

Ghosh Lin Estimation

1.1 Setup

Let D denote the time to a terminal event (e.g. death), C an independent censoring time, and $N^*(t)$ the number of recurrent events by time t . While censoring is assumed independent of D and $N^*(t)$, no restrictions are placed on the dependence of recurrent or terminal events. Due to censoring, an observation takes the form $\{N(\cdot), U, \delta\}$, where:

$$N(t) = N^*(t \wedge C), \quad U = \min(C, D), \quad \delta = \mathbb{I}(D \leq C).$$

The observed data $\mathcal{D} = \{N_i(\cdot), U_i, \delta_i\}$ are IID replicates of $\{N(\cdot), U, \delta\}$.

1.2 Mean Cumulative Function

Definition 1.2.1. The **mean cumulative function** (MCF) is defined as:

$$\mu(t) = \mathbb{E}\{N^*(t)\}.$$

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Proposition 1.2.1. The MCF is expressible as:

$$\mu(t) = \int_0^t S(u) dR(u),$$

where $S(u) = \mathbb{P}(D > u)$ is the survival function, and $dR(u) = \mathbb{E}\{dN^*(t) | D \geq u\}$. ◆

Proof.

$$\begin{aligned} \mu(t) &= \int_0^t \mathbb{E}\{dN^*(u)\} = \int_0^t \mathbb{P}\{dN^*(u) = 1\} = \int_0^t \mathbb{P}\{dN^*(u) = 1, D \geq u\} \\ &= \int_0^t \mathbb{P}(D \geq u) \mathbb{P}\{dN^*(u) = 1 | D \geq u\} = \int_0^t S(u) dR(u). \end{aligned}$$

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Example 1.2.1. Suppose the gap times for the recurrent event process $N^*(t)$ are independent and exponentially distributed with arrival rate λ_A . In the absence of terminal events, $N^*(t)$ is a Poisson process with MCF $\mu(\tau) = \mathbb{E}\{N^*(\tau)\} = \lambda_A \tau$. Suppose death occurs independently according to an exponential distribution with arrival rate λ_D , then:

$$\mu(\tau) = \int_0^\tau e^{-\lambda_D t} \lambda_A dt = \frac{\lambda_A}{\lambda_D} \{1 - e^{-\lambda_D \tau}\}.$$

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Definition 1.2.2. The **Ghosh Lin** estimator [1] of the MCF is:

$$\hat{\mu}(t) = \int_0^t \hat{S}(u) d\hat{R}(u),$$

where $\hat{S}(u)$ is the Kaplan-Meier estimator for $\mathbb{P}(D > u)$ and $\hat{R}(u)$ is the Nelson-Aalen estimator of cumulative recurrence:

$$\hat{R}(t) = \int_0^t \frac{dN(u)}{Y(u)} = \sum_{i=1}^n \int_0^t \frac{dN_i(u)}{Y(u)}.$$

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Discussion 1.2.1.

- In the recurrent events framework, a subject remains under observation after the occurrence of the event. The subject is only lost to observation due to censoring or a terminal event.
- In the absence of terminal events, $\hat{S}(u) \equiv 1$ and the Ghosh-Lin estimator reduces to the Nelson-Aalen estimator $\hat{R}(t)$.
- Regarding terminal events as censoring results in systematic overestimation of the MCF for t greater than or equal to the first terminal event time.
- If the event of interest can occur at most once per patient, then $\hat{\mu}(t)$ is the standard estimator of the cumulative incidence curve with death acting as a competing risk.

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Example 1.2.2 (Estimation). The Ghosh Lin curve may be tabulated as follows. Let $\tau_1 < \dots < \tau_K$ denote the distinct observed event, censoring, or death times. Let $e_k = dN(\tau_k)$ denote the number of events occurring at τ_k , $d_k = dN^D(\tau_k)$ the number at deaths, and $n_k = Y(\tau_k)$ the number at risk. The instantaneous event rate at time τ_k is $\hat{r}_k = e_k/n_k$, and the instantaneous hazard is $\hat{h}_k = d_k/n_k$. The Kaplan-Meier estimate of the survival at time τ_k is the cumulative product:

$$\hat{S}_k = \hat{S}(\tau_k) = \prod_{j \leq k} (1 - \hat{h}_j).$$

Finally, the Ghosh-Lin estimate MCF at time τ_k is:

$$\hat{\mu}_k = \hat{\mu}(\tau_k) = \sum_{j \leq k} \hat{S}_j \cdot \hat{r}_j.$$

Consider the following table in which an event occurs at τ_1 , followed by a death at τ_2 , then a second event at τ_3 , a censoring at τ_4 , and a final event at τ_5 . Note that the number at risk decreases following a terminal event (or censoring), but not after an event. For clarity, the number of censorings c_k is also tracked.

τ_k	c_k	e_k	d_k	n_k	\hat{r}_k	\hat{h}_k	\hat{S}_k	$\hat{\mu}_k$
τ_1	0	1	0	10	1/10	0	1	1/10
τ_2	0	0	1	10	0	1/10	9/10	1/10
τ_3	0	1	0	9	1/9	0	9/10	2/10
τ_4	1	0	0	9	0	0	9/10	2/10
τ_5	0	1	0	8	1/8	0	9/10	5/16
\vdots								\vdots



1.3 1-Sample Asymptotics

Proposition 1.3.2 (Influence Function Expansion).

$$\sqrt{n}\{\hat{\mu}(t) - \mu(t)\} = \frac{1}{\sqrt{n}} \sum_{i=1}^n \psi_i(t) + o_p(1), \quad (1.3.1)$$

where:

$$\psi_i(t) = \int_0^t \frac{\mu(u)}{y(u)} dM_i^D(u) - \mu(t) \int_0^t \frac{1}{y(u)} dM_i^D(u) + \int_0^t \frac{S(u)}{y(u)} dM_i(u), \quad (1.3.2)$$

is the influence function, where $y(u) = \mathbb{P}(U \geq u)$ is the probability limit of $n^{-1}Y(u)$,

$$M_i(t) = N_i(t) - \int_0^t Y_i(u) dR(u),$$

is the recurrent events martingale and:

$$M_i^D(t) = N_i^D(t) - \int_0^t Y_i(u) dA^D(u)$$

is the terminal event martingale.



Proof. The normalized difference is expressible as:

$$\sqrt{n}\{\hat{\mu}(t) - \mu(t)\} = \sqrt{n} \int_0^t \hat{S}(u) d\hat{R}(u) - \sqrt{n} \int_0^t S(u) dR(u).$$

Adding and subtracting $\sqrt{n} \int_0^t \hat{S}(u) dR(u)$ gives:

$$\sqrt{n}\{\hat{\mu}(t) - \mu(t)\} = I_1(t) + I_2(t),$$

where:

$$\begin{aligned} I_1(t) &= \sqrt{n} \int_0^t \{\hat{S}(u) - S(u)\} dR(u) \\ I_2(t) &= \sqrt{n} \int_0^t \hat{S}(u) d\{\hat{R}(u) - R(u)\}. \end{aligned}$$

From:

$$\sqrt{n} \frac{\{\hat{S}(u) - S(u)\}}{-S(u)} = \sqrt{n}\{\hat{A}^D(u) - A^D(u)\} + o_p(1),$$

the first term is asymptotically equivalent to:

$$\begin{aligned} I_1(t) &= -\sqrt{n} \int_0^t \frac{\{\hat{S}(u) - S(u)\}}{-S(u)} \cdot S(u) dR(u) \\ &= -\int_0^t \sqrt{n}\{\hat{A}^D(u) - A^D(u)\} \cdot d\mu(u) + o_p(1), \end{aligned}$$

where $A^D(u)$ is the cumulative hazard for terminal events, and $\hat{A}^D(u)$ is the corresponding Nelson-Aalen estimator.

Integrating by parts:

$$\begin{aligned} & -\int_0^t \sqrt{n}\{\hat{A}^D(u) - A^D(u)\} \cdot d\mu(u) \\ &= -\sqrt{n} \left[\{\hat{A}^D(u) - A^D(u)\} \mu(u) \right]_{u=0}^{u=t} + \sqrt{n} \int_0^t \mu(u) \cdot d\{\hat{A}^D(u) - A^D(u)\} \\ &= -\sqrt{n}\{\hat{A}^D(t) - A^D(t)\} \mu(t) + \sqrt{n} \int_0^t \mu(u) \cdot d\{\hat{A}^D(u) - A^D(u)\}. \end{aligned}$$

Using the martingale expansion of the Nelson-Aalen estimator:

$$\sqrt{n}\{\hat{A}^D(t) - A^D(t)\} = \frac{1}{\sqrt{n}} \int_0^t \frac{dM^D(u)}{y(u)} + o_p(1),$$

$I_1(t)$ becomes:

$$I_1(t) = -\frac{\mu(t)}{\sqrt{n}} \int_0^t \frac{dM^D(u)}{y(u)} + \frac{1}{\sqrt{n}} \int_0^t \frac{\mu(u)}{y(u)} dM^D(u) + o_p(1).$$

Now consider $I_2(t)$. By uniform consistency of the Kaplan-Meier estimator:

$$I_2(t) = \sqrt{n} \int_0^t S(u) d\{\hat{R}(u) - R(u)\} + o_p(1).$$

From Ghosh Lin (A.8):

$$\sqrt{n}\{\hat{R}(t) - R(t)\} = \frac{1}{\sqrt{n}} \int_0^t \frac{dM(u)}{y(u)} + o_p(1),$$

where:

$$M(t) = N(t) - \int_0^t Y(u) dR(u).$$

Consequently:

$$\sqrt{n} \int_0^t S(u) d\{\hat{R}(u) - R(u)\} = \frac{1}{\sqrt{n}} \int_0^t \frac{S(u)}{y(u)} dM(u) + o_p(1),$$

and overall:

$$\sqrt{n}\{\hat{\mu}(t) - \mu(t)\} = \int_0^t \frac{\mu(u)}{y(u)} dM^D(u) - \mu(t) \int_0^t \frac{1}{y(u)} dM^D(u) + \int_0^t \frac{S(u)}{y(u)} dM(u) + o_p(1).$$

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Corollary 1.3.1. $\sqrt{n}\{\hat{\mu}(t) - \mu(t)\}$ converges weakly to a mean-zero Gaussian process with covariance function:

$$\gamma(s, t) = \mathbb{E}\{\psi(s) \cdot \psi(t)\},$$

which is estimable by:

$$\hat{\gamma}(s, t) = \frac{1}{n} \sum_{i=1}^n \psi_i(s) \cdot \psi_i(t).$$

In particular:

$$\sqrt{n}\{\hat{\mu}(t) - \mu(t)\} \rightsquigarrow W\{\sigma_{\text{MCF}}^2(t)\},$$

with:

$$\sigma_{\text{MCF}}^2(t) = \mathbb{E}\{\psi^2(t)\},$$

♣

Discussion 1.3.1. Since $\mu(t)$ is non-negative, point-wise confidence intervals may be constructed via:

$$\sqrt{n}\{\ln \hat{\mu}(t) - \ln \mu(t)\} = \sqrt{n} \frac{\{\hat{\mu}(t) - \mu(t)\}}{\mu(t)} + o_p(1).$$

In particular, an asymptotic $(1 - \alpha)$ level confidence interval is given by:

$$\hat{\mu}(t) \exp \left\{ \pm \frac{z_{1-\alpha/2} \hat{\sigma}_{\text{MCF}}^2(t)}{\sqrt{n} \hat{\mu}(t)} \right\}.$$

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1.4 2-Sample Asymptotics

Definition 1.4.1. The two sample log-rank statistic for equality of two MCFs, $H_0 : \mu_1(t) = \mu_0(t)$ for all $t \in [0, \tau]$ is:

$$T_{\text{LR}}(\tau) = \int_0^\tau \omega(t) d\{\hat{\mu}_1(t) - \hat{\mu}_0(t)\},$$

where:

$$\omega(t) = \frac{n}{n_1 n_0} \frac{Y_1(t) Y_0(t)}{Y_1(t) + Y_0(t)}.$$

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Proposition 1.4.3. Under $H_0 : \mu_1(t) = \mu_0(t)$:

$$\left(\frac{n_1 n_0}{n}\right)^{1/2} T_{\text{LR}} \xrightarrow{d} N(0, \sigma_{\text{LR}}^2),$$

where:

$$\hat{\sigma}_{\text{LR}}^2 = \frac{n_0}{n n_1} \sum_{i=1}^{n_1} \left\{ \int_0^\tau \omega(t) d\psi_{1i}(t) \right\}^2 + \frac{n_1}{n n_0} \sum_{i=1}^{n_0} \left\{ \int_0^\tau \omega(t) d\psi_{0i}(t) \right\}^2$$

and $\psi_{ij}(t)$ is the influence function for subject i in arm j from (1.3.2). ◆

Proof. Consider the log-rank statistic:

$$\begin{aligned} \left(\frac{n_1 n_0}{n}\right)^{1/2} \hat{T}_{\text{LR}} &= \left(\frac{n_1 n_0}{n}\right)^{1/2} \int_0^\tau \omega(t) d\{\hat{\mu}_1(t) - \mu_1(t)\} \\ &\quad - \left(\frac{n_1 n_0}{n}\right)^{1/2} \int_0^\tau \omega(t) d\{\hat{\mu}_0(t) - \mu_0(t)\} \end{aligned}$$

From (1.3.1):

$$\sqrt{n_j} \{\hat{\mu}_j(t) - \mu_j(t)\} = \frac{1}{\sqrt{n_j}} \sum_{i=1}^{n_j} \psi_{ij}(t) + o_p(1).$$

Applied to the log-rank statistic:

$$\begin{aligned} \left(\frac{n_1 n_0}{n}\right)^{1/2} \hat{T}_{\text{LR}} &= \left(\frac{n_0}{n}\right)^{1/2} \frac{1}{\sqrt{n_1}} \sum_{i=1}^{n_1} \int_0^\tau \omega(t) d\psi_{i1}(t) \\ &\quad - \left(\frac{n_1}{n}\right)^{1/2} \frac{1}{\sqrt{n_0}} \sum_{i=1}^{n_0} \int_0^\tau \omega(t) d\psi_{i0}(t) + o_p(1). \end{aligned}$$

Suppose $n_1, n_0 \rightarrow \infty$ such that $n_0/n \rightarrow \pi_0$ and $n_1/n \rightarrow \pi_1$, the normalized log-rank statistic converges in distribution to a zero-mean random variable with variance:

$$\sigma_{\text{LR}}^2 = \pi_0 \cdot \mathbb{E} \left\{ \int_0^\tau \omega(t) d\psi_1(t) \right\}^2 + \pi_1 \cdot \mathbb{E} \left\{ \int_0^\tau \omega(t) d\psi_0(t) \right\}^2$$

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Area Under the Mean Cumulative Function

2.1 Asymptotics

Definition 2.1.1. Define the area under the MCF as:

$$U(\tau) = \int_0^\tau \mu(t)dt = \int_0^\tau \left\{ \int_0^t S(u)dR(u) \right\} dt.$$

By exchanging the order of integration:

$$U(\tau) = \int_0^\tau \int_0^\tau \mathbb{I}(u \leq t) S(u) dR(u) dt = \int_0^\tau (\tau - u) S(u) dR(u).$$

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Proposition 2.1.1 (Influence Function Expansion).

$$\sqrt{n}\{\hat{U}(\tau) - U(\tau)\} = \frac{1}{\sqrt{n}} \sum_{i=1}^n \psi_i(\tau) + o_p(1),$$

where:

$$\psi_i(\tau) = \int_0^\tau \frac{(\tau - u)S(u)}{y(u)} dM_i(u) - \int_0^\tau \frac{\int_u^\tau (\tau - s)d\mu(s)}{y(u)} dM_i^D(u),$$

is the influence function, $y(u) = \mathbb{P}(U \geq u)$ is the probability of being at risk,

$$M_i(t) = N_i(t) - \int_0^t Y_i(u) dR(u),$$

is the recurrent events martingale and:

$$M_i^D(t) = N_i^D(t) - \int_0^t Y_i(u) dA^D(u)$$

is the terminal event martingale.

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Proof. Consider the distribution of:

$$\sqrt{n}\{\hat{U}(\tau) - U(\tau)\} = \sqrt{n} \int_0^\tau (\tau - u) \hat{S}(u) d\hat{R}(u) - \sqrt{n} \int_0^\tau (\tau - u) S(u) dR(u).$$

Adding and subtracting $\sqrt{n} \int_0^\tau (\tau - u) \hat{S}(u) dR(u)$ gives:

$$\sqrt{n}\{\hat{U}(\tau) - U(\tau)\} = I_1(\tau) + I_2(\tau),$$

where:

$$\begin{aligned} I_1(\tau) &= \sqrt{n} \int_0^\tau (\tau - u) \hat{S}(u) d\{\hat{R}(u) - R(u)\}, \\ I_2(\tau) &= \sqrt{n} \int_0^\tau (\tau - u) \{\hat{S}(u) - S(u)\} dR(u). \end{aligned}$$

From Ghosh and Lin (A.8):

$$\sqrt{n}\{\hat{R}(t) - R(t)\} = \frac{1}{\sqrt{n}} \int_0^t \frac{dM(u)}{y(u)} + o_p(1),$$

the first integral is expressible as:

$$\begin{aligned} I_1(\tau) &= \int_0^\tau (\tau - u) \hat{S}(u) \cdot \sqrt{n} d\{\hat{R}(u) - R(u)\} \\ &= \int_0^\tau (\tau - u) \hat{S}(u) \cdot \frac{1}{\sqrt{n}} \frac{dM(u)}{y(u)} + o_p(1) \\ &= \frac{1}{\sqrt{n}} \int_0^\tau \frac{(\tau - u) S(u)}{y(u)} dM(u) + o_p(1) \\ &= \frac{1}{\sqrt{n}} \sum_{i=1}^n \left\{ \int_0^\tau \frac{(\tau - u) S(u)}{y(u)} dM_i(u) \right\} + o_p(1). \end{aligned}$$

From:

$$\sqrt{n} \frac{\{\hat{S}(u) - S(u)\}}{-S(u)} = \sqrt{n} \{\hat{A}^D(u) - A^D(u)\} + o_p(1),$$

the second integral is expressible as:

$$\begin{aligned} I_2(\tau) &= -\sqrt{n} \int_0^\tau (\tau - u) \frac{\{\hat{S}(u) - S(u)\}}{-S(u)} \cdot S(u) dR(u) \\ &= -\sqrt{n} \int_0^\tau (\tau - u) \{\hat{A}^D(u) - A^D(u)\} \cdot d\mu(u) + o_p(1). \end{aligned}$$

Integrating by parts:

$$\begin{aligned} &-\sqrt{n} \int_0^\tau (\tau - u) \{\hat{A}^D(u) - A^D(u)\} d\mu(u) \\ &= - \left[\sqrt{n} (\tau - u) \{\hat{A}^D(u) - A^D(u)\} \mu(u) \right]_{u=0}^{u=\tau} + \sqrt{n} \int_0^\tau \mu(u) d\{(\tau - u) (\hat{A}^D(u) - A^D(u))\}. \end{aligned}$$

The first term vanishes, leaving:

$$I_2(\tau) = \sqrt{n} \int_0^\tau \mu(u) d\{(\tau - u) (\hat{A}^D(u) - A^D(u))\}.$$

Expanding the differential:

$$I_2(\tau) = -\sqrt{n} \int_0^\tau \mu(u) \{\hat{A}^D(u) - A^D(u)\} du + \sqrt{n} \int_0^\tau \mu(u) (\tau - u) d\{\hat{A}^D(u) - A^D(u)\}.$$

Using the martingale expansion for the cumulative hazard:

$$\sqrt{n}\{\hat{A}^D(t) - A^D(t)\} = \frac{1}{\sqrt{n}} \int_0^t \frac{dM^D(u)}{y(u)} + o_p(1),$$

the second integral takes the form:

$$\begin{aligned} I_2(\tau) &= - \int_0^\tau \mu(u) \cdot \sqrt{n}\{\hat{A}^D(u) - A^D(u)\} \cdot du + \int_0^\tau \mu(u)(\tau - u) \cdot \sqrt{n}d\{\hat{A}^D(u) - A^D(u)\} \\ &= -\frac{1}{\sqrt{n}} \int_0^\tau \mu(u) \left\{ \int_0^u \frac{dM^D(s)}{y(s)} \right\} du + \frac{1}{\sqrt{n}} \int_0^\tau \frac{\mu(u)(\tau - u)}{y(u)} dM^D(u) + o_p(1). \end{aligned}$$

These terms may be combined as follows:

$$\begin{aligned} I_2(\tau) - o_p(1) &= -\frac{1}{\sqrt{n}} \int_0^\tau \int_0^\tau \mathbb{I}(s \leq u) \frac{\mu(u)}{y(s)} dM^D(s) du + \frac{1}{\sqrt{n}} \int_0^\tau \frac{\mu(u)(\tau - u)}{y(u)} dM^D(u) \\ &= -\frac{1}{\sqrt{n}} \int_0^\tau \int_u^\tau \mu(s) ds \cdot \frac{dM^D(u)}{y(u)} + \frac{1}{\sqrt{n}} \int_0^\tau \mu(u)(\tau - u) \cdot \frac{dM^D(u)}{y(u)} \\ &= \frac{1}{\sqrt{n}} \int_0^\tau \left\{ \mu(u)(\tau - u) - \int_u^\tau \mu(s) ds \right\} \frac{dM^D(u)}{y(u)}. \end{aligned}$$

The term in braces $\{\}$ simplifies by reversing integration by parts. In particular:

$$\begin{aligned} \int_u^\tau (\tau - s) d\mu(s) &= \left\{ (\tau - s)\mu(s) \right\}_{s=u}^{s=\tau} - \int_u^\tau \mu(s) d(\tau - s) \\ &= -(\tau - u)\mu(u) + \int_u^\tau \mu(s) ds, \end{aligned}$$

therefore:

$$\mu(u)(\tau - u) - \int_u^\tau \mu(s) ds = - \int_u^\tau (\tau - s) d\mu(s).$$

The second integral is now expressible as:

$$\begin{aligned} I_2(\tau) &= -\frac{1}{\sqrt{n}} \int_0^\tau \left\{ \int_u^\tau (\tau - s) d\mu(s) \right\} \frac{dM^D(u)}{y(u)} \\ &= -\frac{1}{\sqrt{n}} \sum_{i=1}^n \int_0^\tau \frac{\int_u^\tau (\tau - s) d\mu(s)}{y(u)} dM_i^D(u) + o_p(1). \end{aligned}$$

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Example 2.1.1. For implementation, let $\tau_1 < \dots < \tau_K$ denote the distinct observed event, censoring, or death times. For subject i , the martingale increments are approximated as:

$$\begin{aligned} d\hat{M}_{ik} &= d\hat{M}_i(\tau_k) = dN_i(\tau_k) - Y_i(\tau_k) \cdot \hat{r}_k, \\ d\hat{M}_{ik}^D &= d\hat{M}_i^D(\tau_k) = dN_i(\tau_k) - Y_i(\tau_k) \cdot \hat{h}_k \end{aligned}$$

where \hat{r}_k and \hat{h}_k are the sample event rate and hazard (of death) at time τ_k .

For a truncation time $\tau \geq \tau_K$, the first term of the influence function is:

$$\int_0^\tau \frac{(\tau - u)S(u)}{y(u)} dM_i(u) = \sum_{k=1}^K \frac{(\tau - \tau_k)\hat{S}(\tau_k)}{Y(\tau_k)/n} d\hat{M}_{ik}.$$

At time τ_k , the numerator in the second term of the influence function is:

$$\begin{aligned} \nu_{ik} &= \int_{\tau_k}^\tau (\tau - u) d\mu(u) \\ &= \int_{\tau_k}^\tau (\tau - u) S(u) dR(u) \\ &= \int_0^\tau (\tau - u) S(u) dR(u) - \int_0^{\tau_k} (\tau - u) S(u) dR(u) \\ &= \sum_{j=1}^K (\tau - \tau_j) \hat{S}(\tau_j) \hat{r}_j - \sum_{j \leq k} (\tau - \tau_j) \hat{S}(\tau_j) \hat{r}_j. \end{aligned}$$

Now, the second term of the influence function is:

$$\int_0^\tau \frac{\int_u^\tau (\tau - s) d\mu(s)}{y(u)} dM_i^D(u) = \sum_{k=1}^K \frac{\nu_{ik}}{Y(\tau_k)/n} d\hat{M}_{ik}^D.$$

Overall, the influence function is:

$$\hat{\psi}_i(\tau) = \sum_{k=1}^K \frac{(\tau - \tau_k)\hat{S}(\tau_k)}{Y(\tau_k)/n} d\hat{M}_{ik} - \sum_{k=1}^K \frac{\nu_{ik}}{Y(\tau_k)/n} d\hat{M}_{ik}^D.$$



References

- [1] Lin DY. “Non-parametric inference for cumulative incidence functions in competing risks studies”. In: *Statistics in Medicine* 16.3 (1997), pp. 901–910.