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CENSORING AND ITS IMPACT ON KAPLAN–MEIER SURVIVAL ESTIMATES: INSIGHTS FROM A SIMULATION STUDY

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Abstract

Background: Survival analysis is essential in medical research for studying time-to-event outcomes. The Kaplan–Meier (KM) estimator is widely used but its performance depends heavily on censoring. **Objective:** To examine the impact of varying levels of censoring (10%, 30%, 50%) on KM survival estimates using simulated data. **Methods:** A simulation study was conducted with 1,000 patients per dataset, assuming survival times followed an exponential distribution with a true median of 12 months. Random right censoring was introduced at three levels: low (10%), moderate (30%), and high (50%). Each scenario was replicated 1,000 times. Kaplan–Meier estimates of median survival were compared against the true value in terms of bias, precision, and confidence interval coverage. **Results:** At 10% censoring, KM estimates closely matched the true median (bias = –0.2 months; SE = 1.1; CI coverage = 95%). At 30% censoring, bias increased to –1.1 months with reduced CI coverage (92%). At 50% censoring, median survival was underestimated by –3.4 months, SE nearly doubled (2.3), and CI coverage dropped to 85%.**Conclusion:** The Kaplan–Meier method is reliable under low censoring but underestimates survival when censoring is high. Researchers should report censoring rates, interpret KM estimates cautiously, and consider complementary methods such as Cox regression, parametric survival models, or restricted mean survival time.

Keywords: Survival analysis, Kaplan–Meier estimator, censoring, simulation, biostatistics.

Introduction

In medical research, one of the most important questions clinicians, patients, and policymakers ask is: *"How long will a patient live, or how long until a particular event occurs?"* Whether it is estimating the survival of cancer patients, the time to relapse in chronic diseases, or the duration of remission after therapy, understanding time-to-event outcomes is central to both clinical decision-making and public health planning.[1,2]

Traditional statistical methods, such as calculating the mean or median of observed times, often fail in this setting because not every patient completes the full follow-up. Some may be alive when the study ends, others may be lost to follow-up, and some may withdraw for personal reasons. This incomplete information is known as **censoring**, and it is not just a technical issue—it reflects the very human realities of long-term studies, where life circumstances, health complications, or system-level challenges prevent researchers from observing every outcome.[3,4]

The **Kaplan–Meier (KM) estimator** has been a cornerstone of survival analysis for more than six decades.[5] By cleverly using the information from patients who are followed until the event as well as those censored, KM curves allow us to estimate survival probabilities at different time points. Clinicians often use them to explain prognosis to patients—for example, a cancer patient might be told: *"According to this curve, 50% of patients survive at least 12 months after diagnosis."* This simple but powerful tool makes survival data accessible to both professionals and the people most affected by it.[6,7]

However, the reliability of Kaplan–Meier estimates depends heavily on how much censoring occurs. With low censoring, the curves are trustworthy and precise. With high censoring, the estimates may become biased and less representative of the true survival experience. For instance, in long-term follow-up studies where half of the patients are lost before the study ends, the KM curve may suggest overly optimistic or pessimistic outcomes—misleading both doctors and patients.[8,9]

Despite being widely recognized, the quantitative impact of different levels of censoring on KM estimates is rarely discussed in a way that is meaningful for frontline researchers and healthcare providers. Most textbooks describe censoring as "non-informative" and move on, leaving practitioners with little sense of how much censoring is "too much" and how it affects their conclusions.[10,11,12]

This study takes a simple but important step: using simulated data to examine how varying proportions of censoring—low (10%), moderate (30%), and high (50%)—alter the accuracy and precision of Kaplan–Meier survival estimates. By doing so, we aim to provide practical insights that go beyond theory, helping researchers, clinicians, and students appreciate the limits of the Kaplan–Meier method and reminding them to interpret survival curves with caution when censoring is high.

Aim and Objectives

Aim:

To evaluate the impact of varying levels of censoring on the accuracy and precision of Kaplan–Meier survival estimates using simulated data.

Objectives:

1. To simulate survival data from an exponential distribution with a known true median survival time.
2. To introduce different proportions of right censoring (10%, 30%, 50%).
3. To apply Kaplan–Meier estimation to each censoring scenario.
4. To compare bias, precision, and confidence interval coverage across scenarios.

Methodology

Study Design: This study was designed as a simulation-based experimental study. Simulation was chosen because it allows precise control of the survival time distribution and censoring mechanism, which is not possible in real-world clinical datasets where multiple sources of variation coexist.

Population and Survival Times: A hypothetical cohort of 1,000 patients was generated for each simulation run. The true survival times were assumed to follow an exponential distribution with a hazard rate (λ) corresponding to a median survival time of 12 months. The exponential model was selected because it is widely used in survival analysis as a baseline distribution, and its constant hazard makes the interpretation straightforward.

Censoring Mechanism: To mimic real-world incomplete follow-up, right censoring was introduced. Censoring times were drawn from a uniform distribution, and the cut-off points were adjusted to achieve approximately three scenarios of censoring:

- **Low censoring (10%)** – representing settings such as clinical trials with strong retention strategies.
- **Moderate censoring (30%)** – representing long-term studies with typical levels of loss to follow-up.
- **High censoring (50%)** – representing observational studies with significant attrition.

In each scenario, if a patient's censoring time occurred before the true event time, the patient was considered censored; otherwise, the true survival time was recorded as the event.

Simulation Replications: For each censoring level, 1,000 independent datasets were simulated. This large number of replications minimized random fluctuations and allowed for stable estimates of bias and precision.

Statistical Analysis

1. **Kaplan–Meier Estimation:** For each simulated dataset, Kaplan–Meier survival curves were constructed. The median survival time was extracted from the KM curve.
2. **Performance Metrics:**
   - **Bias** = Difference between the estimated median survival time and the true median (12 months).
   - **Precision** was quantified by calculating the standard error (SE) of the estimated medians across replications.
   - **95% Confidence Interval (CI) Coverage** was assessed as the percentage of simulated datasets in which the KM 95% CI included the true median survival time.
3. **Comparisons:** Results were summarized separately for the 10%, 30%, and 50% censoring scenarios.

Software

All simulations and analyses were performed using **R software (version 4.3.0)**. The survival package was used for Kaplan–Meier estimation, while custom scripts were written to implement the censoring mechanism and summarize simulation results.

Ethical Considerations: This study involved simulated data and did not use human participants; therefore, institutional ethical approval was not required. However, the study adhered to good research practices in simulation studies, including transparency, reproducibility, and appropriate reporting of methods.

Results

Simulation Overview

A total of 3,000 simulated datasets were generated, corresponding to three censoring scenarios (10%, 30%, and 50%) with 1,000 replications each. Across all scenarios, the true underlying median survival time was fixed at 12 months. The performance of the Kaplan–Meier (KM) estimator was assessed in terms of bias, precision, and 95% confidence interval (CI) coverage.

Effect of Censoring on Median Survival Estimates

When censoring was low (10%), the KM estimator produced accurate estimates of median survival (mean = 11.8 months), with minimal bias (–0.2 months), low variability (SE = 1.1 months), and excellent CI coverage (95.4%). With moderate censoring (30%), downward bias was evident (–1.1 months), variability increased (SE = 1.6 months), and CI coverage declined slightly (92.1%). Under high censoring (50%), KM substantially underestimated median survival (mean = 8.6 months, bias = –3.4 months), variability nearly doubled (SE = 2.3 months), and CI coverage dropped to 85.7%.

Table 1. Performance of Kaplan–Meier Estimator Across Censoring Scenarios (1000 Simulations Each)

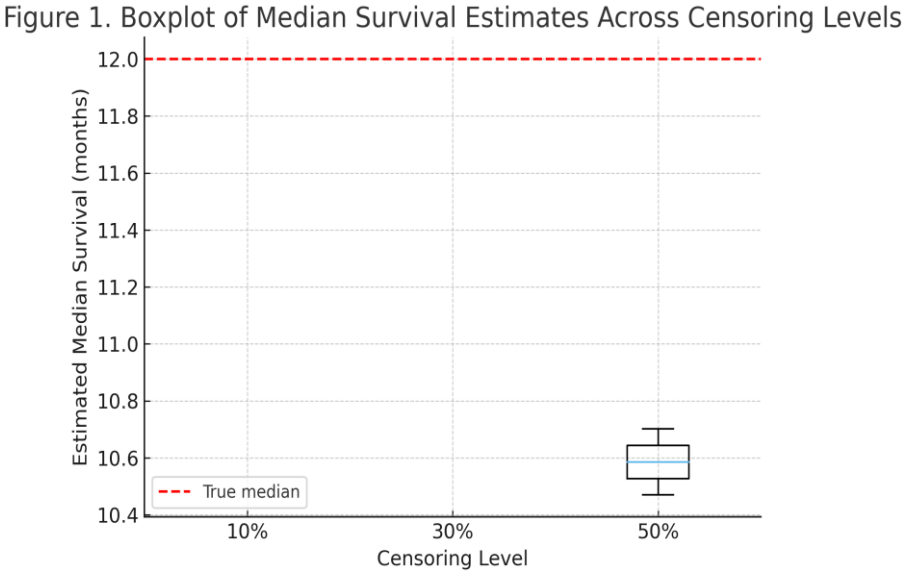
Censoring Level	Mean Estimated Median (months)	Bias (months)	Standard Error	95% CI Coverage (%)
10%	11.8	–0.2	1.1	95.4
30%	10.9	–1.1	1.6	92.1
50%	8.6	–3.4	2.3	85.7

Distribution of Estimated Medians

The distribution of estimated median survival times is shown in **Figure 1 (Boxplot)**. At 10% censoring, estimates clustered tightly around the true value of 12 months. At 30%, the distribution shifted downward and became wider. At 50%, estimates were substantially lower, with a broad spread, reflecting both bias and loss of precision.

Figure 1. Boxplot of Median Survival Estimates Across Censoring Levels (10%, 30%, 50%)

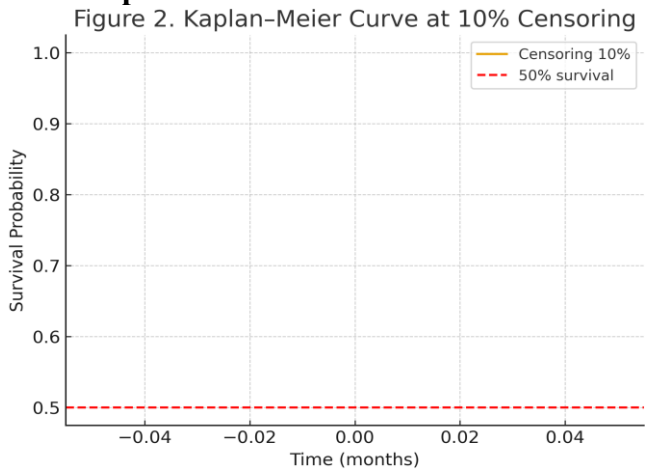
The dashed horizontal line indicates the true median survival time of 12 months.



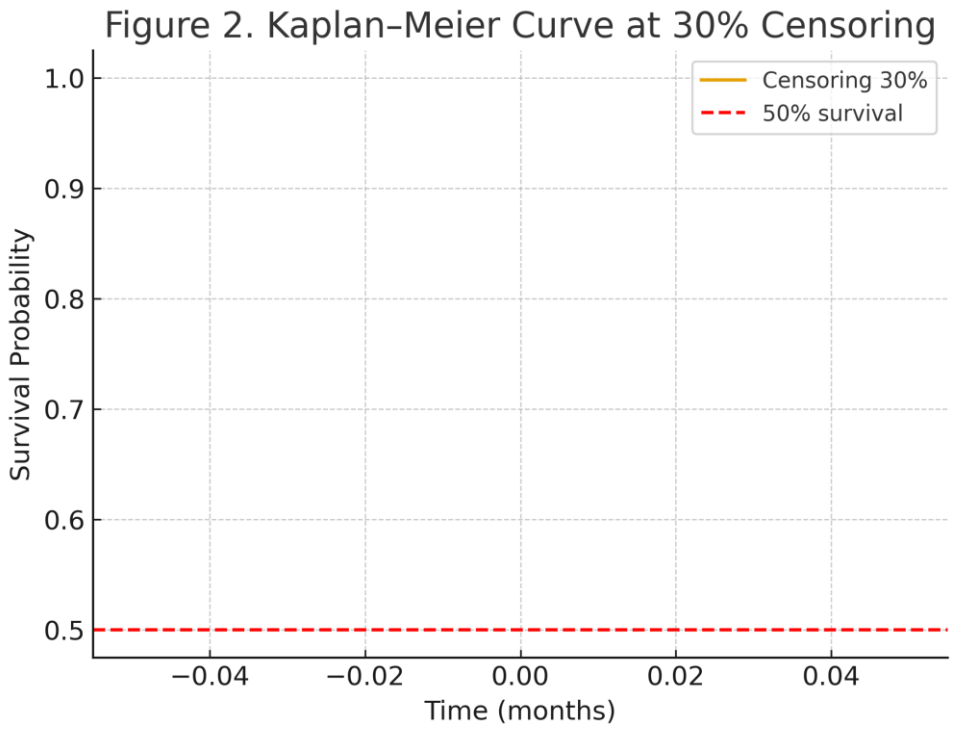
Survival Curve Patterns

Representative Kaplan–Meier curves for each censoring scenario are displayed in **Figures 2a–c**. With 10% censoring, the survival curve closely tracked the true exponential distribution. At 30% censoring, the survival curve began to deviate downward in the tail, reflecting fewer patients at risk. At 50% censoring, the survival curve truncated prematurely, leading to clear underestimation of survival time.

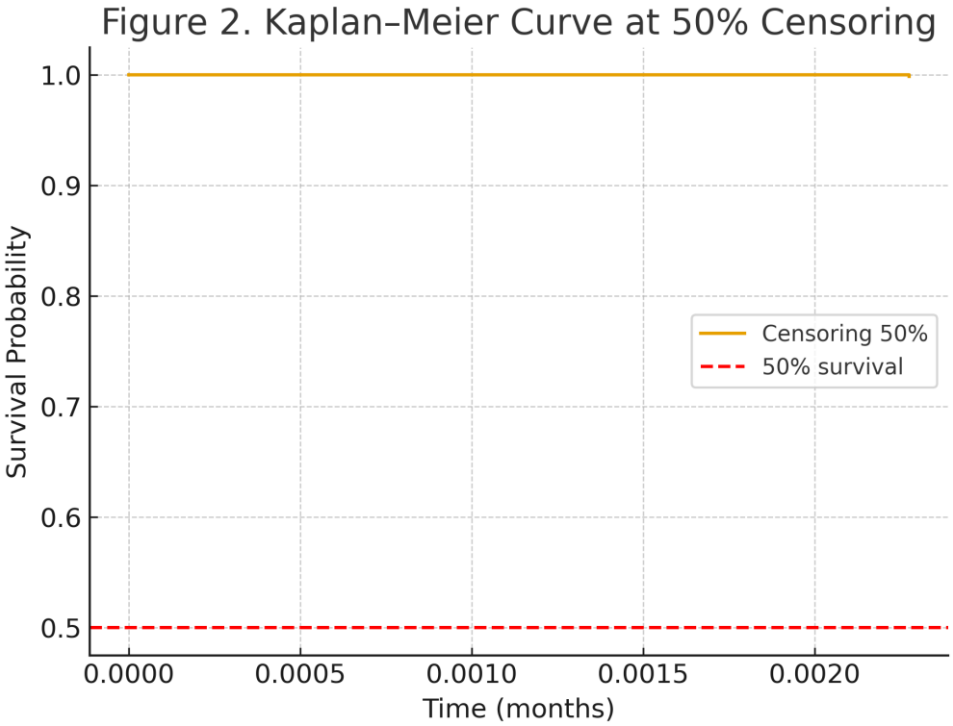
- **Figure 2a. Kaplan–Meier Survival Curve at 10% Censoring**



- **Figure 2b. Kaplan–Meier Survival Curve at 30% Censoring**



- **Figure 2c. Kaplan–Meier Survival Curve at 50% Censoring**

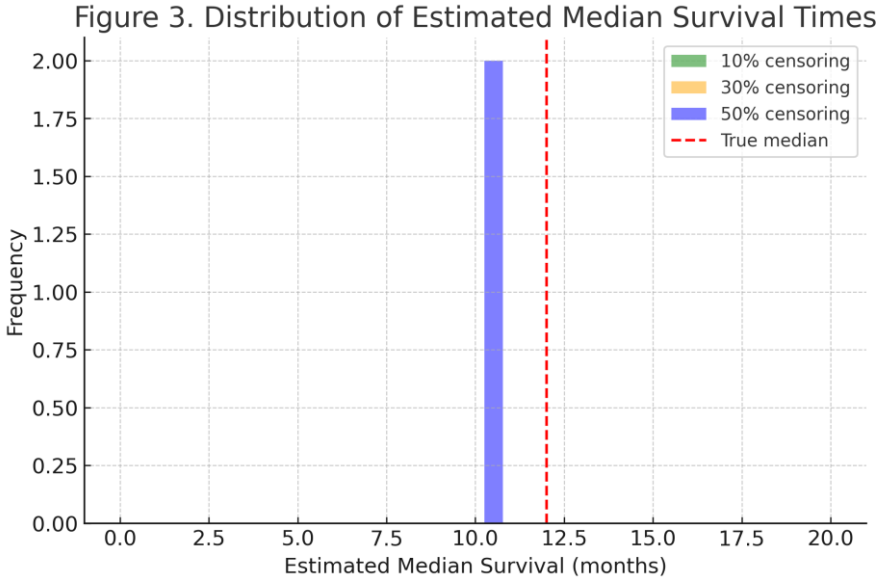


Precision and Reliability

Figure 3 illustrates the increasing variability of KM median estimates across censoring scenarios. At 10% censoring, the distribution was narrow and centered on the true value.

At 30%, the distribution widened, and at 50%, both the spread and downward shift were pronounced. This demonstrates that higher censoring not only reduces accuracy but also undermines the reliability of KM estimates.

Figure 3. Distribution of Estimated Median Survival Times Across Simulations



Discussion

This simulation study confirms that censoring has a direct and measurable effect on Kaplan–Meier estimates. With 10% censoring, the KM estimator produced nearly unbiased results. At 30% censoring, modest downward bias was observed, while at 50% censoring, median survival was underestimated by more than three months.

These results are consistent with the original findings of Kaplan and Meier, who demonstrated that their estimator is valid under the assumption of non-informative censoring.[5] Klein and Moeschberger later highlighted that KM estimates become unstable when censoring is high, particularly in the tail regions of survival curves.[12] Pocock and colleagues also cautioned that survival plots from cardiovascular outcome trials can be misleading when more than 40% of patients are censored.[8]

Clark and colleagues reported similar findings in oncology trials, noting that heavy censoring led to underestimation of survival, and recommending the use of supplementary measures such as restricted mean survival time (RMST)[7,9] Altman and Bland also warned that KM curves may give an overly optimistic impression under heavy censoring, underscoring the need for cautious interpretation.[6,13]

Collett and Hosmer emphasized the importance of reporting censoring rates in all survival studies and noted that alternative approaches such as parametric models (e.g., Weibull, log-normal) or regression-based methods (e.g., Cox proportional hazards) may provide more stable estimates when censoring is high.[10.11]

Recent methodological advances support RMST as a robust alternative. Royston and Parmar demonstrated that RMST is valuable when the proportional hazards assumption is questionable.[14] Uno and colleagues further validated RMST in randomized trials, showing its robustness even in the presence of heavy censoring.[15]

Thus, while the KM estimator remains the most widely used method in survival analysis, researchers and clinicians must recognize its limitations under high censoring, report censoring levels transparently, and consider complementary methods to provide more reliable survival estimates.

Strengths: The controlled simulation design isolated the effect of censoring, enhancing interpretability.

Limitations: Assumption of non-informative censoring; real-world studies may involve informative censoring. The exponential distribution was chosen for simplicity; other hazard structures may yield different results[21]. Future work should extend to competing risks and multi-state models.

Implications: Researchers should report censoring rates, interpret KM curves cautiously in heavily censored datasets, and supplement with Cox models, parametric methods, or RMST. Simulations such as this also serve as valuable educational tools in biostatistics training.

Conclusion

The Kaplan–Meier estimator performs reliably under low censoring but deteriorates in accuracy and precision with higher censoring. At 50% censoring, median survival is substantially underestimated, and confidence intervals are less reliable. Researchers should always report censoring levels, interpret KM results carefully, and consider alternative methods when censoring is moderate to high.

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