





# Avaliação de Tecnologias em Saúde e o Impacto na Imagem Médica

Luís Lança, Ph.D. ESTeSL Lisboa/Portugal







### Sumário

- 1. Avaliação de Tecnologias em Saúde (ATS)
- 2. Métodos para a ATS na imagem médica
- 3. Influência da ATS na imagem médica







## Objetivos

- Definir o conceito de Avaliação de Tecnologias em Saúde (ATS)
- Identificar métodos de pesquisa para ATS no âmbito da imagem médica
- Entender o valor de revisões sistemáticas e metaanálise em ATS
- Compreender a influência da ATS na imagem médica





## Introdução

- Os sistemas de saúde em todo o mundo, estão confrontados com o desafio de como gerir a prestação de cuidados de saúde, em contexto de restrição de recursos
- Há uma necessidade de maximizar o impacto positivo das intervenções de cuidados de saúde na saúde da população









Prestação de cuidados de saúde em contexto de restrição de recursos

Aumento do número de exames radiológicos







## Introdução

- O paradigma da ATS surgiu como uma resposta às perguntas dos decisores sobre a difusão incontrolada de equipamento médico dispendioso
- A ATS começou no início dos anos 1970, quando a rápida demanda por tomografia computadorizada se tornou uma questão de política pública devido ao seu elevado custo







### Questões

- O que é a Avaliação de Tecnologias em Saúde (ATS)?
- Que métodos de pesquisa estão disponíveis para a ATS na imagem médica?
- Como é que a ATS pode influenciar a imagem médica?







## O que é a ATS?

- Qualquer intervenção que pode ser utilizada para promover a saúde, prevenir, diagnosticar ou tratar a doença, ou para a reabilitação, ou cuidados de longa duração
- Engloba os dispositivos médicos, desde os mais simples aos mais sofisticados sistemas de imagem médica; medicamentos; procedimentos médicos e cirúrgicos e os sistemas organizacionais e de suporte, em que esses cuidados são prestados





## O que é a ATS?

- A avaliação sistemática das propriedades, efeitos e/ou impactos da tecnologia nos cuidados de saúde
- Pode tratar das consequências directas das tecnologias, bem como as suas consequências não intencionais, indiretas
- O seu principal objetivo é informar acerca da formulação de políticas relacionadas com a tecnologia na área da saúde
- É conduzida por grupos interdisciplinares utilizando quadros analíticos explícitos a partir de uma variedade de métodos







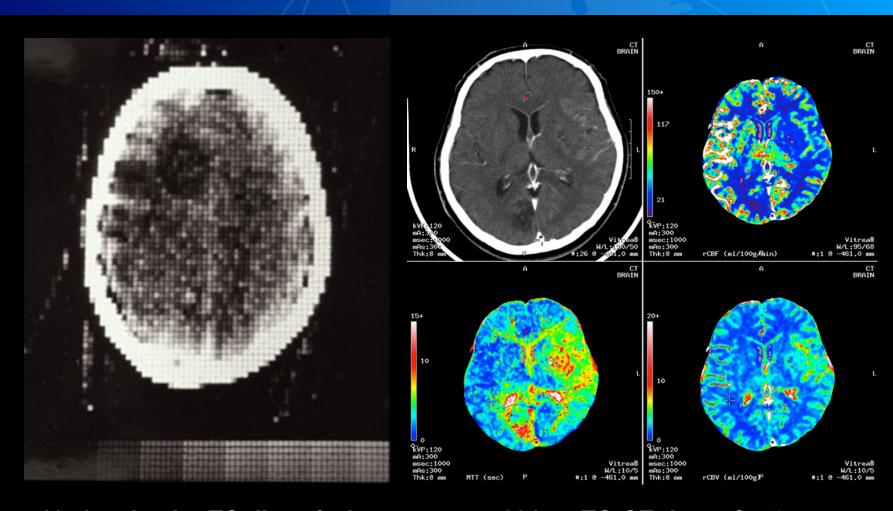
## Porquê a ATS?

- Pense numa tecnologia de imagem que teve uma evolução tecnológica assinalável nos últimos anos:
  - Conseguimos entender o que eram a imagem e o diagnóstico há 40 anos atrás?







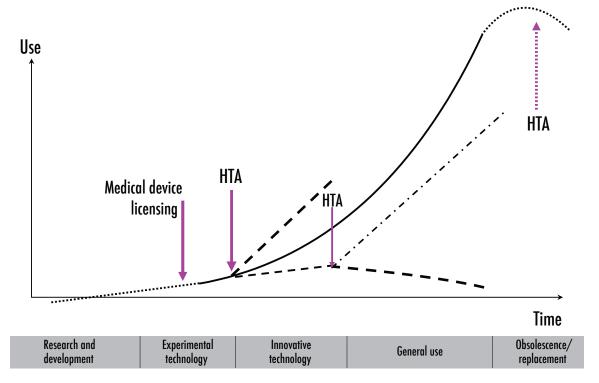


1971: primeira TC diagnóstica: Atkinson Morley's Hospital

2014 – TC-CE de perfusão com mapa de côr







A avaliação de tecnologias em saúde e a difusão de tecnologias em saúde





## Qual é a função da ATS?

- Tecnologia em Saúde é tudo aquilo que pode ser utilizado em procedimentos e processos médicos
  - i.e. medicamentos, dispositivos, equipamentos e acessórios, procedimentos médicos e cirúrgicos, sistemas de apoio e sistemas organizacionais e de gestão







## Qual é a função da ATS?

- Inclui a avaliação da eficácia e eficiência dos equipamentos e das técnicas
  - Eficácia obtenção da melhoria da saúde pela aplicação da ciência e da tecnologia nas condições mais favoráveis (controladas)
  - Eficiência Capacidade em reduzir os custos dos cuidados, sem diminuir a efectividade destes
- Compreende vários métodos para avaliar tecnologias em saúde







Hierarquia para avaliação da eficácia das tecnologias de diagnóstico: exemplo da RM

#### Technical performance

 Does MRI reliably result in good quality images which are anatomically representative?

#### Diagnostic performance

 Do the images produced allow accurate diagnoses to be made?

#### Diagnostic impact

 Does MRI change diagnostic confidence and displace other investigations?

#### Therapeutic impact

 Do the results of MRI contribute to planning and delivery of therapy?

#### Patient outcome

 Does the use of MRI contribute to the improved health of a patient?

#### Societal

 Is the cost (borne by the society as a whole) of MRI acceptable?







## Métodos para ATS em imagem médica

- Tipologias
  - Testes de diagnóstico
  - Ensaios clínicos aleatórios
  - Avaliação económica
  - Revisões sistemáticas e meta-análise





Eur Radiol DOI 10.1007/s00330-014-3333-4

#### COMPUTED TOMOGRAPHY

## Testes de diagnóstico

### Comparing five different iterative reconstruction algorithms for computed tomography in an ROC study

Kristin Jensen • Anne Catrine T. Martinsen • Anders Tingberg • Trond Mogens Aaløkken • Erik Fosse

Received: 15 January 2014/Revised: 1 July 2014/Accepted: 8 July 2014 © European Society of Radiology 2014

#### Key Points

- Iterative reconstruction algorithms affected lesion detection differently at different dose levels.
- One iterative algorithm improved lesion detectability compared to filtered back projection.
- Three algorithms did not significantly improve lesion detectability.
- One algorithm improved lesion detectability at the lowest dose level







### ATS com ensaios clínicos aleatórios

- Definem geralmente:
  - O objetivo do estudo
  - Como os participantes são expostos à intervenção
  - O número de participantes
  - Como a intervenção é avaliada





Sierink et al. BMC Emergency Medicine 2012, 12:4 http://www.biomedcentral.com/1471-227X/12/4



#### STUDY PROTOCOL

Open Access

## A multicenter, randomized controlled trial of immediate total-body CT scanning in trauma patients (REACT-2)

Joanne C Sierink<sup>1\*</sup>, Teun Peter Saltzherr<sup>1</sup>, Ludo FM Beenen<sup>2</sup>, Jan SK Luitse<sup>1</sup>, Markus W Hollmann<sup>3</sup>, Johannes B Reitsma<sup>4</sup>, Michael JR Edwards<sup>5</sup>, Joachim Hohmann<sup>6</sup>, Benn JA Beuker<sup>7</sup>, Peter Patka<sup>8</sup>, James W Suliburk<sup>9</sup>, Marcel G W Dijkgraaf<sup>4</sup> and J Carel Goslings, <sup>1</sup>, for the REACT-2 study group

#### Abstract

Background: Computed tomography (CT) scanning has become essential in the early diagnostic phase of trauma care because of its high diagnostic accuracy. The introduction of multi-slice CT scanners and infrastructural improvements made total-body CT scanning technically feasible and its usage is currently becoming common practice in several trauma centers. However, literature provides limited evidence whether immediate total-body CT leads to better clinical outcome then conventional radiographic imaging supplemented with selective CT scanning in trauma patients. The aim of the REACT-2 trial is to determine the value of immediate total-body CT scanning in trauma patients.

Methods/design: The REACT-2 trial is an international, multicenter randomized clinical trial. All participating trauma centers have a multi-slice CT scanner located in the trauma room or at the Emergency Department (ED). All adult, non-pregnant, severely injured trauma patients according to predefined criteria will be included. Patients in whom direct scanning will hamper necessary cardiopulmonary resuscitation or who require an immediate operation because of imminent death (both as judged by the trauma tearn leader) are excluded. Randomization will be computer assisted. The intervention group will receive a contrast-enhanced total-body CT scan (head to pelvis) during the primary survey. The control group will be evaluated according to local conventional trauma imaging protocols (based on ATLS guidelines) supplemented with selective CT scanning. Primary outcome will be in-hospital mortality. Secondary outcomes are differences in mortality and morbidity during the first year post trauma, several trauma work-up time intervals, radiation exposure, general health and quality of life at 6 and 12 months post trauma and cost-effectiveness.

**Discussion:** The REACT-2 trial is a multicenter randomized clinical trial that will provide evidence on the value of immediate total-body CT scanning during the primary survey of severely injured trauma patients. If immediate total-body CT scanning is found to be the best imaging strategy in severely injured trauma patients it could replace conventional imaging supplemented with CT in this specific group.

Trial Registration: ClinicalTrials.gov: (NCT01523626).

ATS com ensaios clínicos aleatórios







## Avaliação económica

- Lidar com os custos e resultados das atividades
- A finalidade básica de uma avaliação económica é identificar, medir, avaliar e comparar os custos e as alternativas





#### **HEALTH TECHNOLOGY ASSESSMENT**

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## Avaliação económica (exemplo)

A systematic review and economic evaluation of new-generation computed tomography scanners for imaging in coronary artery disease and congenital heart disease: Somatom Definition Flash, Aquilion ONE, Brilliance iCT and Discovery CT750 HD

M Westwood, M Al, L Burgers, K Redekop, S Lhachimi, N Armstrong, H Raatz, K Misso, J Severens and J Kleijnen

Conclusions: NGCCT may be sufficiently accurate to diagnose clinically significant CAD in some or all difficult-to-image patient groups. Economic analyses suggest that NGCCT is likely to be considered cost-effective for difficult-to-image patients with CAD, at current levels of willingness to pay in the NHS. For patients with suspected CAD, NGCCT only would be most favourable; for patients with known CAD, NGCCT-ICA would be most favourable. No studies assessing the effects of NGCCT on therapeutic decision making, or subsequent patient outcomes, were identified. The ideal study to address these questions would be a large multi-centre RCT. However, one possible alternative might be to establish a multicentre tracker study. High-quality test accuracy studies, particularly in obese patients, patients with high coronary calcium, and those with previous bypass grafts are needed to confirm the findings of our systematic review. These studies should include patients with multiple difficult to image criteria.







## Revisões sistemáticas e meta-análise

- O que é uma revisão sistemática?
- O que é uma meta-análise?
- Como fazer?







Meta-analysis

Systematic review

Randomized controlled trial

Cohort study

Case control study

Case series/case reports/expert opinion

Animal research

In vitro research

#### Hierarquia de tipos de estudo

Hierarquia da evidência





## Revisões sistemáticas e meta-análise – princípios básicos comuns

- Identificar literatura relevante selecione artigos relevantes
- Avaliar criticamente os artigos
- Identificar padrões gerais de resultados
- Identificar discordâncias cruciais e controvérsias
- Propor explicações válidas para as discordâncias
- Fornecer um resumo claro sobre o estado-da-arte





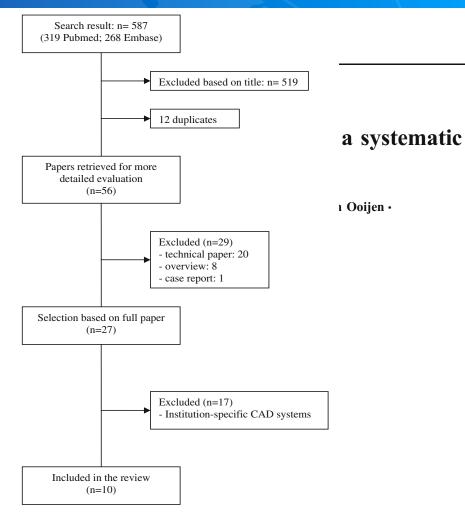
Revisões sistemáticas e meta-análise – princípios básicos comuns

 Identificar literatura relevante selecione artigos relevantes Eur Radiol (2011) DOI 10.1007/s00

**BREAST** 

Comput review a

Monique D. D Ruud M. Pijn



 ${\bf Fig.~1}~$  Flow chart of search results, with reasons for exclusion and the total number of studies included







### Revisão sistemática

- Revisão formal da evidência sobre um determinado tópico com uma pergunta de partida específica, com uma estratégia de pesquisa detalhada que permita a replicação
- Envolve a seleção de aspetos-chave das publicações, tais como metodologia, características dos sujeitos, medidas utilizadas em outros estudos (avaliação qualitativa)







#### Revisão sistemática Exemplo



Z. Munn, Z. Jordan / Radiography 17 (2011) 323-331

they meet patients at a critical time in their life, <sup>10</sup> and through studies such as those included in this review, gain a better understanding of the experience of their patients, with the hope of improving practice. imaged.<sup>11</sup> Some issues that have been identified in the literature include fear,<sup>26</sup> claustrophobia,<sup>27</sup> dehumanisation,<sup>28</sup> and an uncomfortable or unusual experience.<sup>29</sup> There is now a small but worthwhile qualitative literature base focussing on the patient experience in medical imaging. As far as we are aware, there is no

Review objectives

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The objective of this systematic review was to identify and describe from the available literature the experience and perceptions of people undergoing diagnostic imaging with high technologies, such as Magnetic Resonance Imaging, Computed Tomography, and Nuclear Medicine procedures. The question that the researchers were seeking to answer was: 'How do patients/ clients being scanned with high technology imaging experience the imaging procedure?'

coined in 1992),18 and evidence-based healthcare, has increased exponentially since the 1990s. Evidence-based medicine has been defined as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.<sup>19</sup> Systematic reviews can be seen as the pillar on which evidence-based healthcare rests, as they provide health professionals with a comprehensive synthesis of the existent literature on a certain healthcare topic. 19-21 Evidence-based organisations such as the Cochrane Collaboration and the Joanna Briggs Institute, both established in the 1990s, have been set up to develop methodologies and guidance on the process of systematic reviews. The applicability, importance and need for systematic reviews for medical imaging professionals has been stressed in previous articles,<sup>20,22,23</sup> and there does exist published examples in radiography<sup>24</sup> and radiotherapy.<sup>25</sup> However; the focus of these reviews are all quantitative in nature. Qualitative systematic reviews also play an important role in evidence-based healthcare, to inform healthcare professionals regarding issues that are not conducive to empirical research methods.21

#### The patient experience

When presenting to an imaging department, the person who is to be imaged is often in a vulnerable state, and out of their comfort zone. It is the role of the radiographer to produce a high quality image and facilitate patient care throughout the imaging process. Qualitative research is necessary to better inform the radiographer and to help them to understand the experience of the person being

or included a qualitative aspect, including, but not limited to, designs such as phenomenology, ground theory, ethnography, action research, qualitative descriptive studies, and feminist research. These were limited to English language studies, with no time limit.

#### Types of participants

This review included publications that included persons of any age who had undergone high technology medical imaging. These participants may have received medical imaging for a wide range of indications, and may have any pre-existing condition or disability.

#### Phenomena of interest

This review considered studies that investigated the patient experience of diagnostic imaging using high technology imaging, and the meaningfulness of that experience. Advanced, high technology imaging procedures are increasingly prevalent scans and there is rapid growth in these imaging modalities.<sup>3</sup> MRL (T. FPT and SPECT are the procedures considered high technology or advanced medical imaging.<sup>1,3,26</sup> and were searched for particularly. Standard digital radiography was not included. All diagnostic imaging procedures included in this review were non-invasive or minimally invasive. Interventional diagnostic procedures were not included, as their experience may be considerably different due to the invasive nature.

#### arch strategy

The search strategy aimed to find both published studies and grey literature, as advised by the Joanna Briggs Institute, 30 and was

Munn, Z., & Jordan, Z. (2011). The patient experience of high technology medical imaging: A systematic review of the qualitative evidence. Radiography, 17(4), 323–331.







**Table 2** Included Studies.

Study	Methodology	Methods/analysis	Participants	Modality	Phenomena of interest
Boljeko et al. (2008) <sup>31</sup>	Qualitative study	Semi-structured interview Analysed according to a template analysis Consistent with themes specified in interview guide	10 adult patients	MRI	<ol> <li>Patient's experiences of MRI</li> <li>Assess the value of written information</li> <li>Evaluate patient's perceptions of the</li> </ol>
Cooke et al. (2007) <sup>32</sup>	Qualitative study	Questionnaire and Semi-structured interview. Thematic analysis	44 adult patients had a questionnaire, 10 interviews	fMRI and MEG	information booklet Participant's experiences of taking part in research conducted using fMRI or MEG
Davies et al. (2004) <sup>27</sup>	Phenomenology	Semi-structured interviews, thematic analysis	6 deaf adult patients, 4 radiographers	Imaging department (CT and MRI)	1. Experience of deaf patients in a diagnostic imaging department, 2.Radiographer's perceptions
Laidlaw & Henwood (2003) <sup>34</sup>	Qualitative design	Unstructured interviews, Open thematic coding	8 adults with MS	MRI	Patients with MS holistic experience of MRI
Leithner et al. (2009) <sup>33</sup>	Qualitative design	Semi-structured interviews pre and post scan, Qualitative content analysis	62 pregnant women	MRI	Perception of foetal magnetic resonance imaging
Murphy (2001) <sup>35</sup>	Qualitative study	Semi-structured interviews, iterative mode of analysis	40 adults,19 MRI, 21 CT	MRI and CT	Patient's beliefs and knowledge of imaging procedures (MRI or CT)
Murphy (2001) <sup>26</sup>	Grounded theory, Symbolic interactionism	Semi-structured interviews, Coding, structuring and linking concepts to develop theories, Continuous interplay between analysis and data collection	26 adults, 13 CT, 13 MRI	MRI and CT	Patient experience when undergoing a high technology radiological investigation

findings from CT and MRI were combined in this review, as they were in some of the studies. This was done as it was felt many of the individual findings were complementary, and could be experienced in both imaging settings, and it was felt the synthesised findings were applicable to both modalities. The eventual synthesised

findings appear to be general across high technology imaging, and are not specific to any one modality. However, for clarity's sake, when reporting findings from studies that explored the experiences of patients in MRI and CT scanners jointly, every effort has been made to distinguish which scan was experienced. If the





### Meta-análise

- Procedimento sistemático para resumir os resultados publicados a partir de um conjunto de trabalhos de investigação
- Consiste numa agregação dos resultados de vários artigos numa única análise estatística (avaliação quantitativa)





### Meta-análise

 Combina o resultado de todos os estudos incluídos, que são comparáveis







## Meta-análise exemplo

#### ORIGINAL RESEARCH

E.D. Greenberg
R. Gold
M. Reichman
M. John
J. Ivanidze
A.M. Edwards
C.E. Johnson
J.P. Comunale
P. Sanelli



## Diagnostic Accuracy of CT Angiography and CT Perfusion for Cerebral Vasospasm: A Meta-Analysis

**BACKGROUND AND PURPOSE:** In recent years, the role of CTA and CTP for vasospasm diagnosis in the setting of ASAH has been the subject of many research studies. The purpose of this study was to perform a meta-analysis of the diagnostic performance of CTA and CTP for vasospasm in patients with ASAH by using DSA as the criterion standard.

MATERIALS AND METHODS: The search strategy for research studies was based on the *Cochrane Handbook for Systematic Reviews*, including literature data bases (PubMed, Embase, Cochrane Database of Systematic Reviews, and the Web of Science) and reference lists of manuscripts published from January 1996 to February 2009. The inclusion criteria were the following: 1) published manuscripts, 2) original research studies with prospective or retrospective data, 3) patients with ASAH, 4) CTA or CTP as the index test, and 5) DSA as the reference standard. Three reviewers independently assessed the quality of these research studies by using the QUADAS tool. Pooled estimates of sensitivity, specificity, LR+, LR-, DOR, and the SROC curve were determined.

**RESULTS:** CTA and CTP searches yielded 505 and 214 manuscripts, respectively. Ten research studies met inclusion criteria for each CTA and CTP search. Six CTA and 3 CTP studies had sufficient data for statistical analysis. CTA pooled estimates had 79.6% sensitivity (95% CI, 74.9%–83.8%), 93.1% specificity (95% CI, 91.7%–94.3%), 18.1 LR+ (95% CI, 7.3–45.0), and 0.2 LR- (95% CI, 0.1–0.4); and CTP pooled estimates had 74.1% sensitivity (95% CI, 58.7%–86.2%), 93.0% specificity (95% CI, 79.6%–98.7%), 9.3 LR+ (95% CI, 3.4–25.9), and 0.2 LR- (95% CI, 0.04–1.2). Overall DORs were 124.5 (95% CI, 28.4–546.4) for CTA and 43.0 (95% CI, 6.5–287.1) for CTP. Area under the SROC curve was 98  $\pm$  2.0% for CTA and 97  $\pm$  3.0% for CTP.

**CONCLUSIONS:** The high diagnostic accuracy determined for both CTA and CTP in this meta-analysis suggests that they are potentially valuable techniques for vasospasm diagnosis in ASAH. Awareness of these results may impact patient care by providing supportive evidence for more effective use of CTA and CTP imaging in ASAH.

ASAH (aneurysmal subarachnoid hemorrhage)





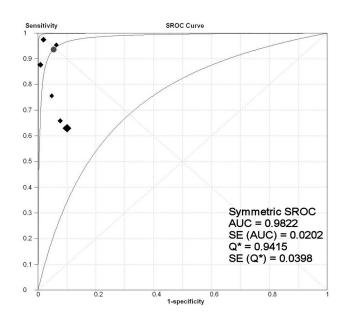


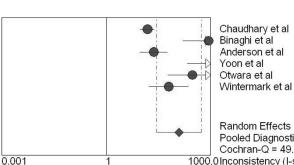
#### Meta-análise exemplo

Authors	Patients	Segments	Sensitivity	Specificity	PPV	NPV	Accuracy
Anderson et al <sup>17</sup> 2000 <sup>a,b</sup>	17	172	57, 64, 100	93, 97, 100	54, 58, 100	93, 98, 100	88, 95, 100
Binaghi et al <sup>18</sup> 2007 <sup>b</sup>	27	286	87.7	99.2	98.3	94.1	95.4
Chaudhary et al <sup>19</sup> 2008 <sup>b</sup>	33	886	63	90	43	95	87
Joo et al <sup>20</sup> 2006	8	24	NA	NA	NA	NA	NA
Ko et al <sup>21</sup> 2003	6	30	60	100	NA	37	NA
Ochi et al <sup>22</sup> 1997	2	10	NA	NA	NA	NA	NA
Otawara et al <sup>23</sup> 2002 <sup>b</sup>	20	154	NA	NA	NA	NA	NA
Takagi et al <sup>24</sup> 1998	13	NA	NA	NA	NA	NA	NA
Wintermark et al <sup>25</sup> 2006 <sup>b</sup>	27	123	75.6	95.3	79.5	94.2	91.4
Yoon et al <sup>26</sup> 2006 <sup>b</sup>	17	251	97.5	98.1	90.7	99.5	98

<sup>&</sup>lt;sup>a</sup> Values given for mild, moderate, and severe vasospasm groups, respectively.

<sup>&</sup>lt;sup>b</sup> The study was included in the statistical calculations of the meta-analysis.





Diagnostic Odds Ratio

#### Diagnostic OR (95% CI)

15.32 (9.42 - 24.92) 884.13 (160.31 - 4,875.94) 23.34 (9.37 - 58.12) 2,013.63 (217.70 - 18,625.14 304.57 (60.73 - 1,527.53) 62.82 (16.77 - 235.31)

Random Effects Model

Pooled Diagnostic Odds Ratio = 124.53 (28.38 to 546.35)

Cochran-Q = 49.90; df = 5 (p = 0.0000)

1000.0 Inconsistency (I-square) = 90.0 %

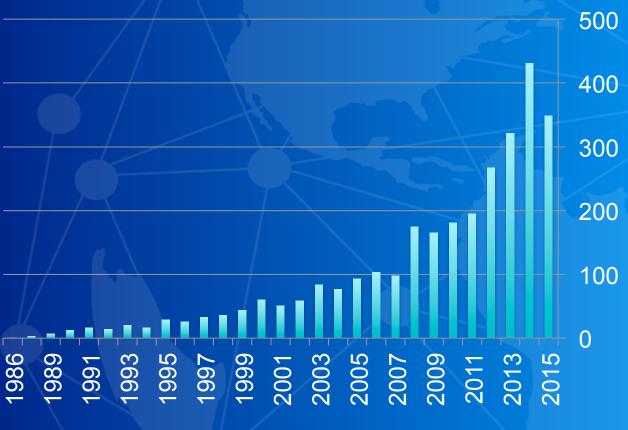
Tau-squared = 2.8837

Greenberg, E. D., Gold, R., Reichman, M., John, M., Ivanidze, J., Edwards, a M., ... Sanelli, P. (2010). Diagnostic accuracy of CT angiography and CT perfusion for cerebral vasospasm: a meta-analysis. AJNR. American Journal of Neuroradiology, 31(10), 1853-60.









## Publicações com meta-análise na PubMed

Número de publicações de meta-análise em radiologia, até 23 de outubro de 2015 (resultados de busca PubMed usando texto "meta-analysis" AND radiology).







## Acesso rápido a resumos actualizados regularmente

The Cochrane Library www.cochrane.org

The Centre for Evidence-Based Medicine www.cebm.net

The NHS Centre for Reviews and Dissemination <a href="https://www.york.ac.uk/inst/crd">www.york.ac.uk/inst/crd</a>

The Joanna Briggs Institute www.joannabriggs.edu.au/pubs/systematic reviews.php

The Campbell Collaboration www.campbellcollaboration.org

Bandolier www.medicine.ox.ac.uk/bandolier

PubMed Clinical Queries: Find Systematic Reviews

www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml







### Ferramentas úteis

- PRISMA http://www.prisma-statement.org
- QUADAS <a href="http://www.bris.ac.uk/quadas/">http://www.bris.ac.uk/quadas/</a>







## Como é que a ATS pode influenciar a imagem médica?

- Prática baseada na evidência
- Avaliação económica
- A tomada de decisão e governança
- A avaliação de tecnologias em saúde e inovação







### Conclusões

- ATS é conduzida por grupos interdisciplinares utilizando quadros analíticos explícitos, a partir de uma variedade de métodos
- Vários métodos e técnicas de pesquisa estão disponíveis para ATS na imagem médica
- As revisões sistemáticas e meta-análise são uma tendência e constituem métodos de pesquisa com valor para a ATS



## Muito obrigado!

luis.lanca@estesl.ipl.pt



ESCOLA SUPERIOR DE TECNOLOGIA DA SAÚDE DE LISROA

INSTITUTO POLITÉCNICO DE LISBOA

