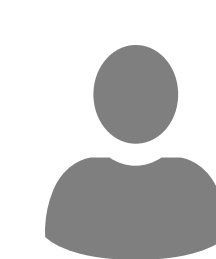


Using a time-varying covariate in the Cox proportional hazards model discerns early/late treatment efficacy. Use with caution.

Use of time-varying covariate in assessing disease remission in the early and late phases of treatment with application to RITAZAREM trial.



Marianna Nodale



BACKGROUND

RITAZAREM, an open-label, multi-centre RCT, aims to assess the efficacy of rituximab compared to the current standard of care in the prevention of relapse in ANCA-associated vasculitis.

Design: N = 170 patients, 1:1 allocation, 90% power at $\alpha = 5\%$ for HR = 0.42.

Outcome: time to disease relapse.

Primary analysis: Cox proportional hazard model for overall efficacy & time-varying covariate to investigate during/post treatment efficacy.

METHODS

1. Censoring and relapse times simulated with a Weibull distribution (sample N = 167, 83 events).
2. Simulated $HR_{early} \neq HR_{late} \in (0.3-0.9)$
3. True change point for HR $\tau = 20$.
4. Relapse times after change point simulated with a conditional Weibull distribution.

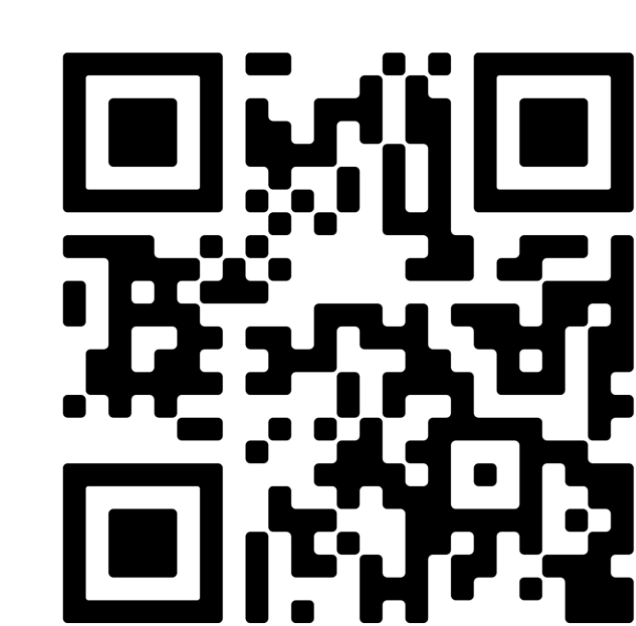
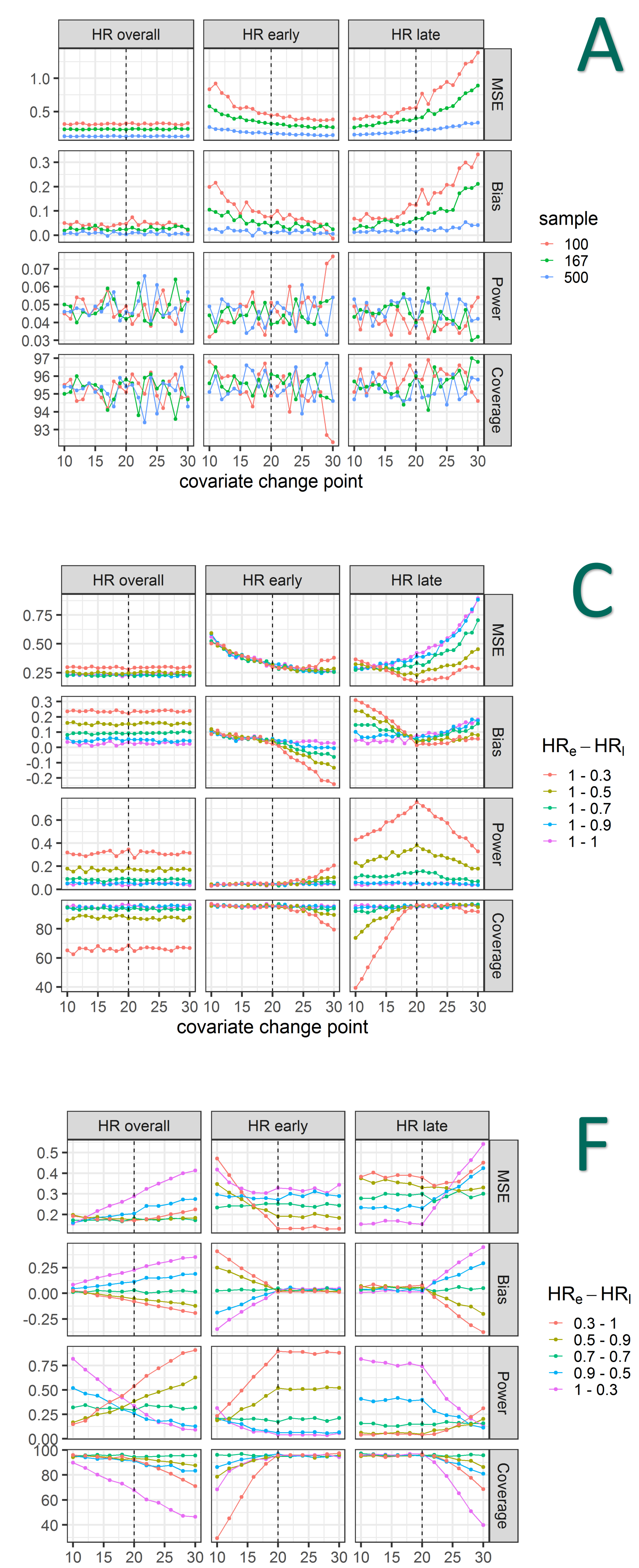
RESULTS

Simulations (n=1000) investigate the operational characteristics of the model under a variety of assumptions:

- A. Null hypothesis
- B. Constant overall efficacy
- C. Early efficacy
- D. Late efficacy
- E. Different early/late efficacy
- F. Wrong change point τ

DISCUSSION

- First point
- Second point
- Third point



Main finding goes here, translated into plain English. Emphasize the important words.

Use of time-varying covariate in assessing disease remission in the early and late phases of treatment with application to RITAZAREM trial.

 Marianna Nodale

BACKGROUND

- Just give context for the gap you’re filling
- You’re not going to get yelled at if you don’t cite the 5 papers from 1937 that defined this construct. They’ll download your paper if they want that.

METHODS

1. N = ###,
2. Collected this
3. Tested with X statistical test

RESULTS

- Graph or table with essential results only.
- All the other correlations in the ammo bar.

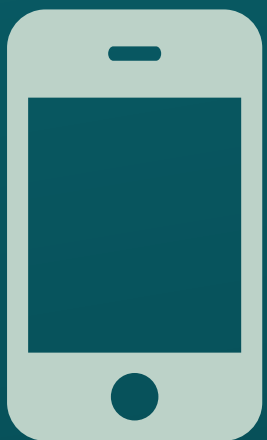
DISCUSSION

- “If this result actually generalized and I didn’t have to humbly disclaim the possibility of a thousand confounds and limitations, it would imply that....”

AMMO BAR

Delete this and replace it with your...

- Extra Graphs
- Extra Correlation tables
- Extra Figures
- Extra nuance that you’re worried about leaving out.
- **Keep it messy!** This section is just for you.



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