The Challenges of Quantifying Benefits and Risks Associated with Diagnostic Imaging: A Literature Review

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Objective
To perform a search of the literature for quantitative benefit-risk analyses (BRAs) of medical imaging tests.

Background
Challenges for quantifying benefits and harms of imaging
- Most imaging technologies pass through less regulated approval channels, thus benefits/risks/harms are not well characterized
- Life cycles of imaging technologies are short, limiting longer-term studies
- Adherence to practice guidelines for medical testing is poor
- Current approaches focus on test characteristics and do not capture many of the downstream impacts of information provided by the imaging test

Examples of an imaging test’s characteristics
- Performance
- Diagnostic accuracy
- Positive/negative predictive value
- Dose of ionizing radiation exposure

Imaging tests indirectly impact, positively and/or negatively, the patient’s experience

benefits
- Appropriate risk stratification and clinical management
- Improvements in decision making by patients and providers
- Improvement in outcomes
- Improvements in survival
- Decreased anxiety

harms
- Inappropriate risk stratification and clinical management
- Adverse reactions to contrast material
- Unnecessary confirmatory tests
- Over diagnosis
- Missed disease cases
- Increased anxiety

Methods
- Using PubMed and the Cochrane Library, two separate computerized searches were performed to identify studies published between January 1979 and March 2013.
- Searches were limited to include benefit risk analyses quantifying at least one benefit and one risk/harm of imaging tests in screening or diagnostics

Search Strategy 1
First order words
- imaging
- computed tomography
- positron emission tomography
- medical devices

Second order words
- benefit-risk or risk-benefit
- harms

Search Strategy 1*
(gradient imaging NOT microcopy) and ((statistics and numerical data) and (imaging[tiab] and risk[ti] OR benefit[ti] OR harm[ti]))

768 results
- studies of benefit-harm in interventions other than medical imaging removed

997 results
- studies quantifying at least one benefit and one harm were kept

342 results
- studies mentioned benefits and risks associated with medical imaging tests but only 19 studies explicitly quantified at least one benefit and one risk/harm (Table)

Results
- 342 studies mentioned benefits and risks associated with medical imaging tests but only 19 studies explicitly quantified at least one benefit and one risk/harm (Table)
- The ratio of benefits-only to harms-only reports was 3:1
- The most studied technology was mammography
- Benefits were reported in terms of life extension
- Harms were reported as radiation-related cancer risk, loss of life-years or numbers of false-positive results
- Quantitative methods included micro-simulation modeling, epidemiological (randomized controlled trials, retrospective chart review/cohort analyses) or survey methods
- In any study, up to 2 benefits but only a single harm were included in the study design

Limitations
- Search captured only studies of outcomes referred to as benefits or harms/risks
- Publication bias may exist as studies showing insignificant benefit may not reach publication
- Search was limited to technologies with ionizing radiation exposure

Conclusions
- Few quantitative BRAs have been performed in imaging
- A comprehensive picture of imaging benefit-harm trade-offs is often called for but rarely provided
- The focus of the majority of studies remains benefits from early detection of disease
- Studies either investigate benefits or harms of imaging but rarely incorporate both
- The inclusion of multiple benefit and harm endpoints is encouraged in future study designs and modeling simulations

*Articles were included if they described results in humans and were written in English

### Oncology

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