

Meta Analytic Prior

Summary of selected publications

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Linked to historical controls

- 18 Use of historical data. (Wandel et al., 2015)
- 22: Use of historical control data for assessing treatment effects in clinical trials. (Viele et al., 2014)
- 30: Incorporating historical control data in planning phase II clinical trials (Thall and Simon, 1990)
- 31: Power priors based on multiple historical studies for binary outcomes (Gravestock and Held, 2019)

Other topics related to MAP

- 6: How to use prior knowledge and still give new data a chance? (Weber et al., 2018)
- 13: Bayesian methods for the design and analysis of noninferiority trials (Gamalo-Siebers et al., 2016)
- 14: gsbDesign: An R Package for Evaluating the Operating Characteristics of a Group Sequential Bayesian Design (Gerber et al., 2016)
- 16: On the relationship between the causal-inference and meta-analytic paradigms for the validation of surrogate endpoints (Alonso Abad et al., 2015)
- 19: A practical guide to Bayesian group sequential designs (Gsponer et al., 2014)
- 21: A note regarding meta-analysis of sequential trials with stopping for efficacy (Senn, 2014)

MAP main articles

- 20: Robust Meta-Analytic-Predictive Priors in Clinical Trials with Historical Control Information (Schmidli et al., 2014)
- 25: From historical data to priors. (Neuenschwander, 2011)
- 27: Summarizing historical information on controls in clinical trials (Neuenschwander et al., 2010)

Hands on MAP

- 2: RBeST for a Normal Endpoint (Li, 2018)
- 4: RBeST for a Binary Endpoint (Weber, 2018)
- 5: RBeST: R Bayesian Evidence Synthesis Tools (Weber, 2018)
- 32: Applying Meta-Analytic-Predictive Priors with the R Bayesian evidence synthesis tools (Weber et al., 2019)

More on meta-analysis specific

- 3: bayesmeta: Bayesian random-effects meta analysis. R package (Röver, 2018)
- 8: Meta-analysis of two studies in the presence of heterogeneity with applications in rare diseases (Friede et al., 2017)
- 9: Meta-analysis of aggregate data on medical events (Holzhauer, 2017)
- 17: Hartung-Knapp-Sidik-Jonkman Approach and its modification for random-effects meta-analysis with few studies. (Röver et al., 2015)

More details on MAP

- 10: Including historical data in the analysis of clinical trials: Is it worth the effort? (van Rosmalen et al., 2017)
- 11: Bayesian synthesis of historical information for robust prediction and extrapolation (Schmidli, 2017)
- 12: Meta-analytic-predictive use of historical variance data for the design and analysis of clinical trials (Schmidli et al., 2017)
- 15: On the Use of Co-Data in Clinical trials (Neuenschwander et al., 2016)
- 23: Anti-interleukin-17A monoclonal antibody secukinumab in treatment of ankylosing spondylitis: a randomized, double-blind, placebo controlled trial. (Baeten et al., 2013)
- 24: Using historical control information for the design and analysis of clinical trials with overdispersed count data (Gsteiger et al., 2013)
- 26: The network meta-analytic-predictive approach to non-inferiority trials (Schmidli et al. 2013)
- 28: Dynamically borrowing strength from another study through shrinkage estimation (Röver and Friede, 2019)
- 29: The combination of randomized and historical controls in clinical trials (Pocock, 1976)

Article

Heinz Schmidli, Sandro Gsteiger, Satrajit Roychoudhury, Anthony O'Hagan, David Spiegelhalter, and Beat Neuenschwander
Robust meta analytic predictive priors in clinical trials with historical control information
Biometrics 2014;70(4):1023-1032

Description

The article provides an approximate MAP prior by using a mixture distribution, as the MAP prior is not available in an analytical form. The authors consider the use of historical controls in meta-analytic framework. The focus is on a Bayesian version with a robust prior derived from historical controls. They discuss a two-stage design where more patients are randomised to control in the second stage, if interim results suggest prior data conflict. They approximate the MAP prior by a mixture of conjugate priors. Conclusion: If historical and control data are in clear conflict, the prior will essentially be discarded, if the MAP prior is robust. This may result in inconclusive results, as not enough control information may then be available. Adaptive designs allow to increase the number controls based on interim data, and hence reduce this risk.

Classification: General

Reader level: Advanced

Recommendation

It seems like that the decrease in the number of control subjects is a lot in some examples, however having historical data and current control data in such a consistency seems difficult. This seems to be the best method in the literature so far and implementations needs to be explored. The paper provides some input for small populations. The pros and cons for using these approaches in small population are:

Pros: - This method can incorporate controls from historical trials, and this will reduce the number of patients overall.

- This papers indicates other papers when only test treatment controls are available, which could be more appropriate in small populations.

Cons: - Using historical controls assumes using the same patient population but for rare disease, the number of historical controls could be very limited.

- This paper presents an example with several historical trials - could be of limited use for small population.

Article

Neuenschwander B, Capkun-Niggli G, Branson M and Spiegelhalter DJ

Summarizing historical information on controls in clinical trials

Clinical Trials 2010; 7(1):5-18

Description

Authors provided the conceptual and methodological aspects of meta-analytic predictive framework using hierarchical models. The authors describe how to obtain the predictive distribution in meta-analytic framework. They use the predictive distribution from historical data meta-analysis as a prior in the current trial. They could also quantify the amount of borrowed information using n^* (prior effective size). Prior effective sample size is mainly driven by between trial heterogeneity. Even if a lot of historical information is available, this may not be of relevance if between trial variability is considerable.

Classification: General

Reader level: Introduction

Recommendation

This is one of the first papers on the topic and it constitutes the core of MAP prior. They give 3 examples where they use historical internal data to make decisions for the ongoing trials. The method provides good amount of information from historical data when the trials are not very heterogeneous (trials run at the same centres, using same design even with the same investigators). When one wants to use historical data from different settings (in practical settings we usually see high heterogeneity in trials coming from different centres, investigators, settings), the method would not bring a lot of information. Their last application, using 1 historical trial data with considerable heterogeneity, they could decrease the ongoing trial control size from 14 to 7. This seems a bit optimistic. Even with two trials, it is controversial to perform a meta-analysis, and the quantification of heterogeneity is really difficult.

Conference Proceeding

Neuenschwander B,

From historical data to priors

Biometrics Section JSM 2011;

Description

The paper outlines the MAP approach with a practical example and different aspects

Classification: General

Reader level: Introduction

Recommendation

In this paper different aspects of MAP are discussed. They provide an example from phase II oncology trial where there are 4 previous trials. They describe the MAP approach, how to choose prior distributions, number of historical trials, etc. Using historical controls from 4 previous trials with approximately 360 subjects led to a decrease in sample size by 22 control subjects.