

Evaluating and Extending Three-Arm Study in the Treatment of Superficial Bladder Cancer

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Background

Superficial Bladder Cancer

- ▶ Also known as Stage 1 bladder cancer
- ▶ Common diagnosis (75% of bladder cancer cases¹) and rarely life-threatening on its own.
- ▶ Thought to arise due to urinary issues¹ or through “abnormalities of tryptophan metabolism”²
- ▶ Particular interest in preventing recurrence of disease
 - ▶ Natural history study conducted in Sweden saw that “death was directly related to tumor grade, number of tumors, and volume of recurrences.”³

Pyridoxine and Thiotepa

- ▶ *Pyridoxine* (vitamin B_6) thought to reduce “abnormalities of tryptophan metabolism”
- ▶ *Thiotepa* has been the standard of care for the treatment of superficial bladder cancers.
- ▶ Effects of these two therapies compared in randomized clinical trial conducted by Byar and Blackard in 1977

Byar and Blackard (1977)

- ▶ Primary clinical interest: prevent and reduce recurrence of Stage 1 bladder cancer.
- ▶ Event time agnostic analysis conducted included comparing overall rates and percentages of occurrence between groups
 - ▶ Pairwise difference detected in rate of recurrence between thiotepa and placebo, and thiotepa and pyridoxine
 - ▶ No other differences in event incidence between groups detected
- ▶ Survival analysis conducted involved the construction of life-table estimates.
 - ▶ Life-table analysis indicate that the time to first recurrence was significantly different between pyridoxine and placebo groups.
 - ▶ Analysis restricted to subjects who experienced recurrence after at least 10 months of follow-up

Proposed Project

Motivation

- ▶ Research ought to be reproducible, especially if data has become open-source
- ▶ Different models may be more informative than just the actuarial curves constructed

Analysis Plan

1. Reproduce analysis conducted in original study to see if results are reproducible
2. Construct models that differ from original study to see if they can be more informative

References

1. Superficial bladder cancer. Division of Urologic Surgery. (n.d.). Retrieved from <https://urology.wustl.edu/urologic-cancers/bladder-cancer/surgery-for-superficial-b/>
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3. Pasin, E., Josephson, D. Y., Mitra, A. P., Cote, R. J., & Stein, J. P. (2008). Superficial bladder cancer: An update on etiology, molecular development, classification, and natural history. Reviews in urology. Retrieved December 3, 2022, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2312342/>