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GRAPHICAL TESTS WITH CENSORED DATA

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We review recent results on graphical goodness-of-fit tests for censored survival data. These include tests based on survival curves, hazard rates, cumulative hazards, and spacings. Specific attention is directed to goodness-of-fit using simulatneous confidence bands. A medical example for prostate cancer is investigated by plots.

1. INTRODUCTION

This paper reviews recent results on graphical goodness-of-fit tests for censored survival data based on survival curves, hazard rates, cumulative hazards, and spacings. Specific attention is directed to graphical presentation of goodness-of-fit in terms of simultaneous confidence bands. Small sample properties are briefly addressed. Two-sample tests for are presented as plots for a medical example.

Much of the recent literature on goodness-of-fit for survival models, in particular the exponential model, was reviewed in Burke [6], Csörgő and Horváth [15] and Doksum and Yandell [19]. We focus here upon goodness-of-fit tests that can be presented as graphs of a curve or curves and accompanying simultaneous confidence bands. Tests consist of noticing whether the suspected (parametric) curve, e.g., exponential, lies entirely within the confidence band. For two samples, one constructs a test as a confidence band for the difference, or as two suitably modified bands. We discuss inference for hazard rates, cumulative hazards, survival curves, and spacings.

Section 2 presents notation and estimates. The main questions and theoretical results appear in Section 3. Graphical tools are arrayed in Section 4. Section 5 focuses upon small sample properties, raising some problems through simulation results. An example for two-sample goodness-of-fit is presented in Section 6.

2. NOTATION AND ESTIMATES

The notation follows Sections 10 and 11 of Doksum and Yandell [19]. Let the survival time for an individual be denoted by T. The survival probability is denoted by $S(t) = P(T \geqslant t)$. The hazard rate, h, is that function which is proportional to the infinitesimal probability that $T = t$, that is

$$h(t)\, dt = P(t \leqslant T < t + dt \mid T \geqslant t) + o(dt), \qquad t \geqslant 0.$$

Further, let H denote the cumulative hazard, the integral of the hazard rate. Note that $H(t) = -\log S(t)$. When more that one curve is under discussion, subscripts will be used in a natural way.

Randomly censored data may be thought of in at least two ways. We observe the time of failure or censure, Y, and an indicator D as to whether the event is a failure $(D = 1)$ or a censure $(D = 0)$. We assume that the censoring and survival mechanisms act independently. An alternative mathematical formulation under this independence assumption is that $Y = \min(T, C)$, and $D = \chi[T \geqslant C]$, with C the "potential" censoring time. Note that for any individual we only observe T or C. Thus for many biological applications, such as clinical trials, this later "potential survival time" formulation is nonsensical, as one of these random variables may be undefined and incapable of being realized. For convenience we

denote the distribution of Y by $L(y) = P(Y \geqslant y)$.

Consider a sample of n individuals, $(Y_1, D_1), (Y_2, D_2), \ldots, (Y_n, D_n)$. Let the number dead and the number at risk be, respectively,

$$N_n(t) = \#\{i \mid Y_i \leqslant t,\ D_i = 1\},$$

$$R_n(t) = \#\{i \mid Y_i \geqslant t\}.$$

Well studied estimates of S, H, and h for such a sample are, respectively, the Kaplan–Meier survival curve

$$(2.1) \qquad S_n(t) = \prod_{\{Y_i \leqslant t\}} \left(1 - \frac{D_i}{R_n(Y_i)}\right),$$

the Nelson–Aalen empirical cumulative hazard

$$(2.2) \qquad H_n(t) = \int_0^t R_n^{-1}\, dN_n = \sum_{\{Y_i \leqslant t\}} \frac{D_i}{R_n(Y_i)},$$

and the Watson–Leadbetter kernel hazard rate (Blum and Susarla [2], Burke [7], Burke and Horváth [9], Yandell [33])

$$(2.3) \qquad h_n(t) = \int K_b(t, y)\, dH_n(y) = \sum_{i=1}^{n} K_b(t, Y_i) \frac{D_i}{R_n(Y_i)}.$$

Here K_b is some kernel, which may have a fixed width or variable width (e.g., nearest neighbor) across the domain. A typical fixed width kernel would be

$$K_b(t, y) = \frac{1}{b}\, w\left(\frac{t - y}{b}\right)$$

with $w(\cdot)$ a smooth symmetric density function centered about 0, and with $b \to 0$ and $\frac{nb}{\log n} \to \infty$ as $n \to \infty$.

The asymptotic variances of the above estimates are

$$(2.4) \qquad n\, \mathrm{VAR}\,(H_n(t)) = V_H(t) = \int_0^t L(x^-)^{-1}\, dH(x)$$

$$(2.5) \qquad n\, \mathrm{VAR}\,(S_n(t)) = S^2(t)\, V_H(t)$$

2.6) $$nb\,\mathrm{VAR}\,(h_n(t)) = V_h(t) = \int K_b(t,x)\,dV_H(x).$$

'hese are estimated in a natural way by substituting estimates. For in-tance, an estimate of V_H is

$$V_{H_n}(t) = n\int_0^t R_n(x^-)^{-1}\,dH_n(x)$$

$$= n\int_0^t R_n(x)^{-1}R_n(x^-)^{-1}\,dN_n(x).$$

3. QUESTIONS AND THEORY

One wishes to state with a picture that an hypothesized curve does or loes not agree with the evidence of the data. This has been done heuristi-:ally with plots for some time. However, recent results allow one a justifi-:ation, albeit asymptotic, in terms of simultaneous confidence bands for n array of curves.

3.1. Survival and cumulative hazard. The graphical tests using simul-aneous confidence bands are based on results for maximal deviations of he forms

3.1) $$\sup_{a\le t\le A}\left|\frac{n^{\frac{1}{2}}(H_n(t)-H(t))}{(1+V_H(t))}\right| \overset{D}{\Rightarrow} \sup_{0\le u\le 1}|B^0(u)|,$$

3.2) $$\sup_{a\le t\le A}\left|\frac{n^{\frac{1}{2}}(H_n(t)-H(t))}{V_H(A)}\right| \overset{D}{\Rightarrow} \sup_{0\le u\le 1}|B(u)|,$$

n which $\Rightarrow$ stands for convergence in distribution, B^0 is a Brownian ridge and B is standard Brownian motion. These transformations were roposed by Aalen [1], Hall and Wellner [22], and Csörgő and Iorváth [16]. Reviews on the transformations of product-limit and elated processes can be found in Nair [26] and in Csörgő and Iorváth [18]. The exact choice of a and A depend on tail conditions f the true distribution. An estimate of the variance process, e.g. V_{H_n}, can e substituted provided that it converges uniformly at a fast enough rate, nd that appropriate additional conditions are placed on a and A. Similar

results hold for survival curves, with $(H_n - H)$ replaced by $\frac{S_n - S}{S}$ or $\frac{S_n - S}{S_n}$. These results have been strengthened from weak convergence to strong approximation by the "Hungarian embedders" (Burke, Csörgő and Horváth [8], Csörgő and Horváth [16], [17]), allowing approximations of integrals of empirical processes.

One can emphasize particular portions of the domain by introducing a weight function g, with $g(t)t^{-\frac{1}{2}}$ nonincreasing in a neighborhood of 0. This weight would be $g\left(\frac{V_H(t)}{1+V_H(t)}\right)$ in (3.1) and $g\left(\frac{V_H(t)}{V_H(A)}\right)$ in (3.2) for the left hand sides, and $g(u)$ for the right hand sides. Here, a and A must tend to finite limits within the domain of survival. Further, although one can substitute V_{H_n} for V_H with a weight function in (3.2), no general result has been found for such a substitution in (3.1). One choice for g yields bands with the distribution of $\sup|B|$.

(3.3) $$H_n(t) \pm C_1 n^{-\frac{1}{2}},$$

$$S_n(t) \neq C_1 n^{-\frac{1}{2}} S_n(t).$$

Equal variance bands, with distribution tabled by Borovkov and Sycheva [3], arise for another choice of g,

(3.4) $$H_n(t) \pm C_2 n^{-\frac{1}{2}} V_{H_n}(t)^{\frac{1}{2}},$$

$$S_n(t) \pm C_2 n^{-\frac{1}{2}} S_n(t) V_{H_n}(t)^{\frac{1}{2}}.$$

Finally, one can obtain Kolmogorov–Smirnov type distribution bands of the form

(3.5) $$H_n(t) \pm C_3 n^{-\frac{1}{2}}(1 + V_{H_n}(t)),$$

$$S_n(t) \pm C_3 n^{-\frac{1}{2}} S_n(t)(1 + V_{H_n}(t)).$$

Note that one has constant width bands for the cumulative hazard with (3.3). One obtains constant width bands for the survival curve with (3.5) in the case of no censoring. The bands in (3.4) correspond to a uniform widening of pointwise confidence intervals.

Another approach to choosing what portions of the distribution to emphasize is a composite band introduced recently by Mason and Schuenemeyer [25] in which one takes the minimum of a Kolmogorov–Smirnov statistic and Rényi statistics at each end; however their work only applies to the case of no censoring. Fleming and Harrington [20] and Csörgő and Horváth [18] discuss alternative bands which remove the effect of censoring on the variance of the pivotal statistic. See the reviews and cited articles.

3.2. Log cumulative hazard. The log of the cumulative hazard has been studied recently by, Schumacher [28] showing similar types of weak convergence results. In particular, for $a \leqslant t \leqslant A$,

$$\frac{n^{\frac{1}{2}} H(t)(\log H_n(t) - \log H(t))}{(1 + V_H(t))} \xrightarrow{D} B^0\left(\frac{V_H(t)}{1 + V_H(t)}\right),$$

$$\frac{n^{\frac{1}{2}} H(t)(\log H_n(t) - \log H(t))}{V_H(A)} \xrightarrow{D} B\left(\frac{V_H(t)}{V_H(A)}\right).$$

These lead to simultaneous confidence bands with the same weight functions as in the previous section, namely

$$\log H_n(t) \pm C_1 n^{-\frac{1}{2}} H_n(t)^{-\frac{1}{2}},$$

$$\log H_n(t) \pm C_2 n^{-\frac{1}{2}} \left(\frac{V_{H_n}(t)}{H_n(t)}\right)^{\frac{1}{2}}, \tag{3.6}$$

$$\log H_n(t) \pm C_2 n^{-\frac{1}{2}} H_n(t)^{-\frac{1}{2}} (1 + V_{H_n}(t)).$$

3.3. Hazard rate. Simultaneous confidence bands for hazard rates using kernel estimates with censored data were derived at about the same time by Burke [7] and Yandell [33]. See also Burke and

Horváth [9]. The results follow earlier work on density estimation, yielding bands of the form, $a \leqslant t \leqslant A$,

$$h_n(t) \pm Ck_{1n}(nb)^{-\frac{1}{2}} (V_{h_n}(t))^{\frac{1}{2}}, \tag{3.7}$$

or alternatively

$$h_n(t) \pm Ck_{2n}(nb)^{-\frac{1}{2}} \left(\frac{h_n(t)}{L_n(t)}\right)^{\frac{1}{2}},$$

in which k_{in} depend on $(A - a)$, b and the fixed kernel $w(\cdot)$.

It appears that, based on work of Csörgő and Révész [14], one could derive similar bands for nearest neighbor estimates of the hazard rate. Tanner and Wong [31] have explored such an estimator empirically.

3.4. Total time on test. Tests based on spacings are discussed briefly in Doksum and Yandell [19]. Csörgő et al. [11] obtained a strong approximation for the total time on test process by a Gaussian process in the case of uncensored data. Csörgő et al. [13] extended the total time on test transforms to censored data.

For this section, let $F = 1 - S$ and $F_n = 1 - S_n$. The empirical total time on test statistic is

$$H_n^{-1}(u) = \int_0^{F_n^{-1}(u)} (1 - F_n(t))\, dt, \qquad 0 \leqslant u \leqslant 1,$$

with

$$F_n^{-1}(u) = \min\{T_i \mid F_n(T_i) \geqslant u,\ i = 1, \ldots, n\}.$$

The scaled total time on test statistic is

$$D_n^{-1}(u) = \frac{H_n^{-1}(u)}{H_n^{-1}(1)},$$

it has not been possible to obtain uniform results over the entire interval $0 \leqslant u \leqslant 1$. Instead fix $p_0 < F(T_C)$, with $T_C = \inf\{t \mid P(C_i \geqslant t) = 0\}$.

Csörgő et al. [13] show that one can obtain convergence in distribution of

$$t_n(u) = n^{\frac{1}{2}}(H_n^{-1}(u) - H_F^{-1}(u))$$

and

$$s_n(u) = n^{\frac{1}{2}}(D_n^{-1}(u) - D_F^{-1}(u))$$

to Gaussian processes uniformly over the interval $[0, p_0]$. However, the covariance processes depend in complicated ways on F and on V_H, the variance process. Further, the only known choice which leads to a Gaussian process with a tabled distribution is exponential F and no censoring. In this case the scaled total time on test pivot s_n converges to a Brownian Bridge. For other choices of F and V_H one can make statements about pointwise confidence intervals only, unless one can transform the data such that it would have an exponential distribution.

Recently, Csörgő et al. [12] proved bootstrap versions of the convergence in distribution for uncensored data. Work appears to be in progress to extend these results to censored data, providing an empirical way to bootstrap simultaneous confidence bands. However, finite sample bootstraped confidence intervals and bands may suffer from low coverage probability (Loh [24], Schenker [27]).

3.5. Two-sample bands. The two-sample problem is closely connected to the problem of goodness-of-fit. If one has (asymptotically) independent estimators H_{1n} and H_{2n}, say, one can construct a simultaneous confidence band for the difference as

$$H_{1n}(t) - H_{2n}(t) \pm C_2\left(\frac{V_{1n}(t)}{n_1} + \frac{V_{2n}(t)}{n_2}\right)^{\frac{1}{2}}.$$

Alternatively, one could construct bands for each curve,

$$\text{(3.8)} \qquad \begin{aligned} &H_{1n}(t) \pm C_2 n_1^{-\frac{1}{2}} V_{1n}(t)^{\frac{1}{2}} W(t), \\ &H_{2n}(t) \pm C_2 n_2^{-\frac{1}{2}} V_{2n}(t)^{\frac{1}{2}} W(t), \end{aligned}$$

with

$$W(t) = \frac{\left(\frac{V_{1n}(t)}{n_1} + \frac{V_{2n}(t)}{n_2}\right)^{\frac{1}{2}}}{\left(\frac{V_{1n}(t)}{n_1}\right)^{\frac{1}{2}} + \left(\frac{V_{2n}(t)}{n_2}\right)^{\frac{1}{2}}}.$$

Note that whenever these two bands overlap, the band for the difference covers 0. Hence gaps between the two bands indicate domains of difference. If $V_{1n} = V_{2n}$ (that is, if one has a common estimate for $V_1 = V_2$) and $n_1 = n_2$, then $W = \frac{1}{\sqrt{2}}$.

Similar results hold for the proportional hazards model, in which one is concerned whether or not $h_1 = ah_2$. In this case, if there is a consistent estimate of a which converges at a sufficiently fast rate, one may find a simultaneous confidence band for $H_1 - aH_2$. This is demonstrated in the example.

4. GRAPHICAL TOOLS

The chief graphical tools available for goodness-of-fit are plots of curve estimates against time or of the estimated curve against the hypothesized curve. For instance, one can plot an estimated survival curve and simultaneous confidence bands along with the guessed "null" curve. The test is whether or not the hypothesized curve is enclosed by the confidence band. In fact, one need not even plot the survival curve itself.

Alternatively one may do some transformation such that the hypothesized curves, or family of curves, are straight lines. Two well-known examples are the $P-P$ and $Q-Q$ plot, being respectively plots of $S^0(t)$ vs. $S_n(t)$ and $(S^0(t))^{-1}$ vs. $(S_n(t))^{-1}$. Note that the $P-P$ plot can be viewed as a plot of the points $(u, S_n((S^0(u))^{-1})$, that is a plot of S_n on a time-changed axis. Nair (1981) showed how to construct simultaneous bands for the $P-P$, $Q-Q$, and for analogous plots for cumulative hazards. In the latter case, $(u, H_n((H^0(u))^{-1})$ should plot as a straight line. That is, the confidence band should completely contain a straight line through the origin.

Hazard rates are usually plotted against time, with the estimate h_n and hypothesized h^0 on the same axis. In the case of increasing hazard rate, one might consider plotting h_n vs. h^0. The total time on test plot provides a graphic tool for examining increasing hazard rate. However, as indicated earlier, simultaneous bands only make sense when the underlying model is exponential.

Several types of plots suggest themselves for two-sample comparison, in addition to the obvious extension of the goodness-of-fit type plots such as $P-P$ and $Q-Q$. Note that a confidence band for the difference $S_{1n} - S_{2n}$ is equivalent to a confidence band around the $P-P$ line. In this case, the question is whether the confidence band covers the diagonal. Plots of S_{in} or H_{in} against time can be analysed using the readjusted confidence bands presented in Section 3.5. Kay [23] suggested plotting $\log(H_{in})$ vs. *time*, noting that the curves would have a constant separation if the hazards were proportional. The confidence bands (3.7), or bands adjusted for two samples, would formalize the graphical procedure.

Another possible two-sample plot compares cumulative hazards H_{in}, $i = 1, 2$, with a common hazard estimate H_n. The curves should both be linear if the hazards are proportional, and they should be coincident if their underlying hazards are the same. One could in fact plot $\log(H_{in})$ vs. $\log(H_n)$, making the curves linear and parallel if the hazards are proportional. It is not readily apparent to the author how one would construct confidence bands to encompass both the shape and the question of proportionality for these curves.

5. SMALL SAMPLE PROPERTIES

Small sample properties were briefly discussed in Doksum and Yandell [19]. Chen, Hollander and Langberg [10] obtained exact small sample results for the Kaplan–Meier estimator. Gillespie and Fisher [21] showed that large sample approximations may be poor for moderate sample size (see discussion in Csörgő and Horváth [17]). However, Nair [26] showed that the large-sample approximations for survival bands (3.3) and (3.4) are quite good with samples of size 100, even

with 25% censoring. Other important simulation work is due to Fleming and Harrington in several papers. Similar empirical work for cumulative hazards would be expected, but does not appear to have been done yet.

Little work has been done on small sample properties of hazard rates. Tanner and Wong [31] have computed moments. The simultaneous convergence leading to the strong approximation and maximal deviation results appears to parallel that of density estimates. In other words, convergence is slow. Empirical choice of smoothing parameters for density estimates has been a subject of much interest recently (Bowman [4], Bowman, Hall and Titterington [5], Stone [30]). Again, this work would appear to be analogous to that needed for hazard rates.

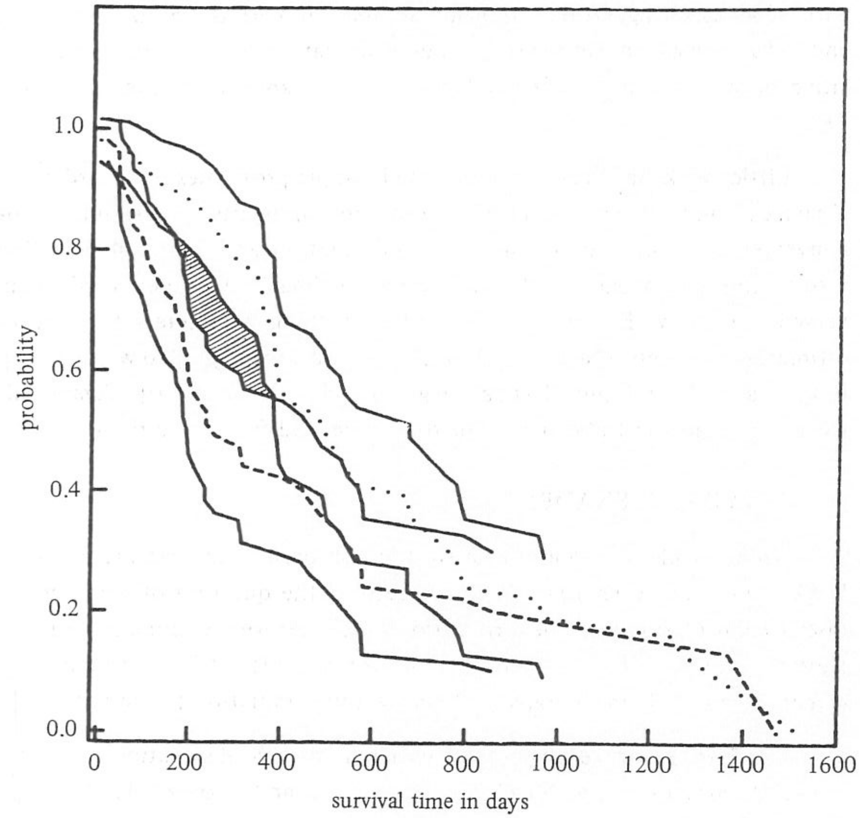
6. MEDICAL EXAMPLE

An example of goodness-of-fit for censored data was presented in Doksum and Yandell [19], concerning the question of whether the distribution of survival times from prostate cancer were exponential or not. Here we show some two-sample plots for a clinical trial comparing the effectiveness of chemotherapy with and without radiation treatment.

The two groups each had 45 patients, with 8 observations censored in each treatment group. Stablein, Carter and Novak [29] showed the survival curves and log cumulative hazard curves, but concentrated their attention on log-rank tests and the question of proportional hazards. Here we present (Figure 1) the survival curves with 80% confidence bands, adjusted as in Section 3.5. From this figure and the discussion of Stablein, Carter and Novak [29] one sees that the curves differ in the middle section but draw together after about 1.5 years. The real question is: how do they differ? The proportional hazards assumption is central to much analysis of censored survival data. In other words, one supposes that

$$H_1(t) = aH_2(t), \quad t \geq 0,$$

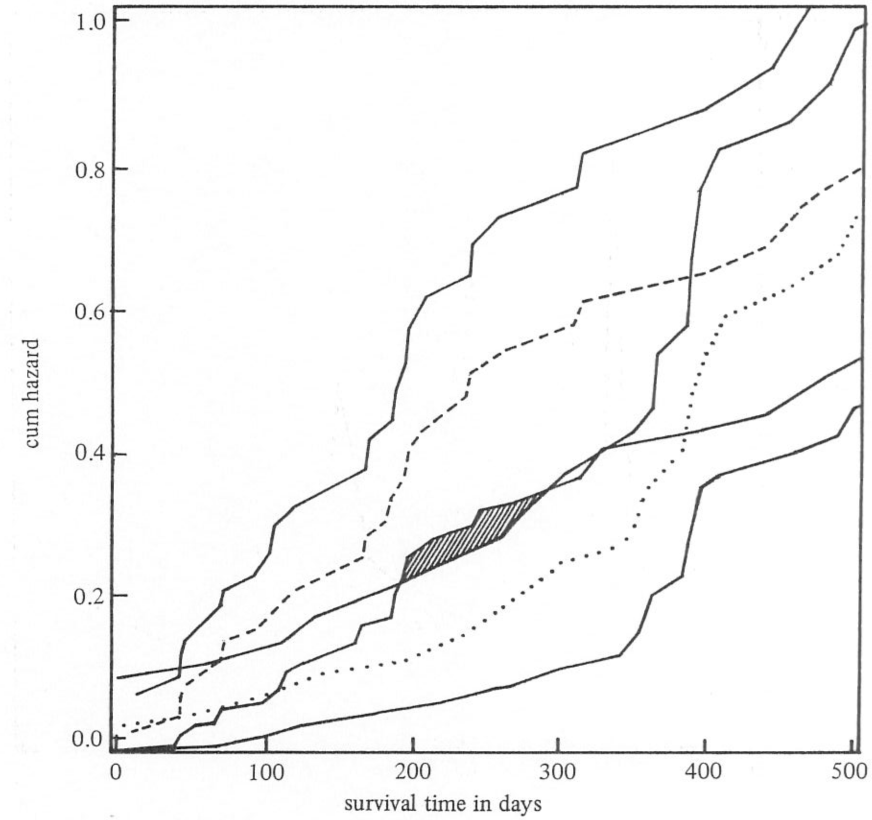
in which 1 and 2 stand respectively for chemotherapy only and chemotherapy + radiation. However, as noted by Stablein, Carter and



Kaplan–Meier survival curves. Dashed line = chemotherapy only; dotted line = chemotherapy plus radiation; solid lines for 80% simultaneous confidence bands for difference. Shaded region is area of differential survival.

Figure 1 Chemotherapy survival

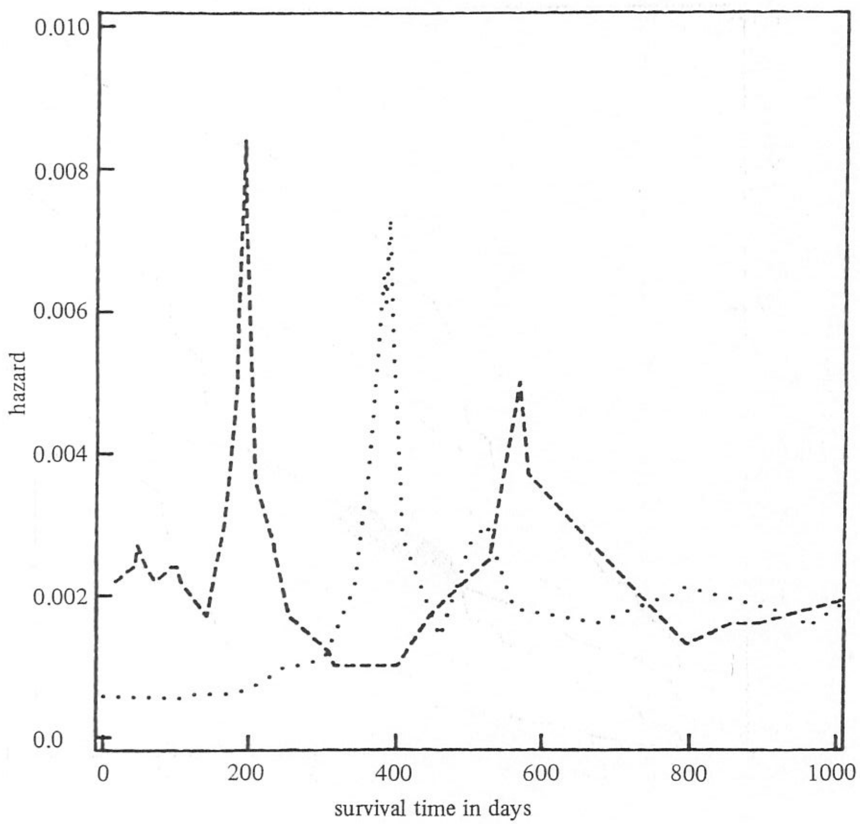
Novak [29], it appears suspect in this problem. We take the constant of proportionality from Stablein, Carter and Novak [29], $a = \exp(-0.2666)$, and plot H_{1n} and aH_{2n}, with 80% confidence bands, adjusted as in 3.5 (Figure 2). Note that the curves differ between 200 and 300 days, and appear to have similar slopes except in two places.



Nelson–Aalen cumulative hazard curves, adjusted for proportional hazards. See Figure 1 for details. Shaded region is area of nonproportional hazards.

Figure 2 Proportional hazards check

A plot of the hazard rates (Figure 3), based on 4 nearest-neighbors, clearly shows these two places as times of high risk for the respective groups. That is, chemotherapy only patients are subject to increased risk around 200 days, while this increased risk is evidenced 200 days later for those with chemotherapy and radiation. Risk of death at other times seems fairly constant. These hazard rates are plotted without confidence bands, as the asymptotic bands are too wide for this scale. There is empirical



Nearest-neighbor hazard rate curves. Dashed line = chemotherapy only; dotted line = chemotherapy + radiation.

Figure 3 Chemotherapy NN hazard

and theoretical evidence (Yandell, unpublished) that bands for hazard rates could be much narrower, but for now we can view Figure 3 as an heuristic tool. Stablein, Carter and Novak [29] did not find the specific hazard picture evidenced in the cumulative hazard and hazard rate plots, probably in large part because they did not have these tools directly available to them.

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