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A general estimator of the treatment effect when the data are heavily censored

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SUMMARY

A generalized Hodges–Lehmann type estimator for the treatment effect in the two-sample problem with right censoring, is proposed based on an inverse-quantile-type idea using truncated versions of the Kaplan–Meier estimators over the subspace where they are consistent. Its strong consistency and asymptotic normality can be obtained, under no conditions on the uninformative censorings, and the resulting variance is easily estimable from the data. In simulation studies the proposed estimator is superior to existing procedures in the presence of heavy unequal censoring.

Some key words: Bootstrap; Censoring; Hodges–Lehmann estimator; Kaplan–Meier estimator; Scale parameter; Shift parameter; Treatment effect.

1. INTRODUCTION

An important problem in survival analysis within biostatistics and reliability testing is to estimate the difference between two treatments, or a treatment and a control, the two-sample problem. This problem is complicated in the presence of right censoring, especially when such censoring is informative. We shall focus on uninformative but arbitrary censoring.

Most of the methods in the existing literature address this problem through one of two models, the accelerated life model and the proportional hazards model. (Cox & Oakes, 1984, Ch. 5.) We concentrate on the location shift model, which is equivalent to the accelerated life model, with a log transformation. This model is specified by the hazard rate function $\lambda(t)=f(t)\{1-F(t)\}^{-1}$, where F is the cumulative distribution function of the survival times and $f=F'$. It is assumed that $\lambda(t)=\lambda_0(te^{-\beta})e^{-\beta}$, where $\lambda_0(t)$ is the baseline hazard function. The treatment effect is thus to accelerate or decelerate the time to failure. This model can be expressed as a regression problem with β replaced by $z\beta$ where z is a row vector of covariates for each study subject and β a column vector of regression parameters. This formulation can be used to address the two-sample problem by selecting $z=0$ for the first sample and $z=1$ for the second. Linear regression methods can be used to solve the hypothesis testing and estimation problems (Cox & Oakes, 1984, p. 65).

A few direct procedures for the two-sample problem impose fewer assumptions than the regression methods. Wei & Gail (1983) propose an estimation procedure, indirectly through testing procedures based on test statistics from Gill's (1980, p. 46) K^+ class. They impose fairly strong conditions to warrant the consistency and asymptotic normality of their estimator, and the variance of their estimator depends on the unknown density functions and their derivatives, which are hard to estimate well in the presence of censoring. As a result, they propose test-based confidence intervals for the parameter. Padgett & Wei (1982) address the scale version of the two-sample problem. To establish the consistency of their estimator, they assume that the support of the censorings exceed the support of the true survival distributions. If this condition is violated, the consistency of their estimate is questionable, as we demonstrate with Example 2 in § 6. Such will be the case if the second sample is heavily censored. Note that the asymptotic normality of that estimator was not discussed by Padgett & Wei (1982).

Akritas (1986) introduced a general method for quantile estimation in the shift version of the two-sample problem, using the distribution of the differences between the two lifetimes and truncating the samples before the upper limits of the supports of the censorings. He suggested that this method could be used to estimate the shift parameter. To do this, however, one must know in advance the proportion of the differences on the truncated spaces that are smaller than the shift. This is not common, since this proportion is a function of the unknown underlying distribution, unless the supports of the censorings extend to infinity, in which case this proportion is equal to $\frac{1}{2}$.

In the present paper, we propose a generalized Hodges–Lehmann estimator that avoids the difficulties and problems mentioned above. The Hodges–Lehmann estimator has been widely used because of its robustness and simplicity, and our generalization preserves these desirable properties. After developing necessary notation in § 2, we present in § 3 the motivation and definition of our estimator. Its large-sample properties are given in § 4. These results are obtained under very weak conditions on the survival distributions and under no conditions on the censoring mechanisms. Section 5 describes a method for consistently estimating its large-sample variance, and § 6 presents simulation studies as well as a brief discussion on some practical issues.

Note that the method used for estimating the shift parameter can easily be transformed to answer the scale question. Or if desired, one can apply the shift method directly to the log-transformed data. In fact these two procedures lead to the same estimator. Since the distribution of the estimator is asymptotically known, confidence intervals for the parameter can be directly derived, and thus the procedure described herein can be applied to testing problems, for instance to test the hypothesis of 'no difference' in location or scale.

2. STATEMENT OF THE PROBLEM AND NOTATION

Assume $x_1^0, \ldots, x_n^0$ are independent and identically distributed random variables according to the survival function $\bar{F}(s) = \mathrm{pr}\,(x_i^0 \geqslant s)$, with a similar assumption for $y_1^0, \ldots, y_m^0$ according to $\bar{G}(s) = \mathrm{pr}\,(y_j^0 \geqslant s)$. In the location shift model it is assumed that $G(s) = F(s - \Delta)$, Δ being an unknown parameter, to be estimated.

In the presence of right censoring, we cannot observe the x_i^0's or y_j^0's directly, since they have been censored by two sequences of random variables u_i and v_j, independent of the x_i and y_j. Here the u_i's and v_j's are independent and identically distributed according to $\bar{U}(s) = \mathrm{pr}\,(u_i \geqslant s)$ and $\bar{V}(s) = \mathrm{pr}\,(v_j \geqslant s)$, respectively. Instead, we observe the pairs

$$\{x_i = \min\,(x_i^0, u_i),\ \varepsilon_i = 1_{(x_i^0 \leqslant u_i)},\ i = 1, \ldots, n\},$$

$$\{y_j = \min\,(y_j^0, v_j),\ \gamma_j = 1_{(y_j^0 \leqslant v_j)},\ j = 1, \ldots, m\}.$$

Let $\bar{F}_n(s)$, $\bar{G}_m(s)$ be the Kaplan–Meier estimators of $\bar{F}(s)$, $\bar{G}(s)$ respectively. Define $F_n(s)=1-\bar{F}_n(s)$ and $G_m(s)=1-\bar{G}_m(s)$. Let T_1 and T_2 be preselected constants such that $\bar{F}(T_1)>0$, $\bar{G}(T_2)>0$ and almost surely, as $n, m\to\infty$,

$$\sup_{s\leq T_1}|F_n(s)-F(s)|\to 0, \quad \sup_{s\leq T_2}|G_m(s)-G(s)|\to 0.$$

Now define

$$K_1(\delta)=\text{pr}\,(y-x\leq\delta, x\leq T_1)=\int_{-\infty}^{T_1} G(s+\delta)\,dF(s),$$

$$K_2(\delta)=1-\text{pr}\,(y-x\geq\delta, y\leq T_2)=1-\int_{-\infty}^{T_2} F(s-\delta)\,dG(s),$$

$$P_1=\int_{-\infty}^{T_1} F(s)\,dF(s), \quad P_2=1-\int_{-\infty}^{T_2} G(s)\,dG(s).$$

Their estimators $\hat{K}_1(\delta)$, $\hat{K}_2(\delta)$, $\hat{P}_1$ and $\hat{P}_2$ are obtained by replacing F and G in the expressions above by F_n and G_m, respectively. Notice that both $K_r(\delta)$ and $\hat{K}_r(\delta)$ $(r=1,2)$ are monotone functions of δ.

3. Motivation and definition of our estimator

If in the problem above there is no censoring, then (Hodges & Lehmann, 1963) the shift hypothesis is, assuming that such Δ is unique,

$$\text{pr}\,(Y-X\geq\Delta)=\text{pr}\,(Y-X\leq\Delta)=\tfrac{1}{2}. \tag{3·1}$$

This generates the process for estimating Δ. Let

$$K(\delta)=\text{pr}\,(Y-X\leq\delta)=\int_{-\infty}^{\infty} G(x+\delta)\,dF(x), \quad P=\int_{-\infty}^{\infty} F(x)\,dF(x)=\tfrac{1}{2}.$$

Then (3·1) becomes $K(\Delta)-P=0$ and Δ can be thought of as $\Delta=K^{-1}(P)=K^{-1}(\frac{1}{2})$. Thus using the empirical estimator analogue for $K^{-1}(\delta)$, the estimator proposed by Hodges & Lehmann is $\hat{\Delta}=\hat{K}^{-1}(P)=\hat{K}^{-1}(\frac{1}{2})$, which in fact minimizes $|\hat{K}(\delta)-\frac{1}{2}|$ and thus it turns out that $\hat{\Delta}$ is the median among all differences y_j-x_i. In the problem at hand though, empirical distributions are no longer consistent because of the censoring. Natural substitutes in this case are the Kaplan & Meier (1958) estimators. But it is known that these estimators might not be consistent beyond the supports of the censorings. Thus we use the truncated versions $K_1(\delta)$, $K_2(\delta)$ and P_1, P_2, referred to in § 2. So now we have

$$K_1(\Delta)-P_1=0, \quad K_2(\Delta)-P_2=0, \tag{3·2}$$

instead of $K(\Delta)-P=0$. Note that (3·2) corresponds to shifting G by Δ to the left or F by Δ to the right. In the estimation process we seek to minimize

$$|\hat{K}_1(\delta)-\hat{P}_1|=\left|\int_{-\infty}^{T_1} G_m(s+\delta)\,dF_n(s)-\int_{-\infty}^{T_1} F_n(s)\,dF_n(s)\right|, \tag{3·3}$$

$$|\hat{K}_2(\delta)-\hat{P}_2|=\left|\int_{-\infty}^{T_2} F_n(s-\delta)\,dG_m(s)-\int_{-\infty}^{T_2} G_m(s)\,dG_m(s)\right| \tag{3·4}$$

over δ, subject to the consistency of the Kaplan-Meier estimators. Since both F_n and G_m are present in each expression, the consistency of both is needed. In (3·3), F_n is, by the selection of the upper limit of integration, T_1. In order to guarantee that $G_m(s+\delta)$ is consistent, we must have $s+\delta \leqslant T_2$. It is enough to impose the restriction $\delta \leqslant T_2 - T_1$ since $s \leqslant T_1$. The solution of this constrained minimization is, up to $O(n^{-1})$, $\hat{\Delta}_1 = \min\{\hat{K}_1^{-1}(\hat{P}_1), T_2 - T_1\}$, which is a consistent estimator for $\min(\Delta, T_2 - T_1)$. With a similar argument, using (3·4) we obtain $\hat{\Delta}_2 = \max\{\hat{K}_2^{-1}(\hat{P}_2), T_2 - T_1\}$, which is a consistent estimator for $\max(\Delta, T_2 - T_1)$. Since

$$\min(\Delta, T_2 - T_1) + \max(\Delta, T_2 - T_1) = \Delta + T_2 - T_1,$$

we propose as an estimator for Δ

$$\hat{\Delta}_{nm} = \hat{\Delta}_1 + \hat{\Delta}_2 - (T_2 - T_1).$$

Notice that in the absence of censoring, when $T_1 = T_2 = \infty$ the proposed estimator reduces to the Hodges–Lehmann estimator. Two differences with it, however, are worth pointing out. The Hodges–Lehmann estimator is the 50th percentile, i.e. the median, of the differences $Y_j - X_i$. But in the censored case we do not have a fixed, known proportion any more. Instead we have the quantities P_1 and P_2 that are unknown and have to be estimated. Thus the solutions, no matter which expression we use, (3·3) or (3·4), are no longer the median among the $y_j - x_i$ which have nonzero weight. Secondly, the solution depends on the minimization of both expressions (3·3) and (3·4). Thus by inverting two monotone functions instead of one we gain flexibility in dealing with differences in the censoring distributions.

4. Large-sample properties of $\hat{\Delta}_{nm}$

The following two theorems give the large-sample properties of $\hat{\Delta}_{nm}$, namely its consistency and its asymptotic normality.

THEOREM 1. *Suppose that Δ is the unique solution for $K_r(\delta) = P_r$ $(r = 1, 2)$, where $K_r(\delta)$, P_r are defined in § 2. Then $\hat{\Delta}_{nm} \to \Delta$, almost surely, as $n, m \to \infty$.*

THEOREM 2. *Let $\lambda = \lim\{n/(n+m)\}$ and $t_0 = \min(T_1, T_2 - \Delta)$. Assuming $0 < \lambda < 1$, $F(t)$ is continuous and*

$$d(t_0) = \lim_{\varepsilon \to 0} \frac{1}{\varepsilon} \int_{-\infty}^{t_0} \{F(t+\varepsilon) - F(t)\} dF(t)$$

exists and is positive, then $(n+m)^{\frac{1}{2}}(\hat{\Delta}_{nm} - \Delta)$ is asymptotically normally distributed, as $n, m \to \infty$, with mean zero and variance

$$\frac{\lambda^{-1}\sigma_1^2(t_0) + (1-\lambda)^{-1}\sigma_2^2(t_0)}{\{d(t_0)\}^2},$$

where

$$\sigma_1^2(t_0) = \frac{1}{4} \int_{-\infty}^{t_0} \frac{\{\bar{F}^2(t) - \bar{F}^2(t_0)\}^2}{\bar{F}(t)\bar{H}_F(t)} dF(t), \tag{4·1}$$

$$\sigma_2^2(t_0) = \frac{1}{4} \int_{-\infty}^{t_0+\Delta} \frac{\{\bar{G}^2(t) - \bar{G}^2(t_0+\Delta)\}^2}{\bar{G}(t)\bar{H}_G(t)} dG(t). \tag{4·2}$$

Here $\bar{H}_F(t) = \bar{F}(t)\bar{U}(t)$, $\bar{H}_G(t) = \bar{G}(t)\bar{V}(t)$ are the observed survival distribution functions.

Note that

$$d(t_0) = \int_{-\infty}^{t_0} f^2(t)\, dt$$

if $F(t)$ has density $f(t)$.

When there is no censoring, in which case $T_1 = T_2 = \infty$, this variance reduces to

$$\left\{12\lambda(1-\lambda) \int_{-\infty}^{\infty} f^2(t)\, dt\right\}^{-1},$$

the asymptotic variance of the Hodges–Lehmann estimator (Hodges & Lehmann, 1963).

5. Estimation of the variance of $\hat{\Delta}_{nm}$

To estimate the large-sample variance of $\hat{\Delta}_{nm}$, we can use the Kaplan–Meier estimators $\bar{F}_n$ and $\bar{G}_m$ for the true survival distributions $\bar{F}$ and $\bar{G}$, and the empirical distribution functions $\bar{H}_F^{(n)}$ and $\bar{H}_G^{(m)}$ for the observed survival distributions $\bar{H}_F$ and $\bar{H}_G$ respectively in (4·1) and (4·2), but $d(t_0)$ needs special treatment. For this we use an adaptation of a method of Rao (1983, pp. 269–70). In his notation, let $\{\phi_k(t), k \geq 0\}$ be an orthonormal basis in the space of square integrable functions. Through Parseval's equality $\int f^2(t)\, dt = \Sigma\, a_k^2$, where $a_k = \int f(t)\phi_k(t)\, dt = \int \phi_k(t)\, dF(t)$, with the integrals over the range (a, b), we can estimate

$$\int_a^b f^2(t)\, dt \quad \text{by} \quad \sum_{k=0}^{q(n)} \hat{a}_k^2,$$

where

$$\hat{a}_k = \int_a^b \phi_k(t)\, d\hat{F}(t) = \sum_{x_i \leq t_0} \phi_k(x_i) w_i \varepsilon_i.$$

Here w_i is the Kaplan–Meier weight of x_i, replacing the equal weights n^{-1} used by Rao in the uncensored case, and $q(n) = o(n^{\frac{1}{2}})$. A simple choice for $\phi_k(t)$ can be

$$\phi_k(t) = \begin{cases} (b-a)^{-\frac{1}{2}} & (k=0), \\ 2(b-a)^{-\frac{1}{2}} \cos\{\pi k(t-a)(b-a)^{-\frac{1}{2}}\} & (k \geq 1), \end{cases}$$

where $b = t_0$, and $a = 0$ since it is usually assumed in practice that the support of these distributions starts from 0. In general, one can select a so that the probability mass for values of t between $-\infty$ and a is negligible. Thus we can estimate the variance consistently, without having to estimate the density of the survival function.

6. Examples and discussion

In this section we present some simulation results to demonstrate the effectiveness of the proposed procedure, and to compare it with the method of Padgett & Wei (1982), which has the same degree of computational simplicity as ours, but with added conditions on the censoring mechanisms. We use the following notation in the examples below. Let $\mathscr{E}(\lambda, a)$ be the exponential distribution with mean λ starting from a, $\mathscr{C}(\alpha, \beta)$ be the Cauchy distribution centred at α and scaled by β and $\mathscr{U}[a, b]$ be the uniform distribution over $[a, b]$.

Example 1. We performed a Monte Carlo study with two combinations of lifetime and censoring distributions. In the first combination F is $\mathscr{E}(1, 5)$ with $\Delta = 2$, U is $\mathscr{E}(1, 6{\cdot}2)$ and V is $\mathscr{E}(1, 8)$. In the second combination F is $\mathscr{C}(5, 1)$ with $\Delta = 2$, U is $\mathscr{U}[5, 7]$ and V is $\mathscr{U}[8, 10]$. Notice that the censorings in each case are not equal even after shifting. The sample sizes are $n = 40$ and $m = 50$. The values for T_1 and T_2 were selected so that they will be within the support of the censoring distributions. In particular, we chose $T_1 = 6{\cdot}5$ and $T_2 = 8{\cdot}1$ for the first combination and $T_1 = 6$ and $T_2 = 9$ for the second combination. Table 1 gives the simulation results over 500 Monte Carlo repetitions. The first and second columns contain the sample mean and the sample standard deviation, S_{MC}, of $\hat{\Delta}_{nm}$, over the 500 repetitions. The third contains the sample mean of the estimate of the standard deviation of $\hat{\Delta}_{nm}$, S_{est}, over the same 500 repetitions, using the method of § 5, the fourth the bootstrap estimate of the standard deviation, S_{boot}, over 21 samples drawn from the chosen distributions and the last one the true value of the asymptotic standard deviation, S_{true}, whenever it is possible to calculate it directly from the formula in Theorem 2. The results in the exponential case clearly show the consistency of the estimate and give a satisfactory estimate for the variance. In the Cauchy case the standard deviation estimate is not as satisfactory, and the bootstrap gives better results. Note that the application of the bootstrap is straightforward since it only involves repeated random sampling with replacement from the pairs (x_i, ε_i) and (y_j, γ_j) (Efron, 1981; Lo & Singh, 1986). Finally, for the exponential case we plot in Fig. 1 the inverse of the asymptotic relative efficiency of our procedure with respect to the one proposed by Padgett & Wei (1982), as a function of t_0, defined in Theorem 2. It should be clear that as t_0 approaches infinity our estimator coincides with the Padgett–Wei estimator and thus its asymptotic relative efficiency becomes one. On the other hand, as t_0 approaches the beginning of the support of F our estimator demonstrates superefficiency since it becomes the maximum likelihood estimator, which in this case is the difference of the minimum sample order statistics among the observed uncensored values.

Table 1. *Simulation results for shift estimate and standard deviation comparisons in the exponential and Cauchy-uniform cases*

	$\bar{\Delta}_{nm}$	S_{MC}	S_{est}	S_{boot}	S_{true}
Exponential	2·0001	0·1112	0·0800	0·1206	0·1046
Cauchy-uniform	1·9232	0·3829	0·5846	0·3666	—

$\bar{\Delta}_{nm}$, S_{MC}, mean value and standard deviation of estimate over 500 Monte Carlo replications; S_{est}, mean estimated standard deviation; S_{boot}, bootstrap estimate of standard deviation; S_{true}, true asymptotic standard deviation.

Example 2. In this simulation we used Cauchy survival distributions and uniform censoring. In particular F is $\mathscr{C}(5, 1)$ with $\Delta = 2$, U is $\mathscr{U}[11, 13]$ and V is $\mathscr{U}[7, 8]$. In the first sample there is practically no censoring, whereas in the second there is very heavy censoring and the upper end of its support is below that of the corresponding survival, thus violating the conditions of Padgett & Wei. Again 500 Monte Carlo replications were generated, with $n = 180$ and $m = 220$. Our procedure resulted in an average estimated shift 1·9828 with a standard deviation of 0·173 whereas Padgett & Wei's method yielded an average estimated shift 1·7996 with a standard deviation of 0·171 over the 500

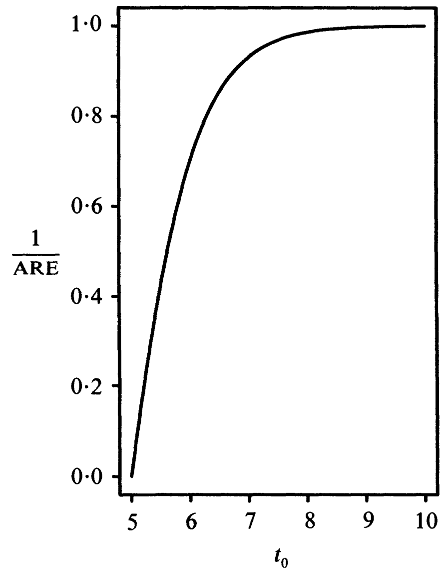

Fig. 1. Inverse of asymptotic relative efficiency of proposed estimator with respect to that of Padgett & Wei (1982) as a function of t_0. Survival and censoring functions are exponentials used in Example 1.

replications. Since the Monte Carlo mean of the Padgett–Wei estimator for Δ falls more than 10 of its standard deviations away from the true value, the consistency of their estimator is questionable in this case. Because the consistency of our estimator is guaranteed regardless of the censoring mechanisms, it gives good results even in this very unbalanced situation.

Example 3. We now address the issue of the choice of T_1 and T_2 and the sensitivity of the estimator and its variance to this choice. Table 2 presents the effects of the various choices when the distributions are the exponential pair from Example 1 and the Cauchy-uniform pair from Example 2 with sample sizes $n = 40$ and $m = 50$. The values of T_1 and T_2 were selected in the following fashion. First, since the distributions were known, we selected fixed T_1 and T_2, corresponding to the first row of the table, so that they seemed

Table 2. *Choosing different T_1 and T_2*

	Exponential		Cauchy-uniform	
T_1, T_2	$\bar{\Delta}_{nm}$	S_{MC}	$\bar{\Delta}_{nm}$	S_{MC}
Fixed*	2·0031	0·1214	2·0672	0·3868
Max	1·9911	0·1481	2·0515	0·3714
98%	1·9911	0·1434	2·0676	0·3853
95%	1·9971	0·1395	2·0696	0·3886
90%	1·9965	0·1369	2·0747	0·3949
80%	1·9963	0·1289	2·0860	0·4196
70%	1·9940	0·1200	2·0861	0·4549
60%	1·9905	0·1074	2·0779	0·5162
P&W	1·9950	0·1474	1·8057	0·3523

* For exponential, $T_1 = 6{\cdot}5$, $T_2 = 8{\cdot}1$; for Cauchy-uniform, $T_1 = 12$, $T_2 = 7{\cdot}5$.

P&W, Padgett & Wei's (1982) estimator.

reasonable. Then we selected them in a data-dependent way starting with the maximum uncensored observation, then proceeding to the 98th percentile of all observations, uncensored and censored, then the 95th, 90th, 80th, 70th and 60th percentiles. We also include the Padgett-Wei estimator, in the last row, for comparison purposes. Within each case, the two columns give the average value of the estimate $\hat{\Delta}_{nm}$ from 500 Monte Carlo repetitions and its sample standard deviation S_{mc} over these repetitions. In the exponential-exponential case it is clear that the average values are almost unchanged with the change in T_1 and T_2, whereas the variances decrease as discussed in Example 1. In the Cauchy-uniform case again the variation in the average values is very little, but the variance increases as we truncate more observations.

As a matter of practical choice, the investigator can decide what values of T_1 and T_2 to use before the data are collected, if this is possible. Otherwise, our suggestion to the potential user of our method would be to select the 90th or 95th sample percentile of the observed survival times, a choice that our simulation results support. The optimal choice of T_1 and T_2 which result in the minimum asymptotic variance is still an open problem.

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