

A new approach to deal with the absence of clinical trials in systematic reviews: a proportional meta-analysis of case series studies

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Background: Evidence-based medicine is defined as the link between good scientific research and clinical practice and it uses existing and available scientific evidence, with good internal and external validity, to apply its results in clinical practice. Systematic reviews are criticized for frequently offering inconsistent evidences and absence of straightforward recommendations [1]. Their value seems to be depreciated when the conclusions are uncertain or based on less than the highest grading of evidence. For these reasons the need to create strategies to deal with the absence of clinical trials is crucial.

Objective: To describe a new method of evaluating case series studies in health care when there is absence of clinical trials.

Methods: We provide illustrations from recent experiences [2] and discuss the impact of the level of evidence in the clinical practice. Proportional meta-analysis of case series studies was performed on surgical outcomes taking as an example: (a) case series studies, (b) use of cryoablation (CA) or radiofrequency ablation (RFA), (c) patients with renal tumors regardless of tumor size, and (d) the studies specified a measure of clinical efficacy based on follow-up imaging. The statistically significant difference between both interventions studied was defined if their combined 95% confidential interval (CI) did not overlap.

Results: The pooled proportion of clinical effectiveness was 89% [95% CI 0.83 to 0.94] in CA from 20 studies with a total of 457 cases (Figure 1). The pooled proportion of clinical efficacy was 90% [95% CI 0.86 to 0.93] in RFA therapy from 11 studies with a total of 426 cases (Figure 2). There was no significant difference between CA and RFA regarding clinical effectiveness as their CIs overlapped. Although we are leading to a low level of evidence to determine efficacy and safety of interventions this alternative method can help surgeons, physicians and health professionals for decision making in health care while clinical trials are ethically unacceptable or methodologically biased. It's not a replacement for the gold standard randomized clinical trial, but an alternative for clinical research.

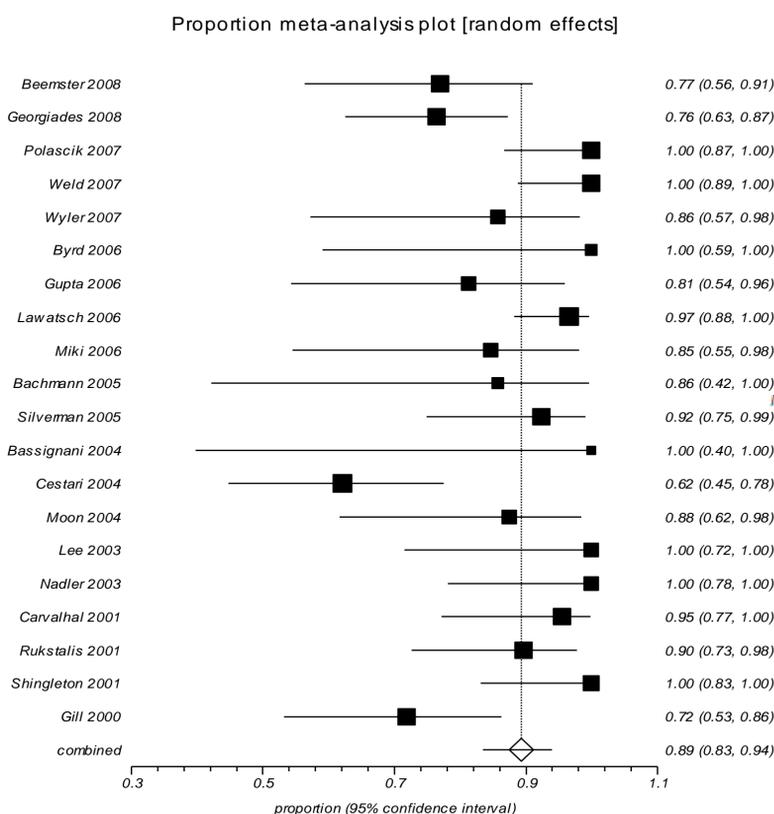


Figure 1. Proportional meta-analysis of CA case series studies.

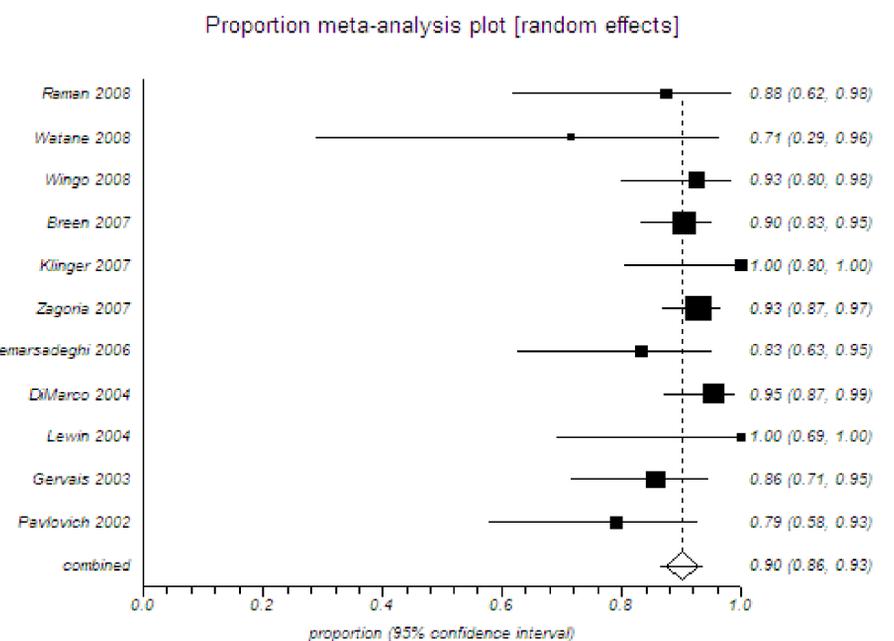


Figure 2. Proportional meta-analysis of RFA case series studies.

Conclusions: We describe a method to evaluate case series studies in health care reviews. This method is extended to be used in the absence of clinical trials, mainly, in surgical procedures where there are many barriers to design well-conducted clinical trials. The use of this method leads to substantial gains in the scientific community as it supports the clinicians and surgeons in their clinical practice until higher-quality primary studies are conducted, although we cannot ruled out the possibility of clinical and methodology heterogeneity due to the nature of these type of studies.

References

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