COME SCRIVERE UN ARTICOLO SCIENTIFICO

Master Class SISET 2016

Paolo Bucciarelli

Centro Emofilia e Trombosi "A. Bianchi Bonomi"
Fondazione IRCCS Ca' Granda
Ospedale Maggiore Policlinico, Milano

bucciarelli@policlinico.mi.it

Parti strutturali di un articolo scientifico

- Titolo/Autori
- Abstract
- Introduzione
- Metodi
- Risultati
- Discussione
- Tabelle/Figure
- Bibliografia

Abstract

- E’ lo “specchio” dell’articolo
- Spesso è l’unica cosa che viene letta dell’articolo (deve attirare l’attenzione del lettore)
- In poco spazio (200 o 250 parole) deve contenere tutte le informazioni essenziali dell’articolo

Introduzione

- Deve contenere un breve “state of the art” dell’argomento oggetto dello studio
- Deve indicare quali sono le lacune scientifiche che lo studio cerca di colmare
- Alla fine deve riportare lo **scopo dello studio** (chiaro, non “fumoso”)

Metodi

- Deve contenere il **disegno dello studio**
  (RCT, coorte, caso-controllo, cross-sectional…).
  Uso del termine "prospective" spesso inflazionato.

- Dettagli sulla selezione della casistica (setting, criteri di inclusione ed esclusione)

- Definizione di esposizione e outcome (per studi di coorte)

- Dettagli su test di laboratorio, raccolta di parametri clinici (cambiano a seconda dello studio)

- Analisi statistica (dettagliata, deve contenere il **calcolo del sample size** e tutti i test utilizzati per ricavare i risultati, correzione del "confounding", eventuali "sensitivity analyses", test di interazione)

Risultati

- Devono essere strutturati con logica sequenziale:
  - presentazione della casistica (Table 1)
  - risultati obiettivo primario dello studio
  - risultati obiettivo(i) secondari(o) dello studio
  - risultati sensitivity analysis (sottogruppi)
  - risultati test di interazione
- Non ripetere pedissequamente nel testo tutti i risultati riportati nelle Tabelle o Figure
- Nessun commento dei risultati in questa sezione
- **Preferire stime e 95% CI ai p-values**

Use and misuse of p-values

- **Cosa rappresenta il p-value?**
  E' il risultato di un test di ipotesi che ci indica la probabilità di sbagliare nel rifiutare l'"ipotesi nulla" di uguaglianza a favore di un'ipotesi alternativa di differenza (errore α "accettato" fino a 5% → $p \leq 0.05$)

- **Cosa NON rappresenta il p-value?**

  a) Non è un test per l'uguaglianza: se non riesco a rifiutare l'ipotesi nulla (i.e., p-value non significativo), ciò non vuol dire che posso accettarla ("the absence of evidence is not the evidence of absence")

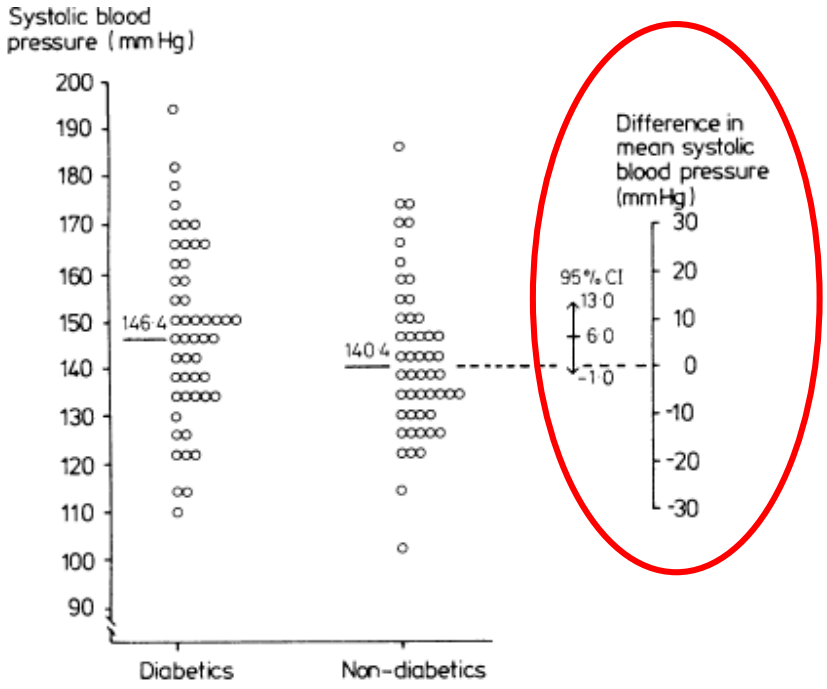
  b) Non è un parametro di "bontà" o "predittività" di un modello statistico

  c) Non indica la grandezza di una stima (diff. medie, rischio relativo, etc.)

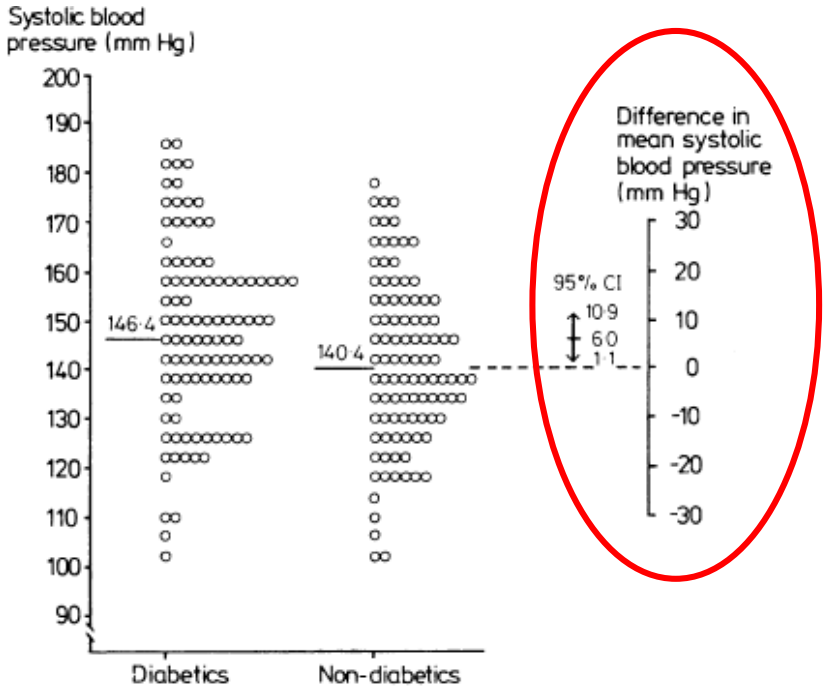
- **Significatività statistica non è sinonimo di significatività (rilevanza) clinica**
  (→ scopo di uno studio clinico non è trovare una significatività statistica, ma stabilire la grandezza di alcuni fattori di interesse (es. rischi di malattia)

Stime e 95% CI……

- Danno un'informazione più appropriata e completa sulla grandezza di un certo fattore di interesse (es. diff. media, rischio relativo…) e sulla precisione della stima



N = 50 p = 0.10



N = 100 p = 0.04

Table 1. Baseline Characteristics of the Study Population Stratified by Severity of CAD

	All Participants (n=282)	No CAD (n=51)	Mild CAD (n=75)	Moderate CAD (n=74)	Severe CAD (n=45)	Extremely Calcified (n=37)*	*P* Value
Age in years, median (min–max)	60 (34–83)	55 (36–76)	60 (34–78)	61 (43–83)	60 (37–79)	64 (42–78)	0.004
Male sex, n (%)	183 (64.9)	31 (60.8)	40 (53.3)	46 (62.2)	37 (82.2)	29 (78.4)	0.017
BMI, kg/m^2	26.7 (24.5–29.0)	26.9 (24.7–28.7)	26.3 (24.4–28.7)	26.4 (24.0–29.3)	27.1 (25.6–28.8)	26.8 (24.0–29.9)	0.595
Creatinine, µmol/L	79 (70–88)	80 (70–88)	78 (70–88)	80 (72–90)	82 (70–91)	76 (65–88)	0.558
Smoking, n (%)	70 (24.8)	9 (17.6)	17 (22.7)	18 (24.3)	14 (31.1)	12 (32.4)	0.482
Diabetes mellitus, n (%)	29 (10.3)	5 (9.8)	9 (12.0)	4 (5.4)	4 (8.9)	7 (18.9)	0.565
Family history of CAD, n (%)	105 (37.2)	16 (31.4)	35 (46.7)	27 (36.5)	15 (33.3)	12 (32.4)	0.280
VKA therapy, n (%)	40 (14.2)	3 (5.9)	14 (18.7)	7 (9.5)	10 (22.2)	6 (16.2)	0.046
Aspirin therapy, n (%)	93 (33.0)	15 (29.4)	24 (32.0)	21 (28.4)	19 (42.2)	14 (37.8)	0.432
Lipid-lowering therapy, n (%)	101 (35.8)	11 (21.6)	30 (40.0)	26 (35.1)	20 (44.4)	14 (37.8)	0.087
Antihypertensive therapy, n (%)	66 (23.4)	5 (9.8)	19 (25.3)	19 (25.7)	12 (26.7)	11 (29.7)	0.114
Involvement score, n of segments	2 (0–5)	0 (0–0)	2 (1–4)	5 (2–6)	5 (3–7)	…	<0.001
Calcified lesions, n	1 (0–3)	0 (0–0)	1 (0–2)	2 (1–4)	2 (1–4)	…	<0.001
Mixed lesions, n	1 (0–2)	0 (0–0)	0 (0–1)	1 (1–2)	2 (0–2)	…	<0.001
Noncalcified lesions, n	0 (0–1)	0 (0–0)	0 (0–0)	0 (0–1)	0 (0–1)	…	<0.001
Coronary calcium score	88 (1–356)	0 (0–0)	44 (5–102)	168 (63–355)	197 (46–501)	1211 (948–2295)	<0.001

- Concentrare l'analisi statistica sull'ipotesi di studio
- Evitare un eccesso di confronti statistici (problema legato al "multiple testing" (→ possibilità di false associazioni)

Discussione

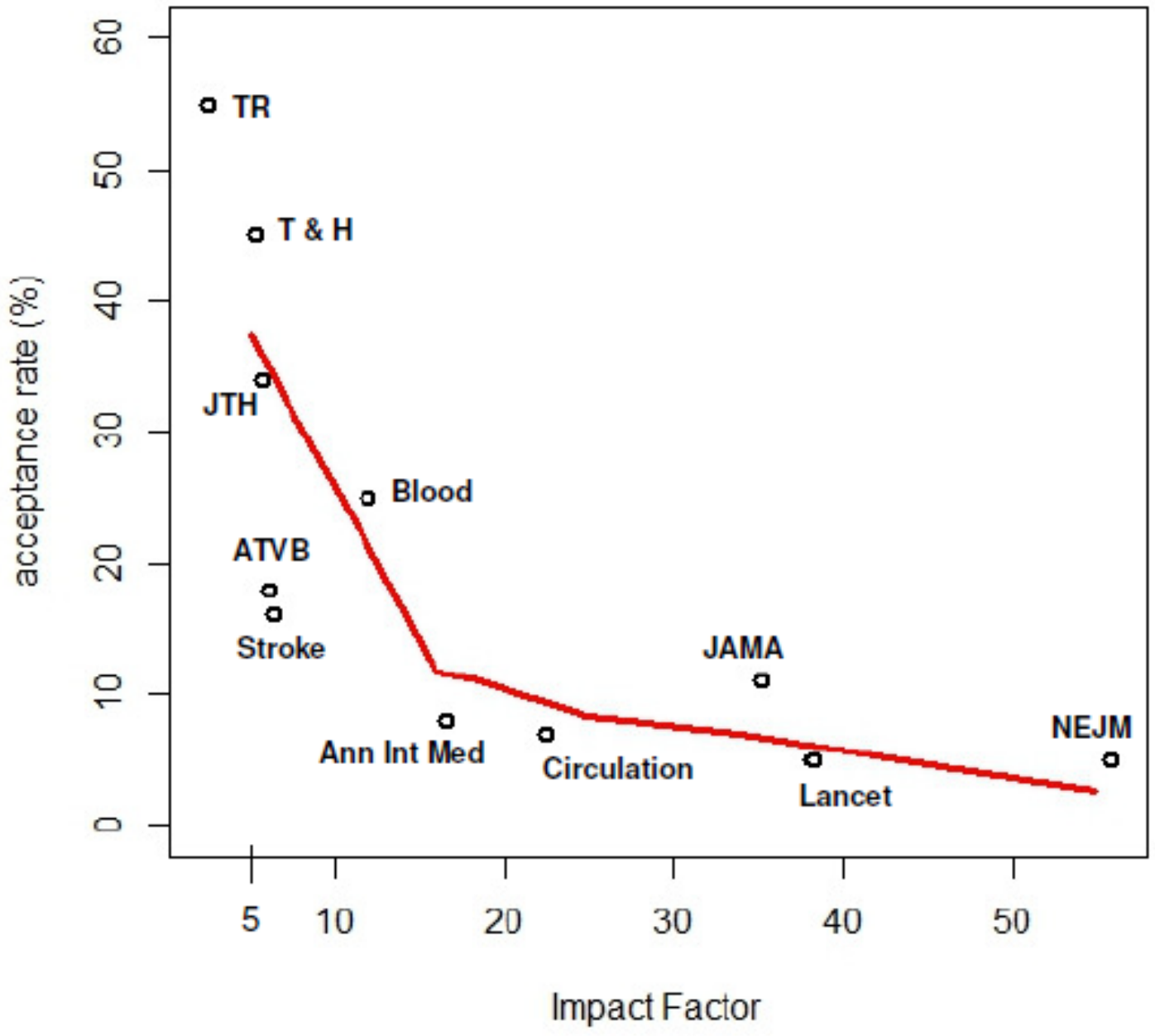
- Deve essere strutturata con logica sequenziale:

  - breve riassunto dei risultati principali
  - confronto con dati già pubblicati in letteratura
  - spiegazioni plausibili dei risultati
  - punti di forza dello studio
  - **limitazioni dello studio** (non esiste lo studio perfetto!)
  - breve conclusione con rimando a studi futuri

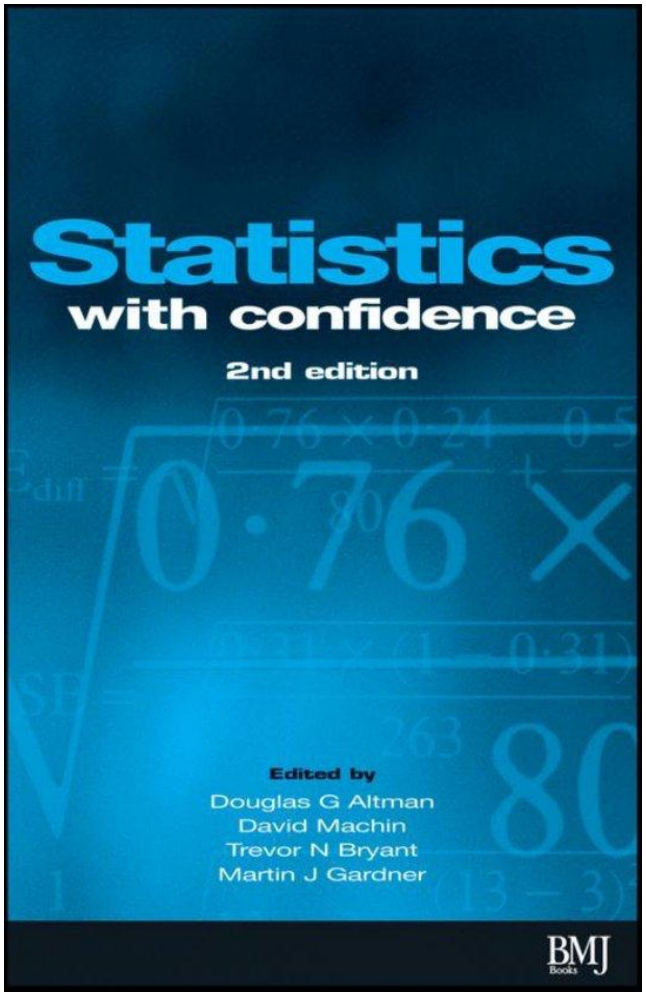
- Non ripetere i risultati in questa sezione

Notazioni “estetiche”

- Controllare la consistenza dei numeri tra abstract, testo e Tabelle/Figure
- Tabelle/Figure: per le variabili continue, riportare l’unità di misura e spiegare quali misure di centralità e di dispersione vengono usate (mean, median, SD, IQR…)
- Figure: attenti alla scale di misura!!!


acceptance rate (%)
0
10
20
30
40
50
60
TR
T & H
JTH
Blood
ATVB
Stroke
JAMA
Ann Int Med
Circulation
Lancet
NEJM
5
10
20
30
40
50
Impact Factor

Some useful reading…..



ACADEMIA AND CLINIC

Toward Evidence-Based Medical Statistics. 1: The *P* Value Fallacy

Steven N. Goodman, MD, PhD

Toward Evidence-Based Medical Statistics. 2: The Bayes Factor

Steven N. Goodman, MD, PhD

Ann Intern Med 1999;130 (12)

EDITOR'S CHOICE

Uncertainty and significance

Commentary: The *P*-value, devalued

Steven Goodman

Int J Epidemiol 2003;32

….. and guidelines

- **STROBE** (observational studies) *BMJ* 2007
- **CONSORT** (clinical trials) *BMJ* 2010
- **PRISMA** (meta-analysis) *BMJ* 2009
- **TRIPOD** (predictive models) *Ann Intern Med* 2015

European Journal of Case Reports in Internal Medicine

The European Journal of Case Reports in Internal Medicine is an official journal of the European Federation of Internal Medicine (EFIM). The journal wants to promote the practice of internal medicine in Europe.

EJCRIM welcomes papers describing unusual or complex cases that an internist may encounter in everyday practice. Case series are also welcomed as long as they demonstrate the appropriateness of a therapeutical approach or unusual manifestation of a disease.

After 2 years of publishing, the EJCRIM wants to improve its case reports and articles by strengthening their:

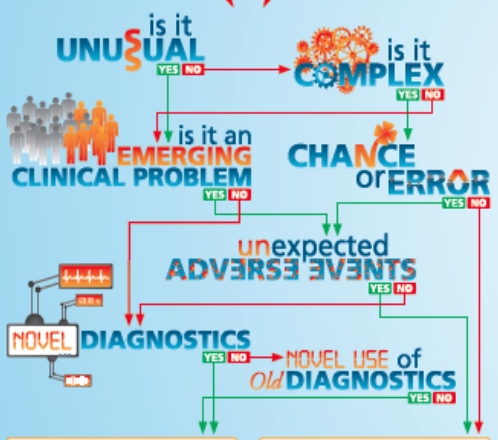
- structure;
- value to the reader - i.e. of interest, increase in knowledge, skill and competence;
- teaching power (i.e. value when shared amongst both experienced and inexperienced colleagues);
- relevance to all medical specialties including general practitioners, surgeons, and all clinical scientists.

SEE HOW INSIDE!

What's IMPORTANT about your case?

THE CASE ITSELF | THE PROCESS THAT LED TO DIAGNOSIS AND TREATMENT

why?



SUBMIT A CASE REPORT

TRY WITH A CLINICAL SKILL CASE

and now... THINK AGAIN!

What did you learn from the patient/case?

What importance does it have for the other physicians?

THESE ARE YOUR LEARNING POINTS

make them CLEAR

make them THREE

Lastly,

have you reviewed the literature to see if the case isn't already well established?

CLINICAL SKILL CASE

...SO YOUR CASE IS EVIDENCE-BASED WITH A TRADITIONAL APPROACH

1 SYMPTOMS

- How did you recognize the symptoms?
- Explain how not to get confused by mixed signals and confounding symptoms.

2 HISTORY TAKING

- How did you get your info/ anamnesis if the patient and family weren't collaborative (unconscious patient, paniciding relative, etc)?

3 BEDSIDE MEDICINE

- Any physical examination, or any objective symptoms?
- Did you perform any triggering maneuvers?

4 TREATMENT SKILLS

- What did you do to keep the patient at bay?
- Were you waiting for diagnostics results?

5 DIAGNOSTIC ALGORITHMS

- Did you avoid excessive testing?
- Hence, did you save money?
- Did you avoid delay in diagnosis (see treatment)?
- Guidelines. Are they current?

6 ANY INSTRUCTIVE ERRORS?

- Insufficient info (see history taking)?
- Lack of bedside skills?
- Lack of follow up?

HOW TO PRESENT YOUR CASE

1 Start with your **learning points**: they constitute the "core business" of the EJCRIM. They should be stated at the beginning of the article and made of **3 or 4 bullet points**. Authors should analyze their case report and identify what they personally learnt from it. What about it would improve medical knowledge and practice and help them and their colleagues better scrutinize a patient, avoid mistakes and useless exams, costly technologies, etc.. This message of the case could hinge on the recognition of a symptom, on overlooked historical information, on avoiding diagnostic distractors or "red herrings", or on choosing the correct diagnostic and/or therapeutic tool, strategy, etc.

2 **DO NOT start** your case presentation stating the final diagnosis. Instead, describe the reason the patient sought medical attention, followed by the clinical presentation (symptoms, signs, initial paraclinical data) and the timing of the development of the patient's disease.

3 The **less recent history** of the case that is relevant to the current clinical problem (eg: previous hospital admittance, therapies, lab tests), if any.

4 Initial diagnostic hypothesis: **this should NOT be exhaustive**, but a short list of the most plausible.

5 Investigative strategy: make sure you **justify and explain the rationale** if risky and/or expensive and/or invasive examinations or maneuvers are used.

6 Diagnostic **conclusion**: explained in relation to the available data.

7 Therapeutic strategy: describe **what was undertaken and WHY** (i.e. to treat or not treat; reference evidence in the literature, therapeutical aim and treatment response)

8 Management critique: things you did **right** and things you did **wrong** or would not do next time. **DO include** possible signs or misconceptions that led your attention away from the main hypothesis towards other types of diagnosis ("confounding signs"). A poor decision compared to a wiser one that might have been made instead is often a case's most important learning point.

9 Review your **learning points** and check if the description of your case and its conclusion correctly support your learning points. **DO NOT include** an exhaustive description or review of the disease – only concentrate on those issues that support the case's learning points.

10 Make sure you have retrieved **patient's consent** (if needed) and you have signed the Copyright forms.

HAPPY WRITING!

www.ejcrim.com

SUBMISSION MANUAL

www.EJCRIM.com

EFIM

Official Journal of the European Federation of Internal Medicine

www.efim.org ISSN: 2284-2594

Continuous publishing starting from 2013

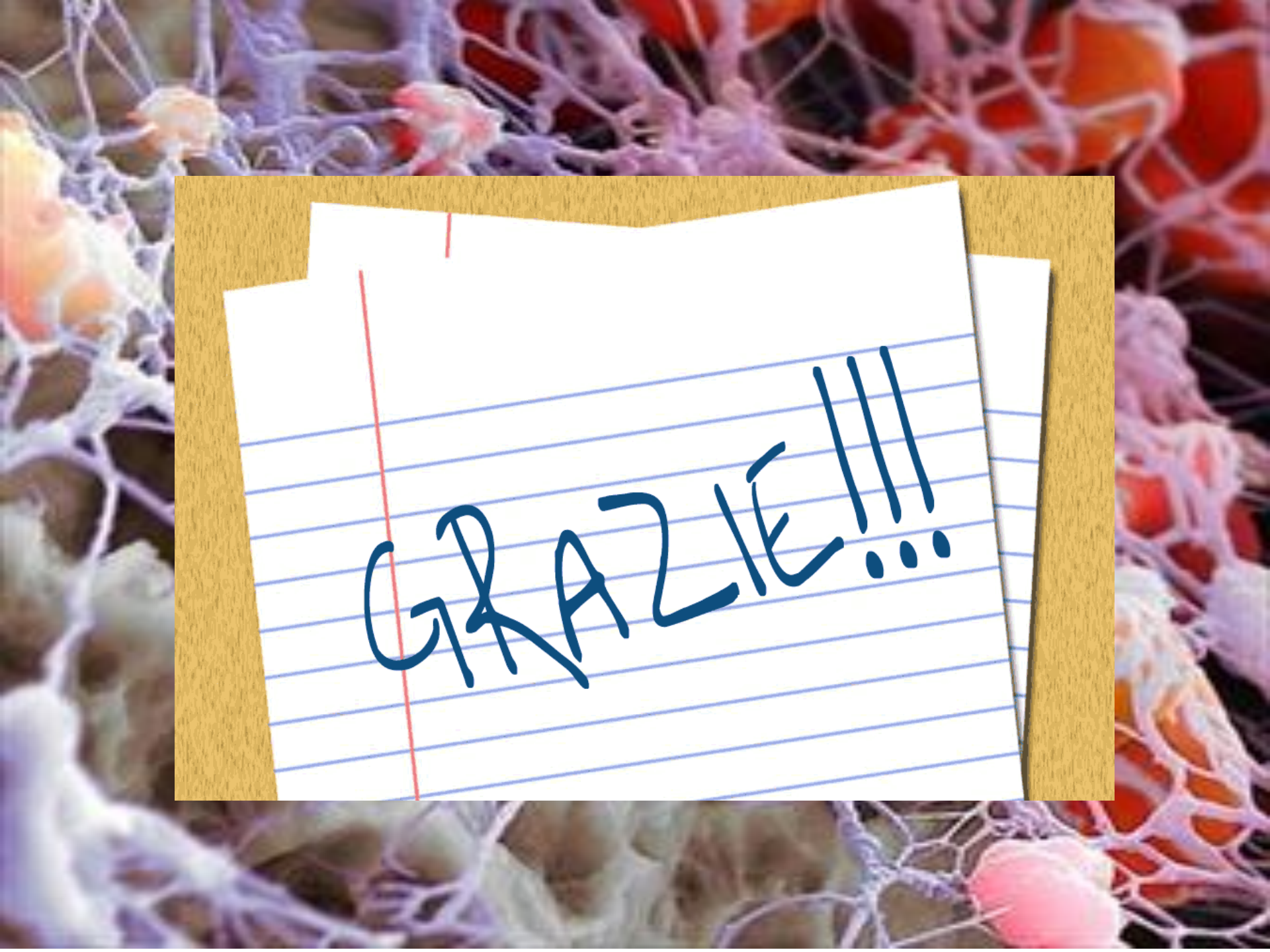
smc media srl

Publisher: SMC media Srl

Via Giovenale, 7 - 20136 Milano - Italy

P.IVA 07626490960

ejcrim@smc-media.eu


GRAZIE!!!