

Historical Controls

Summary of selected publications

Francois Aubin, Carol Reid, Tal Otiker

Key publications

- The combination of randomized and historical controls in clinical trials (Pocock 1976)
- Summarizing historical information on controls in clinical trials (Neuenschwander et al 2010)
- Hierarchical Commensurate and Power Prior Models for Adaptive Incorporation of Historical Information in Clinical Trials (Hobbs et al 2011)
- Use of historical control data for assessing treatment effects in clinical trials (Viele et al 2014)
- Incorporation of historical data in the analysis of randomized therapeutic trials (Rietbergen et al 2011)
- Matching Methods for Causal Inference: A review and a look forward (Stuart 2010)
- An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies (Austin 2011)

The combination of randomized and historical controls in clinical trials

Stuart J. Pocock

Reviewer comments:

This paper provides an introduction to the concept of historical controls and discusses the idea that the mean in the control arm is essentially a weighted mean of the observed controls in the current study and the historical controls. It also provides very useful criteria for selection of appropriate historical controls. This paper would be the first step into the world of historical controls.

> Clin Trials. 2010 Feb;7(1):5-18. doi: 10.1177/1740774509356002.

Summarizing historical information on controls in clinical trials

Beat Neuenschwander¹, Gorana Capkun-Niggli, Michael Branson, David J Spiegelhalter

Reviewer comments:

This paper provides an excellent introduction to the meta-analytic-predictive (MAP) approach of incorporating historical data into the analysis of a new study. This is also illustrated in a couple of practical examples. The paper has a good mix of theory and application and is highly recommended as an introduction to the MAP method. In addition to introducing the topic, it also raises some extremely important points regarding the challenges of using the MAP method when the number of historical studies included in the meta analysis is small.

➤ [Biometrics](#). 2011 Sep;67(3):1047-56. doi: 10.1111/j.1541-0420.2011.01564.x. Epub 2011 Mar 1.

Hierarchical commensurate and power prior models for adaptive incorporation of historical information in clinical trials

[Brian P Hobbs](#)¹, [Bradley P Carlin](#), [Sumithra J Mandrekar](#), [Daniel J Sargent](#)

Reviewer comments:

This paper provides an introduction to Bayesian hierarchical models and in particular the commensurate prior method. The majority of the paper is dedicated to discussing the properties of this method and comparing it to other methods. There is also one practical example.

Use of historical control data for assessing treatment effects in clinical trials

Kert Viele ¹, Scott Berry, Beat Neuenschwander, Billy Amzal, Fang Chen, Nathan Enas, Brian Hobbs, Joseph G Ibrahim, Nelson Kinnersley, Stacy Lindborg, Sandrine Micallef, Satrajit Roychoudhury, Laura Thompson

Reviewer comments:

This paper describes 6 methods to incorporate historical data and distinguish dynamic from static borrowing. As claimed they provide a clear review of the key issues involved in historical borrowing and comparisons of several methods. Setting and impact are well described and are helpful to make a selection which method to prefer in a concrete situation.

Review

> Contemp Clin Trials. 2011 Nov;32(6):848-55. doi: 10.1016/j.cct.2011.06.002.

Epub 2011 Jun 25.

Incorporation of historical data in the analysis of randomized therapeutic trials

Charlotte Rietbergen ¹, Irene Klugkist, Kristel J M Janssen, Karel G M Moons, Herbert J A Hoijtink

Reviewer comments:

The paper describes in a clear step-by step manner how to use power-prior distributions for the case of one as well as multiple historical trials, including sensitivity analysis on the power weight.

[Stat Sci](#). Author manuscript; available in PMC 2010 Sep 22.

PMCID: PMC2943670

Published in final edited form as:

NIHMSID: NIHMS200640

Stat Sci. 2010 Feb 1; 25(1): 1–21.

PMID: [20871802](#)

doi: [10.1214/09-STS313](#)

Matching methods for causal inference: A review and a look forward

[Elizabeth A. Stuart](#)

Reviewer comments:

The paper provides an introduction to matching methods as well as a list of software.

› [Multivariate Behav Res.](#) 2011 May;46(3):399-424. doi: 10.1080/00273171.2011.568786.

Epub 2011 Jun 8.

An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies

[Peter C Austin](#) ¹

Reviewer comments:

The paper provides a good introduction to propensity score methods. Although the paper is focused on observational studies, the methods are applicable to randomized controlled trials.