Cum să scrii un articol științific medical – cercetare originală clinică

C Baicus

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De ce să publicăm?

- Împărtășim cunoștințele
- Revendicăm prioritatea
- Carieră
- Finanțarea cercetării

Scrisul științific

- Propoziții simple
 - Subject verb object
 - Doar prezent (cu excepția past tense pt ce s-a întâmplat în trecut)
 - Fără condițional, mai mult ca perfect etc
 - Limitați utilizarea frazelor cu multe propoziții subordonate, jargonului tehnic, abrevierilor multiple

- Tipuri de studii clinice (prospectiv, retrospectiv; serie de cazuri, caz-martor, de cohorta, interventional)
- Etapele parcurgerii unui studiu clinic
 - Ipoteza de lucru
 - Objective
 - Design-ul studiului
 - Abordarea statistica
 - Obtinerea aprobarilor pentru desfasurarea studiului
 - Desfasurarea studiului
 - Stabilirea concluziilor (importanta rezultatelor obtinute si aplicabilitate)

STUDIILE ANALITICE

- Forţa asocierii dintre expunere şi efect (risc relativ, odds ratio, coeficient de corelatie)
- Semnificaţia statistică a asocierii (p, interval de încredere)

Studii dg: curba ROC, Sn, Sp, LR, (cu Cl)

PROTOCOL

- De ce se face studiul?
- Ce se va face si de catre cine?
- Cum vor fi analizate rezultatele?

Protocolul de cercetare clinica

- 1. Obiectivul/obiectivele cercetarii
- Justificarea studiului
- 3. Ipoteza
- 4. Tipul de studiu
- 5. Variabilele
- 6. Erori posibile : erori sistematice, factori de confuzie
- 7. Subiectii
- 8. Culegerea si gestionarea datelor
- 9. Analiza datelor

OBIECTIV

- Principal
- Secundare

Tipuri de studii

- Prevalenta (transversal)
- Etiologic (cohorta, caz-martor)
- Prognostic (cohorta)
- Terapeutic (RCT)
- Diagnostic (transversal, RCT)

Proiecte IDEI / CNCSIS

- Titlu
- Rezumat
- Prezentarea proiectului
 - Importanta si relevanta (background)
 - Objective
 - Material si metode
 - Resurse necesare
- Managementul proiectului

Articolul științific

Document care să conțină suficientă informație, astfel încât cititorii să poată:

- -Evalua observațiile făcute
- -Repeta experimentul, dacă doresc
- Determina dacă concluziile trase sunt justificate de date

(ce intrebare s-a pus?)

(cum a fost studiata?)

R (ce s-a gasit?)

And

D (ce semnificatie au rezultatele?)

Părțile unui articol

- Titlu
- Abstract
- Introducere
- Material şi metode
- Rezultate

- Discuţii
- Acknowledgements (recunoașteri)
- Referințe
- Tabele şi figuri
- Legendele figurilor

INTRODUCEREA

- Care este întrebarea de cercetat?
- Ce ştim deja?
- Care sunt golurile de cunoaștere?
- Ce adaugă acest studiu?

scurtă

introducerea

- Identificați întrebarea la care se răspunde
- Prezentați fundalul relevant pt această cercetare (nu faceți review pt tot domeniul)
- Explicați de ce întrebarea este importantă
- Cum s-a răspuns la întrebare?
- Prezentați răspunsul (cititorul nu va merge mai departe dacă nu-l găsește; nu scrieți un roman polițist)

Ferritin above 100 mcg/L could rule out colon cancer, but not gastric or rectal cancer in patients with involuntary weight loss.

Baicus C, Caraiola S, Rimbas M, Patrascu R, Baicus A. BMC Gastroenterol. 2012 Jul 9;12:86

Background

Involuntary weight loss (IWL) is an important health problem, as 3-5% of the patients in internal medicine departments are admitted for this [1, 2, 3], and among them, a quarter have cancer [4], part of them having gastrointestinal cancer. For this reason, gastrointestinal endoscopy is recommended in the diagnosis of IWL, after the initial investigations consisting in history and physical examination, chest radiography, abdominal ultrasonography and standard laboratory tests [2, 5].

As it is known, iron deficiency anaemia appears in gastrointestinal cancer due to occult blood loss. However, anaemia as a diagnostic test for gastrointestinal cancer is not sensitive, because a high proportion of patients with gastrointestinal cancer (50%) do not have anaemia at the moment of tumour diagnosis [6, 7, 8].

In the succession of events that leads to iron deficiency anaemia, ferritin diminution appears early, immediately after the waning of the iron stores in the bone marrow, and before occurrence of all the other changes in iron deficiency anaemia: decrease in transferrin saturation, serum iron, red cell volume and haemoglobin [9], and this allows us to hope that ferritin would have a higher sensitivity for the diagnosis of gastrointestinal cancer. In fact, ferritinaemia is the test with the highest accuracy in the diagnosis of iron deficiency anaemia compared to the above-mentioned parameters [10, 11, 12].

Serum ferritin was assessed in a few, retrospective studies for the diagnosis of gastrointestinal cancer, and the results showed that it has no value as a screening test [13], probably because it lowers only when the tumour has grown enough [14], condition that might be satisfied in the case of IWL [15]. In one study, 10% of the 143 patients having a ferritin less than 50 mcg/L had gastrointestinal cancer [16], in two patients without anaemia, a low ferritin (<18 mcg/L) lead to the discovery of colon cancer [17], and in 414 patients referred for colonoscopy because of anaemia, a ferritin higher than 100 mcg/L excluded colorectal cancer [18]. However, in a retrospective study on 359 consecutive elderly inpatients referred to colonoscopy because of symptoms suggesting colorectal cancer, ferritin was not useful in the diagnosis [19].

To the date, no studies were done in patients with IWL.

We therefore conducted a diagnostic study to determine whether ferritin higher than 100 mcg/L is sensitive enough to exclude gastrointestinal cancer in patients with IWL.

Baicus C, Rimbas M, Baicus A, Caraiola S; Grupul de Studiu al Scaderii Ponderale Involuntare..

Cancer and involuntary weight loss: failure to validate a prediction score.

PLoS One. 2014 Apr 24;9(4):e95286

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 evaluate the validity of the prediction rule.

Introduction

The frequency of involuntary weight loss (IWL) is 5% in patients who are admitted to internal medicine departments [1], [2]. Cancer is diagnosed in 25% patients who have IWL [1]. The history and physical examination may provide important information to help determine the cause of IWL, but in some patients the cause of IWL of unknown origin may be difficult to determine. Most patients who have IWL do not have cancer, and 30% patients who have IWL have psychiatric disorders or IWL of unidentified cause [3]. However, it is important to determine whether or not the patient has a life threatening disease such as cancer.

A study of 101 patients who had IWL showed that the probability of having cancer was unlikely when the evaluation had normal testing including physical examination, complete blood count, C-reactive protein (CRP), aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), lactate dehydrogenase (LDH), albumin, ferritin, chest radiography, and abdominal ultrasound; all 22 patients who had cancer had at least one abnormal laboratory test [4]. However, 50% patients who did not have an organic diagnosis had ≥1 laboratory abnormality [4]. Age, anemia, and erythrocyte sedimentation rate (ESR) may help predict whether a patient has IWL associated with cancer; in patients who have IWL, the probability of having cancer is 64% in patients aged >62 years who have anemia and high erythrocyte sedimentation rate (ESR) but only 9% in patients younger than 63 years who have normal hemoglobin and ESR [3].

The Hernandez score is a prediction score to identify cancer. The score was retrospectively developed in 256 patients who had unexplained IWL and was validated prospectively in 52 patients, at the same site [5]. The independent predictors of cancer included elevated alkaline phosphatase level, elevated LDH level, high white blood cell count, low albumin level, and age >80 years [5]. This prediction score is cited in several point-of-care clinical sources, UpToDate [6], Essential Evidence Plus [7] and First Consult. A clinical calculator of cancer risk is available from Essential Evidence Plus [7].

The purpose of the present study was to validate externally the Hernandez score.

METODE

- Study design si desfaşurarea
- Alegerea subiectilor
- Marimea esantionului
- Datele colectate / masuratori
- Analiza statistica

Suficient detaliu pt ca oricine sa poata reproduce studiul Sectiunea care este cel mai frecvent cauza respingerii definitive (validitate)

Ferritin above 100 mcg/L could rule out colon cancer, but not gastric or rectal cancer in patients with involuntary weight loss.

Baicus C, Caraiola S, Rimbas M, Patrascu R, Baicus A. BMC Gastroenterol. 2012 Jul 9;12:86

Methods

Setting and patients

We prospectively studied adult patients referred for IWL (without evident origin after clinical assessment), admitted as inpatients or referred to the day hospital in the Departments of Internal Medicine of a secondary care university hospital. All consecutive patients, 18 years of age or more, were included if they fulfilled one of the following criteria: 1) documented IWL of at least 5% of body weight within the last 6 months, or 2) declaration of a "very much" or "much" concerning the amount of weight loss, on a Lickert scale with five levels ("very much", "much", "average", "little" and "not at all"). The second criterion was applied only for the selection of patients for whom there was no baseline weight documentation, and the amount of weight loss could not be computed in order to fulfil the first criterion; for these patients, the existence of the weight loss had to be confirmed by a relative, or by changes in clothes or belt size. The patients with voluntary weight loss or with a known malignancy were not included in the study.

The study was conducted according to the Declaration of Helsinki, the protocol was approved by the ethics committee of Colentina University Hospital and all patients agreed to participate in the study and signed the informed consent before enrolling.

Study design

The investigative work-up was not standardized; it was decided by every participating physician, depending on clinical and biological diagnostic clues - therefore only patients in whom gastrointestinal cancer was suspected had upper endoscopy and/or colonoscopy. In order to avoid misclassification concerning the final diagnosis (gastrointestinal cancer or not) for patients who did not have endoscopic studies, after leaving the hospital all the patients were followed up for six months, verifying the final diagnosis, survival, state of health and further weight change.

All patients had blood collected at admission. Because ferritin was measured especially for this study, blood was centrifuged and the serum was frozen at -70°C; ferritin level was determined later in another laboratory, therefore the physicians and the endoscopists were blinded to the results. As one of the objectives of the research project was the validation of several simple clinical and biological parameters, found as diagnostic for cancer in IWL patients in three previous studies [20–22], all patients had a complete blood cell count (including MCV and RDW) and determination of blood erythrocyte sedimentation rate (ESR), serum C reactive protein (CRP), iron, albumin, alkaline phosphatase (ALP), alanin aminotranspherase (ALAT) and lactate dehydrogenase (LDH) levels, determined in the hospital laboratory. All variables were first recorded by every physician in a preformed questionnaire, and then registered by one of the authors into the database.

Laboratory procedures

The RDW, haemoglobin level and MCV were determined using the Sysmex XT 1800i counter (Sysmex Corporation, Kobe, Japan). Ferritin was measured with Chemwell 2910 analyzer (Awareness Technology, Palm City, Florida, USA), while serum albumin, iron, ALP, ALAT, LDH and CRP levels were measured using the Cobas 6000 Modular P 800 analyzer (Roche Diagnostics, Rotkreuz, Switzerland). ESR was measured by Westergreen method. Throughout the study, the quality of results was validated by regular internal quality control procedures and participation in an external quality assessment scheme.

Statistical analysis

The outcomes were gastrointestinal cancer/colorectal cancer as a cause of IWL, while the predictor variable was ferritin.

Results were expressed as frequencies for categorical variables, and median and extremes for non normal continuous variables. Stata 11 (StataCorp, College Station, Texas, USA) was used for the database construction and data analysis (area under the curve calculation with confidence intervals, and logistic regression). Hypothesis testing was 2-tailed, with P < .05 considered statistically significant. EBM calculator 1.0 (http://www.cebm.utoronto.ca) was used for the calculations of sensitivity, specificity, predictive values and likelihood ratios.

Baicus C, Rimbas M, Baicus A, Caraiola S; Grupul de Studiu al Scaderii Ponderale Involuntare..

Cancer and involuntary weight loss: failure to validate a prediction score.

PLoS One. 2014 Apr 24;9(4):e95286

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 >12×10⁹/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

REZULTATE

- Descrierea caracteristicilor populatiei
- Descrierea a ceea ce am gasit
 - Tabele / text
 - Nu repetați în text ce ați scris în tabele
- Nu dati doar p prezentati si CI 95%
- (Descrierea rezultatelor majore/relevante)
- Prezentare clara si concisa; past tense)

Secțiunea cel mai ușor de scris

Figuri și tabele

- Titlul trebuie să spună concluzia
- Trebuie să se înțeleagă totul din legendă (să fie înțeles mesajul înafara articolului)

Table 1

Patients' characteristics

Characteristic	Patients without cancer	Patients with gastrointestinal cancer	Patients with other cancers
Age (yr)	67 (22, 94)	70 (55, 82)	66 (44, 93)
Male sex	104 (48%)	12 (54%)	30 (58%)
RDW (%)	14.5 (10.3, 26.7)	14.8 (12.3, 20.4)	15.1 (11.5, 20.8)
Haemoglobin (g/dL)	12.6 (6.14, 17.4)	11.3 (7.9, 15.1)	11.8 (5.42, 17.7)
MCV (fL)	88 (62, 124)	84.5 (64, 98)	88.2 (72, 102)
Serum iron (mcg/dL)	54 (10, 197)	35.5 (10, 118)	35 (4, 162)
Ferritin (mcg/L)	99.5 (3, 2000)	26.5 (10, 500)	226 (15, 1105)
ESR (mm/h)	28 (2, 140)	44.5 (3, 140)	58 (11, 140)
CRP (mg/L)	5 (0.51, 328)	22 (1.6, 125)	46 (1, 550)
ALAT (u/L)	18 (6, 325)	18 (10, 71)	26 (10, 143)
Total number	216	22	52

Table 2

Areas under the curve for ferritin, MCV, serum iron, haemoglobin and RDW in the diagnosis of gastrointestinal cancer

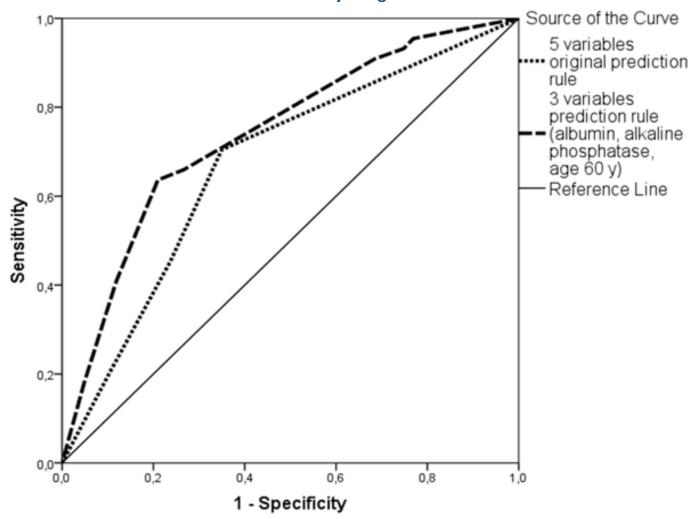
	Gastrointestinal cancer	Colorectal cancer	
	AUC (95% CI)	AUC (95% CI)	
Ferritin	0.746 (0.691-0.794)	0.765 (0.713-0.813)	
MCV	0.627 (0.568-0.684)	0.669 (0.612-0.725)	
Serum iron	0.636 (0.571-0.697)	0.650 (0.584-0.710)	
Haemoglobin	0.590 (0.530-0.646)	0.552 (0.491-0.609)	
RDW	0.541 (0.476-0.602)	0.463 (0.401-0.528)	

Table 3

Ferritin with cut-off values of 100 mcg/L and 50 mcg/L, and anaemia in the diagnosis of gastrointestinal cancers (in paranthesis are 95% CI)

		Gastrointestinal cancer	Colorectal cancer
Ferritin (cut-off 100 mcg/L)	Sensitivity (%)	86 (67–95)	93 (69–100)
	Specificity (%)	57 (51–62)	56 (50–62)
	Positive predictive value (%)	14 (9–21)	10 (6–16)
	Negative predictive value (%)	98 (94–100)	99 (96–100)
	Positive likelihood ratio	2	2.1
	Negative likelihood ratio	0.24	0.13
	Sensitivity (%)	68 (47–84)	64 (39–84)
	Specificity (%)	51 (45–57)	50 (44–56)
Anaemia	Positive predictive value (%)	10 (6–16)	6 (3–11)
	Negative predictive value (%)	95 (90–98)	97 (92–99)
	Positive likelihood ratio	1.4	1.3
	Negative likelihood ratio	0.63	0.71

Figure 2. Receiver Operating Characteristic Curves of the Hernandez and Present Models in Patients Who Had Involuntary Weight Loss.



Baicus C, Rimbas M, Baicus A, Caraiola S, Grupul de Studiu al Scaderii Ponderale Involuntare (2014) Cancer and Involuntary Weight Loss: Failure to Validate a Prediction Score. PLOS ONE 9(4): e95286. doi:10.1371/journal.pone.0095286 http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0095286

TENTH ANNIVERSARY

Table 5. Modified Regression Model For the Relation Between Clinical Variables and Probability of Having Cancer in Patients Who Had Involuntary Weight Loss*.

	Variable		Probability	of
Age >60 y	Alkaline Phosphatase >104 U/L	Albumin <3.5 g/dL	Having Cancer (%) (95% Confidence Interval)	Not Having Cancer (%) (95% Confidence Interval)
No	No	No	5 (3-8)	95 (92-97)
No	No	Yes	11 (8-14)	89 (86-92)
No	Yes	No	13 (10-17)	87 (83-90)
Yes	No	No	20 (16-24)	80 (76-84)
No	Yes	Yes	25 (21-30)	75 (70-79)
Yes	No	Yes	34 (30-39)	66 (61-70)
Yes	Yes	No	40 (35-45)	60 (56-65)
Yes	Yes	Yes	59 (54-64)	41 (36-46)

^{*}N = 290 patients.

doi:10.1371/journal.pone.0095286.t005

Baicus C, Rimbas M, Baicus A, Caraiola S, Grupul de Studiu al Scaderii Ponderale Involuntare (2014) Cancer and Involuntary Weight Loss: Failure to Validate a Prediction Score. PLOS ONE 9(4): e95286. doi:10.1371/journal.pone.0095286 http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0095286

TENTH ANNIVERSARY

DISCUTII

- Rezumati rezultatele
- Descrieti cum se incadreaza in cunostintele actuale
- Discutati orice limitari ale studiului (metode)
- Trageti concluzii si faceti sugestii pentru cercetari viitoare

Rule of Thirds

Introduction

- Background (literature review).
- Significance of problem/issue.
- Hypothesis and brief synopsis of results; emphasize what is novel, implications.

Discussion

- Synopsis of results, emphasize what is novel.
- Place in perspective of literature; limitations.
- How has work led to new model? Future impact and directions?
 OK to speculate.

Referințe

- Instrucțiuni pt autori
- Sisteme Vancouver / Harvard
- Nu informatii nepublicate

Referințe

- Includeți referințe la
 - Competitori
 - Articole care nu sunt de acord cu voi
 - Articole publicate în timp ce voi cercetați
- Reviewer-ii vor cauta mai ales articolele lor
- Citați articolele cele mai importante autorii lor probabil vor fi reviewer-ii vostri

TITLUL

- Cu cat mai simplu, cu atat mai bine
- Ganditi-va la cititorii ţintă
- Titlurile scurte sunt mai clare şi mai frapante
- Evitati adjectivele excesive si substantivele multiple
- Evitati stilul senzațional

Figure 1

Title and Title Page

- Declarative statement; something "flashy" to catch the reviewers' and readers' attention.
- · Word count; spell out abbreviations (know journal guidelines).
- · Running title: brief version of full title.
- Key words: usually 4–6 (choose general words).
- · Sources of funding.
- All authors: include relevant conflicts of interest and roles in study and development of manuscript.
- Other information as required by journal.

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M

R

A

250 cuvinte

Background

Objectives

Design

Setting

Subject

Main outcome

Dupa titlu, este partea cea mai citita (si cel mai frecvent singura)

- Document care sa reziste independent
- Prezinta efectele principale cu Cl95%
- Duce la concluzii valide

- Contine esenta articolului si trebuie sa poata rezista independent
- 4 parti
 - De ce a fost facut studiul
 - Ce s-a facut
 - Ce s-a gasit
 - Care sunt concluziile
- Max 150 cuvinte (nestructurat)/ 250 (structurat)
- Fii clar si evita detaliile nenecesare

TITLU, ABSTRACT, AUTORI

- Titlu cat mai scurt si interesant
- Abstract concis, clar si informativ
- Autori cat mai putini posibil

Names department(s) and institution(s) of all authors.

(In online submission system, confirm that all listed authors meet ICMJE http://www.icmje.org/
authorship criteria and that nobody who qualifies for authorship has been excluded. Credit for
authorship should be based on: [1] substantial contributions to research design, or the
acquisition, analysis or interpretation of data; [2] drafting the paper or revising it critically; [3]
approval of the submitted and final versions. Authors should meet all three criteria.)

Short description of each authors' contribution. (Examples of categories for authors' contributions: Concept/design, Data analysis/interpretation, Drafting article, Critical revision of article, Approval of article, Statistics, Funding secured by, Data collection, Other)

Ordinea firească a lucrurilor...

- De obicei se termină cercetarea, după care se scrie articolul (ceea ce deseori te duce înapoi în laborator)
- Abordare alternativă: începeți scrisul, apoi faceți cercetarea pentru a obține datele de care aveți nevoie
- Decideți autorii de la început

Înainte de a începe să scrieți

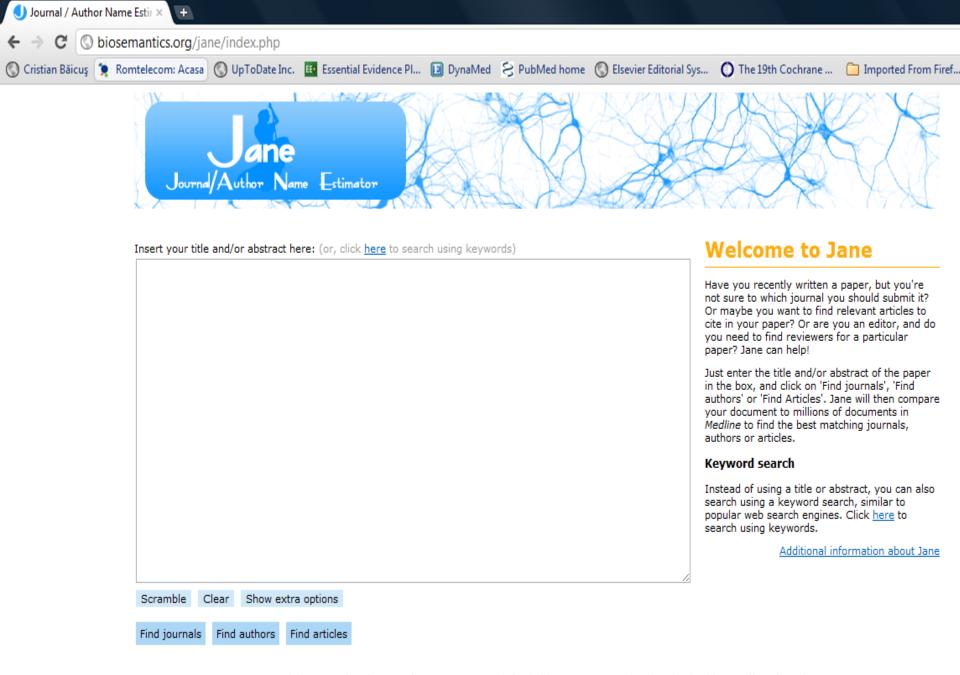
- Discutați cine este autor și pe ce loc
 - Autori / acknowledgements
- A fi autor
 - Contribuție semnificativă la design, execuție, interpretare și prezentare a cercetării
 - Ordinea autorilor
 - Responsabilitatea autorilor
 - Autor corespondent

Scrierea articolului

- Scrieţi zilnic
- Strategie:
 - 1. Autorii și ordinea
 - 2. Figuri/Tabele
 - 3. Metode
 - 4. Rezultate
 - 5. Introducere, Discuții
 - 6. Abstract și Titlu

How Do I Choose a Journal for Submission?

- Your work will influence journal choice: look through journals, talk to people.
 - If work is broad based, select a more general journal.
 - If work is very focused, select a journal that is specific.
- · If work is novel, try top journal initially.
 - Mechanism(s) is(are) important.
- Regardless, choose as high an impact journal as possible in the initial submission.
- If necessary, have a list of journals to try next if submission to top choice is not accepted.





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- REMARK checklist

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