

Bladder Cancer Analysis

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Data

The analysis includes all data in `survival::bladder1` treated with placebo or thiotepa, and excluding 1 subject (`id == 1`) whose observation `start` and `stop` times were both equal to zero.

LWYY Analysis

Without Covariate Adjustment

```
## Call:
## coxph(formula = Surv(time = start, time2 = stop, event = status) ~
##       arm, data = data, robust = TRUE, cluster = id)
##
##   n= 208, number of events= 132
##
##           coef exp(coef) se(coef) robust se      z Pr(>|z|)
## arm -0.4096    0.6639   0.1840   0.2954 -1.387   0.166
##
##       exp(coef) exp(-coef) lower .95 upper .95
## arm    0.6639    1.506    0.3721    1.185
##
## Concordance= 0.55 (se = 0.034 )
## Likelihood ratio test= 5.14 on 1 df,  p=0.02
## Wald test               = 1.92 on 1 df,  p=0.2
## Score (logrank) test = 5.03 on 1 df,  p=0.02,   Robust = 2  p=0.2
##
## (Note: the likelihood ratio and score tests assume independence of
##       observations within a cluster, the Wald and robust score tests do not).
```

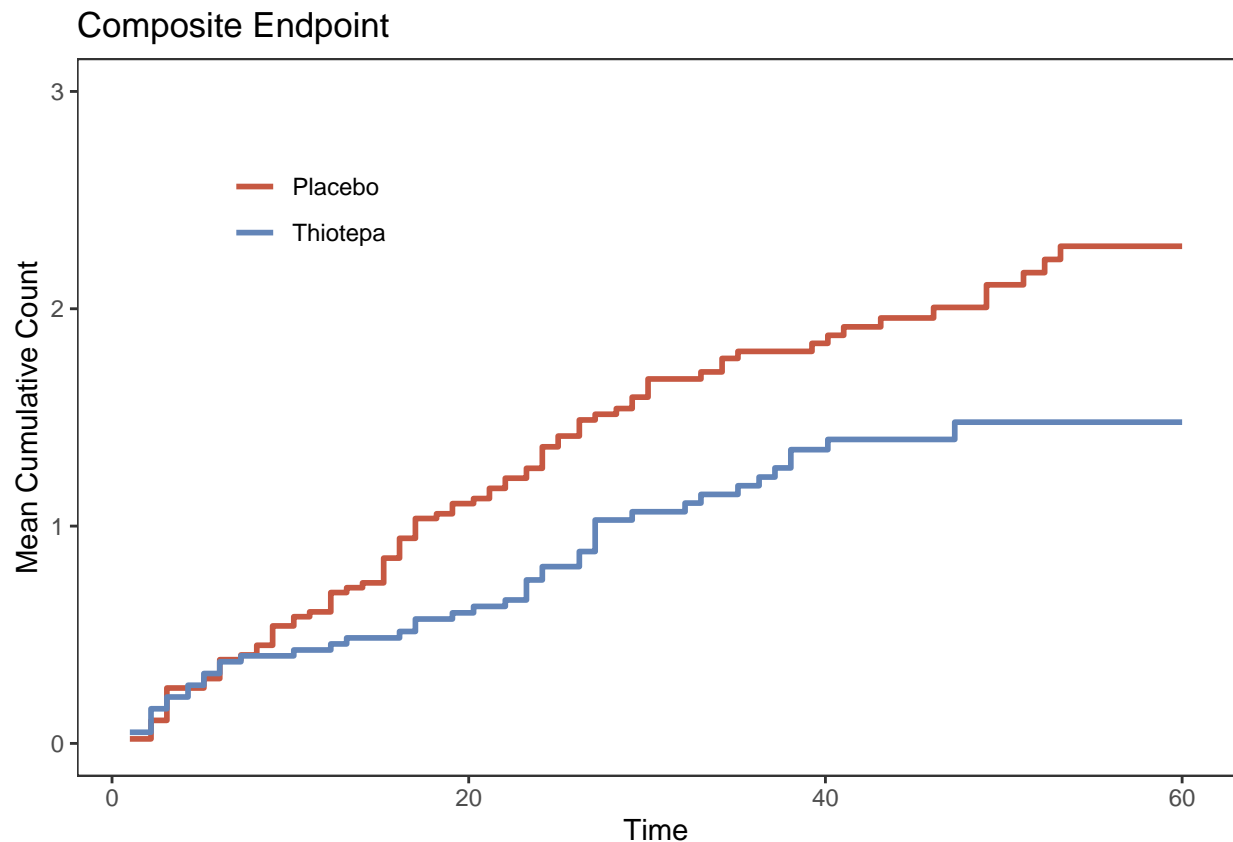
With Covariate Adjustment

```
## Call:
## coxph(formula = Surv(time = start, time2 = stop, event = status) ~
##       arm + number + size, data = data, robust = TRUE, cluster = id)
##
##   n= 208, number of events= 132
##
##           coef exp(coef) se(coef) robust se      z Pr(>|z|)
## arm   -0.52924    0.58905   0.18685   0.26950 -1.964   0.04955 *
## number  0.20415    1.22648   0.04336   0.06558  3.113   0.00185 **
## size   -0.04095    0.95988   0.06478   0.07756 -0.528   0.59751
## ---
```

```
## Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
##
##      exp(coef) exp(-coef) lower .95 upper .95
## arm      0.5891      1.6976   0.3473   0.999
## number    1.2265      0.8153   1.0785   1.395
## size      0.9599      1.0418   0.8245   1.117
##
## Concordance= 0.642  (se = 0.031 )
## Likelihood ratio test= 26.78  on 3 df,   p=7e-06
## Wald test              = 14.01  on 3 df,   p=0.003
## Score (logrank) test = 30.06  on 3 df,   p=1e-06,   Robust = 11.5  p=0.009
##
## (Note: the likelihood ratio and score tests assume independence of
## observations within a cluster, the Wald and robust score tests do not).
```

AU MCF Analysis

Composite Endpoint of Recurrence or Death



Baseline Analysis

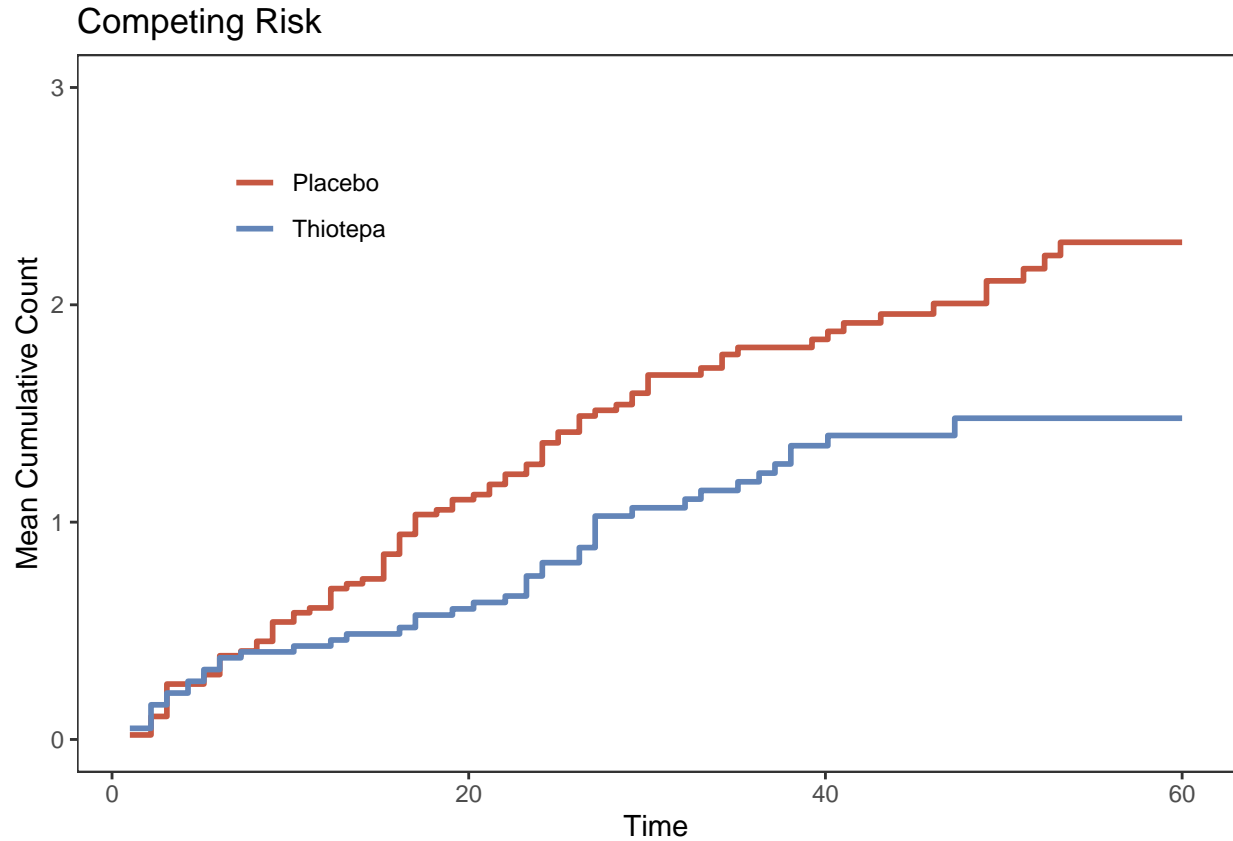
```
## Marginal Areas:
##   arm  n  area  se tau
## 1    0 47 113.0 16.8 60
## 2    1 38  82.8 17.6 60
##
```

```
##
## CIs:
##      method contrast observed      se  lower upper
## 1 asymptotic   A1-A0 -29.800 24.400 -77.600 17.90
## 3 bootstrap    A1-A0 -29.800 24.800 -78.200 20.80
## 2 asymptotic   A1/A0   0.735 0.191   0.442 1.22
## 4 bootstrap    A1/A0   0.735 0.200   0.408 1.23
##
##
## P-values:
##      method contrast observed      p
## 1 asymptotic   A1-A0 -29.800 0.221
## 3 bootstrap    A1-A0 -29.800 0.231
## 5 permutation   A1-A0 -29.800 0.257
## 2 asymptotic   A1/A0   0.735 0.237
## 4 bootstrap    A1/A0   0.735 0.231
## 6 permutation   A1/A0   0.735 0.241
```

Augmentation Analysis

```
## Marginal Areas:
##   arm  n tau area  se
## 1   0 47  60 113.0 16.8
## 2   1 38  60  82.8 17.6
##
##
## CIs:
##      method contrast observed      se lower upper
## 1 asymptotic   A1-A0   -39.2 22.6 -83.5  5.17
## 2 bootstrap    A1-A0   -39.2 22.6 -82.2  5.34
##
##
## P-values:
##      method contrast observed      p
## 1 asymptotic   A1-A0   -39.2 0.0834
## 2 bootstrap    A1-A0   -39.2 0.0900
## 3 permutation   A1-A0   -39.2 0.1250
```

Recurrence with Death as a Competing Risk



Baseline Analysis

```
## Marginal Areas:
##   arm  n area  se tau
## 1    0 47 89.9 14.2  60
## 2    1 38 58.5 13.4  60
##
##
## CIs:
##   method contrast observed    se  lower upper
## 1 asymptotic   A1-A0  -31.400 19.500 -69.700  6.85
## 3 bootstrap    A1-A0  -31.400 19.700 -68.700  6.90
## 2 asymptotic   A1/A0   0.651  0.181  0.377  1.12
## 4 bootstrap    A1/A0   0.651  0.186  0.348  1.10
##
##
## P-values:
##   method contrast observed    p
## 1 asymptotic   A1-A0  -31.400 0.108
## 3 bootstrap    A1-A0  -31.400 0.109
## 5 permutation   A1-A0  -31.400 0.148
## 2 asymptotic   A1/A0   0.651 0.122
## 4 bootstrap    A1/A0   0.651 0.109
## 6 permutation   A1/A0   0.651 0.122
```

Augmentation Analysis

```
## Marginal Areas:
##   arm  n tau area   se
## 1   0 47  60 89.9 14.2
## 2   1 38  60 58.5 13.4
##
##
## CIs:
##   method contrast observed   se lower upper
## 1 asymptotic   A1-A0    -37.8 18.4 -73.9 -1.65
## 2 bootstrap    A1-A0    -37.8 18.6 -74.9 -1.64
##
##
## P-values:
##   method contrast observed    p
## 1 asymptotic   A1-A0    -37.8 0.0404
## 2 bootstrap    A1-A0    -37.8 0.0400
## 3 permutation   A1-A0    -37.8 0.0760
```