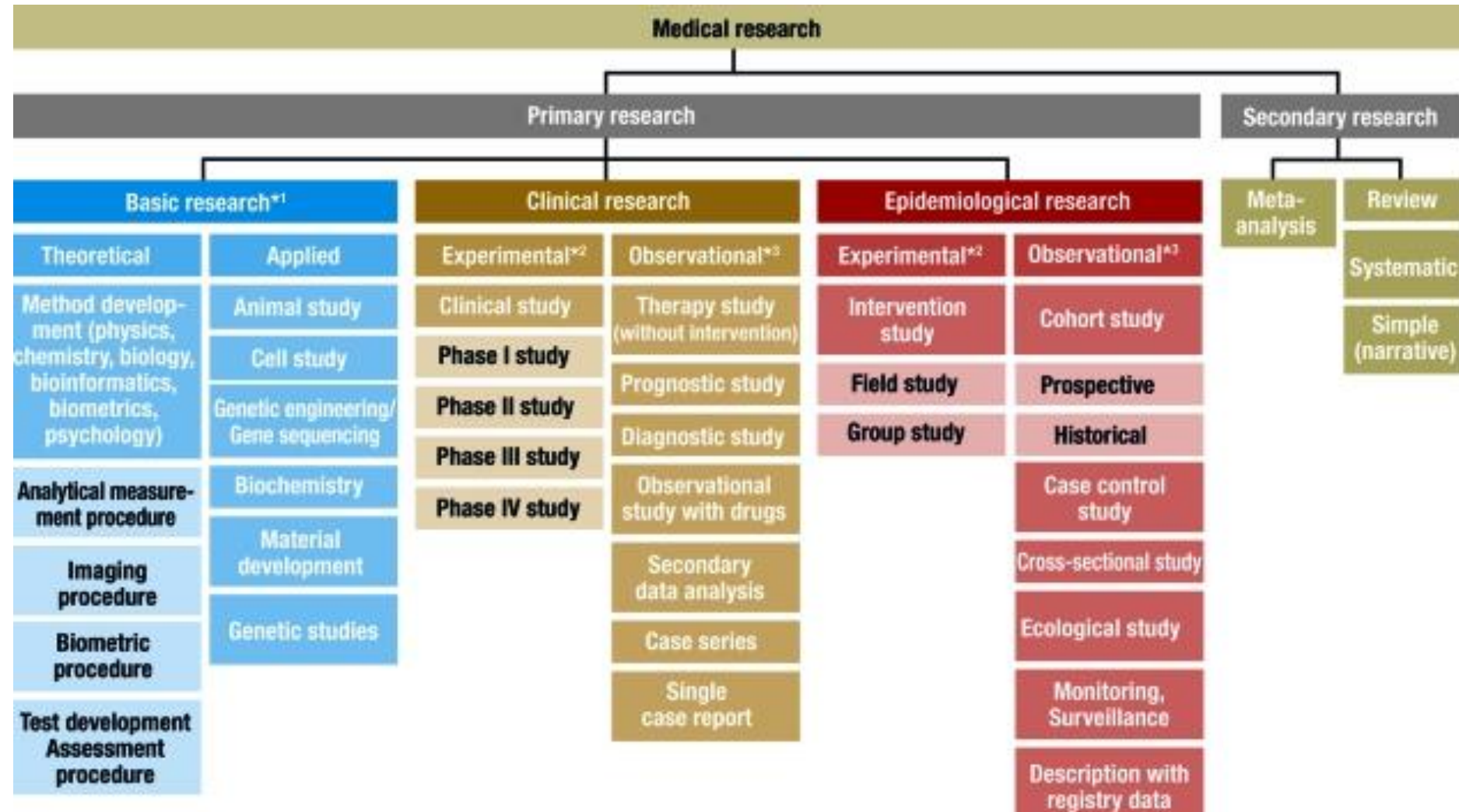


## DESIGN-UL STUDIULUI: Cercetarea secundară

Sorana D. Bolboacă

# Cercetare primară vs. cercetare secundară



# Cercetarea secundară

## Elaborarea tezei de licență sub forma unei analize sistematice

### Definiție – analiză sistematică

**Analiza sistematică** este o analiză a literaturii de specialitate axată pe o temă de cercetare care încearcă să identifice, evalueze, selecteze și rezume toate studiile relevante pentru această temă de cercetare.

Spre deosebire de alte abordări ale analizei literaturii de specialitate, analiza sistematică utilizează o abordare bine definită și uniformă pentru a identifica toate studiile relevante legate de tema de cercetare și a prezenta rezultatele studiilor selectate.

### Redactarea lucrării de licență. Ghid pentru studenți

# Cercetarea secundară

## Definiție – meta-analiză

**Meta-analiza** constă în utilizarea de metode statistice pentru a rezuma rezultatele unei analize sistematice. Nu toate analizele sistematice conțin meta-analize. Prin combinarea informațiilor provenite din toate studiile relevante, meta-analizele pot furniza estimări mai precise ale efectului unei intervenții comparativ cu estimările derivate din studii izolate incluse în meta-analiză.

Redactarea lucrării de licență. Ghid pentru studenți

# Sinteze ...

*“SINTÉZĂ, sinteze, s. f. 1. Metodă științifică de cercetare a fenomenelor, bazată pe trecerea de la particular la general, de la simplu la compus, pentru a se ajunge la generalizare; îmbinare a două sau a mai multor elemente care pot forma un tot.”*

[dexonline](#)

Sinteza narativă  
(*Review*)

Sinteza sistematică  
(*Systematic review*)

Meta-analiza

Sinteza critică  
(*Critical Review*)

Sinteza literaturii  
(*State-of-the-art review*)

... *Scoping review &  
Systematic search  
and review &  
Systematized review*

# Sinteza narativă

## Descriere

Termen generic: rezumat al literaturii [medicale] care prezintă cunoașterea din literatura de specialitate

## Căutare

În general nu include o căutare sistematică a literaturii de specialitate

## Evaluare

În general nu include o evaluarea calitativă a literaturii de specialitate

## Sinteza

De obicei narativ, dar poate include caracteristici tabelare

## Analiza

Analiza poate fi cronologică, conceptuală, tematică etc.

# Sinteza sistematică

## Descriere

Căutare și evaluare sistematică a dovezilor din literatura de specialitate

## Căutare

Vizează o căutare exhaustivă, cuprinzătoare

## Evaluare

Evaluarea calității poate determina includerea/excluderea

## Sinteza

De obicei narativ cu sumarizare tabelară

## Analiza

Ce se știe; recomandări pentru practică. Ce rămâne necunoscut; incertitudinea în jurul constatărilor, recomandări pentru cercetări viitoare

# Meta-analiza

Descriere	Tehnica care combină statistic rezultatele studiilor cantitative pentru a oferi un efect global, mai precis al rezultatelor
Căutare	Vizează o căutare exhaustivă, cuprinzătoare. Poate folosi diagrama pânzie pentru a evalua caracterul complet
Evaluare	Evaluarea calității poate determina includerea/excluderea și/sau analizele de sensibilitate
Sinteza	Grafice și tabele cu comentariu narativ
Analiza	Analiza numerică a măsurilor de efect presupunând absența eterogenității



# Căutarea sistematică și sinteza

## *Systematic search and review*

Descriere	Combină punctele forte ale sintezei critice cu un proces cuprinzător de căutare. De obicei abordează întrebări ample pentru a produce „cea mai bună sinteză a dovezilor”
Căutare	Vizează o căutare exhaustivă, cuprinzătoare
Evaluare	Poate include sau nu evaluarea calității
Sinteza	Narațiune minimă, rezumat tabelar al studiilor
Analiza	Ce se știe; recomandări pentru practică. Limitări

# Sinteza narativă vs. sinteza sistematică vs. meta-analiza

---

Sinteza narativă: recenzie a literaturii științifice care combină cunoștințele rezultate din studii experimentale sau neexperimentale, respectiv experimente teoretice.

---

Sinteza sistematică: analiza literaturii se concentrează pe o singură întrebare și se identifică, evaluează, selectează și sintetizează toate cercetările primare cu înaltă calitate științifică

---

Meta-analiza: tehnică statistică utilizată adesea în sintezele sistematice, care permite ca rezultatele unui număr de studii să fie combinate într-o metrică comună pentru a determina efectul. Permite compararea eficienței diferitelor tehnici.

# Sinteza sistematică vs. Sinteza narativă

Caracteristici	Sistematică	Narativă
Răspunde la	O singură întrebare	Mai multe întrebări
Strategia de căutare a articolelor	Explicită și reproductibilă	-
Criterii de includere	Explicite	-
Combinarea rezultatelor studiilor	+ dacă este însoțită și de meta-analiză	-

# Sinteza sistematică

- Lucrări științifice care adună într-un mod sistematic toată cunoașterea anterioară cu privire la un subiect de cercetare bine definit
- Resurse:
  - Cochrane Database of Systematic Reviews: <http://www.cochranelibrary.com/cochrane-database-of-systematic-reviews/>
  - [Finding Studies for Systematic Reviews: A Resource List for Researchers](#)
  - Protocoale de sinteze sistematice: [www.crd.york.ac.uk/](http://www.crd.york.ac.uk/)
  - Systematic Review Data Repository: <https://srdhr.ahrq.gov/>
  - JBI Database of Systematic Reviews and Implementation Reports: <http://journals.lww.com/jbisrir/>

# Pași în realizarea unei sinteze sistematice

Întrebare de  
interes clar  
formulată (vezi  
PICO)

Strategie de  
căutare  
reproductibilă

Evaluarea calității  
articolelor  
identificate

Sumarizarea  
rezultatelor

Analiza statistică  
(meta-analiză)

Interpretare

Concluzii și  
recomandări

# 1. Întrebare de interes clar formulată

## STADIUL ACTUAL AL CUNOAȘTERII CLAR, SCOP ȘI CADRU CLARE

### *Effectiveness of quality improvement interventions for patient safety in radiology: a systematic review protocol*

*Review question/objective: The objective of this review is to find the best available evidence regarding effectiveness of quality improvement interventions in clinical radiology and the experiences and perspectives of staff and patients. More specifically, the review questions are:*

- How effective are the interventions that may improve or affect patient safety and quality in clinical radiology?*
- What are the experiences and perspectives of staff and patients of patient safety and quality improvement interventions?*

## 2. Strategie de căutare reproductibilă

### CRITERII DE INCLUDERE

Participanți	<i>this review will consider studies that include <u>patients</u> undergoing radiological examinations and/or <u>healthcare professionals</u> (radiologists, radiographers, medical imaging nurses and other personnel) working in hospitals or stand-alone healthcare facilities or “super-clinics</i>
Intervenții	<i>will evaluate the following types of quality improvement interventions: <u>human factors</u>, <u>HIT</u>, <u>training and education</u>, <u>staffing arrangements</u> (staffing levels, skill mix, grade mix and qualification mix), <u>regulation</u>, <u>incident reporting and management</u>, <u>peer review</u> (re-validation), <u>clinical audit</u>, <u>teamwork and communication interventions</u> (e.g. TeamSTEPPS), <u>safety checklists</u>, <u>local (clinical) governance</u> and any other intervention that meets the definition of quality improvement interventions.</i>

## 2. Strategie de căutare reproductibilă

### CRITERII DE INCLUDERE

Fenomenul urmărit	<i>the <u>experiences and perspectives</u> of staff and patients undergoing, or being exposed to, the quality improvement intervention. These experiences or perspectives could include descriptions of safety concerns, the context and culture of the workplace (including factors such as conflict and how it is managed, teamwork behaviors or the attitudes of staff to patient safety), the management of adverse events and near misses or changes to work practices</i>
Context	<i>will consider studies that are based on a radiological setting</i>
Rezultatul	<i>this review will consider studies of “<u>patient safety</u>” outcomes including adverse <u>events and near misses</u> (incidents), and any validated quantitative measurement of safety culture (such as the SAQ or HSOPSC tools)</i>
Tipul de studii	<i>this review will consider <u>Randomized Controlled Trials (RCTs)</u> or <u>Cluster Randomized Controlled trials (CRCTs)</u>. In the absence of RCTs or CRCTs, other experimental study designs including <u>non-randomized controlled trials</u>, <u>quasi-experimental</u>, <u>controlled before after trials</u> and <u>interrupted time series trials</u> will also be considered for inclusion</i>



## 2. Strategie de căutare reproductibilă

### STRATEGIA DE CĂUTARE

Obiectiv	<i>aims to find <u>published</u> and <u>unpublished</u> studies</i>
Căutare primară	<i>EMBASE and MEDLINE (termeni și cuvinte cheie în titlul și abstract + termeni utilizați la indexare)</i>
Căutare secundară	<i>EMBASE, MEDLINE, CINAHL, Cochrane Central Register of Controlled Trials, PsycINFO and Web of Science. The search for unpublished studies will include Mednar, Trove, Google Grey and OCLC WorldCat Dissertations and Theses (toți termenii și cuvintele cheie identificate în căutarea primară)</i>
Căutarea terțiară	<i>reference list of all identified reports and articles will be searched for additional studies</i>
Limba	<i>Studies published in English</i>
Timp	<i>Studies published from 1990 (when the first substantive patient safety research study... onward will be considered for inclusion in this review.</i>

## 2. Strategie de căutare reproductibilă

### *keywords*

**Radiology and its modalities:** Radiology, diagnostic imaging, medical imaging, clinical radiology, X-Rays, computed tomography, angiography, mammography, magnetic resonance imaging, ultrasound, positron emission tomography, single photon emission computed tomography (Using OR Boolean operator).

**Populations:** Healthcare professional, health personnel, radiologist, radiology nurse, radiographer, radiology technician, radiology registrar, radiology consultant, ultra-sonographer, patient, consumer, private hospital, public hospital, stand-alone facility, super clinic, radiology department (using OR Boolean operator).

**Interventions:** Health information technology, picture archiving communication system, radiology information system, computer aided diagnosis, voice recognition technology, human factors, ergonomics, human engineering, training, education, staffing arrangement, incident reporting, peer review, clinical audit, teamwork intervention, communication intervention, team training, safety checklist, local governance, quality improvement intervention (using OR Boolean operator).

## 2. Strategie de căutare reproductibilă

### *keywords*

**Outcomes:** Patient safety, incident, sentinel event, event, near miss, adverse event, adverse incident, safety incident, patient safety incident, event register, safety culture, nontechnical skills, patient throughput, workflow, patient experience, patients perspective, staff experience, staff perspective (using OR Boolean operator).

**Types of studies:** Randomized controlled trials, cluster randomized controlled trials, quasi experimental, controlled before and after trials, interrupted time series analysis, grounded theory, ethnography, phenomenology (using OR Boolean operator).

Radiology and its modalities AND populations AND interventions AND Outcomes AND Types of studies. (using AND Boolean operator).

### 3. Evaluarea calității articolelor identificate

- Validitate a metodologiei pentru includerea în studiu

2 cercetători

Utilizarea unor **instrumente standardizat**

Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI)

Joanna Briggs Institute Qualitative Assessment and Review Instrument (JBI-QARI)

Dacă vor exista dezacorduri se vor rezolva prin discutarea fiecărui ca în parte (cei 2 cercetători ± alți cercetători)

### 3. Evaluarea calității articolelor identificate

#### **Evaluarea critică a cercetărilor primare**

*Critical appraisal will be conducted on these papers. All papers will be included in the review. Where possible, sensitivity analysis will be conducted to determine if methodological quality impacts on the results of meta-analysis. The results of higher quality papers (in which a score of 80% or more is achieved in critical appraisal) will be compared with lower quality papers (a score of less than 80% in critical appraisal).*

Există criterii de evaluare pentru majoritatea tipurilor de studii medicale! [PEDro](#)

# PEDro

**Table 3** PEDro critical appraisal results

	Bottoni et al. [4]	Marcacci et al. [26]	Meighan et al. [28]	Petersen and Laprell [34]	Sgaglione et al. [35]	Wasilewski et al. [42]
Eligibility criteria	1	0	1	0	1	0
Random allocation	1	0	1	0	0	0
Concealed allocation	1	0	0	0	0	0
Baseline comparability	1	0	0	0	0	1
Blind subject	0	0	0	0	0	0
Blind clinician	0	0	0	0	0	0
Blind assessor	0	0	1	0	0	0
Adequate follow-up	1	1	1	0	1	1
Intention-to treat analysis	0	0	1	0	0	0
Between-group analysis	1	1	1	1	1	1
Point estimates and variability	1	0	0	1	1	0
Total score	7	2	6	2	4	3

1 one point, 0 no point

## 4. Sumarizarea rezultatelor

### EXTRAGEREA DATELOR

Cantitative	<i>Quantitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-MAStARI (Appendix III). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.</i>
Calitative	<i>Qualitative data will be extracted from papers included in the review using the standardized data extraction tool from JBI-QARI (Appendix IV). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives.</i>

**JBI Data Extraction Form for  
Experimental / Observational Studies**

Reviewer \_\_\_\_\_ Date \_\_\_\_\_  
Author \_\_\_\_\_ Year \_\_\_\_\_  
Journal \_\_\_\_\_ Record Number \_\_\_\_\_

**Study Method**

RCT ☐      Quasi-RCT ☐      Longitudinal ☐  
Retrospective ☐      Observational ☐      Other ☐

**Participants**

Setting \_\_\_\_\_  
Population \_\_\_\_\_

**Sample size**

Group A \_\_\_\_\_ Group B \_\_\_\_\_

**Interventions**

Intervention A \_\_\_\_\_  
\_\_\_\_\_  
Intervention B \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Authors Conclusions:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Reviewers Conclusions:**

\_\_\_\_\_  
\_\_\_\_\_  
4/28/2023

**Study results**

**Dichotomous data**

Outcome	Intervention (    ) number / total number	Intervention (    ) number / total number

**Continuous data**

Outcome	Intervention (    ) number / total number	Intervention (    ) number / total number



## 4. Sumarizarea rezultatelor

### SUMARIZAREA DATELOR

*Quantitative papers will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the standard Chi-square and I-square. Heterogeneity will also be explored using subgroup analyses based on the different quantitative study designs included in this review. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.*

*Qualitative research findings will, where possible, be pooled using JBI-QARI. This will involve the aggregation or synthesis of findings to generate a set of statements that represent that aggregation, through assembling the findings rated according to their quality, and categorizing these findings on the basis of similarity in meaning. These categories are then subjected to a meta-synthesis to produce a single comprehensive set of synthesized findings that can be used as a basis for evidence-based practice. Where textual pooling is not possible, the findings will be presented in narrative form.*

## 5. Analiza statistică (±meta-analiza)

PRISMA

### ABOUT THE FETAL RISKS FROM DIAGNOSTIC USE OF RADIATION DURING PREGNANCY: A SYSTEMATIC REVIEW AND PROPOSAL OF A CLINICAL PROTOCOL

*Results: Deterministic effects like pregnancy loss, congenital malformations, growth retardation and neurobehavioral abnormalities have threshold doses greater 100-200 mGy, being the risk considered negligible at 50 mGy. No diagnostic exam exceeds this limit. The most crucial time to avoid radiation exposure is from the 8<sup>th</sup> to the 15<sup>th</sup> week of gestation. The risk of carcinogenesis is slightly higher than the general population, although very similar. Intravenous contrast is discouraged, except in highly-selected patients.*

*Conclusion: Measures to diminish radiation are essential and affect the fetal outcome. Nonionizing procedures should be considered whenever possible and every radiology center should have its own data on fetal radiation exposure.*

# 5. Analiza statistică

## COCHRANE RISK OF BIAS TOOL (MODIFIED) FOR QUALITY ASSESSMENT OF RANDOMIZED CONTROLLED TRIALS

Study Validity Domains	Assessment*
1. <b>Sequence generation:</b> Was the allocation sequence adequately generated?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
2. <b>Allocation Concealment:</b> Was the sequence generation adequately concealed before group assignments?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
3. <b>Blinding of participants and personnel:</b> Was knowledge of the allocated interventions adequately hidden from the participants and personnel after participants were assigned to respective groups?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
4. <b>Blinding of outcome assessors:</b> Was knowledge of the allocated interventions adequately hidden from the outcome assessors after participants were assigned to respective groups?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
5. <b>Incomplete outcome data:</b> Were incomplete outcome data adequately addressed?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
6. <b>Selective outcome reporting:</b> Are reports of the study free of suggestion of selective outcome reporting?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
7. <b>Other sources of bias:</b> Was the study apparently free of other problems that could put it at a risk of bias?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unclear
Study Quality <sup>†</sup> :	

\*For assessments, please refer to Judging criteria described on the next two pages.

<sup>†</sup> “Yes” in all Domains would place a study at “Low Risk of Bias”;

“No” in any of the Domains would place a study at “High Risk of Bias”;

“Unclear” in any of the domains would place the study at “Unclear Risk of Bias”

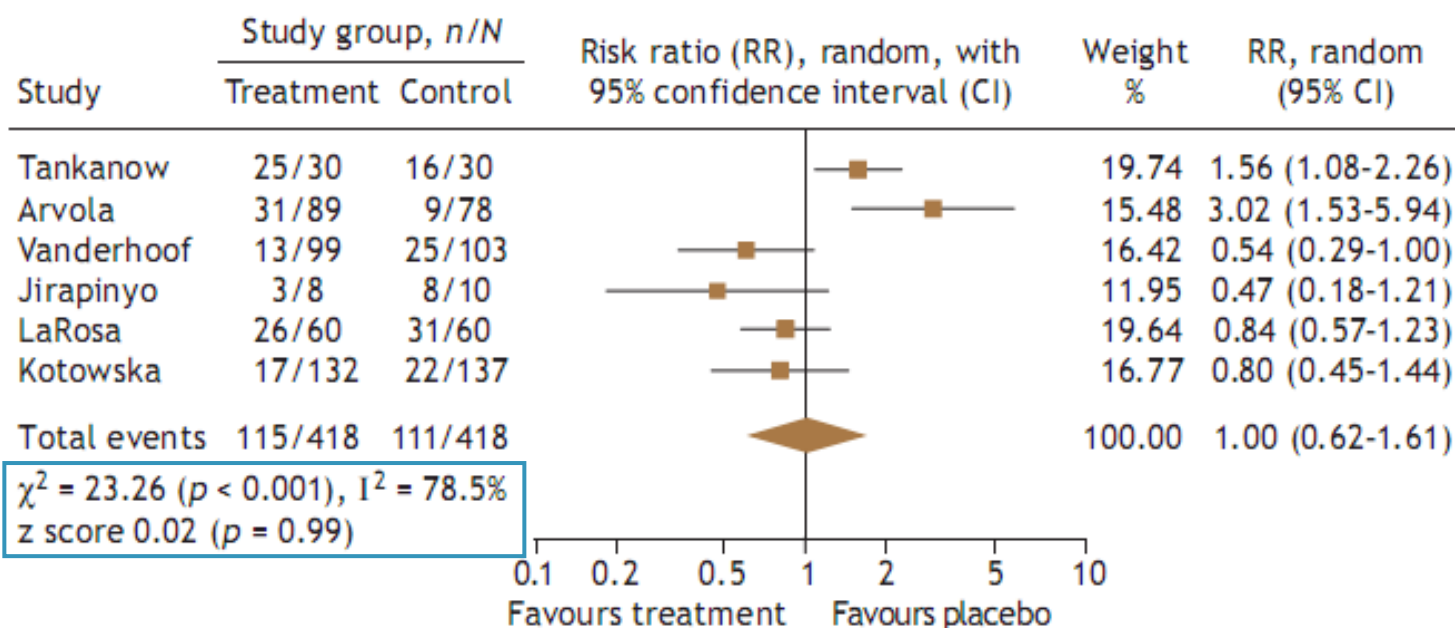
# 5. Analiza statistică



## 5. Analiza statistică

### Heterogenitatea (diversitatea)

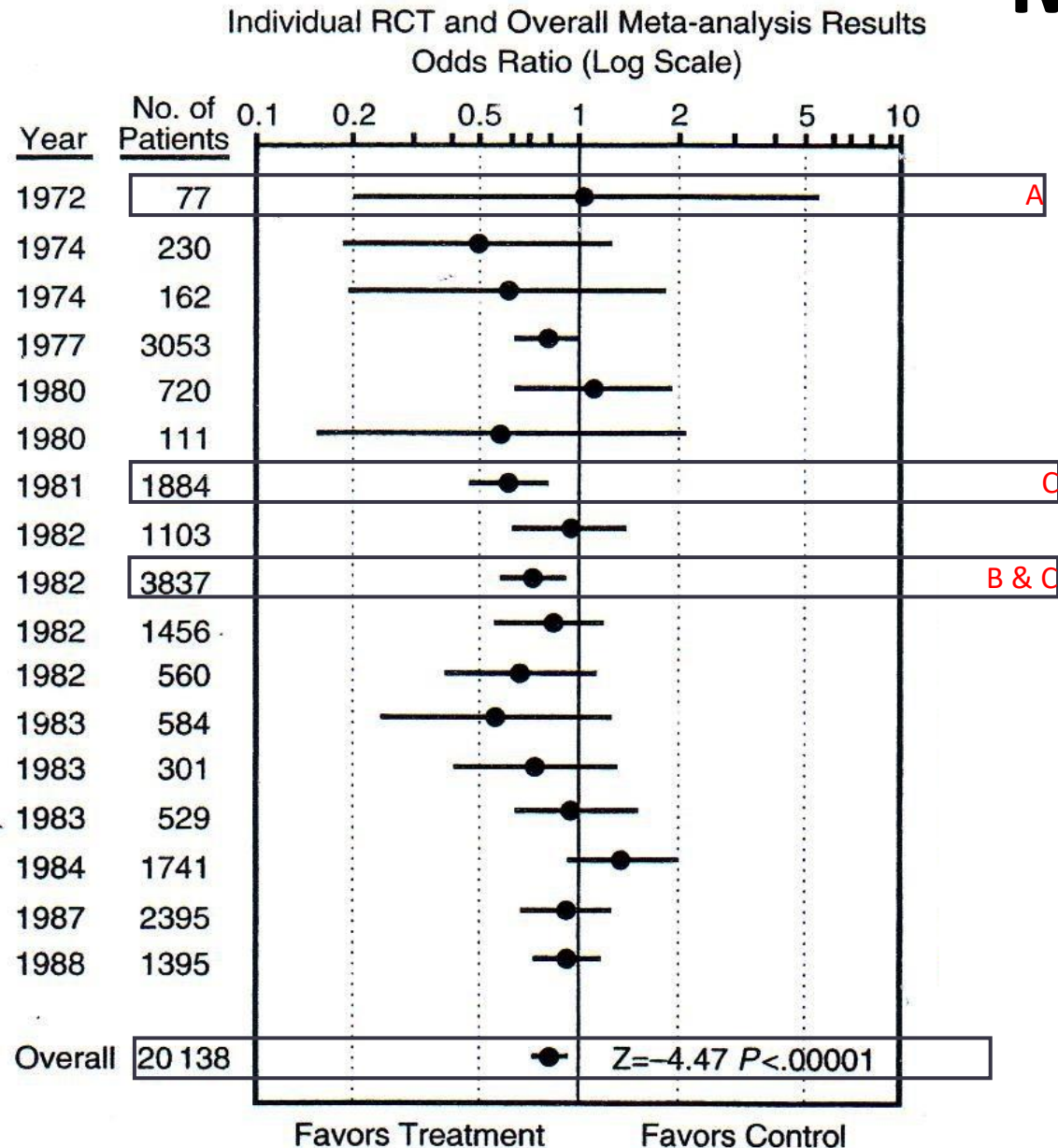
- *Clinică*: variabilitatea participanților, a intervențiilor și/sau a răspunsului urmărit
- *Metodologică*: diversitatea tipurilor de design-uri de experiment și risc de eroare
- *Statistică*: efectul observat e diferit de cel așteptat – erori aleatorii



**Fig 3:** Incidence of antibiotic-associated diarrhea — intention-to-treat analysis. The analysis showed a nonsignificant difference between probiotics and placebo (z score) and statistically significant heterogeneity.



# Meta-analiza

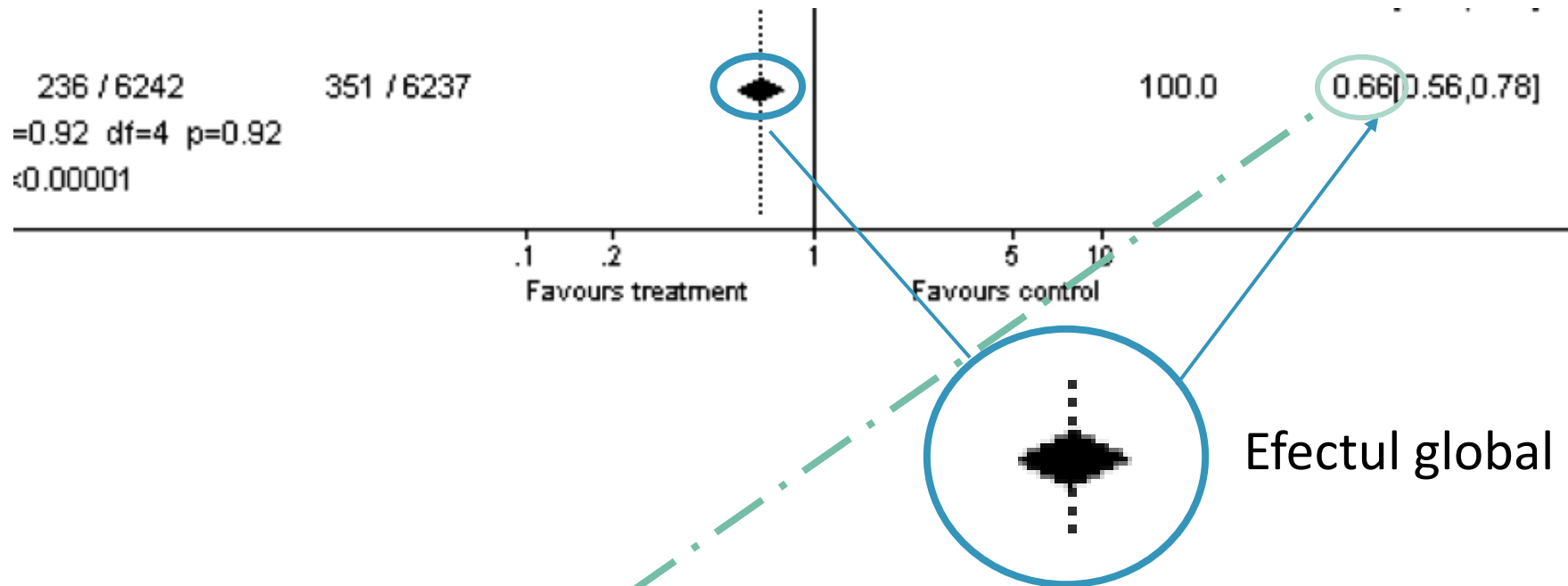


- A. Care e studiul cu cei mai puțini pacienți?
- B. Care e studiul cu cei mai mulți pacienți?
- C. Care sunt studiile cu rezultate semnificative statistic?

Intervalul de încredere intersectează linia corespunzătoare valorii 1 → nu există diferențe semnificative statistic (tratamentul nu e mai bun decât placebo)

E tratamentul mai bun comparativ cu placebo? → Da

# Meta-analiza



Mărimea efectului =  $1 - 0,66 = 0,34$

$0,34 \times 100 = 34\% \rightarrow$  În grupul celor care primesc tratament riscul de deces este de 34% mai mic comparativ cu cei din grupul martor.

## 6. Interpretare

## 7. Concluzii și recomandări

### A Systematic Review and Meta-Analysis of Diagnostic Performance of MRI for Evaluation of Acute Appendicitis

Eugene Duke<sup>1</sup>  
Bobby Kalb<sup>1</sup>  
Hina Arif-Tiwari<sup>1</sup>  
Zhongyin John Daye<sup>2</sup>  
Dorothy Gilbertson-Dahdal<sup>1</sup>  
Samuel M. Keim<sup>3</sup>  
Diego R. Martin<sup>1</sup>

**OBJECTIVE.** A meta-analysis was performed to determine the accuracy of MRI in the diagnosis of acute appendicitis in the general population and in subsets of pregnant patients and children.

**MATERIALS AND METHODS.** A systematic search of the PubMed and EMBASE databases for articles published through the end of October 2014 was performed to identify studies that used MRI to evaluate patients suspected of having acute appendicitis. Pooled data for sensitivity, specificity, and positive and negative predictive values were calculated.

**RESULTS.** A total of 30 studies that comprised 2665 patients were reviewed. The sensitivity and specificity of MRI for the diagnosis of acute appendicitis are 96% (95% CI, 95–97%) and 96% (95% CI, 95–97%), respectively. In a subgroup of studies that focused solely on pregnant patients, the sensitivity and specificity of MRI were 94% (95% CI, 87–98%) and 97% (95% CI, 96–98%), respectively, whereas in studies that focused on children, sensitivity and specificity were found to be 96% (95% CI, 95–97%) and 96% (95% CI, 94–98%), respectively.

**CONCLUSION.** MRI has a high accuracy for the diagnosis of acute appendicitis, for a wide range of patients, and may be acceptable for use as a first-line diagnostic test.



# Exemple (protocoale/articole)

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The effectiveness of interventions to prevent or reduce Contrast Media Extravasations among patients undergoing computerized tomography scanning: a systematic review protocol

---

Diagnostic accuracy of clinical stroke scores for distinguishing stroke subtypes: a systematic review

---

Effectiveness of quality improvement interventions for patient safety in radiology: a systematic review protocol

---

A Systematic Review and Meta-Analysis of Diagnostic Performance of Imaging in Acute Cholecystitis

# Cercetare primară

[Eur J Epidemiol](#). 2014 Apr;29(4):293-301. doi: 10.1007/s10654-014-9900-9. Epub 2014 Apr 19.

## **Leukemia and brain tumors among children after radiation exposure from CT scans: design and methodological opportunities of the Dutch Pediatric CT Study.**

[Meulepas JM](#)<sup>1</sup>, [Ronckers CM](#), [Smets AM](#), [Nivelstein RA](#), [Jahnen A](#), [Lee C](#), [Kieft M](#), [Laméris JS](#), [van Herk M](#), [Greuter MJ](#), [Jeukens CR](#), [van Straten M](#), [Visser O](#), [van Leeuwen FE](#), [Hauptmann M](#).

### **Author information**

### **Abstract**

Computed tomography (CT) scans are indispensable in modern medicine; however, the spectacular rise in global use coupled with relatively high doses of ionizing radiation per examination have raised radiation protection concerns. Children are of particular concern because they are more sensitive to radiation-induced cancer compared with adults and have a long lifespan to express harmful effects which may offset clinical benefits of performing a scan. This paper describes the design and methodology of a nationwide study, the Dutch Pediatric CT Study, regarding risk of leukemia and brain tumors in children after radiation exposure from CT scans. It is a retrospective record-linkage cohort study with an expected number of 100,000 children who received at least one electronically archived CT scan covering the calendar period since the introduction of digital archiving until 2012. Information on all archived CT scans of these children will be obtained, including date of examination, scanned body part and radiologist's report, as well as the machine settings required for organ dose estimation. We will obtain cancer incidence by record linkage with external databases. In this article, we describe several approaches to the collection of data on archived CT scans, the estimation of radiation doses and the assessment of confounding. The proposed approaches provide useful strategies for data collection and confounder assessment for general retrospective record-linkage studies, particular those using hospital databases on radiological procedures for the assessment of exposure to ionizing or non-ionizing radiation.

# Structura generală a unei cercetări primare

## Procesul

Identificarea temei de interes

- PICO
- Căutarea informațiilor în literatura de specialitate  
→ Introducere

Design-ul experimental → Material și Metodă

- Locația
- Eșantionul
- Metode

Colectarea datelor → Material și Metodă

Analiza datelor → Rezultate

Interpretarea rezultatelor → Discuții

Comunicarea rezultatelor → Teza de licență /  
4/28/2023 disertație / articol / prezentare congres / etc.

## Structura articolului

Titlul

Rezumatul (Abstract)

Introducere (Background/Introduction)

- Stadiul actual al cunoașterii
- Scop/Obiective

Material și Metodă

- Design-ul experimental

Rezultate

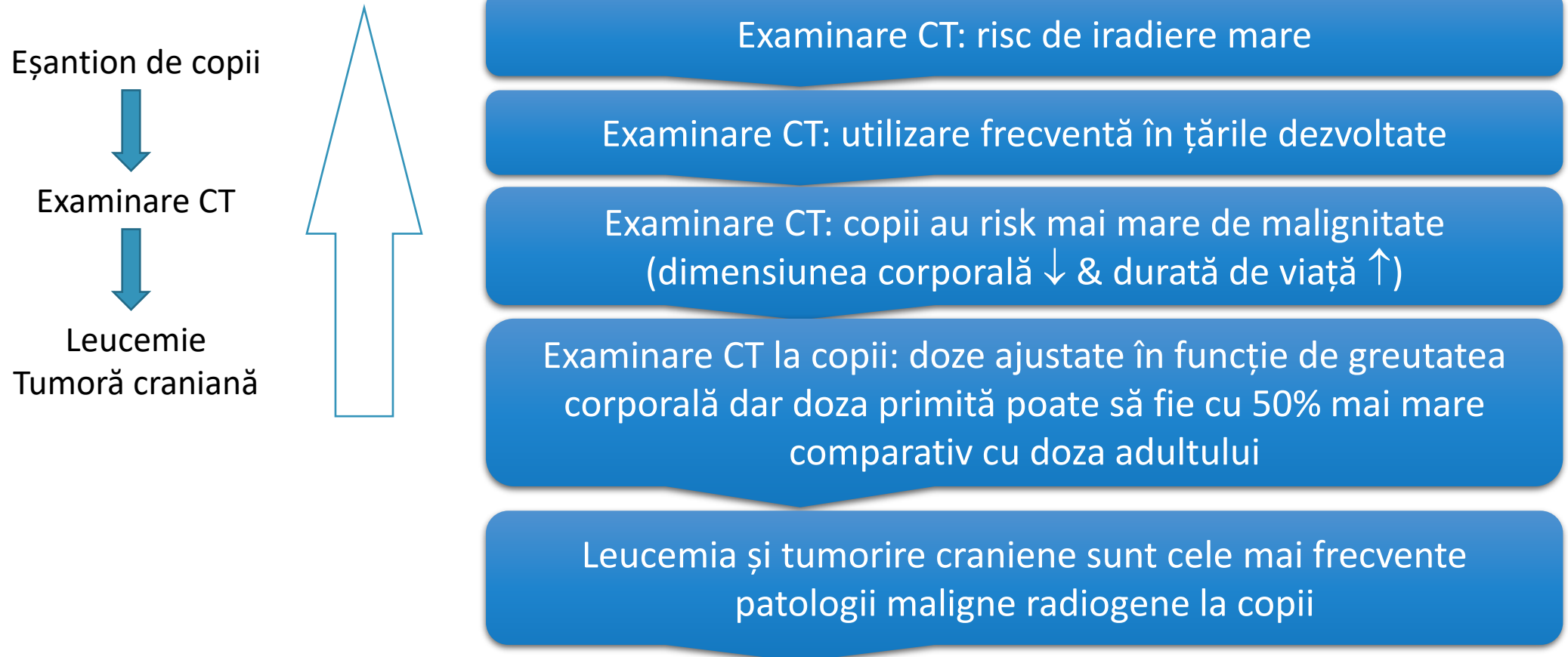
Discuții

Concluzii

Referințe

## **Leukemia and brain tumors among children after radiation exposure from CT scans: design and methodological opportunities of the Dutch Pediatric CT Study.**

Meulepas JM<sup>1</sup>, Ronckers CM, Smets AM, Nievelstein RA, Jahnen A, Lee C, Kieft M, Laméris JS, van Herk M, Greuter MJ, Jeukens CR, van Straten M, Visser O, van Leeuwen FE, Hauptmann M.



## **Leukemia and brain tumors among children after radiation exposure from CT scans: design and methodological opportunities of the Dutch Pediatric CT Study.**

Meulepas JM<sup>1</sup>, Ronckers CM, Smets AM, Nivelstein RA, Jahnen A, Lee C, Kieft M, Laméris JS, van Herk M, Greuter MJ, Jeukens CR, van Straten M, Visser O, van Leeuwen FE, Hauptmann M.

We are currently conducting a large epidemiologic study, *the Dutch Pediatric CT Study*, which aims (1) to describe nationwide patterns of CT scan use in Dutch children and (2) to evaluate the association between radiation exposure from CT scans and subsequent risk of leukemia and brain tumors in children and young adults in the Netherlands. *The Dutch Pediatric CT Study* is an attempt to combine the advantages of both study designs: a large cohort study with detailed and electronically recorded information on exposure and potential confounders from

Descrierea modelului național  
Olandez de utilizare a CT-ului la copii

Evaluarea asocierii dintre expunerea  
la radiație post examinare CT și riscul  
de leucemie sau tumori craniene la  
copii și adulții tineri din Olanda

## **Leukemia and brain tumors among children after radiation exposure from CT scans: design and methodological opportunities of the Dutch Pediatric CT Study.**

Meulepas JM<sup>1</sup>, Ronckers CM, Smets AM, Nivelstein RA, Jahnen A, Lee C, Kieft M, Laméris JS, van Herk M, Greuter MJ, Jeukens CR, van Straten M, Visser O, van Leeuwen FE, Hauptmann M.

### Design-ul experimental (Study design)

Studiu de cohortă național retrospectiv

Populația de interes: subiecți cu vârstă < 18 ani care au avut cel puțin o examinare CT într-un spital din Olanda

Sursa datelor:

- Radiology Information System (RIS) & Picture Archiving and Communication System (PACS), sisteme utilizate de rutină în spitale
- Limitat la spitalele care fac cel puțin 10 examinări CT pediatrice pe an

RIS: date personale, date ale examinărilor, tipul de examinare, raportul examinării  
PACS: parametri tehnici ai examinării & imagini



Eur J Epidemiol. 2014 Apr;29(4):293-301. doi: 10.1007/s10654-014-9900-9. Epub 2014 Apr 19.

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### Design-ul experimental (Study design)

#### Colectarea datelor:

- De la introducerea RIS (anii '80)
- Urmărirea pacientului se va face până în 2013 utilizând informațiile din registrul național de cancer Olanda (Netherlands Cancer Registry - NCR)

# Leukemia and brain tumors among children after radiation exposure from CT scans: design and methodological opportunities of the Dutch Pediatric CT Study.

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## Rezultate (Methods and results)

Descriptiv (frecvențe absolute și relative - %):

- 12456 subiecți incluși în studiu
- Cele mai multe examinări realizate la grupa de vârstă 10-14 ani (3092)
- Numărul de examinări CT a variat de la 1 (8190) la peste 20 (18 cazuri)
- Băieții sunt mai frecvent investigați CT decât fetele (care e distribuția pe gen la copii din Olanda în perioada investigată?)
- Există o tendință de creștere a numărului de examinări (creștere demografică? Modificări în ceea ce privește accesibilitatea?)

Table 1 Characteristics of 12,456 patients from the AMC Amsterdam who received at least one CT scan under the age of 18 years in the period 1983–2012

	Male		Female		All <sup>a</sup>	
	N	%	N	%	N	%
<i>Age at first scan (years)</i>						
<1	1,161	16.8	888	16.1	2,050	16.5
1–4	1,262	18.2	918	16.7	2,182	17.5
5–9	1,534	22.1	1,075	19.5	2,611	21.0
10–14	1,636	23.6	1,452	26.3	3,092	24.8
15–18	1,339	19.3	1,182	21.4	2,521	20.3
<i>Number of CT scans</i>						
1	4,526	65.3	3,656	66.3	8,190	65.8
2	1,208	17.4	972	17.3	2,181	17.5
3–10	1,108	16.0	831	15.1	1,939	15.6
11–20	80	1.2	48	0.9	128	1.1
>20	10	0.1	8	0.2	18	0.2
<i>Calendar year of first recorded CT scan<sup>b</sup></i>						
1984–1987	312	4.7	269	5.1	583	4.9
1988–1991	586	8.8	435	8.2	1,021	8.5
1992–1995	994	14.9	743	14.1	1,739	14.6
1996–1999	913	13.7	665	12.6	1,579	13.2
2000–2003	982	14.8	750	14.2	1,733	14.5
2004–2007	1,253	18.8	1,032	19.5	2,285	19.1
2008–2011	1,613	24.2	1,394	26.4	3,008	25.2



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## Rezultate (Methods and results)

### Descriptiv (frecvențe absolute și relative - %)

**Table 2** Number of CT scans by sex and body part among 12,456 patients from the AMC Amsterdam who received at least one CT scan under the age of 18 years in the period 1983–2012

	Male		Female		All <sup>a</sup>	
	N	%	N	%	N	%
<i>Body part</i>						
Head and neck	8,776	66.2	6,456	63.2	15,241	64.9
Chest	1,808	13.6	1,345	13.2	3,153	13.4
Extremities	911	6.9	969	9.5	1,880	8.0
Abdomen and pelvis	1,007	7.6	840	8.2	1,847	7.9
Spine	548	4.1	434	4.3	983	4.2
Miscellaneous/ unknown	207	1.6	174	1.7	381	1.6

<sup>a</sup> Sex not known for ten CT scans

**Table 3** Estimated radiation doses to the red bone marrow (RBM) and the brain by scan type and age at CT scan for 150 series with sufficient data from 249 pediatric CT scans<sup>a</sup>

	N	RBM dose (mGy)		Brain dose (mGy)	
		Mean	Range	Mean	Range
<i>Head CT (years)</i>					
<1	5	4.5	1.0–7.7	11.9	3.1–21.3
1–<2.5	11	4.9	1.6–11.4	13.6	4.4–32.1
2.5–<7.5	14	6.3	3.0–15.8	18.0	8.2–47.7
7.5–<12.5	28	7.0	2.1–13.3	28.7	10.4–52.3
12.5–<16.5	33	5.0	0.7–10.7	24.9	3.6–51.0
16.5–<18	14	4.5	0.8–7.4	22.6	3.9–29.0
<i>Chest CT (years)</i>					
<1	9	2.1	1.5–3.6	1.1	0.2–2.6
1–<2.5	4	2.1	1.8–2.6	0.2	0.1–0.2
2.5–<7.5	4	4.4	3.5–5.3	0.3	0.2–0.4
7.5–<12.5	7	2.9	0.8–5.3	0.2	0.0–0.4
12.5–<16.5	2	2.3	1.4–3.1	0.1	0.1–0.2
16.5–<18	5	2.4	1.4–4.6	0.1	0.0–0.2

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## Rezultate (Methods and results)

Analitic (OR = rata șansei)

- Studii anterioare au sugerat că statutul socio-economic e asociat cu incidența leucemiei la copii și respectiv probabilitatea de examinare CT (factori de confuzie)

**Table 5** Number of CT scans per patient among population-based quintiles of SES based on income and odds ratios (OR) of low (<40th percentile of Dutch population) versus high SES (>40th percentile of Dutch population) by the number of CT scans among 11,023 patients from the AMC Amsterdam who received at least one CT scan under the age of 18 years in the period 1983–2012

No. of scans	SES based on income										OR most deprived versus least deprived <sup>a</sup>	
	1 (least deprived)		2		3		4		5 (most deprived)		OR	95 % CI
	N	%	N	%	N	%	N	%	N	%		
1	1,301	65.7	901	63.6	1,883	65.8	1,719	67.8	1,486	66.8	1.00	
2–5	581	29.3	456	32.2	824	28.8	704	27.8	636	28.6	1.09	(1.00–1.19)
6–10	76	3.8	46	3.2	120	4.2	81	3.2	78	3.5	1.19	(0.97–1.47)
>10	23	1.2	14	1.0	36	1.3	32	1.3	26	1.2	0.99	(0.70–1.40)

Example: a child with 6–10 scans has a 1.19-fold elevated chance for his/her SES to be below the 40th percentile compared with a child with one scan

SES socio-economic status, OR odds ratio, CI confidence interval

<sup>a</sup> Most deprived <40th percentile of Dutch population; least deprived >40th percentile of Dutch population

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### Rezultate (Methods and results)

Nu sunt raportate rezultate cu privire la al doilea obiectiv al studiului

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### Discuții (Discussion)

#### **Ce conține**

- De ce rezultatele acestui studiu sunt importante
- Ce s-a raportat în studii anterioare
- Punctele tari ale studiului curent
- Concluzii

#### Ce trebuie să conțină:

- Principalul rezultat
- Dacă scopul sau obiectivele au fost atinse
- Discutarea rezultatelor cu trimitere la tabele și figuri.
- Discutarea rezultatelor comparativ cu studiile anterioare.
- Limitele studiului (dacă există).
- Importanța clinică a rezultatelor raportate.



# Cercetare secundară

*Gastrointest Endosc.* 2019 Apr 17. pii: S0016-5107(19)31600-1. doi: 10.1016/j.gie.2019.04.217. [Epub ahead of print]

## EUS versus Magnetic Resonance Imaging in Staging Rectal Adenocarcinoma: A Diagnostic Test Accuracy Meta-Analysis.

Chan BP<sup>1</sup>, Patel R<sup>1</sup>, Mbuagbaw L<sup>2</sup>, Thabane L<sup>3</sup>, Yaghoobi M<sup>4</sup>.

### ➕ Author information

### Abstract

**BACKGROUND AND AIMS:** EUS and magnetic resonance imaging (MRI) are both used for locoregional staging of rectal cancer, which determines treatment options. There is a lack of consensus on the best modality for locoregional staging, with studies supporting both EUS and MRI. In this study, we performed the first **diagnostic test accuracy meta-analysis** to compare the **diagnostic accuracy**, sensitivity, and specificity of EUS and MRI in the staging of rectal cancer.

**METHODS:** A comprehensive electronic literature search up to June 2018 was performed to identify prospective cohort studies directly comparing the **accuracy** of EUS to MRI in staging nonmetastatic rectal cancer with surgical pathology as the reference standard. Quality of the included studies was measured by using the QUADAS-2 tool. A bivariate hierarchical model was used to perform the **meta-analysis** of **diagnostic test accuracy** according to the Cochrane approved methodology. Summary receiver operating characteristics were developed and the area under the curve was calculated for overall and individual T and N staging, for EUS, MRI, and head-to-head comparison.

**RESULTS:** Six out of 2475 studies including 234 patients were eligible. Pooled sensitivity and specificity in T staging were 0.79 (95% CI, 0.72 - 0.85) and 0.89 (95% CI, 0.84 - 0.93) for EUS and 0.79 (95% CI, 0.72 - 0.85) and 0.85 (95% CI, 0.79 - 0.90) for MRI, respectively. Pooled sensitivity and specificity in N staging were 0.81 (95% CI, 0.71 - 0.89) and 0.88 (95% CI, 0.80 - 0.94) for EUS and 0.83 (95% CI, 0.73 - 0.90), and 0.90 (95% CI, 0.82 - 0.95) for MRI, respectively. In area under the curve head to head analysis, EUS was superior to MRI in overall T staging ( $p < 0.05$ ). EUS outperformed MRI in overall T, overall N, T1, and T3 staging ( $p < 0.01$ ), after excluding studies using an endorectal coil for MRI. MRI was superior to EUS in T2 staging ( $p = 0.01$ ) in both analyses.

**CONCLUSIONS:** EUS and MRI both provide reasonable **diagnostic accuracy** in the staging of non-metastatic rectal cancer. EUS was superior to MRI in overall T staging, and overall T and N staging after adjusting for MRI technology. Practitioners should be aware of advantages and disadvantages of both modalities and choose appropriate methods while considering **diagnostic accuracy** of each test, and institutional practices and limitations.

# Structura generală a unei cercetări secundare

## Procesul

Identificarea temei de interes

- PICO
- Căutarea informațiilor în literatura de specialitate  
→ Introducere

Design-ul experimental → Material și Metodă

- Strategia de căutare
- Criterii de eligibilitate

Colectarea datelor → Material și Metodă

- Extragerea datelor din cercetările primare
- Criterii de evaluare a calității
- Criterii de evaluare a erorilor

Analiza datelor → Rezultate

Interpretarea rezultatelor → Discuții

Comunicarea rezultatelor → Teza de licență /  
disertație / articol / prezentare congres / etc.

## Structura

Titlul

Rezumatul (Abstract)

Introducere (Background/Introduction)

- Stadiul actual al cunoașterii
- Scop/Obiective

Material și Metodă

- Design-ul experimental

Rezultate

Discuții

Concluzii

Referințe

## **EUS versus Magnetic Resonance Imaging in Staging Rectal Adenocarcinoma: A Diagnostic Test Accuracy Meta-Analysis.**

Chan BP<sup>1</sup>, Patel R<sup>1</sup>, Mbuagbaw L<sup>2</sup>, Thabane L<sup>3</sup>, Yaghoobi M<sup>4</sup>.

### Introducere (Introduction)

Cancerul colorectal:

- Cea mai frecventă tumoră malignă gastrointestinală
- Tratamentul e diferențiat în funcție de stadializare
- CT utilizat pentru evaluarea metastazelor la distanță
- EUS sau RM utilizate pentru evaluarea invaziei tumorale locale și regionale (limfogranglioni)

Evaluări anterioare → rezultate contradictorii

- EUS cu acuratețe mai mare comparativ cu RM în evaluarea invaziei locale
- EUS și RM au rezultate similare
- RM, EUS, CT nu pot oferi o evaluare fiabilă a metastazelor nodulilor limfatici

*None of these studies used the recently developed methodology by the Cochrane Collaboration to perform a diagnostic test accuracy meta-analysis to compare the diagnostic accuracy, specificity, and sensitivity of these 2 modalities*

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### Introducere (Introduction)

Meta-analysis of diagnostic test accuracy was specifically designed by the Cochrane Collaboration group to analyze and compare the accuracy, sensitivity, and specificity of a diagnostic test compared with a reference standard.<sup>7</sup> It differs from a conventional meta-analysis in the quality assessment of articles, and statistical analysis. The present study aims to determine the diagnostic test accuracy of EUS and MRI in head to head comparative studies in the staging of rectal cancer compared with the reference standard.



## **EUS versus Magnetic Resonance Imaging in Staging Rectal Adenocarcinoma: A Diagnostic Test Accuracy Meta-Analysis.**

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### Material și Metodă (Methods)

Selectarea studiilor: orice tip de EUS și orice frecvență de transductor; orice tip de examinare RM

Criterii de excludere: examinare US non-endoscopică, studii cu date insuficiente, abstracte, studii pe populație pediatrică, caz martor, duplicații, insuficiente date pentru evaluarea acurateței, studii post-iradiere, studii fără diagnostic standard

Baze de date: OVID MEDLINE, EMBASE, Web of Science, Cochrane Library, și Google Scholar

Articole publicate până în Iunie 2019

Cuvinte cheie: colorectal and rectal - neoplasm, cancer, adenocarcinoma, malignancy and tumour, EUS, endoscopic ultrasound, endosonography, MRI, magnetic resonance imaging

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### Material și Metodă (Methods)

Datele colectate (2 evaluatori independenți): AP, FP, AN, FN pentru stadializarea T și N – EUS și RM

Definiție clară pentru supra (stadializare superioară față de cel al testului de referință) și sub (stadializare inferioară față de cel al testului de referință) estimare

Calitatea metodologică evaluată cu QUADAS-2 (risk de eroare & aplicabilitate)

Rezultatul de interes:

- Primar: acuratețea diagnostică
- Secundar: Se & Sp

# EUS versus Magnetic Resonance Imaging in Staging Rectal Adenocarcinoma: A Diagnostic Test Accuracy Meta-Analysis.

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## Rezultate (Results)

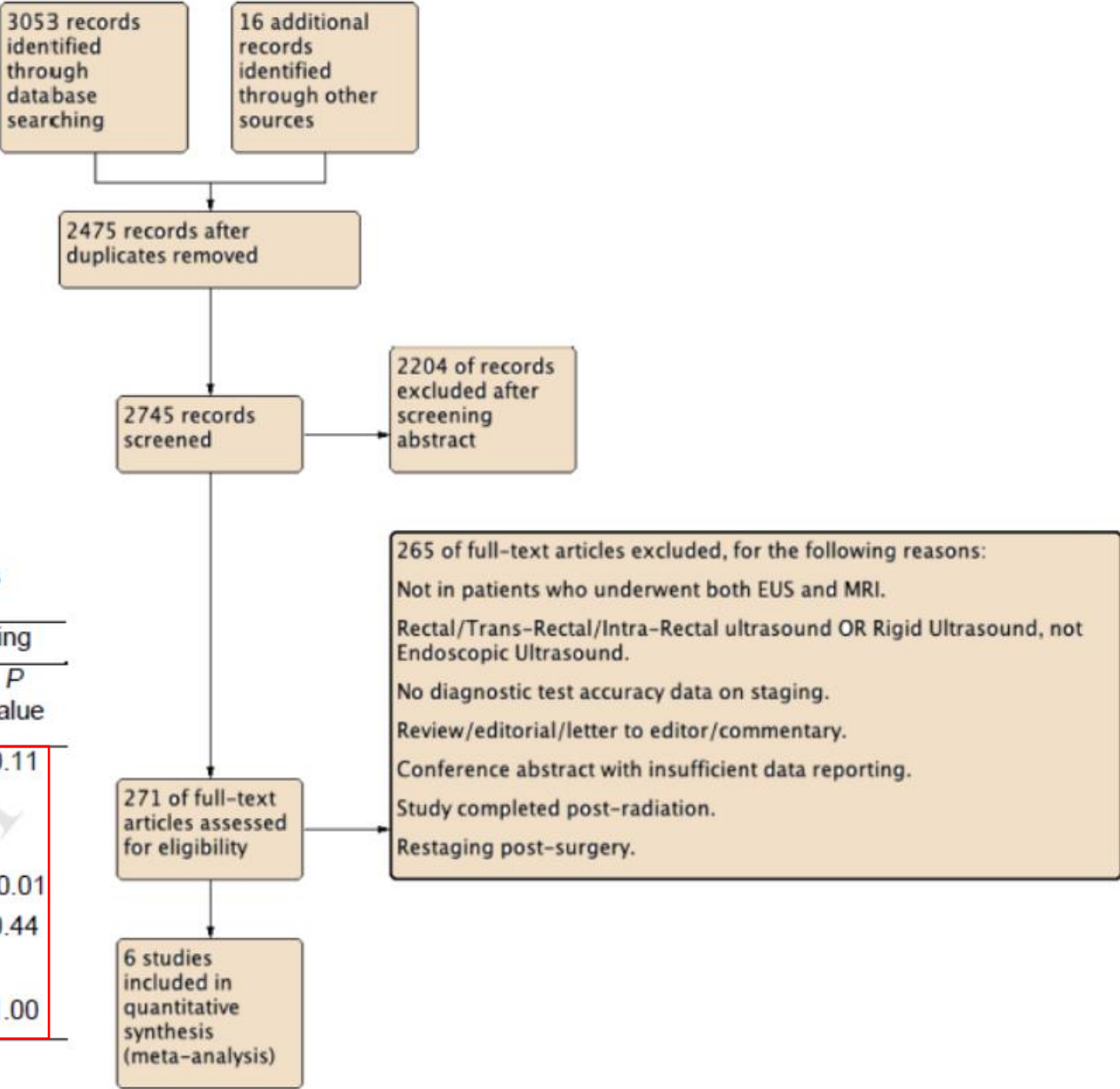
3069 studii identificate → 2475 după excluderea duplicatelor

- 6 studii incluse în meta-analiză
- 6 cu evaluarea T (superior EUS)
- 4 cu evaluare N (rezultate discordante)

**Supplementary Table 1.** Area under the curve for overall T and N staging with individual studies excluded.

Study Removed	Publication Year	AUC Overall T Staging			AUC Overall N Staging		
		EUS	MRI	P value	EUS	MRI	P value
None		0.87	0.82	<0.01	0.90	0.86	0.11
Meyenberger et al <sup>18</sup>	1995	0.87	0.82	<0.01			
Zagoria et. al <sup>19</sup>	1997	0.88	0.82	<0.01			
Maldjian et al <sup>11</sup>	2000	0.87	0.81	<0.01	0.92	0.85	<0.01
Bianchi et al <sup>20</sup>	2005	0.88	0.81	<0.01	0.93	0.91	0.44
Fernandez-Esparrach et al <sup>21</sup>	2011	0.83	0.78	0.02			
Kocaman et al <sup>22</sup>	2014	0.88	0.84	0.01	0.80	0.80	1.00

AUC – area under the curve, MRI – magnetic resonance imaging.



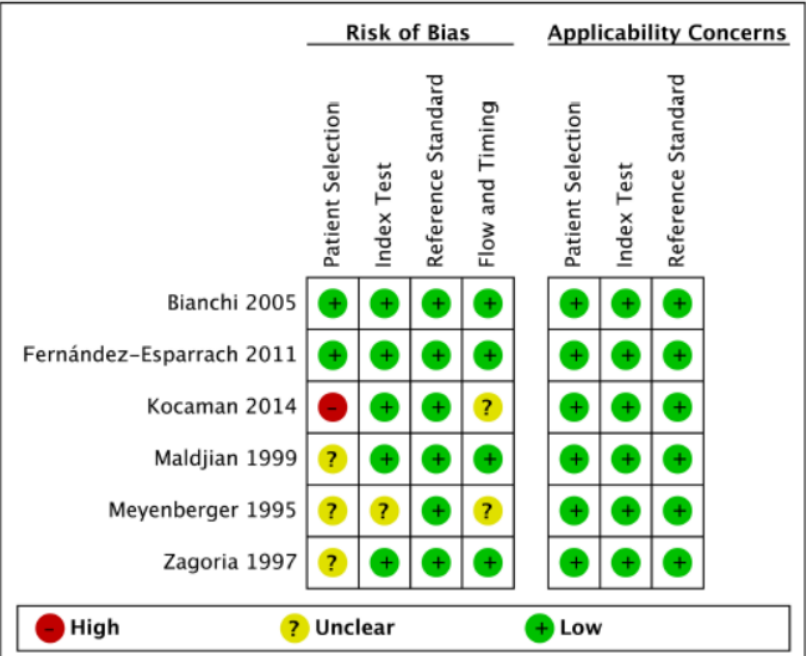
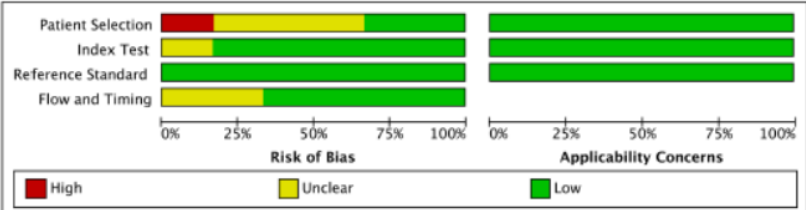
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## Rezultate (Results)

Analiza pentru stadializarea N nu e corectă deoarece volumul de eşantion nu e mai mare de 300

In overall T staging, EUS was significantly superior with an AUC of 0.87 (95% CI, 0.83 – 0.90) as compared with 0.82 (95% CI, 0.78 – 0.86) for MRI ( $p = 0.0001$ ). In overall N staging, there was no difference between groups with AUC of 0.90 (95% CI, 0.85 – 0.94) for EUS as compared with 0.86 (95% CI, 0.81 – 0.92) for MRI ( $p = 0.11$ ) (Figure 3). In pooled individual staging, EUS outperformed MRI in T3 staging (EUS, 0.94; 95% CI, 0.90 – 0.98; MRI, 0.83; 95% CI, 0.77 – 0.89;  $p < 0.01$ ), whereas MRI was superior to EUS in T2 staging (EUS, 0.82; 95% CI, 0.74 – 0.90; MRI, 0.92; 95% CI, 0.87 – 0.97;  $p = 0.005$ ). There were no differences between the groups in pooled AUC otherwise for individual T or N staging.





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## Rezultate (Results)

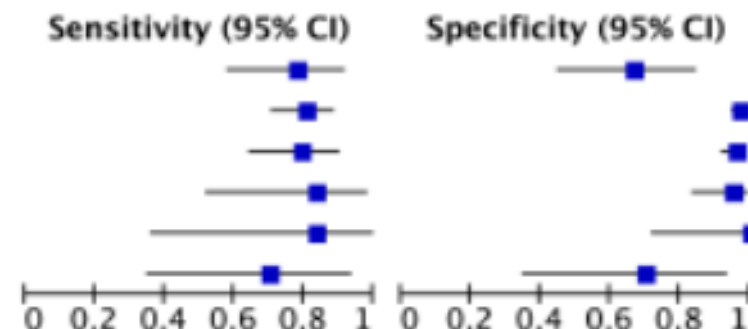
### Pooled Sensitivity and Specificity of EUS

EUS demonstrated pooled sensitivity and specificity of 0.79 (95% CI, 0.72 – 0.85) and 0.89 (95% CI, 0.84 – 0.93), respectively for T staging with a diagnostic odds ratio (DOR) of 31.6 (95% CI, 17.6 – 56.6). The pooled sensitivity and specificity of EUS for N staging was 0.81 (95% CI, 0.71 – 0.89) and 0.88 (95% CI, 0.80 – 0.94). DOR of EUS for N staging was 30.7 (95% CI, 13.7 – 68.8).

### T-Staging EUS

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bianchi 2005	21	8	6	16	0.78 [0.58-0.91]	0.67 [0.45-0.84]
Fernandez-Esparrach 2011	66	8	16	270	0.80 [0.70-0.88]	0.97 [0.94-0.99]
Kocaman 2014	34	6	9	144	0.79 [0.64-0.90]	0.96 [0.91-0.99]
Maldjian 1999	10	2	2	38	0.83 [0.52-0.98]	0.95 [0.83-0.99]
Meyenberger 1995	5	0	1	11	0.83 [0.36-1.00]	1.00 [0.72-1.00]
Zagoria 1997	7	3	3	7	0.70 [0.35-0.93]	0.70 [0.35-0.93]

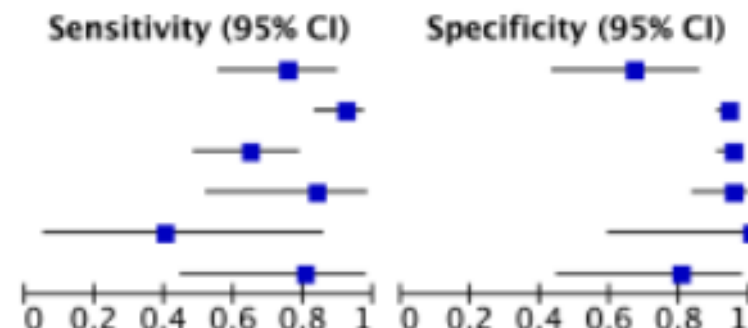
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### T-Staging MRI

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bianchi 2005	21	7	7	14	0.75 [0.55-0.89]	0.67 [0.43-0.85]
Fernandez-Esparrach 2011	66	18	6	270	0.92 [0.83-0.97]	0.94 [0.90-0.96]
Kocaman 2014	27	8	15	150	0.64 [0.48-0.78]	0.95 [0.90-0.98]
Maldjian 1999	10	2	2	38	0.83 [0.52-0.98]	0.95 [0.83-0.99]
Meyenberger 1995	2	0	3	7	0.40 [0.05-0.85]	1.00 [0.59-1.00]
Zagoria 1997	8	2	2	8	0.80 [0.44-0.97]	0.80 [0.44-0.97]

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# EUS versus Magnetic Resonance Imaging in Staging Rectal Adenocarcinoma: A Diagnostic Test Accuracy Meta-Analysis.

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## Rezultate (Results)

### Pooled Sensitivity and Specificity of MRI

Pooled sensitivity and specificity of MRI for T staging was 0.79 (95% CI, 0.72 – 0.85) and 0.85 (95% CI, 0.79 – 0.90), respectively, with a DOR of 21.7 (95% CI, 12.7 – 37.1), which was not significantly different from EUS ( $p = 0.35$ ). Pooled sensitivity and specificity of MRI for N-staging was 0.83 (95% CI, 0.73 – 0.90), and 0.90 (95% CI, 0.82 – 0.95), respectively. DOR was 40.7 (95% CI, 17.1 – 96.6), which was not

### N-Staging EUS

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Bianchi 2005	12	5	13	20	0.48 [0.28-0.69]	0.80 [0.59-0.93]		
Kocaman 2014	48	2	2	48	0.96 [0.86-1.00]	0.96 [0.86-1.00]		
Maldjian 1999	7	5	1	20	0.88 [0.47-1.00]	0.80 [0.59-0.93]		

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### N-Staging MRI

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Bianchi 2005	12	4	7	16	0.63 [0.38-0.84]	0.80 [0.56-0.94]		
Kocaman 2014	45	5	5	45	0.90 [0.78-0.97]	0.90 [0.78-0.97]		
Maldjian 1999	10	1	2	24	0.83 [0.52-0.98]	0.96 [0.80-1.00]		

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## **EUS versus Magnetic Resonance Imaging in Staging Rectal Adenocarcinoma: A Diagnostic Test Accuracy Meta-Analysis.**

Chan BP<sup>1</sup>, Patel R<sup>1</sup>, Mbuagbaw L<sup>2</sup>, Thabane L<sup>3</sup>, Yaghoobi M<sup>4</sup>.

### Discuții (Discussion)

#### **Ce conține**

- Principalul rezultat (EUS e superior RM)
- Discutarea rezultatelor
- Trimiteri la literatura de specialitate.
- Importanța rezultatelor.
- Aplicabilitatea rezultatelor

#### Ce trebuie să conțină:

- Referirea propriilor tabele și figuri.
- Limitele studiului.

**Concluziile referă strict stadializarea cancerului rectal non-metastatic! (prima referire la faptul că e vorba de cancer rectal fără metastaze – nu e corect!)**



# Mulțumesc pentru atenție!

