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THE EXACT ORDER OF NORMAL APPROXIMATION OF THE EFFICIENT SCORES TEST FOR PROPORTIONAL HAZARD MODELS CALCULATED OVER TIME

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Abstract

Efficient score tests are used often in clinical trials where the data are censored. The asymptotic null distribution of such tests was obtained recently by Tsiatis (1981) using ideas of weak convergence. In the present note we establish the exact order of approximation with explicit (up to a generic constant) upper bound.

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1. INTRODUCTION

Let X be the random variable denoting failure time and assume that it has a proportional hazard (failure) rate (see Cox (1972)), i.e., the hazard rate is given by:

$$\lambda(x|z) = \lambda(x) \exp(\beta z), \tag{1.1}$$

where $\lambda(x|z)$ denotes the hazard rate of X given that the covariate Z is equal to z. The covariate Z has a mean μ_Z and variance σ_Z^2. Let Y denote the time of entry into the study. Assume that $\beta = 0$ and that X, Y, and Z are mutually independent (see Tsiatis (1981)).

If the data were to be observed at time t then one may have a random sample of the random vectors $(X_1(t), \Delta_1(t), Z_1), \ldots, (X_n(t), \Delta_n(t), Z_n)$, where $X_i(t) = \max\{0, \min(X_i, t - Y_i)\}$, $\Delta_i(t) = 1$ if $X_i + Y_i < t$ and is 0 otherwise, and Z_i is the covariate.

The efficient score test statistic for testing H_0: $\beta = 0$ is given by (see Tsiatis (1981), formula (2.1)):

$$D_n(t) = \Sigma_{i=1}^{n} \Delta_i(t) \, [Z_i - \Sigma_{j=1}^{N_i(t)} Z_j/N_i(t)], \tag{1.2}$$

where

$$N_i(t) = \Sigma_{j=1}^{n} I(X_j(t) \geq X_i(t)), \quad i = 1, \ldots, n. \tag{1.3}$$

By decomposing $D_n(t)$ into two terms $\bar{D}_n(t)$ and $E_n(t)$, Tsiatis (1981) uses the ideas of weak convergence to show that $n^{-1/2} E_n(t)$ converges in probability to zero and chooses $\bar{D}_n(t)$ so that it is the sum of independent identically distributed random variables with finite variance. Thus he establishes the central limit theorem of $D_n(t)$. Using the usual Cramer-Wold technique he then establishes the asymptotic joint normality of $(D_n(t), D_n(t^*))'$.

In the present note we use a different decomposition and the classical arguments of conditional moments to establish the exact order of this approximation when we allow for the usual moment condition (the third) required in the Berry-Esseen theorem. When only second moments are allowed then we observe that our argument yields Tsiatis' result using a much simpler technique.

2. MAIN RESULTS

Let $t^* > t$ be two points in time and define $(\ddagger)_{11} = \sigma_Z^2\, P[\Delta_1(t) = 1]$, $(\ddagger)_{22} = \sigma_Z^2\, P[\Delta_1(t^*) = 1]$ and $(\ddagger)_{12} = (\ddagger)_{21} = (\ddagger_{11})$, where $(\ddagger)_{ij}$ denotes the (i, j) element of the covariance matrix $\ddagger$. Assume that $P[X_2(t) \leq X_1(t)] > 0$.

THEOREM 1. *If* $E|Z|^3 < \infty$ *and if* $(\ddagger)_{11} = \sigma_1^2$, $(\ddagger)_{22} = \sigma_2^2$, *and* $_{12}/\,[(\ddagger)_{11}\ (\ddagger)_{22}]^{1/2} = \rho(t, t^*) = \rho$, *then for all* $n \geq 1$

$$\sup_{x,y} |P[D_n(t) \leq \sigma_1 x\sqrt{n},\ D_n(t^*) \leq \sigma_2 x\sqrt{n}] - \Phi_\rho(x, y)| \leq Cn^{-1/2}, \quad (2.1)$$

where $C > 0$ *in a positive constant given by:*

$$C = C(\sigma_Z^2, E|Z|^3, \rho(t, t^*), p(t), p(t^*)) = K\theta(1 - \rho^2(t, t^*)) + \frac{\sigma^2}{p(t)} + \frac{\sigma^2}{p(t^*)} + \sqrt{\frac{2}{\pi}}, \quad (2.2)$$

where $K > 0$ *is an absolute constant*, $\theta > E|Z-\mu_Z|^3 / \sigma_Z^2$, *and* $p(t) = P[\Delta_1(t) = 1]$.

Before proving this result we need the following lemma whose proof is given in the Appendix for completeness.

LEMMA 1. *Let* $(X_1, Y_1)'$ *and* $(X_2, Y_2)'$ *be two vectors of random variables such that the distribution function of* $(X_1, Y_1)'$ *is* $F(.,.)$ *and the distribution function of* $(X_1 + X_2, Y_1 + Y_2)'$ *is* $G(.,.)$. *Let further* $\Phi_\rho(x, y)$ *denote the distribution function of the standard bivariate normal* (i.e., *the* d.f. *of* (Z_1, Z_2) *is bivariate normal such that* $EZ_1 = EZ_2 = 0$ *and* $Var(Z_1) = Var(Z_2) = 1$ *and* $Cov(Z_1, Z_2) = \rho$. *Then for any* $\epsilon > 0$,

$$\sup_{x,y}|G(x,y)-\Phi_\rho(x,y)| \leq \sup_x |F(x,y)-\Phi_\rho(x,y)| + P[|X_2|>\epsilon] + P[|Y_2|>\epsilon] + \sqrt{\frac{2}{\pi}}\,\epsilon. \tag{2.3}$$

PROOF OF THEOREM 1. Let

$$\tilde{D}_n(t) = \Sigma_{i=1}^n \Delta_i(t)\,[Z_i - \mu_Z]. \tag{2.4}$$

Then using Lemma 1 above we get that (with $\sigma_1 = \sqrt{\ddagger_{11}}$, $\sigma_2 = \sqrt{\ddagger_{22}}$):

$$\begin{aligned}\sup_{x,y}|P[D_n(t) \leq \sigma_1 x\sqrt{n},\ D_n(t^*) \leq \sigma\, y\sqrt{n}] - \Phi_\rho(x,y)| \\ \leq \sup_{x,y}|P[D_n(t) \leq \sigma_1 x\sqrt{n}, \tilde{D}_n(t^*) \leq \sigma_2 x\sqrt{n}] - \Phi(x,y)| + P[n^{-\frac{1}{2}}|D_n(t) \\ -\tilde{D}_n(t)| \geq \epsilon_n] + P[n^{-\frac{1}{2}}|D_n(t^*) - \tilde{D}_n(t^*)| \geq \epsilon_n] + \sqrt{\frac{2}{\pi}}\,\epsilon_n,\end{aligned} \tag{2.5}$$

where $\rho = \rho(t, t^*) = \text{cov}\,(\tilde{D}_n(t), \tilde{D}_n(t^*))/\sqrt{Var(\tilde{D}_n(t)\ Var(\tilde{D}_n(t^*))} = \{P[\Delta_1(t) = 1]/P[\Delta_1(t^*) = 1]\}^{\frac{1}{2}}$.

Using a theorem of Dunnage (1970) we obtain that the upper bound of the first term in the right-hand side of (2.12) is less than a equal $K\theta(1 - \rho^2)^{-5/2}\, n^{-\frac{1}{2}}$ where $\theta \geq \dfrac{E|Z-\mu_Z|^3 P[\Delta_1(t)=1]}{\sigma_Z^2 P[\Delta_1(t) = 1]} = \dfrac{E|Z-\mu_Z|^3}{\sigma_Z^2}$. Next, we shall show that $n^{-\frac{1}{2}}(D_n(t) - \tilde{D}_n(t))$ converges in probability to zero as $n \to \infty$. Note that

$$D_n(t) - \tilde{D}_n(t) = \Sigma_{i=1}^n \Delta_i(t)[\mu_Z - \Sigma_{j=1}^{N_i(t)} Z_j/N_i(t)]. \tag{2.6}$$

To achieve our goal we shall show that $n^{-1} E(D_n(t) - \tilde{D}_n(t))^2 \to 0$, as $n \to \infty$. First we show that $E(D_n(t) - \tilde{D}_n(t)) = 0$. To see this note that

$$E(D_n(t) - \tilde{D}_n(t)) = E\{\Sigma_{i=1}^n \Delta_i(t)\ E\ [[(\mu_Z - (\Sigma_{j=1}^{N_i(t)} Z_j)/ N_i(t)] | \Delta_i(t),\ N_i(t)]\}. \tag{2.7}$$

But $E\{[(\mu_Z - \Sigma_{j=1}^{N_i(t)} Z_j/N_i(t)) \mid N_i(t)]\} = 0$. Thus $E(D_n(t) - \tilde{D}_n(t)) = 0$. Thus we look at n^{-1} $Var(D_n(t) - \tilde{D}_n(t))$. Let (U, V) be a random vector with finite second moments. Using the well-known result:

$$Var(V) = E[Var(V|U)] + Var[E(V|U)],$$

we have

$$\begin{aligned} n^{-1}Var(D_n(t)-\tilde{D}_n(t)) &= n^{-1}Var[\Sigma_{i=1}^n \Delta_i(t)\{\mu_Z - (\Sigma_{j=1}^{N_i(t)} Z_j/N_i(t))\}] \\ &= n^{-1}E\{Var[\Sigma_{i=1}^n \Delta_i(t)\{\mu_Z - (\Sigma_{j=1}^{N_i(t)} Z_j/ N_i(t))\}|\Delta_i(t)'s,\ N_i(t)'s]\} \\ &\quad + n^{-1}Var\{E[\Sigma_{i=1}^n \Delta_i(t)\{\mu_Z - (\Sigma_{j=1}^{N_i(t)} Z_j/ N_i(t))|\Delta_i(t)'s,\ N_i(t)'s]\}. \end{aligned} \tag{2.8}$$

But the Z_i's are independent of $\Delta_i'(t)$'s and $N_i(t)$'s. Thus

$$E\{\mathrm{Var}\ \Sigma_{i=1}^{n}\Delta_i(t)\{\mu_Z - (\Sigma_{j=1}^{N_i(t)} Z_j/N_i(t))\}|\Delta_i(t)\text{'s},\ N_i(t)\text{'s}\}$$

$$= E\{\Sigma_{i=1}^{n}\Delta_i^2(t)\cdot\frac{\sigma_Z^2}{N_i(t)}\} \leq \sigma_Z^2\ \Sigma_{i=1}^{n} E\,\frac{1}{N_i(t)}\,. \tag{2.9}$$

But for $i = 1, \ldots, n$, $N_i(t) = 1 + X_{n-1}$ where X_{n-1} is binomial with parameters $(n - 1)$ and $p(t) = P[X_2(t) \geq X_1(t)]$. Hence

$$E\,\frac{1}{N_i(t)} = E\,\frac{1}{1 + X_{n-1}} = np(t)^{-1}\ \{1 - [1 - p(t)]^n\}. \tag{2.10}$$

But also,

$$n^{-1}\mathrm{Var}[\{E\Sigma_{i=1}^{n}\Delta_i(t)\{\mu_Z - (\Sigma_{j=1}^{N_i(t)} Z_j/N_i(t)\}|\Delta_i(t)\text{'s},\ N_i(t)\text{'s}]\} = 0 \tag{2.11}$$

Hence from (2.7) - (2.11) we get

$$n^{-1}\mathrm{Var}(D_n(t) - \tilde{D}_n(t)) \leq \sigma_Z^2[1-(1-p(t))^{n-1}]/np(t) \leq \sigma_Z^2/np(t), \tag{2.12}$$

which converges to 0 as $n \to \infty$.

Next, since $n^{-\frac{1}{2}}(D_n(t) - \tilde{D}_n(t))$ converges to 0 in probability we evaluate in place of the second and third terms of the right-hand-side of (2.5) the values $P[n^{-1}(D_n(t) - \tilde{D}_n(t))^2 \geq \epsilon_n]$ and $P[n^{-1}(\tilde{D}_n(t^*) - \tilde{D}_n(t^*))^2 \geq \epsilon_n]$. But by Tchebychev's inequality we have that

$$P[n^{-1}(D_n(t) - D_n(t)^2 \geq \epsilon_n] \leq \frac{\sigma_Z^2}{n\epsilon_n p(t)}\,. \tag{2.13}$$

The bound for the second term is $\frac{\sigma_Z^2}{n\epsilon_n p(t^*)}$. Choosing $\epsilon_n = n^{-\frac{1}{2}}$ we get that the left-hand-side of (2.5) is bounded above by,

$$n^{-\frac{1}{2}}[K\theta(1-\rho^2(t)) + \frac{\sigma_Z^2}{p(t)} + \frac{\sigma_Z^2}{p(t^*)} + \sqrt{\frac{2}{\pi}}] = n^{-\frac{1}{2}}C(E|Z|^3,\ \sigma_Z^2,\ \rho(t),$$

$$p(t),\ p(t^*)), \qquad (2.14)$$

This concludes the proof. QED.

REMARK 1. It follows from the proof of Theorem 1 that if $\sigma_1^2 > 0$ and $\sigma_2^2 > 0$, then $n^{-\frac{1}{2}}(D_n(t) - \tilde{D}_n(t))$ converges in probability to 0 as $n \to \infty$ and since $\tilde{D}_n(t)$ is the sum of n independent identically distributed random variables with mean 0 and variance $n\,\mathrm{Var}[\Delta_1(t)\ (Z_1 - \mu_Z)] = n\sigma_Z^2\ P[\Delta_1(t) = 1]$, by independence of $\Delta_1(t)$ and Z_1 it follows that the univariate CLT holds for $D_n(t)$. Also, since $\mathrm{Cov}(\tilde{D}_n(t), \tilde{D}_n(t^*)) = n\sigma_Z^2\ P[\Delta_1(t) = 1]$, $t^* > t \geq 0$, then in view of the Cramer-Wold technique, $n^{-\frac{1}{2}}(D_n(t), D_n(t^*))$ is asymptotically normal with mean vector $\underline{0}'$ and covariance matrix $\ddagger$. Thus we gave an elementary proof of the result of Tsiatis (1981).

3. FURTHER REMARKS CONCERNING $D_n(t)$.

In this section we throw some more light on the case of one single time $D_n(t)$:

1. If one wishes to use the test statistic $D_n(t)$ sequentially and if the sequence of stopping times (random sample size) $\{N_n\}$ is such that $\frac{N_n}{n}$ converges in probability to a constant (taken to be 1 without loss of generality), then using a result of Anscomb (1952), $N_n^{-\frac{1}{2}} D_{N_n}(t)$ is asymptotically normal with mean 0 and variance $\sigma_Z^2\ P[\Delta_1(t) = 1]$. Also, using the well-known fact, see Richter (1965) "If Y_n converges to 0 in probability and if $\frac{N_n}{n}$ converges to one in probability then

Y_{N_n} converges to 0 in probability", thus $N_n^{-\frac{1}{2}}(D_{N_n}(t) - \tilde{D}_{N_n}(t))$ converges to 0 in probability and hence we have that $N_n^{-\frac{1}{2}} D_{N_n}(t)/\sigma_Z P[\Delta_1(t) = 1]^{\frac{1}{2}}$ is asymptotically standard normal. This result should help in studies of sequential clinical trials.

2. The order of approximation of $D_n(t)$ is also obtainable by using an argument similar to that of Theorem 2.2 leading to:

$$\sup_x |p[D_n(t) \le \sigma_1 x\sqrt{n}] - \Phi(x)| \le n^{-\frac{1}{2}} \{\frac{E|Z-\mu_Z|^3}{\sigma_Z^3\{p[\Delta_1(t)=1]\}^{\frac{1}{2}}}(.8) + \frac{\sigma_Z^2}{p(t)} + \sqrt{\frac{2}{\pi}}\}, \tag{3.1}$$

where the main tool in the proof is a univariate version of Lemma 2.1 above, and (.8) in the first term of the right-hand-side follows from van Beek (1972) (in fact his constant is 0.7975).

3. In this univariate case, other types of approximations are possible, viz., if $E|Z|^3 < \infty$, then

$$\int |p[D_n(t) \le \sigma_1 x \sqrt{n}] - \Phi(x)|dx \le (n^{\frac{1}{2}}-1)^{-1}\{C+\sigma_Z/p(t)\ P^{\frac{1}{2}}[\Delta_1(t)=1] + (2\pi)^{-\frac{1}{2}}\} = O(n^{-\frac{1}{2}}). \tag{3.2}$$

To prove the above result we need the following result whose elementary proof is given in the appendix: Let (X, Y) be a random vector such that F(x) is the d.f. of X and G(x) is the d.f. of X + Y, then for any $\varepsilon>0$,

$$\int |G(x)-\Phi(x)|dx \le \frac{1}{1-\varepsilon}\int |F(x)-\Phi(x)|dx + \frac{1}{\varepsilon}\int_0^\infty P[|Y|>y]dy + (2\pi)^{-\frac{1}{2}}\frac{\varepsilon}{1-\varepsilon}. \tag{3.3}$$

Using this result with $X = n^{-\frac{1}{2}}\tilde{D}_n(t)/\sigma_1$ and $Y = n^{-\frac{1}{2}}(D_n(t) - \tilde{D}_n(t))/\sigma_1$, then

$$\int|P[D_n(t) \le \sigma_1 x \sqrt{n}] - \Phi(x)\,dx \le \frac{1}{1-\varepsilon_n}\int|P[\tilde{D}_n(t) \le \sigma_1 x \sqrt{n}] -$$

$$\Phi(x)|dx + \frac{1}{\varepsilon_n}\int_0^\infty P[n^{-\frac{1}{2}}|D_n(t) - \tilde{D}_n(t)| > y\sigma_1]dy + (2\pi)^{-\frac{1}{2}}(\frac{\varepsilon_n}{1-\varepsilon_n})$$

$$\le \frac{1}{1-\varepsilon_n} C(n^{-\frac{1}{2}}) + \frac{1}{\varepsilon_n\sigma_1}\int_0^\infty P[n^{-1}|D_n(t) - D_n(t)|^2 > w]\,dw + (2\pi)^{-\frac{1}{2}}(\frac{\varepsilon_n}{1-\varepsilon_n})$$

$$\le \frac{C}{(1-\varepsilon_n)n^{\frac{1}{2}}} + \frac{1}{\sigma_1\varepsilon_n} n^{-1}\ E(D_n(t) - \tilde{D}_n(t))^2 + (2\pi)^{-\frac{1}{2}}(\frac{\varepsilon_n}{1-\varepsilon_n})$$

$$\le \frac{C}{(1-\varepsilon_n)n^{\frac{1}{2}}} + \frac{\sigma_Z^2}{\sigma_1\varepsilon_n np(t)} + (2\pi)^{-\frac{1}{2}}(\frac{\varepsilon_n}{1-\varepsilon_n}). \tag{3.4}$$

Choosing $\varepsilon_n = n^{-\frac{1}{2}}$, the last upper bound becomes:

$$\frac{C}{n^{-\frac{1}{2}}-1} + \frac{\sigma_Z^2}{p(t)\{P[\Delta_1(t)=1]\sigma_Z\}^{\frac{1}{2}}n^{\frac{1}{2}}} + (2\pi)^{-\frac{1}{2}}\frac{1}{n^{\frac{1}{2}}-1} = O(n^{-\frac{1}{2}}),$$

where the order of the first term follows from Theorem 16 of Petrov (1975) p. 126.

4. From (2) and (3) above one can obtain an L_p-order of approximation: For any function $\xi(x)$, let $\|\xi\|_p = (\int|\xi(x)|^p dx)^{1/p}$ if $1 \le p < \infty$ and $\|\xi\|_\infty = \sup_x|\xi(x)|$. Thus since for any $1 \le p \le \infty$, $\|\xi\|_p^p \le \|\xi\|_\infty^{p-1}\|\xi\|_1$, we get that for any $1 \le p \le \infty$,

$$\|P[D_n(t) \le \sigma_1\ x\sqrt{n}] - \Phi(x)\|_p = O(n^{-\frac{1}{2}}). \tag{3.5}$$

4. APPENDIX

Proof of Lemma 2.1: For any $\varepsilon > 0$,

$$G(x, y) = P[X_1 + X_2 \le x, \; Y_1 + Y_2 \le y]$$

$$= P[X_1 + X_2 \le x, \; Y_1 + Y_2 \le y, \; |X_2| \le \varepsilon] + P[X_1 + X_2 \le x, \; Y_1 + Y_2 \le y, \; |X_2| > \varepsilon]$$

$$\le P[X_1 \le x + \varepsilon, \; Y_1 + Y_2 \le y] + P[|X_2| > \varepsilon]$$

$$= P[X_1 \le x + \varepsilon, \; Y_1 + Y_2 \le y, \; |Y_2| \le \varepsilon] + P[X_1 \le x + \varepsilon, \; Y_1 + Y_2 \le y, \; |Y_2| > \varepsilon] + P[|X_2| > \varepsilon]$$

$$\le P[X_1 \le x + \varepsilon, \; Y_1 \le y + \varepsilon] + P[|X_2| > \varepsilon] + P\,|Y_2| > \varepsilon]$$

$$= F(x + \varepsilon, y + \varepsilon) + P[|X_2| > \varepsilon] + P[|Y_2| > \varepsilon]. \tag{4.1}$$

Similarly we can show that

$$G(x, y) \ge F(x - \varepsilon, y - \varepsilon) - P[|X_2| > \varepsilon] - P[|Y_2| > \varepsilon]. \tag{4.2}$$

Hence we easily see from (4.1) and (4.2) that:

$$\sup_{x,y} |G(x, y) - \Phi_\rho(x, y)| \le \sup_{x,y} |F(x, y) - \Phi_\rho(x, y)| + \sup_{x,y} |\Phi_\rho(x - \varepsilon, y - \varepsilon) - \Phi_\rho(x, y)| + P[|X_2| > \varepsilon] + P[|Y_2| > \varepsilon]. \tag{4.3}$$

But

$$
\begin{aligned}
|\Phi_\rho(x-\varepsilon, y-\varepsilon) - \Phi_\rho(x, y)| &\le |\Phi_\rho(x-\varepsilon, y-\varepsilon) - \Phi_\rho(x-\varepsilon, y)| + \\
&\quad |\Phi_\rho(x-\varepsilon, y) - \Phi_\rho(x, y)| \\
&\le \int_{-\infty}^{x-\varepsilon} |\Phi(y-\varepsilon|w) - \Phi(y|w)|\, d\Phi(w) + \\
&\quad \int_{-\infty}^{y} |\Phi(x-\varepsilon|w) - \Phi(x|w)|\, d\Phi(w)) \\
&= \int_{-\infty}^{x-\varepsilon} |\Phi(y-\varepsilon-\rho w) - \Phi(y-\rho w)|\, d\Phi(w) + \\
&\quad \int_{-\infty}^{y} |\Phi(x-\varepsilon-\rho w) - \Phi(x-\rho w)|\, d\Phi(w) \\
&\le (2\pi)^{-\frac{1}{2}}\, \varepsilon + (2\pi)^{-\frac{1}{2}}\, \varepsilon = \sqrt{\frac{2}{\pi}}\, \varepsilon. \qquad (4.4)
\end{aligned}
$$

<u>Proof of (3.3)</u>: Again for any $\varepsilon > 0$, we can easily prove that

$$
G(x) - \Phi(x) \le F(x+\varepsilon) - \Phi(x+\varepsilon) + [\Phi(x+\varepsilon) - \Phi(x)] + P[|Y| > \varepsilon], \qquad (4.5)
$$

and

$$
G(x) - \Phi(x) \ge F(x-\varepsilon) - \Phi(x-\varepsilon) + [\Phi(x-\varepsilon) - \Phi(x)] - P[|Y| > \varepsilon] \qquad (4.6)
$$

Hence the result follows directly from the fact that $\int |\Phi(x+\varepsilon) - \Phi(x)|\, dx \le (2\pi)^{-\frac{1}{2}}$. $[\varepsilon/(1-\varepsilon)]$ and $P[|Y| > \varepsilon] \le \frac{1}{\varepsilon} \int_0^\infty P[|Y| > y]\, dy$.

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