Including historical data in the analysis of clinical trials using the modified power prior

Practical considerations for survival models

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Practical considerations in survival models

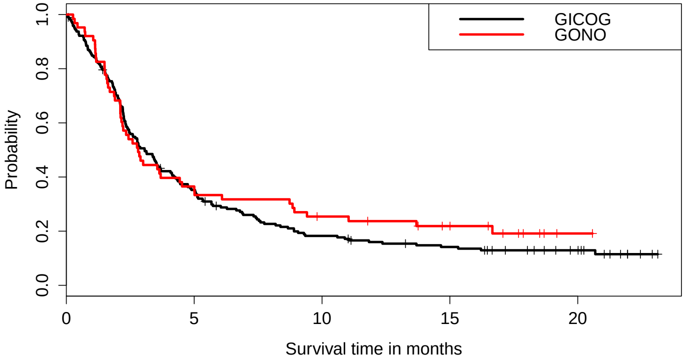
- Motivating example: Ovarian cancer datasets
- Prior of the power parameter
- Calculation of scaling factor $C(\theta)$ in Modified Power Prior
  Laplace approximation
- Definition of commensurate prior as alternative
- Issue of nuisance parameters when using the Modified Power Prior

Ovarian cancer datasets

- Subjects: Women with advanced ovarian cancer
- 2 studies comparing cyclophosphamide plus cisplatin (CP) versus cyclophosphamide, doxorubicin, and cisplatin (CAP).
- Outcome: Time to death
- Covariates: Treatment arms (CP=0, CAP=1)
- Design: RCT
- Question: CP superior CAP?

The data used for this work were made available by the Ovarian Cancer Meta-Analysis Project (Ovarian Cancer Meta-Analysis Project). Cyclophosphamide plus cisplatin versus cyclophosphamide, doxorubicin and cisplatin chemotherapy of ovarian carcinoma: a meta-analysis. J Clin Oncol 9: 1668-1674, 1991).

- Survival estimates for the control group (CP)



- Sample sizes:

Trial	Sample size	Number of events
GICOG	383	321
GONO	125	95

Model

- Cox Proportional hazard model with exponential baseline hazard

$$S(t) = \exp(-\lambda e^{\beta X} t)$$

- X = treatment arm (CP=0, CAP=1)
- β = the treatment effect
- λ = baseline hazard
- Current data = GONO study
- Historical data = GICOG study
- Modified historical data = GICOG study with $t_i = \frac{1}{2} t_{i\ GICOG}$

Analysis

Approach	parameters β	λ	θ
Analysis of the GONO study			
No prior	-0.18 (0.21)	1.55 (0.22)	
GICOG study as prior			
Class. Bayesian	-0.16 (0.10)	1.77 (0.12)	
MPP	-0.16 (0.13)	1.70 (0.16)	0.51 (0.27)
Modified GICOG study as prior			
Class. Bayesian	-0.16 (0.10)	2.80 (0.19)	
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- GONO and GICOG studies are similar
- Modified GICOG studies introduces bias in baseline hazard estimation
- MPP discards the historical data

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Prior for θ

- Vague priors:
  Flat prior $\pi(\theta) = \text{Beta}(1{,}1)$

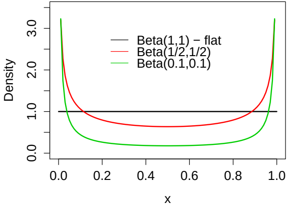
- Jeffreys prior:
  $\pi(\theta) = \text{Beta}(1/2{,}1/2)$

- "quasi dichotomous" priors:

  - Pushes θ towards 0 or 1
    $\Rightarrow$ choose to completely borrow or discard historical data
    but not interested in partial borrowing: θ close to $1/2$

  - Bathtub Beta prior:

    $\pi(\theta) = \text{Beta}(a, a)$ where $a \to 0$



Advantages of "quasi dichotomous" priors

Simple exponential model with rate = λ : Historical data not compatible

	Parameters	
Approach	λ	θ
	$\lambda = 1, n = 100,$	$\lambda_h = 2, n_h = 100$
Class. Bayesian	1.40 (0.12)	
MPP flat prior	1.05 (0.13)	0.14 (0.12)
MPP Beta(0.5,0.5)	1.04 (0.13)	0.12 (0.12)
MPP Beta(0.1,0.1)	1.05 (0.13)	0.09 (0.13)
	$\lambda = 1, n = 100,$	$\lambda_h = 2, n_h = 1000$
Class. Bayesian	1.85 (0.06)	
MPP flat prior	1.10 (0.14)	0.02 (0.03)
MPP Beta(0.5,0.5)	1.08 (0.14)	0.01 (0.02)
MPP Beta(0.1,0.1)	1.04 (0.13)	0.01 (0.01)

- Size of historical data impacts borrowing with the use of flat prior
- Flat prior seem to borrows too much from historical data, less with "quasi dichotomous" prior

Scaling factor $C(\theta)$ in Modified Power prior

- Modified Power Prior:

$$\pi^{MPP}(\beta,\theta) \propto C(\theta)\Big\{L_H(\beta)\Big\}^{\theta}\pi(\beta)\pi(\theta)$$

where

$$\frac{1}{C(\theta)} = \int \Big\{L_H(\beta)\Big\}^{\theta}\pi(\beta)d\beta$$

- No closed form for most survival models
- L_H is numerically unstable

Laplace approximation

$\frac{1}{C(\theta)}$ can be rewritten as:

$$\frac{1}{C(\theta)} = \int \exp\left\{\theta \log\left[L_H(\beta)\right]\right\} d\beta$$

- $\pi(\beta)$ assumed flat
  In most examples also in other situations
- $\log(L_H)$ numerically more stable

Expression can be obtained by Laplace approximation

$$\frac{1}{C(\theta)} \approx \exp\left\{\theta \log\left[L_H(\hat{\beta})\right]\right\} \int \exp\left\{ -\theta(\beta - \hat{\beta})^T H(\beta - \hat{\beta})\right\} d\beta$$

$$\frac{1}{C(\theta)} \approx \exp\left\{\theta \log\left[L_H(\hat{\beta})\right]\right\} \int \exp\left\{-\theta(\beta-\hat{\beta})^T H(\beta-\hat{\beta})\right\} d\beta$$

- $\hat{\beta}$ is MLE of β on historical likelihood
- $H =$ Hessian of $\log L_H$ evaluated at $\hat{\beta}$
- $\hat{\beta}$, H can be computed outside of sampling routine
- Integral term computed from multivariate normal

Calculation of $C(\theta)$ is fast

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Laplace approximation performance

Performance evaluated on:

- Exponential model (closed form for $C(\theta)$)
- Weibull models using stochastic integration

Note:

- Sampling requires evaluation of $C(\theta)$ at each iteration
- Other approaches are time consuming
- Laplace approximation requires $\pi(\beta)$ flat
  - Applicable for some models (e.g. Weibull)
  - Requires some algebra for exponential regression

Commensurate prior

- Alternative to modified power prior (Hobbs et al. 2011)
- Idea:
  - Use independent parameters for current and historical
  - Link the parameters with link density

Definition

$$\pi^C(\beta, \beta_h, \sigma) \propto L_H(\beta_h)\ \psi(\beta, \beta_h, \sigma)\ \pi(\beta_h, \sigma)$$

with:

- β_h specific to historical data
- $\psi(\beta, \beta_h, \sigma)$ density linking β and β_h
- σ measuring the commensurability (compatibility between data) estimated

Purpose: link parameters $\psi(\beta, \beta_h, \sigma)$

- variance $= \sigma^2$ measuring the commensurability between parameters

Typical examples:

- $\beta \in [-\infty, \infty]$: $\psi =$ normal density
- $\beta \in [0, \infty]$:
  - $\psi =$ log-normal
  - $\psi =$ gamma

Comparison between methods

Approach	Parameters λ	λ_h	θ	σ
$\lambda = 1, n = 100, \quad \lambda_h = 1, n_h = 1000$				
MPP flat prior	1.01 (0.07)		0.50 (0.28)	
Commensurate prior	1.00 (0.07)	1.01 (0.04)		0.28 (0.50)
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MPP flat prior	1.10 (0.14)		0.02 (0.03)	
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Commensurate prior	1.02 (0.12)	1.99 (0.07)		1.95 (1.89)

Modified power prior :

- Modulates the whole likelihood
- θ interpretable

Commensurate prior:

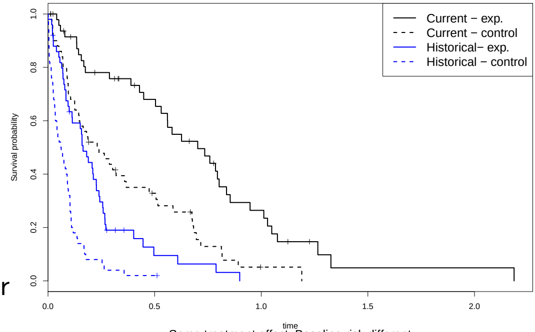
- Impacts on single parameters
- σ not bounded

Nuisance parameters

Example : PH model with exponential baseline hazard

$$S(t) = \exp(-\lambda e^{\beta X} t)$$

- X is the covariate
- β regression parameter
- λ baseline hazard parameter



Same treatment effect, Baseline risk different

What if the historical study can provide information for β
But baseline risk λ is not compatible (nuisance parameter)?

Nuisance parameters: adaptation

- Commensurate prior: straightforward

$$\pi^C(\beta, \lambda, \beta_h, \lambda_h, \sigma) \propto L^H(\beta_h, \lambda_h) \;\; \psi(\beta, \beta_h, \sigma) \;\; \pi(\beta_h, \lambda_h, \sigma)$$

link only on β

Nuisance parameters: adaptation

- Modified power prior: More complex

  Idea: introduce λ_h independent of λ

  - Marginal prior

$$\pi^{MPP}(\beta,\theta) \propto C(\theta)\left\{\int_0^\infty L_H(\lambda_h,\beta)\pi(\lambda_h)d\lambda_h\right\}^\theta \pi(\beta)\pi(\theta)$$

    - Integration complex

  - Nuisance parameters prior

$$\pi^{MPP}(\lambda_h,\beta,\theta) \propto C(\theta)\left\{L_H(\lambda_h,\beta)\right\}^\theta \pi(\lambda_h)\pi(\beta)\pi(\theta)$$

    - λ_h impacts θ

Simulation study: All parameters compatible

	Parameters				
Approach	β	λ	λ_h	θ	σ
Scenario 1: $\beta = 2, \lambda = 1, n = 100,\ \beta_h = 2, \lambda_h = 1, n_h = 100$					
Class. Bayesian	2.02 (0.16)	1.01 (0.12)			
Shared-MPP	1.99 (0.19)	1.03 (0.15)		0.57 (0.25)	
Nuisance-MPP	1.99 (0.19)	1.05 (0.16)	1.02 (0.24)	0.54 (0.27)	
Marginal-MPP	2.00 (0.19)	1.05 (0.17)		0.52 (0.27)	
Commensurate	2.00 (0.19)	1.02 (0.16)	1.02 (0.16)		0.62 (0.99)

- High θ but not close to 1
- Increase of variance due to additional parameters
- Marginal and nuisance MPP similar
- Commensurate and MPP similar

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Class. Bayesian	2.18 (0.16)	1.75 (0.21)			
Shared-MPP	2.01 (0.22)	1.08 (0.18)		0.03 (0.02)	
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- MPP and commensurate do not increase variance
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Ovarian Cancer data

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- Nuisance MPP takes maximum benefit from historical data
- Commensurate and nuisance MPP have similar performances

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Discussion

- "Quasi dichotomous" priors can improve borrowing / discarding of prior data
- Complexity of MPP ($C(\theta)$) can be overcome for some models
- MPP and commensurate adaptively borrow based on compatibility
  - MPP: Too high borrowing when historical is large
  - Commensurate prior less impacted
- When nuisance parameters
  - 2 approaches: nuisance parameters or marginal prior
  - Both approach appear to be equivalent
  - Commensurate prior not impacted by nuisance parameter

Thank you for your attention

Back-up

Combined approach: Commensurate Power Prior (Hobbs et al.)

Issue:

Modest gain in variance of parameter estimates

due to $\theta \sim 0.5$ and not 1 when compatibility

Idea of Hobbs

- Use a prior distribution for θ that is informative
- Informative towards 0 when not compatible, towards 1 when compatible
- Compatibility determined by Hierarchical structure on parameters
- Compatibility still determined by data

Commensurate Power Prior (Hobbs et al.)

Formally (assuming only one parameter for simplicity):

$$\pi^{CP}(\beta,\theta) \quad \propto \quad C(\theta)\int \left(L^H(\beta_0)\right)^{\theta}\pi(\beta_0) \quad \times \quad N(\beta|\beta_0,\frac{1}{\tau}) \;\; d\beta_0$$
$$\times \quad Beta(\theta|\log(\tau),1) \quad \times \pi(\tau)$$

- Different parameter β_0 in historical data

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$$\times\; Beta(\theta|\log(\tau),1) \;\times \pi(\tau)$$

- Different parameter β_0 in historical data
- Hierarchical structure on the parameters β and β_0

Commensurate Power Prior (Hobbs et al.)

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$$\times \;\; Beta(\theta|\log(\tau), 1) \;\; \times \pi(\tau)$$

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- Precision parameter τ measuring the compatibility between β and β_0

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- β_0 integrated out as not relevant for the parameters of interest