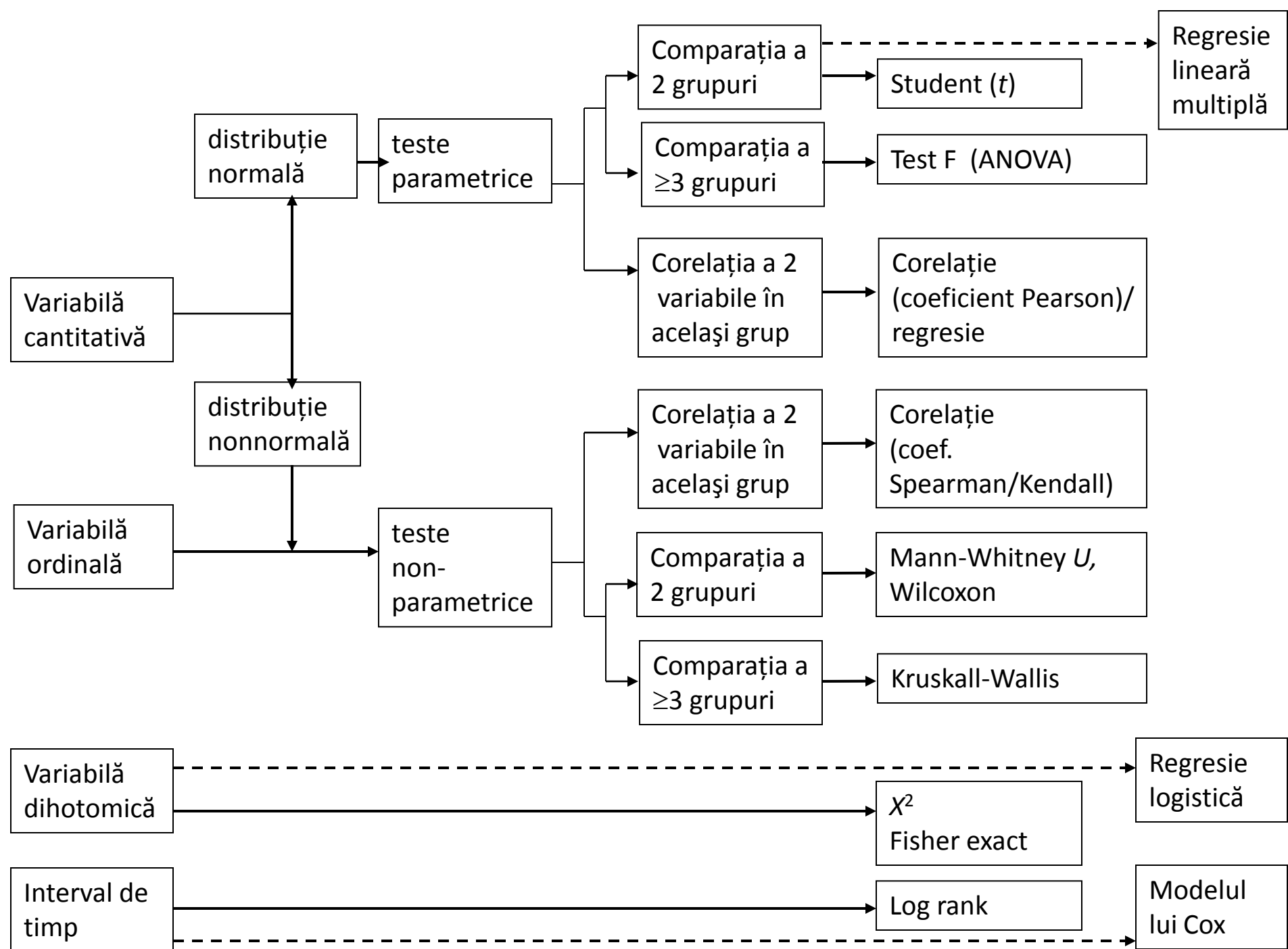
Sample size

It was estimated that ≥ 50 patients who had cancer were needed for multiple logistic regression because the model of Hernandez had 5 variables and ≥ 10 outcome events (patients who had cancer) were necessary for every independent variable in the model [12]. The prevalence of cancer in recent IWL studies was 22% to 38% [3]–[5], [13]. Therefore, we calculated that ≥ 250 patients who had IWL should be included for a worst case prevalence of 20%.

Statistical analysis

Data analysis was performed with statistical software (Stata 11, StataCorp, College Station, TX, USA; and SPSS 16.0, SPSS, Inc., Chicago, IL, USA). An Internet-based calculator (EBM calculator 1.0, www.cebm.utoronto.ca) was used for calculation of sensitivity, specificity, predictive values, and likelihood ratios. The outcome was the diagnosis of cancer as the cause of IWL, and the predictor variables included the clinical variables (age, sex, amount of weight loss, and smoking) and laboratory variables recorded. Categorical variables were reported as frequency and analyzed by Fisher exact test. Continuous variables that were not normally distributed were reported as median (minimum to maximum) and analyzed with Mann-Whitney test, Kruskal-Wallis test, or Kendall τ (tau) rank correlation. Receiver operating characteristic (ROC) curves were generated; areas under the curve (AUC) and 95% confidence intervals (CI) were determined.

The variables associated with cancer in bivariate analysis were evaluated with a logistic regression model. For validation of the model of Hernandez [5], we dichotomized the variables using the same criteria for cutoff values, the normal limits of our laboratory for white blood cell count, serum ALP, LDH, and albumin levels (white blood cell count $>12 \times 10^9/L$ (12 000/ μL), albumin <3.5 g/dL, ALP >104 U/L, and LDH >220 U/L), and we used the cutoff age 80 years. The variables were introduced into the logistic regression model, and AUC values were calculated. A sensitivity analysis was performed by fitting the prediction model only in the subsample of patients who had known amount of weight loss. Age >80 years was not statistically associated with cancer in bivariate or multivariable analysis; therefore, the age cutoff was changed to age >60 years and a new logistic regression model was evaluated with 3 variables (age >60 y, low serum albumin level, and high ALP level), the AUC was calculated, and the positive and negative predictive values with 95% CI were calculated [14]. The variables were selected for logistic regression with the enter method (all studied variables were included, without any sequential selection) [12]. Hypothesis testing was 2-tailed. Statistical significance was defined by $P < .05$.



Variabile numerice cu distributie neGaussiana

Variabile ordinale:

Test Mann-Whitney U

Variabile nominale:

Testul χ^2

Testul exact al lui Fisher

- întotdeauna trebuie data **mărimea efectului** (RR, OR, RAR pt variabile dihotomice, r sau diferența pt numerice), cu CI si p
1. studiu de cohorta: RR (cel mai bun tip de studiu pt prognostic si etiologie); la fel pt RCT.
 2. studiu caz-martor: OR
 3. studiu transversal: OR dupa unii, raportul prevalențelor dupa altii; daca este vorba despre studiu diagnostic: Sn, Sp, VPP, VPN cu CI
 4. studiu diagnostic de evaluare a unui test variabila continua: curba ROC
- (bineinteles, toate cu CI).