

Confidence Intervals for the Median Survival Time under Proportional Censorship

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Abstract

In this paper, we demonstrate the more accurate confidence intervals for median survival time under the simple proportional hazard model of Koziol and Green (1976) via the Edgeworth expansion for the distribution of the studentized ACL estimator derived in Jeong (2000). The numerical results show that the intervals, so-called test-based and reflect intervals (Slud et al., 1984), outperform normal approximating method in the small sample sizes and/or heavy censoring.

1. Introduction

Two important models in survival analysis are a general random censorship model and the simple proportional hazard model of Koziol and Green (1976). The difference between the two models is the way in which the lifetime variable is censored. The former allows the lifetimes to be censored by a non-informative way and the latter has an informative way in which the survival function of censoring variable is some power of the survival function of lifetimes.

In this field of statistics, confidence intervals for median survival times are frequently presented to characterize the survival experience of a group of patients. Typically such intervals are constructed by a consistent estimator with asymptotic normality but the common weakness of these intervals appear to lie in accuracy, since the standardized quantities are often quite skewed and biased for small sample sizes and heavy censoring. Efron (1981) proposed the bootstrap method that provided an alternative procedure for constructing nonparametric confidence intervals. The bootstrap methods often work reasonably well, but it is computationally intensive. Then many researchers have been interested in the nonparametric methods of constructing confidence intervals for the median survival time that avoid these problems based on the first-order normal approximation (Brookmeyer and Crowley, 1982; Emerson, 1982; Jennison and Turnbull, 1985). Slud, Byar and Green (1984) compared the these intervals for median survival time under the headings of test-based and reflected intervals,

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and showed that test-based intervals have less than nominal coverage in small sample through the simulation.

Higher order asymptotic method is the other way to improve a small sample performance. Many techniques have been devised to increase the accuracy of the approximation of the exact distribution of statistics. A well known method is to use the first few terms of an Edgeworth expansion. Recently, some important progresses have been accomplished in the way of producing accurate approximations to the distribution of censored data. For the general random censorship model, Lai and Wang (1993) provided general Edgeworth expansions for the true and bootstrap distributions of an asymptotic U-statistic and derived an Edgeworth expansion for distribution of standardized Nelson-Aalen (NA) estimator. Strawderman and Wells (1997) extended the results of Lai and Wang (1993) to the studentized NA estimator and Strawderman, Parzen and Wells (1997), using Edgeworth expansion, proposed the new test-based and reflect confidence intervals which was very simple to compute and showed that new test-based interval outperforms commonly used methods for computing confidence intervals for small sample sizes and/or heavy censoring.

For the simple proportional hazard model, Cho and Jeong (2000) and Jeong (2000) derived an Edgeworth expansion for the distributions of nonparametric maximum likelihood estimator (ACL estimator) of survival function and showed that the results are applied not only true distributions of the statistics but also for those bootstrap distributions.

In this paper, we derive more accurate confidence intervals for median survival time using the specific formula for the Edgeworth expansion of the studentized ACL estimator and then compare the coverage probabilities and average lengths for these confidence intervals through the Monte Carlo simulation.

2. Model Specification and Edgeworth Expansion

2.1 Simple Proportional Hazard Model

Let T_1, T_2, \dots, T_n be independent and identically distributed (*i.i.d.*) random variables with a continuous distribution function F . These are censored on the right by the *i.i.d.* random variables C_1, C_2, \dots, C_n with a continuous distribution function G , so that the observations available consist of the pairs $X_i = (Z_i, \delta_i)$ for $i = 1, \dots, n$, where $Z_i = T_i \wedge C_i$ and $\delta_i = I_{\{T_i \leq C_i\}}$. Here and in the sequel, $a \wedge b = \min(a, b)$ and $I_{\{A\}}$ denotes the indicator function of the event A .

In the usual general random censorship model one assumes that the lifetimes and censoring sequences are independent. Inferences under this model focus on the estimation of the survival function $\bar{F}(t) = 1 - F(t)$ via Kaplan-Meier (KM) estimators (Kaplan and Meier, 1958). If

censoring is informative, i.e. if the survival function $\bar{G}(t) = 1 - G(t)$ of the censoring variables carries additional information about $\bar{F}(t)$, the efficiency of KM estimator is lost. One such example is the simple proportional hazard model (KG model). The additional condition that let us to the KG model is

$$\bar{G}(t) = [\bar{F}(t)]^\lambda, \quad 0 < t < \infty, \quad (2.1)$$

where λ is a positive constant which is called censoring parameter. This proportional censorship model is characterized by the independence between Z and δ (Armitage, 1959). Then letting H denote the distribution function of the observable Z_i 's and $\bar{H}(t) = 1 - H(t)$ the corresponding survival function, it is easily proved that

$$\bar{F}(t) = [\bar{H}(t)]^\theta, \quad 0 < t < \infty. \quad (2.2)$$

Moreover, in the KG model, $\theta = \frac{1}{1+\lambda}$ is the expected proportion of uncensored observation, i.e. $\theta = P(\delta_1 = 1)$. The case $\lambda = 0$ ($\theta = 1$) corresponds to no censoring and the expected number of the censored observations increases as λ increases. The equation (2.2) motivates the ACL estimator for survival function (Abdushukurov, 1984; Cheng and Lin, 1984, 1987)

$$\bar{F}_n(t) = [\bar{H}_n(t)]^{\theta_n}, \quad 0 < t < \infty, \quad (2.3)$$

where $\bar{H}_n(t) = \frac{1}{n} \sum_{i=1}^n I_{\{Z_i > t\}}$ and $\theta_n = \frac{1}{n} \sum_{i=1}^n \delta_i$ are the empirical counterparts of $\bar{H}(t)$ and θ , respectively. Abdushukurov (1984) and Cheng and Lin (1984, 1987) have also investigated the asymptotic properties of the ACL estimator and showed that in the KG model the ACL estimator is asymptotically more efficient than the KM estimator.

In subsequent development, to get the asymptotic confidence interval for $\bar{F}(t)$ at fixed time, we can obtain a variance estimator $\sigma_n^2(t)$ as follows:

$$\sigma_n^2(t) = \theta_n^2 [\bar{H}_n(t)]^{2\theta_n - 1} H_n(t) + \theta_n(1 - \theta_n) [\bar{H}_n(t)]^{2\theta_n} [\ln \bar{H}_n(t)]^2. \quad (2.4)$$

Then by the strong law of large number we can see $\theta_n \rightarrow \theta$ a.s. and $\bar{H}_n(t) \rightarrow \bar{H}(t)$ a.s. as $n \rightarrow \infty$. Thus $\sigma_n^2(t) \rightarrow \sigma^2(t)$ a.s. as $n \rightarrow \infty$.

2.2 An Edgeworth Expansion for the ACL Estimator

Let $\Phi(\cdot)$ and $\phi(\cdot)$ denote the standard normal cumulative distribution and probability density function. For a fixed time point t and any $z \in R$, define

$$K_n(z; t) = P \left\{ \frac{n^{1/2} (\bar{F}_n(t) - \bar{F}(t))}{\sigma_n(t)} \leq z \right\}, \quad (2.5)$$

where $\sigma_n^2(t)$ is defined in (2.4). Jeong (2000) devised an Edgeworth expansion for

$K_n(z; t)$ and showed that uniformly for $z \in R$

$$K_n(z; t) = \Phi \left\{ z - \frac{\rho_3(t)}{6n^{1/2}}(z^2 - 1) + \frac{\mu_2(t)}{n^{1/2}} - \frac{\rho_2(t)}{2n^{1/2}} \right\} + O(n^{-1}), \tag{2.6}$$

where $\rho_j(t)$, $j = 2, 3$ and $\mu_2(t)$ are the bias- and skewness-corrected term of the usual normal approximation to the distribution of the studentized ACL estimator (see Jeong (2000)).

Using a one-term Cornish-Fisher expansion, the 100α th percentile of the distribution of the studentized ACL estimator is

$$K_n^{-1}(\alpha; t) = z_\alpha + \frac{\rho_3(t)}{6n^{1/2}}(z_\alpha^2 - 1) + \frac{\mu_2(t)}{n^{1/2}} - \frac{\rho_2(t)}{2n^{1/2}} + O(n^{-1}), \tag{2.7}$$

where $\Phi(z_\alpha) = \alpha$. The right-hand side of (2.7) is equal to z_α plus $O(n^{-1/2})$. Incorporating the next term into an approximation for $K_n^{-1}(\alpha; t)$ helps account for the bias and skewness arising in finite samples, thus yield a more accurate approximation to the 100α th percentile of the distribution of $n^{1/2} (\bar{F}_n(t) - \bar{F}(t))/\sigma_n(t)$. Suppose we define

$$\bar{F}_n^{EX}(\alpha; t) = \bar{F}_n(t) - K_n^{-1}(1 - \alpha; t) \frac{\sigma_n(t)}{n^{1/2}}. \tag{2.8}$$

Then

$$\begin{aligned} P\{ \bar{F}_n^{EX}(\alpha; t) \geq \bar{F}(t) \} &= P\left\{ \bar{F}_n(t) - K_n^{-1}(1 - \alpha; t) \frac{\sigma_n(t)}{n^{1/2}} \geq \bar{F}(t) \right\} \\ &= P\left\{ \frac{n^{1/2} (\bar{F}_n(t) - \bar{F}(t))}{\sigma_n(t)} \geq K_n^{-1}(1 - \alpha; t) \right\} \\ &= 1 - K_n(K_n^{-1}(1 - \alpha; t)) \\ &= \alpha \end{aligned}$$

and thus $\bar{F}_n^{EX}(\alpha; t)$ denotes an upper 100α th confidence limit for $\bar{F}(t)$.

If we substitute (2.7) into $\bar{F}_n^{EX}(\alpha; t)$, we obtain

$$\bar{F}_n^{EX}(\alpha; t) = \bar{F}_n(t) - \left(z_{1-\alpha} + \frac{\rho_3(t)}{6n^{1/2}}(z_{1-\alpha}^2 - 1) + \frac{\mu_2(t)}{n^{1/2}} - \frac{\rho_2(t)}{2n^{1/2}} \right) \frac{\sigma_n(t)}{n^{1/2}}. \tag{2.9}$$

3. Confidence Intervals for Median Survival Time

Brookmeyer and Crowley (1982) proposed the test-based interval for median survival time

$$\{ t : |\hat{S}(t) - 0.5| \leq z_{1-\alpha/2} \hat{\xi}_S(t) \}, \tag{3.1}$$

where $\hat{S}(t)$ is the KM estimator of survival function, and $\hat{\xi}_S^2(t)$ is Greenwood's formula

for the variance of $\hat{S}(t)$. The interval (3.1) can directly be applied to ACL estimator of survival function in KG model, since $n^{1/2}(\bar{F}_n(t) - \bar{F}(t))/\sigma_n(t)$ is normally distributed. Thus we obtain

$$I_1 = \{t : \bar{F}(t_{0.5}) \in [C(\alpha/2; t), C(1 - \alpha/2; t)]\}, \tag{3.2}$$

where $C(\alpha; t) = \bar{F}_n(t) - z_{1-\alpha} \frac{\sigma_n(t)}{n^{1/2}}$. An advantage of test-based interval is that the density function of the lifetime distribution need not be estimated. However, the interval (3.2) is obtained using a first-order normal approximation of studentized statistic. The appropriateness of such interval for small sample sizes or under heavy censoring is suspect. Thus we can obtain more accurate confidence limits for median survival time using Edgeworth expansion that are summarized in theorems given in Jeong (2000). We may use the results of section 2.2 to improve upon (3.2). Define

$$I_2 = \{t : \bar{F}(t_{0.5}) \in [\bar{F}_n^{EX}(\alpha/2; t), \bar{F}_n^{EX}(1 - \alpha/2; t)]\}, \tag{3.3}$$

where $\bar{F}_n^{EX}(\alpha; t)$ is defined in (2.9). The interval endpoints $\bar{F}_n^{EX}(\cdot; t)$ are theoretically more accurate than those used to compute (3.2) since I_2 match the corresponding exact endpoints to $O(n^{-3/2})$ instead of $O(n^{-1})$ on the survival function.

Slud et al. (1984) proposed a transformed-reflected confidence interval in terms of the cumulative hazard function for median survival time. Let $\hat{t}_{0.5} = \inf \{t : \bar{F}_n(t) \leq 0.5\}$ denote an estimate of median survival time $t_{0.5}$ based on the ACL estimator. Then this interval can directly be applied to ACL estimator of survival function. Thus we can construct the reflect interval for median survival time as follows:

$$I_3 = \{t : \bar{F}_n(t) \in [C(\alpha/2; \hat{t}_{0.5}), C(1 - \alpha/2; \hat{t}_{0.5})]\}, \tag{3.4}$$

where $C(\alpha; t) = \bar{F}_n(t) - z_{1-\alpha} \frac{\sigma_n(t)}{n^{1/2}}$. Next we can also obtain more accurate confidence limits for median survival time using the expansion (2.9); In particular, define

$$I_4 = \{t : \bar{F}_n(t) \in [\bar{F}_n^{EX}(\alpha/2; \hat{t}_{0.5}), \bar{F}_n^{EX}(1 - \alpha/2; \hat{t}_{0.5})]\}, \tag{3.5}$$

where $\bar{F}_n^{EX}(\alpha; t)$ is defined in (2.9).

We now distinguish the general notions of the test-based and reflect intervals for median survival time. Suppose that for a fixed time point t , $\{\bar{F}_1(t), \bar{F}_2(t)\}$ is a $100(1-\alpha)\%$ confidence interval for $\bar{F}(t)$. We describe the test-based confidence interval of the form $[t: 0.5 \in \{\bar{F}_1(t), \bar{F}_2(t)\}]$, while the corresponding reflect interval is $[t: \bar{F}_n(t) \in \{\bar{F}_1(\hat{t}_{0.5}), \bar{F}_2(\hat{t}_{0.5})\}]$.

Figure 3.1 is graphically seen the difference between these two confidence intervals (Slud et al. (1984)). The test-based interval requires knowledge of $\bar{F}_1(\cdot)$ and $\bar{F}_2(\cdot)$ at many time points. The lower limit, T_1 , is the time t at which $\bar{F}_1(t) = 0.5$, and the upper limit, T_2 is that at which $\bar{F}_2(t) = 0.5$. By contrast, the lower endpoint, R_1 , of the reflect interval is obtained by horizontally projecting the upper confidence bound $\bar{F}_2(\hat{t}_{0.5})$, until it meets $\bar{F}(\cdot)$; the t corresponding the meeting point is taken as R_1 . An analogous procedure using $\bar{F}_1(\hat{t}_{0.5})$ defines R_2 . Then the reflect interval requires calculation of $\bar{F}_1(t)$ and $\bar{F}_2(t)$ only at $t = \hat{t}_{0.5}$.

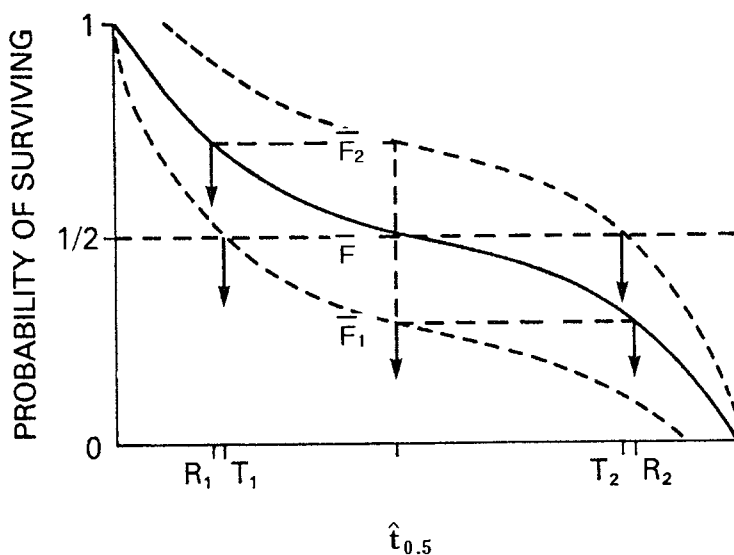


Figure 3.1 Graphic representation of test-based and reflect intervals. T_i are endpoints of test-based interval; R_i are endpoints of reflect interval.

4. Simulation Study

In this section, we consider the performance of the confidence intervals for median survival time through the Monte Carlo simulation.

We assume that the distributions of lifetimes are Weibull ($Weib(a, b)$) whose probability density function is the form

$$f(t) = abt^{b-1}e^{-at^b}, \quad 0 < t < \infty,$$

where $a > 0$ and $b > 0$. The parameters of lifetime distributions are considered $a = 1.0$ and $b = 0.7$ (decreasing failure rate), $b = 1.0$ (constant failure rate) and $b = 1.5$ (increasing failure rate). Since the lifetimes are subject to be censored to the right and the survival function of censoring time is some power of the survival function of lifetime, we set the censoring times are also distributed as an Weibull distribution whose parameter is selected to make censoring rate to be 20%, 30% and 50%, respectively. And we construct confidence intervals for median survival time for sample sizes of $n = 20, 30$ and 50 and nominal coverage levels of 90% and 95% based on 10,000 replications.

We investigate the coverage probability and average length for their confidence intervals. For a given α level, the confidence intervals should have coverage $100(1-\alpha)\%$. And the better confidence intervals have the shorter average lengths.

Table 4.1-4.3 show the coverage probability and average length at the median survival time. We can observe that the coverage probabilities of all intervals achieve the nominal coverage levels as n increases and the censoring rate decreases. And the average lengths are shorter as n increases and the censoring rate decreases. For all types of censoring, all average lengths decrease as the lifetime hazards changed from decreasing to increasing. Table 4.1 summarizes the results for the survival time distribution with decreasing failure rate ($Weib(1.0, 0.7)$), Table 4.2 summarizes those for constant failure rate ($Weib(1.0, 1.0)$) and Table 4.3 summarizes those for increasing failure rate ($Weib(1.0, 1.5)$).

From Table 4.1, in the case of test-based intervals we show that I_2 is closer to the nominal coverage probabilities than the I_1 . But the average lengths of I_2 is slightly longer than that of the I_1 , particularly, in the case of small sample or heavy censoring. In the reflect intervals, I_4 is also outperformed the I_3 in most cases. From the Table 4.2-4.3, we can see almost equal results given in Table 4.1.

So, our simulation study shows that the confidence limits using Edgeworth expansion are more accurate approximation to median survival time than those using the first-order normal approximation and that I_4 is superior to all others considered in terms of maintaining coverage accuracy, being very close to nominal levels in all cases.

Table 4.1 Comparison on the coverage probabilities and average lengths for the decreasing failure rate at the median survival time ($F \sim Weib(1.0, 0.7)$)

Censoring Rate(%)	Sample Size	α	Test-based Interval				Reflect Interval			
			I_1		I_2		I_3		I_4	
			Coverage	Length	Coverage	Length	Coverage	Length	Coverage	Length
10	20	0.05	0.9345	1.1466	0.9585	1.3886	0.9529	1.2568	0.9472	1.1795
		0.10	0.8769	0.9521	0.9103	1.1052	0.9085	1.0347	0.9053	0.9960
	30	0.05	0.9374	0.9165	0.9580	1.0682	0.9558	0.9699	0.9548	0.9555
		0.10	0.8799	0.7512	0.9087	0.8534	0.8987	0.7966	0.9031	0.7551
	50	0.05	0.9400	0.6960	0.9565	0.7663	0.9526	0.7241	0.9517	0.6893
		0.10	0.8887	0.5797	0.8998	0.6093	0.8989	0.5934	0.9010	0.5842
30	20	0.05	0.9210	1.2760	0.9631	1.5671	0.9579	1.3285	0.9534	1.3327
		0.10	0.8762	1.0566	0.9219	1.2723	0.9021	1.0907	0.9013	1.0931
	30	0.05	0.9380	1.0078	0.9598	1.1533	0.9533	1.0373	0.9496	1.0289
		0.10	0.8765	0.8071	0.9139	0.9108	0.8978	0.8306	0.8981	0.8296
	50	0.05	0.9411	0.7437	0.9549	0.7821	0.9521	0.7431	0.9482	0.7500
		0.10	0.8860	0.6133	0.9100	0.6461	0.8983	0.6174	0.8984	0.6167
50	20	0.05	0.9191	1.4670	0.9628	1.7380	0.9610	1.5530	0.9591	1.5598
		0.10	0.8583	1.1990	0.9233	1.4755	0.9229	1.2666	0.9196	1.2801
	30	0.05	0.9298	1.3078	0.9600	1.5732	0.9608	1.2289	0.9575	1.2272
		0.10	0.8766	1.0615	0.9214	1.2371	0.9195	1.0061	0.9145	1.0090
	50	0.05	0.9376	0.8970	0.9588	1.0378	0.9540	0.8704	0.9537	0.8729
		0.10	0.8873	0.7306	0.9116	0.8136	0.9128	0.7083	0.9070	0.7260

Table 4.2 Comparison on the coverage probabilities and average lengths for the constant failure rate at the median survival time ($F \sim Weib(1.0, 1.0)$)

Censoring Rate(%)	Sample Size	α	Test-based Interval				Reflect Interval			
			I_1		I_2		I_3		I_4	
			Coverage	Length	Coverage	Length	Coverage	Length	Coverage	Length
10	20	0.05	0.9348	0.8780	0.9589	1.0241	0.9530	0.9549	0.9491	0.9238
		0.10	0.8802	0.7322	0.9122	0.8371	0.9112	0.7946	0.9049	0.7757
	30	0.05	0.9334	0.7086	0.9551	0.8059	0.9487	0.7492	0.9499	0.7510
		0.10	0.8761	0.5852	0.9084	0.6552	0.8965	0.6199	0.8969	0.5978
	50	0.05	0.9422	0.5503	0.9548	0.5990	0.9546	0.5741	0.9457	0.5529
		0.10	0.8890	0.4606	0.9016	0.4811	0.8993	0.4725	0.9001	0.4684
30	20	0.05	0.9245	0.9398	0.9636	1.1220	0.9534	0.9900	0.9504	0.9993
		0.10	0.8770	0.7953	0.9252	0.9357	0.9048	0.8271	0.9045	0.8305
	30	0.05	0.9324	0.7639	0.9622	0.8639	0.9541	0.7961	0.9477	0.7878
		0.10	0.8712	0.6210	0.9081	0.6936	0.8922	0.6433	0.8901	0.6434
	50	0.05	0.9381	0.5787	0.9585	0.6085	0.9474	0.5843	0.9494	0.5876
		0.10	0.8853	0.4831	0.9051	0.5078	0.8987	0.4897	0.8950	0.4890
50	20	0.05	0.9209	1.0395	0.9617	1.2222	0.9600	1.1299	0.9566	1.1404
		0.10	0.8572	0.8616	0.9266	1.0488	0.9177	0.9276	0.9127	0.9421
	30	0.05	0.9254	0.9167	0.9595	1.0925	0.9541	0.9069	0.9537	0.9056
		0.10	0.8711	0.7638	0.9158	0.8725	0.9154	0.7514	0.9124	0.7542
	50	0.05	0.9394	0.6748	0.9560	0.7652	0.9536	0.6689	0.9535	0.6693
		0.10	0.8900	0.5541	0.9094	0.6121	0.9121	0.5504	0.9075	0.5604

Table 4.3 Comparison on the coverage probabilities and average lengths for the increasing failure rate at the median survival time ($F \sim Weib(1.0, 1.5)$)

Censoring Rate(%)	Sample Size	α	Test-based Interval				Reflect Interval			
			I_1		I_2		I_3		I_4	
			Coverage	Length	Coverage	Length	Coverage	Length	Coverage	Length
10	20	0.05	0.9319	0.6334	0.9596	0.7194	0.9533	0.6875	0.9464	0.6830
		0.10	0.8751	0.5297	0.9145	0.5962	0.9086	0.5764	0.8963	0.5695
	30	0.05	0.9395	0.5234	0.9592	0.5841	0.9548	0.5539	0.9473	0.5620
		0.10	0.8839	0.4334	0.9103	0.4812	0.9047	0.4588	0.8986	0.4478
	50	0.05	0.9412	0.4088	0.9553	0.4412	0.9510	0.4275	0.9496	0.4166
		0.10	0.8910	0.3441	0.9036	0.3573	0.9006	0.3539	0.8999	0.3523
30	20	0.05	0.9207	0.6603	0.9644	0.7771	0.9457	0.7044	0.9567	0.7157
		0.10	0.8743	0.5635	0.9211	0.6559	0.8946	0.5921	0.8945	0.5957
	30	0.05	0.9396	0.5503	0.9612	0.6186	0.9461	0.5796	0.9515	0.5715
		0.10	0.8769	0.4502	0.9144	0.5020	0.8971	0.4691	0.8981	0.4695
	50	0.05	0.9380	0.4262	0.9563	0.4488	0.9486	0.4332	0.9498	0.4345
		0.10	0.8854	0.3562	0.9101	0.3749	0.9012	0.3629	0.9011	0.3621
50	20	0.05	0.9168	0.7146	0.9638	0.8416	0.9595	0.7974	0.9611	0.8106
		0.10	0.8605	0.6012	0.9209	0.7224	0.9232	0.6582	0.9201	0.6707
	30	0.05	0.9338	0.6398	0.9610	0.7542	0.9584	0.6533	0.9580	0.6510
		0.10	0.8820	0.5371	0.9151	0.6121	0.9154	0.5418	0.9137	0.5441
	50	0.05	0.9395	0.4861	0.9605	0.5483	0.9478	0.4899	0.9483	0.4898
		0.10	0.8885	0.4027	0.9096	0.4426	0.9112	0.4055	0.9084	0.4111

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