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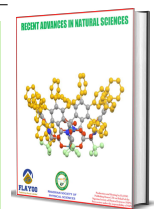

Bernoulli-exponential survival model for estimating proportions in randomised controlled trials with dropouts

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ABSTRACT

Randomised controlled trials often experience dropouts, especially in multi-stage designs where participants must meet induction-phase eligibility requirements before progressing to the main study. Loss of information arising from early non-responders or withdrawal of clinically vulnerable subjects are not always random. Classical survival analysis methods including the Kaplan-Meier estimator, exponential models, and similar techniques assume independent censoring. When this assumption is violated, survival probabilities are overstated, hazard rates are underestimated, and median survival time become biased. Such dropout mechanisms also lead to biased estimates of the proportion of participants who would experience the clinical endpoint, thereby distorting treatment effect measures based on event counts. This study proposed a Bernoulli-Exponential (BE) model that jointly represents the occurrence of an event and the time to event, rather than treating censored subjects as if they share the same risk structure as event completers. The model incorporates a Bernoulli component to describe the probability of belonging to the event-generating subgroup and an exponential component to model event times conditional on experiencing the event. This separation enables the model to account for informative dropouts, induction-phase failures, and scenarios where some participants contribute no event time. We derive the parameter estimates, survival function, and outline procedures for estimating the median survival time, its variance, and confidence interval. Simulation studies were used to assess bias and precision under varying levels of dropout. The BE estimator consistently corrected the upward bias observed in Kaplan-Meier, intention-to-treat, and completers-only estimates under heavy or informative dropout.

1. INTRODUCTION

In classical parametric survival models, such as the Exponential and Weibull models, it is commonly assumed that the survival function approaches zero as time approaches infinity; that is, given sufficient time, all individuals will eventually experi-

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ence the event of interest [1–3]. Similarly, non-parametric models such as the Kaplan-Meier (KM) estimator also rely on the assumption that all study subjects are eventually at risk. These models handle incomplete observations arising from study withdrawal, loss to follow-up, or other intercurrent events by treating them as right-censored. This approach assumes that censoring is non-informative, implying that the reason for censoring is unrelated to the subject's likelihood of experiencing the event [3–5]. However, in randomised controlled trials (RCT), especially those involving long term follow-up or complex adaptive designs, a subset of participants may never be truly at risk of the event. This is because, in trials with induction phases, participants usually receive initial intervention and are required to meet specific response criteria before proceeding to the main study phase. Participants who do not respond during induction phase are excluded from main phase intervention and are usually treated as dropouts (also referred to as induction failure). Furthermore, withdrawal due to worsening symptoms, withdrawal due to feeling better, toxicity-based removal and missing not at random (MNAR) missingness also belong to a class of informative censoring. Conventional survival models treat such early dropouts as right-censored observations, even though these participants are fundamentally different from those who continue in the trial. In such settings, the assumption that all individuals will eventually experience the event of interest in the long-run may not hold. Consequently, conventional survival models may not adequately capture the underlying survival process which may lead to biased survival estimates resulting in misleading inferences. This underscores the need for alternative modeling technique that can explicitly account for the possibility that some participants may never experience the event either due to drop out, cure, or structural design of the trial and thereby more accurately represent the survival trend in such design scenarios.

Furthermore, randomised controlled trials designed with binary outcome as the primary endpoint of interest are often assessed by estimating the proportion of study participants who achieved the event during the study/follow-up period. This proportion is estimated using Intent-To-Treat (ITT) method which divides the number of participants that achieved the event by the totat number of participant in the study. However, for some reasons, some participants, who may not have achieved the event of interest drop out of the study before the end of study/follow-up period. These participants tend to inflate the denominator of the proportion estimated using ITT method, making it biased.

In the domain of classical parametric survival models, studies have shown that popular survival models such as Exponential and Weibull distributions can yield biased mean survival estimates in datasets with cured or long-term survivors. This is associated with the failure of the assumption that all study participants will eventually experience the event of interest in the long-run and this have birthed the mixture cure models (MCM) [6]. The MCM methodology involve segmenting the study population into a susceptible versus cured subgroups, estimating both the cure probability and survival of uncured participants [6]. The MCM has been used in estimating cure proportion and to model durable responses in cancer studies, with extensions to include parametric distributions for the uncured subgroups [7]). Recent innovations to improve the MCM in the setting of Neural networks, support vector machines, and Bayesian methods to model both incidence (cure fraction) and latency (time to event) [8, 9]; dependent censoring and recurrent events for estimating a cure fraction in the framework of joint frailty model [10]; a mixture cure modeling methodology for analysing clustered and interval-censored survival time data by incorporating random effects in both the logistic regression and proportional hazard regression components in the framework of generalized linear mixed model [11]. The implementation of INLA in mixture cure models in the framework of general mixture cure survival model with covariate information for the latency and the incidence model with censored and non-censored information [12]. Inspite their power, mixture cure models face some challenges namely:

(a) Sensitivity to follow-up duration: Trial duration and data density are expository analytic inputs for reliable identification and classification of cured fractions and hence, insufficient and sparsed follow up can simulate a cure plateau, resulting in biased cure and survival estimates [6].

(b) Parametric assumptions: Conventional MCM often rely on the assumption of a pre-specified hazard shapes (e.g., Weibull) for the uncured subpopulation, however, this assumption may fail or may not fit all study design settings [13, 14]

(c) Structural dropouts in adaptive designs: Trials with induction phases produces dropouts due to non-response leading to "not at-risk" censoring. These individuals are often misclassified, and current methods do not typically distinguish them structurally, despite differences in their risk profile.

These challenges show that classical survival models can misrepresent survival outcomes when some study participants do not experience the event of interest. The Mixture cure models is an improvement on this. However, it rely heavily on follow-up length and parametric structures, and may not explicitly capture dropouts from induction stage designs. Therefore, a model that explicitly classify subjects into response versus non response, models timing for subjects who remain at risk, and allows a positive cure/dropout fraction, is necessary to accurately capture data density particularly from trials with staged designs and notable dropouts.

In the domain of proportion estimation for evaluation of trial outcomes , Weichung [15] have raised concerns that even modest dropout due to nonresponse or adverse events can bias treatment effect estimates and violate assumptions of random missingness. The ITT methodology for estimating proportion requires that all randomised subjects be analysed in their assigned study arm, irrespective of adherence or dropout. This method retain the original randomisation and guards against selection bias. However, ITT can be misleading when outcome data are missing or censored due to dropout, especially if dropouts are related to prognosis or treatment assignment [16]. With substantial dropout, the ITT usually underestimates treatment effects and reduces statistical power (for instance, hospice/palliative care trials suffer substantial power loss when participants withdraw before exposure [17]. Modified ITT analyses available in clinical trials may deviate from the strict ITT definition and often rely on unverifiable

assumptions on the missing data mechanism [18]. Completers-only (CO) method estimate event proportions absolutely among subjects who complete the study/follow-up. This approach may overestimate event rates by ignoring dropouts, hypothetically assuming that missingness is completely at random (MCAR) [19]. Furthermore, the CO estimation technique ignore valuable information held in dropout timing, leading to inefficient or biased inference. The Kaplan-Meier (KM) method can improve proportion estimation by using follow-up times and treating dropouts as right-censored. It provides less biased and more efficient estimates than ITT and CO, particularly when censoring occurs mid-study [19]. However, KM still makes critical assumptions namely:

(a) Non-informative censoring: dropout timing is not related to event risk.

(b) No defined cure/dropout fraction: it assumes that if all study participants are followed long enough, they would eventually experience the event (i.e., S(t) → 0 as t → ∞), which may be unrealistic in trials with early withdrawal stages or induction-phase designs.

Since ITT inflates denominators by assuming dropouts will never experience the event, biasing estimates downward; CO overestimates the treatment effect by excluding dropouts, sometimes unjustifiably and the KM, although an improvement, still assumes all study participants are at risk indefinitely and that censoring is non-informative, which often fails in trials involving induction-stage dropouts or potential cured subgroups, the need for a new modeling approach arises from these limitations of ITT, CO, and KM.

This article proposes a probability model with survival function alternative modeling technique that can explicitly account for the possibility that some participants may never experience the event either due to drop out, cure, or structural design of the trial and thereby more accurately represent the survival trend in such design scenarios while simulataneously estimating the treatment effect in the form of proportion of study participants who achieved an event during the study/follow-up period.

The proposed Bernoulli-Exponential (BE) model shares conceptual similarities with cure models, particularly mixture-cure frameworks, where the population is partitioned into susceptible and non-susceptible subgroups. However, cure models typically require long-term follow-up to reliably estimate the cure fraction and are sensitive to heavy censoring. Additionally, estimation often relies on complex EM algorithms or semiparametric assumptions [20–22]. In contrast, the BE model directly separates the event-generating mechanism (Bernoulli component) from the timing mechanism (Exponential component), allowing valid inference even when follow-up duration is short and dropout is informative.

2. THE PROPOSED BERNOULLI-EXPONENTIAL MIXTURE MODEL

Let $X \sim$ Bernoulli (π) represent whether an event occurs ($X = 1$) or the participant is censored ($X = 0$) then the probability distribution function of X is given as:

$$p(X = x) = \pi^x(1-\pi)^{1-x}, x = 0, 1. \quad (1)$$

Given $X = 1$, time to event T follows an exponentian distribution with probability density function given as:

$$f_{T|X=1}(t) = \lambda e^{(-\lambda t)},\ t \geq 0. \quad (2)$$

If $X = 0$, the subject is censored, indicating there is no observed event time. Since censored individuals have no observed event time, their contribution is a point mass at infinity. Thus, the marginal probability density function (*pdf*) of T under this mixture model is:

$$f_T(t) = p(x = 1)f_{T|x=1}(t) + p(x = 0)f_{T|x=0}(t = \infty), t \geq 0. \quad (3)$$

Substituting (1) and (2) in (3) would lead to the marginal *pdf* given as:

$$f_T(t) = \pi\lambda e^{-\lambda t} + (1-\pi)\lambda e^{-\lambda\times\infty}. \quad (4)$$

Since $e^{-\lambda\times\infty} = 0$, the marginal *pdf* would simplify to:

$$f_{BE}(t) = \pi\lambda e^{-\lambda t}. \quad (5)$$

Figure 1 shows the PDF of BE model. The corresponding cummulative distribution function, *CDF* for $f_{BE}(t)$ in (5) is given as:

$$F_{BE}(t) = \int_0^t \pi\lambda e^{-\lambda t} = \pi(1 - e^{-\lambda t}). \quad (6)$$

The survival function derived from the Bernoulli-Exponential distribution in Equation (5) in the context of survival analysis is given as:

$$S_{BE}(t) = P(T > t) = 1 - F_{BE}(t). \quad (7)$$

Substituting $F_{BE}(t)$ in Equation (7) result in the survival function for the Bernoulli-Exponential model given as:

$$S_{BE}(t) = (1-\pi) + \pi e^{-\lambda t},\ t > 0, \quad (8)$$

with the corresponding quantile function given as:

$$Q_{BE}(p) = F_{BE}^{-1}(p) = -\frac{1}{\lambda} ln\left[1 - \frac{p}{\pi}\right], 0 < p < \pi. \quad (9)$$

The survival function in Equation (8) adjusts the standard exponential survival function by modeling the risk set as consisting of two latent subgroups: those who will eventually experience the event with event probability denoted as π and those who will never experience the event (dropouts or cured) with probability denoted as $(1-\pi)$. It suffices from this survival model that:

(a) The model generalizes the exponential distribution by incorporating censoring probability $(1-\pi)$.

(b) The survival function $S_{BE}(t)$ decays more slowly than the exponential and Weibull survival function because some subjects never experience the event.

(c) If $\pi = 1$, (ie no censoring), the survival model reduced to a standard exponential model.

(d) If $\pi < 1$, the survival probability asymptotes to $(1-\pi)$ rather than decaying to 0 and hence, this accounts for the fraction of censored participants, implying that a fraction of the study population remain censored indefinately.

(e) The model allows for estimation of event rate (λ) and probability of an observed event (π).

(f) The hazard function $h_{BE}(t)$ decreases over time rather than remaining constant.

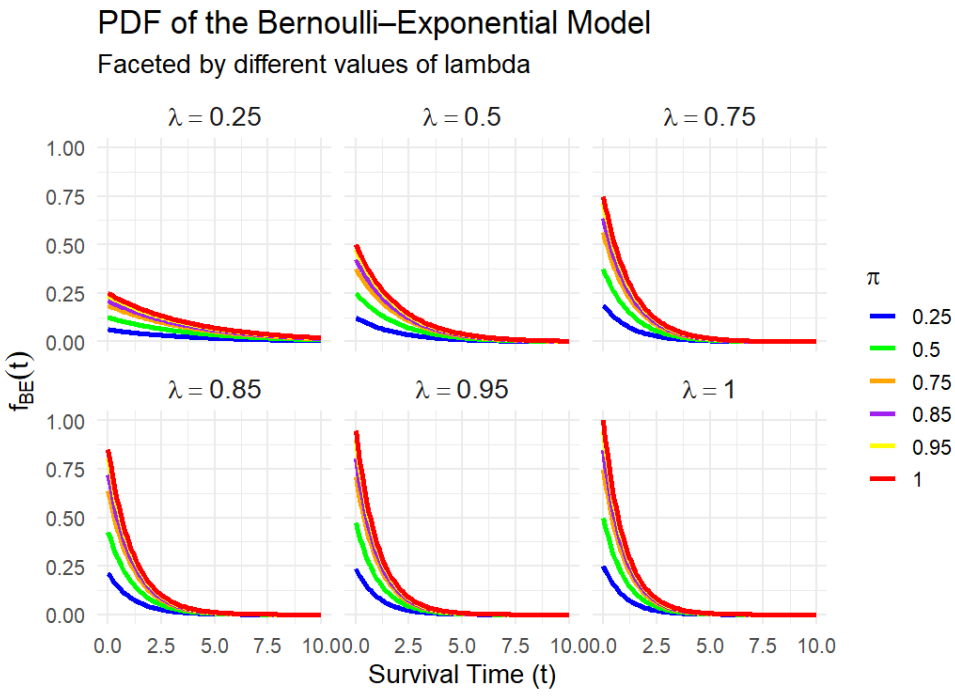

Figure 1. PDF of BE model.

2.1. HAZARD FUNCTION FOR THE BERNOULLI-EXPONENTIAL MODEL

Given the pdf $f_{BE}(t)$ in Equation (5) and the survival function $S_{BE}(t)$ in Equation (8), the hazard function for the Bernoulli-Exponential model is defined as:

$$h_{BE}(t) = \frac{f_{BE}(t)}{S_{BE}(t)} = \frac{\pi\lambda e^{-\lambda t}}{(1-\pi)+\pi e^{-\lambda t}} = \lambda \times \frac{\pi e^{-\lambda t}}{(1-\pi)+\pi e^{-\lambda t}}. \tag{10}$$

Suppose we define [2, 4, 23, 24]:

$$R(t) = \frac{\pi e^{-\lambda t}}{(1-\pi)+\pi e^{-\lambda t}}, \tag{11}$$

to be the conditional probability that the subject is at risk at time t so that

$$h_{BE}(t) = \lambda \times R(t), \tag{12}$$

is a weighted hazard defined as the product of the exponential hazard λ and the probability that the subject is a member of the ‘‘at-risk" subpopulation, given that the subject survived until time t. This Bernoulli-Exponential hazard function is not constant even though the conditional distribution for susceptible subject is exponential. The reason is that $R(t)$, the probability of being at risk at time t declines over time because:

$$R(t) = \frac{\pi e^{-\lambda t}}{(1-\pi)+\pi e^{-\lambda t}} \to 0 \; as \; t \to \infty, \tag{13}$$

so, $h_{BE}(t) \to 0$ as $t \to \infty$ which is the contrasts of the classical exponential hazard, with is constant hazard at λ.

2.1.1. Inference about Bernoulli-exponential hazard function

Several important conceptual and practical inferences can be drawn from the nature of $h_{BE}(t)$, these include:

(a) The Bernoulli-Exponential model has an early hazard that mimics the pattern of exponential hazard function, that is, at $t = 0$:

$$R(0) = \frac{\pi}{(1-\pi)+\pi} = \pi \Rightarrow h_{BE}(0) = \lambda\pi. \tag{14}$$

Hence, the initial hazard is a scaled version of the exponential hazard such that if $\pi = 1$, we recover the classical exponential case.

(b) The Bernoulli-Exponential hazard decreases over time, that is, since $R(t)$ declines exponentially, the hazard is decreasing, which means that the population appears to “age out” of risk. This is because more survivors are likely to be non-susceptible in the subgroup of the $1-\pi$ cured/dropout fraction

(c) The Bernoulli-Exponential hazard has a component $R(t)$ which can be viewed as the conditional probability, under the model assumption, that a participant belongs to the event-prone subgroup given survival up to time t:

$$R(t) = P(at \; risk | T > t). \tag{15}$$

This gives the hazard function an intuition that, as time goes on and a subject hasn’t experienced the event, it becomes more likely they are part of the non-susceptible group.

(d) The Bernoulli-Exponential hazard flexibility makes it more realistic for many clinical applications where:

(i) events starts high and drops (e.g., in oncology, or in trials where events occure at early stage),

(ii) there is need to account for cured/dropout fractions,

(iii) there is need to provide a nuanced explanation for long tails in survival.

From Figure 2, the behavior of the Bernoulli–Exponential model hazard function, $h_{BE}(t)$ depict how dropout-adjusted survival processes evolve over time. Firstly, it can be seen that an increase in the event rate parameter λ results in a higher hazard across all time point given a fixed value of the probability that a subject is susceptible, π. This is obvious because λ directly controls the rate at which events occur among susceptible individuals; such that a larger λ implies a more rapid failure process for those at risk. In addition, the influence of π, the probability that a subject is susceptible is comprehensive in that, as π approaches 1 (i.e., nearly all subjects are at risk), the hazard function flattens and tend to the constant hazard of the classical exponential distribution. In this case, the population is completely homogeneous and the model is reminiscent of a pure exponential survival process. However, for smaller values of π (say $\pi \leq 0.5$), the hazard becomes lower and declines more rapidly over time indicating that as time progresses, the probability that a surviving individual belongs to the susceptible group decreases, resulting to a diminishing hazard. Basically, the hazard function is modulated by the conditional probability of being at risk at time t, leading to variable, time-dependent hazard behavior that represent both early-event dynamics and the long-term effect of dropout or cure.

3. ESTIMATION OF PARAMETERS

The maximum likelihood estimate (*MLE*) of parameters π, λ is presented here alonside the mean, median and variance of the survival function.

3.1. LIKELIHOOD FUNCTION

Given that we observe data $\{(x_i, t_i)\}_{i=1}^{n}$ where:

1. $x_i \in (0, 1)$ represents the event indicator (1 = event, 0 = censored),
2. t_i is the time to event for subjects with $x_i = 1$.

The likelihood function is:

$$L(\pi, \lambda) = \prod_{i=1}^{n} P(X_i = x_i) f(t_i | X_i = x_i). \tag{16}$$

Substituting the marginal pdf's of X and t gives:

$$L(\pi, \lambda) = \prod_{i=1}^{n} \left[\pi^{x_i}(1-\pi)^{1-x_i} \times (\lambda e^{-\lambda t})^{x_i}\right]. \tag{17}$$

Taking the product across i:

$$L(\pi, \lambda) = \pi^{\sum x_i}(1-\pi)^{n-\sum x_i} \lambda^{\sum x_i} e^{-\lambda \sum x_i t_i}. \tag{18}$$

Define:

1. $n_1 = \sum_{i=1}^{n} x_i$ (number of events),
2. $V = \sum_{i=1}^{n} x_i t_i$ (sum of event times) .

Equation (18) becomes:

$$L(\pi, \lambda) = \pi^{n_1}(1-\pi)^{n-n_1} \lambda^{n_1} e^{-\lambda V}. \tag{19}$$

3.2. LOG-LIKELIHOOD FUNCTION

Taking the natural logarithm of Equation (19) gives:

$$\ell(\pi, \lambda) = n_1 \log \pi + (n - n_1) \log(1 - \pi) + n_1 \log \lambda - \lambda V. \tag{20}$$

Solving the partial derivatives $\frac{\partial \ell(\pi,\lambda)}{\partial \pi} = 0$ and $\frac{\partial \ell(\pi,\lambda)}{\partial \lambda} = 0$ yields the *MLE* estimates of π and λ respectively as:

$$\pi = \frac{n_1}{n}, \tag{21}$$

and

$$\lambda = \frac{n_1}{V}. \tag{22}$$

3.3. MEAN, MEDIAN, VARIANCE, STANDARD ERROR AND 95% CI FOR SURVIVAL FUNCTION

The mean of the Bernoulli-Exponential distribution is obtained as:

$$E(t) = \int_0^{\infty} f_T(t) dt = \frac{\pi}{\lambda}. \tag{23}$$

The median survival time is obtained by setting $S_T(t) = 0.5$ and solving for $t_{0.5}$:

$$\Rightarrow (1 - \pi) + \pi e^{-\lambda t_{0.5}} = 0.5. \tag{24}$$

The median becomes:

$$t_{0.5} = -\frac{1}{\lambda} ln\left[\frac{0.5 - (1-\pi)}{\pi}\right] = -\frac{1}{\lambda} ln\left[1 - \frac{0.5}{\pi}\right]. \tag{25}$$

Given the survival function in Equation (8), the variance is defined as:

$$Var[S_T(t)] = \pi^2 \left(\frac{1}{1+2\lambda} - \frac{1}{(1+\lambda)^2}\right). \tag{26}$$

The corresponding standard error and 95% confidence interval for the survival function is given as:

$$SE[S_T(t)] = \sqrt{\frac{\pi^2 \left(\frac{1}{1+2\lambda} - \frac{1}{(1+\lambda)^2}\right)}{n}}, \tag{27}$$

$$CI_{95\%} = S_T(t) \pm 1.96 \times SE[S_T(t)]. \tag{28}$$

4. TREATMENT EFFECT (PROPORTION) ESTIMATION

In a randomised control trials (RCT), treatment effects are often estimated as proportion of subjects who satisfied or responded to the primary endpoint of the study. Standard methods for estimating this proportion include the ITT, which counts the number who reached the event of interest divided by the total number of participants, and the completers-only method (CO), which counts the number who reached the event only among those who completed the entire study. When participants drop out of the study early, the ITT and CO methods may either become biased or inefficient. Consider a 2×2 contingency classification in Table 1, where participants in a randomized controlled trial are classified according to their study completion status (rows) and event status (columns). The ITT method would estimate the treatment effect during the study period as:

$$p_{ITT} = \frac{n_{.1}}{N},$$

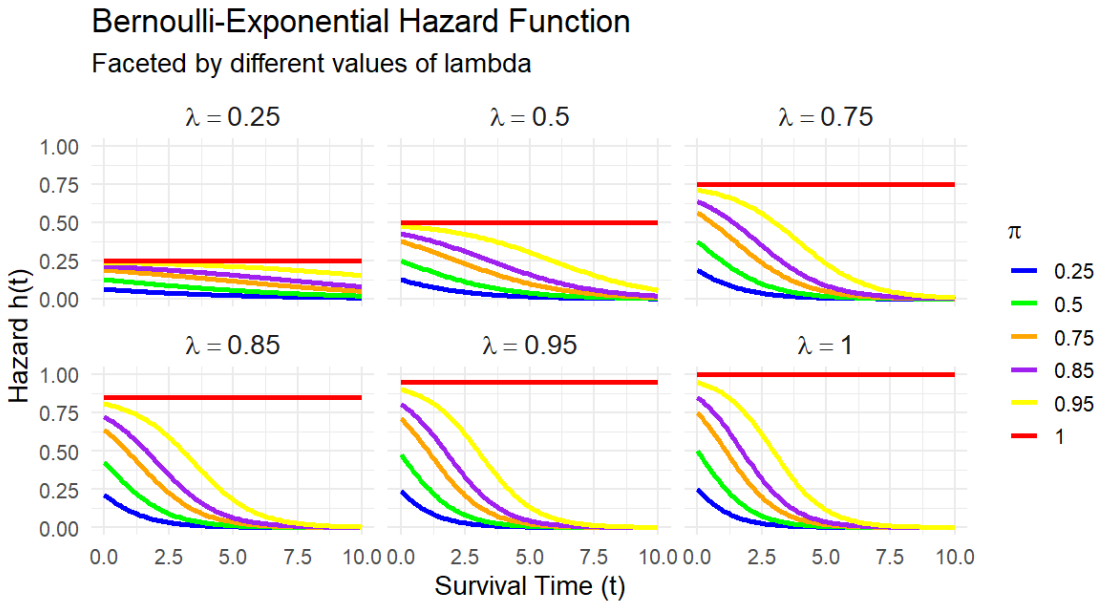

Figure 2. Hazard rate plot.

Table 1. Conceptual cross-classification of completion and event status.

Status	No Event	Event	Total
Dropout	n_{00}	n_{01}	$n_{0\cdot} = n_{00} + n_{01}$
Completed	n_{10}	n_{11}	$n_{1\cdot} = n_{10} + n_{11}$
Total	$n_{\cdot 0} = n_{00} + n_{10}$	$n_{\cdot 1} = n_{01} + n_{11}$	N

with variance given as:

$$ITT_{var} = \frac{p_{ITT}(1 - p_{ITT})}{N}.$$

The completers-only method would estimate the treatment effect during the study period as:

$$p_{CO} = \frac{n_{11}}{n_{1\cdot}},$$

with variance given as:

$$CO_{var} = \frac{p_{CO}(1 - p_{CO})}{n_{1\cdot}}.$$

Recently, Ref. [19] proposed the Kaplan-Meier (KM) method from survival analysis to estimate the proportion of interest in this non-survival setting.

$$S(t) = \begin{cases} 1 & \text{if} \quad t < t_1 \\ \Pi_{t_i \le t}\left[1 - \frac{d_i}{y_i}\right] & \text{if} \quad t_1 \le t \end{cases},$$

where $t_1, t_2, t_3, \cdots, t_D$ are ordered times at which events occur, d_i is the number of participants who experience the events at time t_i, and y_i is the number of succeptible participants at time t_i.

The KM method would estimate the treatment effect during the study period as:

$$p_{KM} = 1 - S(t),$$

with the Greenwood's variance in Ref, [25] given as:

$$KM_{var} = S(t)^2 \sum_{t_i \le t} \frac{d_i}{y_i(y_i - d_i)}.$$

The KM estimator could circumvent the drawbacks of *ITT* and *CO* methods of treatment effect estimation however, the KM method assumes that dropouts are independent and non-informative and are therefore, right-censored. This assumptions may fail and may stretch the survival curve and push the survival estimates upwards leading to biased estimation such as median $t_{0.5}$ and proportion p_{KM}.

We propose to estimate the treatment effect using its survival function of BE model defined in Equation (8) as:

$$S_{BE}(t) = (1 - \pi) + \pi e^{-\lambda t}, t > 0. \tag{29}$$

The estimate of the treatment effect becomes:

$$p_{BE} = 1 - S_{BE}.$$

Following from Ref. [25], we can similarly use variance of the survival function in Equation (26) to estimate the variance of the BE proportion of event so that variance of p_{BE} denoted BE_{var} equals variance of the survival function and given as:

$$BE_{var} = \pi^2 \left(\frac{1}{1 + 2\lambda} - \frac{1}{(1 + \lambda)^2} \right). \tag{30}$$

5. SIMULATION EXPERIMENT

Two simulation experiments were performed. One is to evaluate the performance of BE model in estimating the median survival to compare its bias and variance with the KM estimator while the second simulation experiment evaluates the performance of BE model in estimating treatment effect (proportion) to compare its bias and variance with the KM estimator, ITT estimator, and the CO estimator.

5.1. MEDIAN ESTIMATION SIMULATION EXPERIMENT

The objective of this simulation was to compare the bias in median estimation as well as the variance of BE model and the KM estimator using datasets where the underlying survival distribution was known. This framework makes it possible to quantify how each estimator behaves when dropout is substantial or tied to the event process.

Each simulated dataset consisted of n individuals such that for every individual, an indicator determined whether the subject was capable of experiencing the event. This indicator followed a Bernoulli distribution:

$$X_i \sim \text{Bernoulli}(\pi),$$

which allowed control over dropout severity. Individuals with $X_i = 0$ represent dropouts or those who fail induction-stage progression and therefore contribute no observed event time. Subjects with $X_i = 1$ were assigned event times generated from an exponential distribution,

$$T_i \mid X_i = 1 \sim \text{Exponential}(\lambda).$$

To establish a ground-truth value for comparison, a large reference dataset (e.g., one million observations) was generated from the same mechanism. The empirical median computed from this full dataset was taken as the true median m_{true}. This definition avoids assumptions tied to any particular estimator and provides a stable benchmark for bias evaluation.

For each selected value of π and λ, repeated datasets of size n were generated and for each dataset:

(a) The BE estimator was fitted to obtain $\hat{\pi}$, $\hat{\lambda}$ and the median and variance were computed.

(b) The KM curve was constructed, and the median and Greenwood-based variance were extracted.

Each estimator's performance across simulation replicates was summarized using:

$$\text{Bias} = \hat{m} - m_{\text{true}}, \qquad \text{variance} = \text{var}(\hat{m}).$$

The experiment was repeated over the grid:

$$\pi \in \{0.55, 0.60, \ldots, 0.95\}, \qquad \lambda \in \{0.20, 0.50, 1.00\},$$

allowing assessment under a wide range of dropout intensities and event rates. For each combination (π, λ), bias and variance values for the two estimators were tabulated in Table 2.

Table 2. Simulation results for BE and KM median estimators.

π	λ	BE_{bias}	BE_{var}	KM_{bias}	KM_{var}
0.55	0.20	-	-	4.2781	1.1472
0.55	0.50	-	-	1.6845	0.1973
0.55	1.00	-	-	0.8328	0.0382
0.60	0.20	5.1640	0.0071	3.3730	0.9531
0.60	0.50	1.9473	0.0203	1.2901	0.1194
0.60	1.00	0.9825	0.0302	0.6450	0.0275
0.65	0.20	3.3110	0.0085	2.5731	0.6046
0.65	0.50	1.3238	0.0237	1.0086	0.0917
0.65	1.00	0.6758	0.0352	0.5134	0.0225
0.70	0.20	2.3846	0.0097	2.0204	0.4331
0.70	0.50	0.9343	0.0273	0.8013	0.0703
0.70	1.00	0.4668	0.0409	0.3981	0.0174
0.75	0.20	1.5948	0.0113	1.4607	0.2837
0.75	0.50	0.6609	0.0311	0.6299	0.0529
0.75	1.00	0.3084	0.0473	0.2858	0.0128
0.80	0.20	1.0373	0.0128	1.1247	0.2327
0.80	0.50	0.4307	0.0355	0.4410	0.0373
0.80	1.00	0.2043	0.0535	0.2187	0.0096
0.85	0.20	0.6234	0.0144	0.7789	0.2320
0.85	0.50	0.2371	0.0405	0.2929	0.0380
0.85	1.00	0.1309	0.0600	0.1588	0.0095
0.90	0.20	0.2621	0.0162	0.4809	0.1895
0.90	0.50	0.1052	0.0452	0.1895	0.0250
0.90	1.00	0.0530	0.0676	0.0955	0.0078
0.95	0.20	0.0120	0.0179	0.2414	0.1432
0.95	0.50	0.0107	0.0502	0.0960	0.0219
0.95	1.00	0.0013	0.0751	0.0558	0.0057

5.1.1. Findings from the median estimation simulation experiment

The results of the simulation in Table 2 showed that overall, the patterns across the grid were consistent. Whereas, the KM estimator became progressively biased upward, the BE estimator showed a different pattern. When π was reasonably large, it produced median estimates with modest bias and small variance, but it became unstable when dropout was severe.

Behaviour at $\pi = 0.55$

At the highest level of dropout ($\pi = 0.55$), the BE estimator could not reliably estimate the median. This is why the bias entries for BE in this rows are missing. When nearly half the cohort is incapable of experiencing the event, the likelihood surface becomes flat and the BE median estimate does not exist numerically. The KM estimator performed poorly under this setting too. Its median was consistently inflated, with biases of 4.28, 1.68 and 0.83 as λ increased. This behaviour is expected, because KM treats dropouts as right-censoring, which artificially stretches the survival curve and pushes the estimated median upward.

Moderate dropout ($\pi = 0.60$ to 0.75)

As π increased from 0.60 to 0.75, the BE estimator stabilised quickly. The bias dropped to between 5.16 and 0.31, depending on λ, and the variance stayed small relative to the other methods. The KM estimator continued to overestimate the median in all scenarios, although the magnitude of the bias shrank as dropout became less extreme. A consistent theme in this range is that the BE estimator had the lowest variance. Even when the BE bias was notable, for example at $\pi = 0.60$ and $\lambda = 0.20$ its variance was small enough that the estimator remained stable across repetitions.

High retention ($\pi = 0.80$ to 0.95)

When π reached 0.80 and above, the two estimators behaved well. The BE estimator showed very small bias (often below

0.25), and its variance increased slightly with larger λ, which is expected because higher λ compresses event times and makes the median more sensitive to sampling variability. The KM estimator still had a positive bias, but it was much smaller in this range.

Estimator comparison

Two main findings were apparent:

(a) BE estimator: Performs well when π is not too small. It combines low variance with modest bias and captures the dropout mechanism explicitly. It breaks down only when dropout is extreme ($\pi \leq 0.55$).

(b) Kaplan-Meier: Overestimates the median whenever dropout is substantial. Its bias shrinks as π increases but remains positive across the entire grid. Variance is highest among the three estimators, especially for small π.

Summary

The experiment shows that modelling dropout explicitly, as done in the BE approach, provides clear benefits once the dropout rate is moderate to high. The BE estimator yields tight, stable estimates with smaller variance than KM. Its main limitation appears when the dropout proportion becomes too large to support reliable joint estimation of π and λ. KM is sensitive to dropout and consistently upward-biased.

5.2. PROPORTION ESTIMATION SIMULATION EXPERIMENT

Following the simulation design of experiment for the median estimation simulation experiment, a simulation study was carried out to evaluate and compare four estimators of the event proportion in a cure-rate setting under combinations of the cure fraction parameter π and the event-rate parameter λ. The estimators studied were:

- Bernoulli–Exponential (BE) estimator,
- Kaplan–Meier (KM) estimator,
- Intention-to-Treat (ITT) estimator,
- Completers-Only (CO) estimator.

The true proportion p_{true} was estimated from a large reference dataset (e.g., one million observations) using the same mechanism. The empirical proportion and true variance $true_{var}$ computed from this full dataset was used to measure the estimators biasedness since this definition avoids assumptions tied to any particular estimator and provides a stable benchmark for bias evaluation.

For each selected value of π and λ, repeated datasets of size n were generated and for each dataset:

(a) The BE estimator was fitted to obtain $\hat{\pi}$, $\hat{\lambda}$ and the proportion p_{BE}, proportion bias BE_{bias} and variance BE_{var} were computed.

(b) The KM curve was constructed, and the proportion p_{KM}, proportion bias KM_{bias} and Greenwood-based variance KM_{var} were computed.

(c) The ITT proportion p_{ITT}, proportion bias ITT_{bias} and variance ITT_{var} were computed.

(d) The CO proportion p_{CO}, proportion bias CO_{bias} and variance CO_{var} were computed.

Each estimator's performance across simulation replicates was summarized using:

$$\text{Bias} = \hat{p} - p_{\text{true}}, \qquad \text{variance} = \text{var}(\hat{p}).$$

The experiment was repeated over the grid:

$$\pi \in \{0.55, 0.60, \ldots, 0.95\}, \qquad \lambda \in \{0.20, 0.50, 1.00\},$$

allowing assessment under a wide range of dropout intensities and event rates. For each combination (π, λ), bias and variance values for all four estimators were tabulated in Table 3.

5.2.1. Findings from the proportion estimation simulation experiment

True proportion behavior

The empirical true proportion p_{true} increased monotonically with the cure fraction π, ranging from approximately 0.41 at $\pi = 0.55$ to about 0.71 at $\pi = 0.95$. The empirical variance of the true proportion remained consistently small (approximately 0.0004–0.0006), indicating stable simulation generation.

Bernoulli-exponential (BE) estimator

The BE estimator exhibited negligible bias across all simulation regimen with bias values ranging between approximately –0.0009- 0.0030, and a consistent variance within 0.0004-0.0006. Overall, the BE estimator demonstrated the best overall performance, with minimal bias and consistently low variance in a way that the bias did not show systematic dependence on the value of λ.

Kaplan-Meier (KM) estimator

The KM estimator consistently overestimated the true event proportion with bias values ranging approximately from 0.022 to 0.064, though they tended to decrease slightly as π increased. The variance of the KM estimator ranged from 0.0001 to 0.0005, smaller than BE in some settings.

Intention-to-treat (ITT) estimator

The ITT estimator also showed very small bias, similar in magnitude to BE, ranging approximately from –0.0020 to 0.0041. The sign and magnitude of the bias fluctuated slightly but remained negligible with low variance values (between 0.0003 and 0.0004), comparable to BE.

Completers-only (CO) estimator

The CO estimator was severely positively biased, with bias values ranging from approximately 0.038 to as high as 0.341. The bias was largest for smaller values of π, reflecting the estimator's failure to account for censoring and cured individuals. The variance was extremely small (approximately 10^{-6} to 3×10^{-6}), but this reflects the estimator's structural inadequacy rather than good performance.

Table 3. Simulation results for proportion estimators.

π	λ	p_{true}	$true_{var}$	p_{BE}	BE_{bias}	BE_{var}	p_{KM}	KM_{bias}	KM_{var}	p_{ITT}	ITT_{bias}	ITT_{var}	p_{CO}	CO_{bias}	CO_{var}
0.55	0.2	0.4110	0.0004	0.4115	0.0005	0.0005	0.4751	0.0641	0.0005	0.4126	0.0016	0.0004	0.7523	0.3414	0.0000
0.55	0.5	0.4130	0.0004	0.4138	0.0008	0.0006	0.4761	0.0631	0.0005	0.4140	0.0010	0.0005	0.7523	0.3393	0.0000
0.55	1.0	0.4113	0.0003	0.4113	0.0000	0.0006	0.4743	0.0630	0.0006	0.4120	0.0007	0.0005	0.7524	0.3411	0.0000
0.60	0.2	0.4501	0.0003	0.4506	0.0005	0.0005	0.5132	0.0630	0.0005	0.4516	0.0014	0.0004	0.7522	0.3020	0.0000
0.60	0.5	0.4511	0.0004	0.4502	-0.0009	0.0006	0.5115	0.0604	0.0005	0.4506	-0.0005	0.0004	0.7521	0.3011	0.0000
0.60	1.0	0.4502	0.0004	0.4504	0.0002	0.0006	0.5119	0.0617	0.0005	0.4510	0.0008	0.0005	0.7523	0.3021	0.0000
0.65	0.2	0.4867	0.0004	0.4896	0.0030	0.0005	0.5472	0.0605	0.0004	0.4897	0.0030	0.0004	0.7520	0.2653	0.0000
0.65	0.5	0.4886	0.0004	0.4880	-0.0005	0.0005	0.5459	0.0573	0.0004	0.4884	-0.0002	0.0004	0.7518	0.2632	0.0000
0.65	1.0	0.4873	0.0004	0.4876	0.0003	0.0006	0.5462	0.0589	0.0004	0.4881	0.0008	0.0004	0.7519	0.2646	0.0000
0.70	0.2	0.5253	0.0005	0.5267	0.0014	0.0006	0.5798	0.0545	0.0004	0.5272	0.0019	0.0004	0.7517	0.2264	0.0000
0.70	0.5	0.5252	0.0004	0.5254	0.0002	0.0005	0.5780	0.0528	0.0004	0.5251	-0.0001	0.0004	0.7518	0.2266	0.0000
0.70	1.0	0.5249	0.0004	0.5245	-0.0004	0.0005	0.5793	0.0544	0.0003	0.5263	0.0014	0.0003	0.7517	0.2268	0.0000
0.75	0.2	0.5635	0.0004	0.5639	0.0004	0.0005	0.6112	0.0477	0.0003	0.5636	0.0002	0.0003	0.7516	0.1881	0.0000
0.75	0.5	0.5610	0.0005	0.5642	0.0031	0.0005	0.6115	0.0505	0.0004	0.5652	0.0041	0.0004	0.7516	0.1905	0.0000
0.75	1.0	0.5612	0.0006	0.5639	0.0027	0.0005	0.6112	0.0500	0.0003	0.5646	0.0034	0.0003	0.7516	0.1904	0.0000
0.80	0.2	0.6001	0.0005	0.6028	0.0027	0.0004	0.6427	0.0426	0.0002	0.6027	0.0026	0.0003	0.7516	0.1515	0.0000
0.80	0.5	0.6028	0.0005	0.6027	-0.0001	0.0004	0.6412	0.0385	0.0002	0.6008	-0.0020	0.0003	0.7516	0.1488	0.0000
0.80	1.0	0.6002	0.0005	0.6007	0.0004	0.0004	0.6424	0.0421	0.0002	0.6018	0.0016	0.0003	0.7515	0.1513	0.0000
0.85	0.2	0.6390	0.0005	0.6397	0.0007	0.0004	0.6718	0.0328	0.0002	0.6396	0.0006	0.0003	0.7514	0.1124	0.0000
0.85	0.5	0.6388	0.0005	0.6381	-0.0007	0.0004	0.6703	0.0315	0.0002	0.6382	-0.0006	0.0002	0.7515	0.1127	0.0000
0.85	1.0	0.6370	0.0005	0.6380	0.0010	0.0004	0.6710	0.0341	0.0002	0.6387	0.0017	0.0002	0.7515	0.1145	0.0000
0.90	0.2	0.6754	0.0005	0.6756	0.0002	0.0003	0.6991	0.0238	0.0001	0.6769	0.0015	0.0001	0.7513	0.0760	0.0000
0.90	0.5	0.6757	0.0006	0.6752	-0.0005	0.0004	0.6986	0.0229	0.0001	0.6753	-0.0003	0.0002	0.7513	0.0757	0.0000
0.90	1.0	0.6773	0.0006	0.6771	-0.0003	0.0003	0.6996	0.0222	0.0001	0.6767	-0.0007	0.0002	0.7514	0.0741	0.0000
0.95	0.2	0.7129	0.0006	0.7144	0.0015	0.0003	0.7265	0.0136	0.0001	0.7143	0.0014	0.0001	0.7513	0.0384	0.0000
0.95	0.5	0.7114	0.0005	0.7130	0.0016	0.0003	0.7250	0.0136	0.0001	0.7133	0.0018	0.0001	0.7513	0.0399	0.0000
0.95	1.0	0.7109	0.0006	0.7121	0.0012	0.0003	0.7257	0.0148	0.0001	0.7138	0.0029	0.0001	0.7514	0.0405	0.0000

Table 4. Conceptual cross-classification of completion and event status.

Estimator	Bias	Variance	Overall Performance
BE	Very small	Very small	Best overall estimator
KM	Moderate positive	Small	Bettter though overestimates
ITT	Very small	Very small	Nearly as good as BE
CO	Very large positive	Very small	Poor estimator

Overall comparison

The overall comparison is shown in Table 4.

6. CONCLUSION

This study proposed a methodology for addressing the bias introduced when dropout is related to the underlying event mechanism in randomized controlled trials particularly when standard survival analysis methods, including the Kaplan-Meier estimator and exponential models and other related methods fails. The Bernoulli-Exponential (BE) model proposed in this study provides a principled alternative by jointly modelling the probability of experiencing an event and the distribution of event times among those who are truly at risk. By separating the Bernoulli component from the exponential time component, the model naturally accommodates participants who contribute no event time and correctly handles dropout mechanisms that are informative or structurally induced by multi-stage trial designs. This way, the BE model neither assume that all censored observations definitively belong to the never-event subgroup like the cure model nor that the censored observation are noninformative like the KM model . Rather, censored participants contribute partial information through the likelihood for the Bernoulli component. Their contribution reflects uncertainty about subgroup membership. However, when follow-up time is short relative to the event process, separation between the Bernoulli and Exponential components may be weak, affecting identifiability. Simulation experiments across varying dropout levels showed that the BE estimator consistently reduced the upward drift observed in Kaplan-Meier estimates and avoided the systematic bias inherent in exponential models when censoring depended on event risk. Overall, the BE method offers a robust and practically useful framework for estimating survival probabilities, event proportions, and median survival times in trials where standard methods fail. Its ability to incorporate induction-phase filtering and informative dropout makes it particularly well-suited for modern multi-stage randomized designs, where ignoring such complexities can lead to misleading clinical conclusions.

DATA AVAILABILITY STATEMENT

The data are available with the corresponding author upon request.

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APPENDIX: VARIANCE, STANDARD ERROR AND 95% CI FOR SURVIVAL FUNCTION

The variances, standard errors and 95% CI for the survival function is presented herein. Given the survival function in Equation (8), the varince is defined as:

$$var[S_T(t)] = E[S_T(t)^2] - \{E[S_T(t)]\}^2.$$

$$E[S_T(t)] = (1-\pi) + \pi E[e^{-\lambda t}].$$

For an exponential random variable $T \sim Exp(\lambda)$, we use the moment formula:

$$E[e^{-\lambda t}] = \frac{1}{1+\lambda},$$

$$E[S_T(t)] = (1-\pi) + \pi\frac{1}{1+\lambda},$$

$$\begin{aligned} E[S_T(t)^2] &= E[(1-\pi) + \pi e^{-\lambda t}]^2 \\ &= (1-\pi)^2 + 2(1-\pi)\pi E[e^{-\lambda t}] + \pi^2[e^{-2\lambda t}], \end{aligned}$$

$$E[e^{-2\lambda t}] = \frac{1}{1+2\lambda},$$

$$E[S_T(t)^2] = (1-\pi)^2 + 2(1-\pi)\pi\frac{1}{1+\lambda} + \pi^2\frac{1}{1+2\lambda},$$

$$\begin{aligned} E[S_T(t)]^2 &= \left((1-\pi) + \pi\frac{1}{1+\lambda}\right)^2 \\ &= (1-\pi)^2 + 2(1-\pi)\pi\frac{1}{1+\lambda} + \pi^2\frac{1}{(1+\lambda)^2}, \end{aligned}$$

$$\begin{aligned} var[S_T(t)] &= \left[(1-\pi)^2 + 2(1-\pi)\pi\frac{1}{1+\lambda} + \pi^2\frac{1}{1+2\lambda}\right] \\ &\quad - \left[(1-\pi)^2 + 2(1-\pi)\pi\frac{1}{1+\lambda} + \pi^2\frac{1}{(1+\lambda)^2}\right], \end{aligned}$$

$$Var[S_T(t)] = \pi^2\left(\frac{1}{1+2\lambda} - \frac{1}{(1+\lambda)^2}\right),$$

$$SE[S_T(t)] = \sqrt{\frac{\pi^2\left(\frac{1}{1+2\lambda} - \frac{1}{(1+\lambda)^2}\right)}{n}}.$$

The corresponding 95% confidence interval for the survival function is given as:

$$CI_{95\%} = S_T(t) \pm 1.96 \times SE[S_T(t)].$$