

COMPARING TWO SAMPLES: EXTENSIONS OF THE t , RANK SUM,
AND LOG RANK TESTS

by

Peter C. O'Brien, Ph.D.

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ABSTRACT

We consider the problem of testing the null hypothesis that two populations are identical with respect to the distribution of a continuous variable against the alternative that values tend to be larger in one population. The most commonly used tests for this problem when the data are obtained independently from the two populations are the t , rank sum, and censored data log rank tests. In this paper we: 1) call attention to the observation that these tests may be expected to be insensitive for a large class of situations, 2) propose a criterion for identifying these circumstances in a particular data set, and 3) propose corresponding extensions of the conventional methods. In addition to facilitating the identification of group differences, the proposed methods should be useful descriptively as an aid in their interpretation.

Key Words: t test, rank sum, log rank, censored data, logistic regression, maximum likelihood.

1. INTRODUCTION

One of the most common questions posed by medical investigators is, Do the values in one population (A) tend to be larger than those in a second population (B)? This question may be formulated in the context of classical hypothesis testing in terms of the cumulative distribution functions $H_0: F_A(u) = F_B(u)$ vs $H_A: F_A(u) < F_B(u)$, with strict inequality holding for at least one value of u . In practice, however, the alternative is usually formulated as shift in location, $H_A': F_A(u) = F_B(u-\Delta)$ for uncensored data, or the proportional hazards model for censored data. It has been our experience, verified by review of other published data sets, that the standard tests based on shift in location and proportional hazards alternatives may fail to identify important differences. The purpose of this paper is to 1) draw attention to this problem, 2) distinguish a broad class of situations in which the conventional procedures may be expected to be insensitive, 3) propose a criterion for identifying such circumstances in a particular data set, and 4) propose corresponding extensions of the conventional methods. The methodologies relating to the t and rank sum tests are discussed in the next section, followed by real data examples in section 3. Applications to censored data are discussed in section 4. We emphasize at the outset that the methodologies proposed should be viewed as extensions of the conventional procedures to enhance their usefulness. They are not intended as competitors to be used in place of the corresponding conventional two sample tests.

2. UNCENSORED DATA: THE t AND RANK SUM TESTS

Let $(X_1, \dots, X_m)$ and $(Y_1, \dots, Y_n)$ represent independently obtained samples with cumulative distribution functions F_x and F_y respectively, let $(W_1 < \dots < W_N)$ represent the ordered data in the pooled sample, and define $Z_i = 1$ if W_i corresponds to a member of the Y sample and 0 otherwise ($i=1, \dots, N$). If F_x and F_y are normal distributions differing only in location, $\Pr(Z = 1|W)$ may be expressed as $1/[1 + \exp\{-\alpha - \beta W\}]$, where β is the linear discriminant function (LDF) coefficient. Thus, LDF analysis regressing Z against W using ordinary least squares and comparing the estimated slope to its standard error is formally equivalent to the t test (Anderson, 1958). (Both approaches may be viewed as asymptotically exact approximations to the permutation test derived from randomization theory.) This equivalence suggests two potential sources of inefficiency for the t test: i) the association between Z and W is nonlinear, and ii) the association between Z and W may be estimated more efficiently for non-normal data using the logistic regression model with maximum likelihood estimates (see Halperin et al., 1971 and Press and Wilson, 1978).

These considerations suggest that maximum likelihood estimation in nonlinear logistic regression models may provide a useful extension to the two sample t test. Similar conclusions are obtained regarding the rank sum test from observing that it is formally equivalent to regressing Z_i against i using ordinary least squares. The linearity in this model requires that the expected number of Y values occurring between

successive X values increase (decrease) linearly. The expectation for the run length at any value P of F_X is given approximately by

$$E_P = n \{ F_Y[F_X^{-1}(P)] - F_Y[F_X^{-1}(P-1/m)] \}.$$

In particular, if F_X and F_Y are normal distributions differing only in location, the expected run lengths are found to be a nonlinear function of P , accounting for the inefficiency of the rank sum test relative to the t test in this situation. Since the curve is concave, a more efficient test for normal shift in location may be obtained by using weights which place greater emphasis on the larger ranks, in agreement with the findings of Weissfeld and Wieand (1984).

Methods for evaluating nonlinear associations using either ordinary least squares or logistic regression are, of course, well known. In the present context we propose investigating possible nonlinearity by fitting the second degree polynomial model: $\log \text{ odds } \Pr(Z=1|W) = \alpha + \beta W + \gamma W^2$, with an overall test of association obtained by testing the null hypothesis that $\beta = \gamma = 0$. Since, in general the distribution of either W or W^2 will be distinctly non-normal, we recommend use of maximum likelihood estimation with logistic regression in preference to ordinary least squares.

3. EXAMPLES

In this section we consider 3 real data examples, prototypes of some of the most common studies in medical research, illustrating the potential usefulness of the proposed methods.

Example A (randomized clinical trial).

In general terms, we assume patients are randomly assigned to either of two therapies, experimental (E) or placebo (P), with response measured by a continuous measurement W . The response in the experimentally treated group will consist of the placebo effect plus an added treatment effect if the therapy is efficacious. If the treatment effect adds precisely Δ units to W in each member of the population, then $F_E(w) = F_P(w-\Delta)$ and shift in location is the correct model for the alternative hypothesis. However, in practice, the effect of the experimental therapy will vary among different members of the population. In particular, it is not uncommon that large segments of the population will receive little or no benefit from a new therapy. Thus, a realistic formulation of the alternative hypothesis should incorporate the possibility of heterogeneous response to therapy.

We illustrate these concerns using data from a study undertaken at the Mayo Clinic to determine if plasma pheresis therapy over a three week period has a beneficial effect in treatment of chronic inflammatory demyelinating polyradiculoneuropathy (CIDP), a relatively common neurologic disease which may cause prolonged morbidity and even death. Twenty-nine patients were randomly assigned to either real or sham pheresis, with neither the patient nor the person measuring response aware of the treatment assignment. An overall measure of efficacy was the improvement in a standard clinical neurologic disability score (NDS) occurring over the 3-week period (Table 1). Details of the study design and results are reported in Dyck, et al. (Submitted).

It was anticipated beforehand that pheresis might benefit only a minority of patients. However, neither the disease etiology nor the mechanism of the hoped for treatment effect were sufficiently understood to identify such a subset based on covariate information.

Using a one-sided rank sum test, one observes no evidence of a beneficial treatment effect, $P = .249$, and linear logistic regression on the ranks yields essentially the same results, $P = .238$. We note, however, that pheresis treated patients are found among the patients showing the most deterioration as well as predominating the most improved group of patients, suggesting that a shift in location model may be inappropriate. In agreement with this observation and a priori expectations, there is evidence of a nonlinear association using a second degree model. The linear and quadratic terms are individually significant, $P = .056$ and $P = .039$ respectively, using two-sided tests. In order to formulate an overall one-sided test of the null hypothesis $H_0: \beta = \gamma = 0$, we computed the corresponding 2 d.f. chi-square test, rejecting only if the estimated log odds at W_N exceeded its null expectation of $\ln(n/m)$, and obtained $P = .027$. The nature of the observed nonlinearity in this instance suggests the speculation that plasma pheresis may be especially beneficial in accelerating recovery among patients whose prognosis would have been encouraging even without therapy.

We note that a somewhat ad hoc test may be based on M = the number of values in the pheresis sample exceeding the largest value in the sham group. The null probability that M or more of the largest observations

would all occur in the pheresis group is obtained by performing Fisher's exact test on the 2-way table having rows $(m, 0)$ and $(n - M, M)$. In the present instance, $M = 5$ and $P = .025$.

Example B (Epidemiologic evaluation of a risk factor).

We suppose that an observational study is conducted, measuring a continuous characteristic W in a population (E) of individuals exposed to a certain risk factor and in a comparable unexposed population (U) . If the effect of exposure is to increase the characteristic in each individual by a constant amount Δ , then the shift in location model $H_A: F_E(w) = F_U(w - \Delta)$ is appropriate. In practice, however, the effects of exposure are typically quite variable and large segments of the population often show little or no effect.

We illustrate with an observational study performed at the Mayo Clinic to evaluate the effects of in utero exposure to DES. Details of the study design and results are provided in Leary et al. (1984). Of particular concern was the possible effect exposure may have had on anatomical measurements. Flaccid penis diameters as measured in 262 males exposed to DES and 274 unexposed males are shown graphically in Figure 1. The corresponding means and standard deviations (in cm) were $2.693 \pm .2709$ and $2.669 \pm .2229$, respectively. In this instance there was no a priori expectation for the direction of any DES effect: the occurrence of unusually small or large values, or both, was plausible. (We note that an advantage of the quadratic model is that it will be sensitive to departures from the null hypothesis occurring simultaneously in both directions.) Thus, all tests reported are two-sided.

Two sample t and rank sum tests gave no indication of a difference between groups, $P = .264$ and $P = .593$, respectively. Linear logistic regression applied to the untransformed data and the ranks resulted in $P = .264$ and $P = .592$, respectively. However, as alluded to previously, it appeared probable at the outset that only a subset of exposed subjects would be affected. This expectation is supported by visual inspection of the figure and is confirmed using quadratic logistic regression.

Using the untransformed data, both the linear and quadratic terms are significant, $P = .052$ and $P = .045$, respectively. The overall test for association resulted in $P = .045$. Using ranks, the linear and quadratic terms were also significant, $P = .017$ and $P = .009$, respectively, and the overall test yielded $P = .028$. In view of the nonlinearity observed, one might speculate that the effect of DES exposure operates differentially within a subgroup of males, although the identifying characteristics of this subgroup are unknown.

Example C (Cross-sectional study).

Finally, we consider cross-sectional studies intended to compare a characteristic in each of two patient populations. Again, rather than assume that disease increases values by a constant amount relative to a reference population, it is typically more plausible that the determination as to whether or not alteration occurs in a given individual, as well as the magnitude of any change, will depend on both the characteristics of the patient and the characteristics of the disease as manifested in that patient.

We illustrate using data (Table 2) from a study by Blumberg, West, and Ellis (1954) and used by Lehman (1975) to illustrate the rank sum test. The purpose of the study was to compare psychological test scores in patients with unstable cancer relative to patients with a stable form of the disease. Highly negative values were considered indicative of defensiveness. The results of one-sided t and rank sum tests are $P = .132$ and $P = .050$, respectively. Using linear logistic regression on the ranks yielded $P = .036$. We note, however, that high grade patients are requested among the least defensive patients as well as predominating among the most defensive patients suggesting that the shift in location model may be inappropriate.

Using a quadratic model on the ranks, the two-sided tests for the linear and quadratic terms individually resulted in $P = .133$ and $P = .057$, respectively, and the overall one-sided test for association clearly indicated a difference between groups, $P = .013$. In this instance a quadratic model was not fitted to the original data which included both positive and negative values. The evidence for nonlinearity suggests that increased defensiveness occurs among high grade patients, but that the group is not homogeneous in this regard. In view of the heterogeneity in disease status which one would expect to find within the designation "high grade", as well as differences in the way different persons may respond to similar situations, this finding again accords with a priori expectations.

4. CENSORED DATA: THE LOG RANK TEST

As discussed by Fleming et al. (1980), the log rank test is efficient for comparing two samples subject to arbitrary right censoring when the proportional hazards model holds, whereas the Gehan-Wilcoxon procedure is relatively more sensitive to early differences. If one can specify in advance the precise nature of the difference expected, a corresponding scoring system will provide an efficient test (see Harrington and Fleming, 1982, Prentice, 1978, and Peto and Peto, 1972). Fleming et al., proposed a Smirnov type test in which prior assumptions regarding the nature of the treatment effect are not required. Conversely, however, information which may be available regarding these effects is unused. Another useful approach is to model the relative hazard as a function of time, as described by Cox, 1972. A similar approach may also be simply obtained using the preceding methodology.

Formally, if one assumes a common censoring distribution for both populations, one could ignore the censoring and perform the usual two sample tests on the observation times or their ranks. By implication, one could evaluate nonlinearity using the methods proposed previously. Of course, a more sensitive test is obtained by using scores which take the censoring into account in defining the independent variable. Since these scores will typically take on both negative and positive values, we recommend adding the absolute value of the lowest score to all the scores in fitting the quadratic model. In the following two examples we illustrate this approach using log rank scores. Notationally, let

$t_1 < \dots < t_N$) represent the ordered observation times. Define $S_i = 1$ if t_i corresponds to a death and 0 otherwise and let n_i represent the number of subjects in the risk set just prior to t_i ($i=1, \dots, N$). The log rank score for t_i is given by $c_i = \sum_{j=1}^i S_j/n_j - 1$ and $C_i = c_i + 1$ depending on whether t_i corresponds to a death or censoring, respectively. Let $(W_1 < \dots < W_N)$ represent the ordered log rank scores and define $Z_i = 1$ and W_i corresponds to an observation from the Y sample and 0 otherwise. We propose a log rank type test obtained by regressing Z against W using linear logistic regression and evaluating nonlinearity using the quadratic model described previously.

The next two examples are based on studies conducted at the Mayo Clinic and discussed by Fleming et al. (1980).

Example D. The first example compares the times to progression among 15 patients with low grade cancer versus 20 patients with high grade cancer. The experience was similar in both groups for the first 11 months, but was markedly better among low grade patients beyond 11 months. The two-sided log rank and Gehan-Wilcoxon tests yielded $P = .023$ and $P = .134$, respectively. Using a generalized Smirnov statistic, Fleming et al. obtained $P = .0022$.

Using linear logistic regression with log rank scores, one obtains $P = .022$ in agreement with the usual log rank test. However, it is obvious that the proportional hazards model does not hold. Using quadratic logistic regression, one obtains P values of .055 and .020 for the linear and quadratic terms respectively. The overall test for association

yields $P = .0027$. In this instance, the quadratic analysis is helpful in confirming the visual impression that the relative hazard is not constant and appears to increase with time.

Example E. The second example compares the survival experience of 22 patients treated with 5-Fluorouracil (5-FU) to a second group of 25 patients receiving a control therapy. Visual inspection of the survival curves (Figure 3) suggests a benefit occurred with 5-FU in the interval of 2 to 8 months following treatment, but not otherwise. The results of one-sided log rank and Gehan-Wilcoxon tests in this instance were $P = .418$ and $P = .127$ respectively. Using the generalized Smirnov statistic resulted in $P = .046$. Using linear logistic regression one obtains $P = .414$ which again agrees with the conventional log rank test. With the quadratic model, the two-sided tests for the linear and quadratic terms individually are each significant, $P = .033$ and $.052$, respectively. The overall one-sided test is significant, $P = .020$. In this case, the results of the nonlinear analysis appears to support the visual impression of a benefit associated with 5-FU which is transitory in nature.

Example F. Our final example is based on the results of a clinical trial reported by the Gastrointestinal Study Group (1982) comparing chemotherapy versus combined chemotherapy and radiation therapy in the treatment of locally unresectable gastric cancer. The data are provided in Stablein and Koutrouvelis (1985), and result in crossing survival curves as shown in Figure 4. As indicated by Stablein and Koutrouvelis,

the log rank test gives $P = .64$ (two-sided). Results with the Gehan-Wilcoxon and Smirnov tests are $P = .047$ and $P = .006$ respectively. Using a test designed specifically for sensitivity against crossing hazards, Stablein and Koutrouvelis obtain $P < .01$.

Using linear logistic regression one obtains $P = .64$, in agreement with the usual log rank test. However, with the quadratic model one obtains $P = .0007$ and $P = .0008$ for the linear and quadratic terms, with the overall 2 d.f. test for association providing $P = .0014$, confirming the visual impression of an association with non-proportional hazards.

5. DISCUSSION

In evaluating a treatment effect with uncensored paired data, pre- and post-treatment, it is often necessary to consider the possibility that the magnitude of the effect depends on pretreatment levels. Appropriate methodology generalizing the paired t test, regressing observed changes against initial values, are well known and widely used. (An analogous extension of the signed rank test is to regress the signed ranks against the pretreatment values.) Although the same problem exists with unpaired data, the need for analogous methodology generalizing the two sample t test appears to be less well recognized.

The possibility of enhancing the power of the rank sum test by weighting the ranks unequally is not new. A good overview is provided by Randles and Wolfe (1979), and power comparisons among several procedures are given by Weissfeld and Wieand (1984). However, most of the optimality theory associated with these procedures pertains only to shift in location alternatives, so that optimization is only with respect to

F_X . The larger problem of nonlinearity does not seem to have been considered. We believe that, in practice, nonlinearity is the more significant source of inefficiency. This viewpoint is supported by the examples, since to the extent that inefficiency was due to the form of F_X one would expect a gain in efficiency using linear logistic regression relative to the corresponding conventional procedure. In each instance, however, the two methods provided similar results.

A second concern with the methods alluded to above is that they require that the weights be prespecified. This is usually impractical, and any choice may take on the appearance, if not the character, of data dredging. Adaptive rank tests in which the data are used to fit weights within a predetermined class have been proposed by Behnen and Husková (1984); Behnen, Neuhaus, and Ruymgaart (1983); Eplett (1982), and Beran (1974), who demonstrate the potential for enhanced power. However, these procedures tend to focus on shift in location alternatives, are relatively difficult computationally, and, perhaps for these reasons, are in fact rarely used.

Since the need for weighting systems other than those implied by the standard tests derives from the possibility of nonlinearity in the underlying model, a reasonable solution would appear to be to fit the appropriate nonlinear model. The proposed methodology may be viewed as providing adaptive tests, with the estimated coefficients providing adaptive weights within the family of models considered.

As indicated in the examples, the need for two sample censored data procedures which are sensitive to alternatives involving nonproportional hazards has been well recognized. However, in practice their use

requires a search for interesting P-values among qualitatively different tests. As an alternative strategy, we propose a generalization of the log rank test which is simple to administer and which provides a direct evaluation of the proportional hazards assumption.

For both the censored and uncensored data situations, it may be useful to consider models other than second degree polynomials. For example, the model $\log \text{ odds} = \alpha + \beta W^{\gamma}$ may be worth investigation. However, as discussed by Gallant (1975, 1977), the null distribution of the least squares estimators for this model requires further study. Another approach would be to use a linearizing transformation on W , enabling one to use the conventional two-sample tests on the transformed data. However, under the null hypothesis, the effect of selectively using linearizing transformations will be to artificially decrease the error mean square, so that the true size of the test will be increased over the nominal level. Although the error mean square is similarly decreased by fitting higher order models as we have proposed, the effect on the size of the test is mitigated by the corresponding increase in the numerator degrees freedom.

To summarize, the methods proposed here are viewed as complementing conventional methodology, in much the same way that polynomial regression enhances the usefulness of simple linear regression. They are analogous to conventional methods which have been found to be useful in evaluating paired data, and may be viewed as an extension of this methodology to unpaired study designs. Since nonlinearity in the two sample setting is more difficult to identify visually, we recommend routinely checking for

nonlinearity when performing conventional two sample tests, utilizing maximum likelihood estimation in conjunction with nonlinear logistic regression models. In addition to enabling the detection of important group differences which might otherwise go unobserved, evaluation of the form of nonlinearity may be valuable in understanding the nature of an observed difference.

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Table 1. Data from Dyck et al.

i	W_i	Z_i
1	-69.0	0
2	-7.0	1
3	-6.8	1
4	-6.1	1
5	-6.0	0
6	-5.2	0
7	-4.0	1
8	-3.0	1
9	-2.5	0
10	-2.0	1
11	-0.5	1
12	+1.5	0
13	+4.0	0
14	+5.0	0
15	+5.5	0
16	+8.0	0
17.5	+13.0	0
17.5	+13.0	1
19	+15.0	0
20.5	+16.0	0
20.5	+16.0	1
22	+21.5	0
23	+23.5	1
24	+26.0	0
25	+32.4	1
26	+33.5	1
27	+47.3	1
28	+83.0	1
29	+96.0	1

+ values indicate improvement

$Z_i = 1$ if pheresis

$= 0$ if sham

Table 2. Data from Blumberg et al.

i	W_i	Z_i	i	W_i	Z_i
1	+10	0	25.5	-13	0
2	+7	1	25.5	-13	1
3	+7	1	25.5	-13	1
4.5	+3	0	25.5	-13	1
4.5	+3	1	25.5	-13	1
6	+1	1	29	-14	1
7	-2	0	30	-14	1
8	-3	0	31	-16	0
9	-5	1	32	-16	0
10	-6	0	33	-16	0
11.5	-7	0	34	-16	1
11.5	-7	1	35	-17	1
13	-8	1	38	-18	0
16	-9	0	38	-18	1
16	-9	0	38	-18	1
16	-9	0	38	-18	1
16	-9	0	38	-18	1
16	-9	1	41	-21	0
20	-11	0	42	-21	1
20	-11	0	43.5	-22	1
20	-11	0	43.5	-22	1
22	-12	0	45	-24	1
25.5	-13	0	46	-25	1

Negative values indicate defensiveness.

$Z_i = 1$ if high grade, 0 if low grade.

Legend for Figures:

Figure 1. Data from DES study comparing 262 exposed and 274 unexposed males.

Figure 2. Times to progression, using the Kaplan-Meier method, among 20 high grade and 15 low grade patients. (From Fleming, et. al., 1980.)

Figure 3. Survival curves, obtained using the Kaplan-Meier method, for 22 5-FU treated patients and 25 controls. (From Fleming, et. al., 1980.)

Figure 4. Survival curves, obtained using the Kaplan-Meier method for 45 chemotherapy treated patients and 45 patients receiving chemotherapy + radiation (From Stablein, et al, 1985).

FIGURE 1

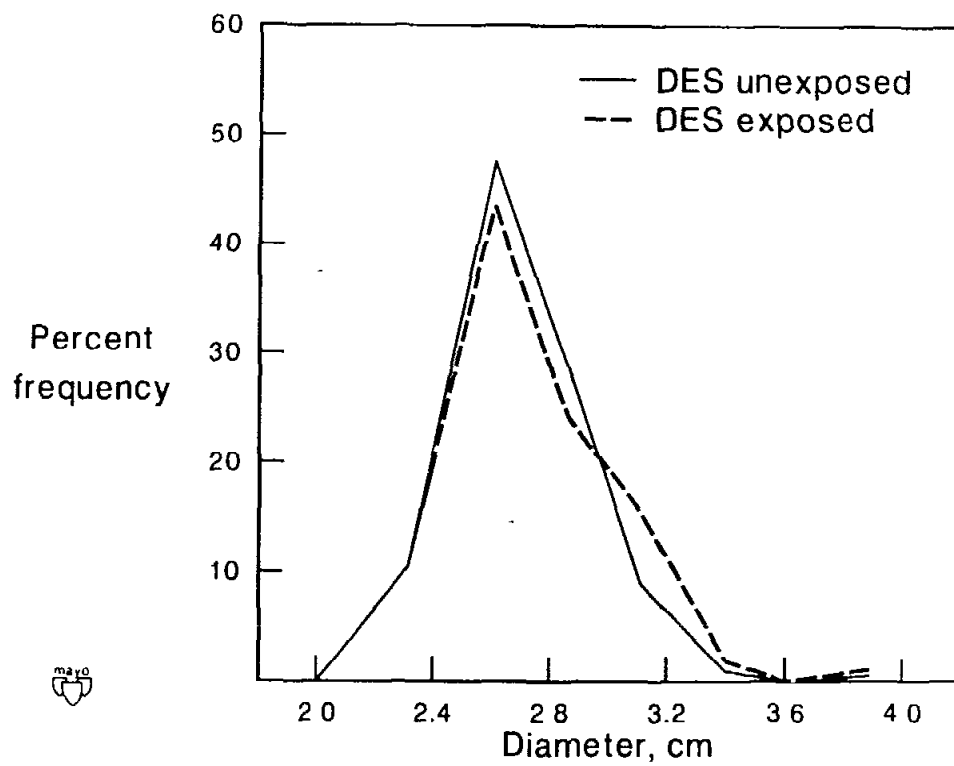


FIGURE 2

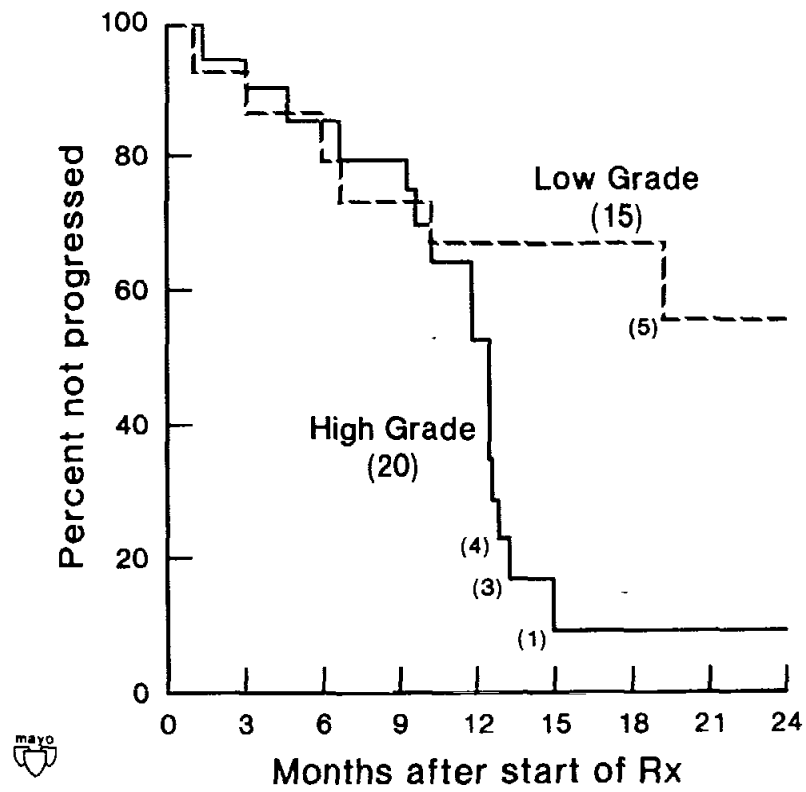


FIGURE 3

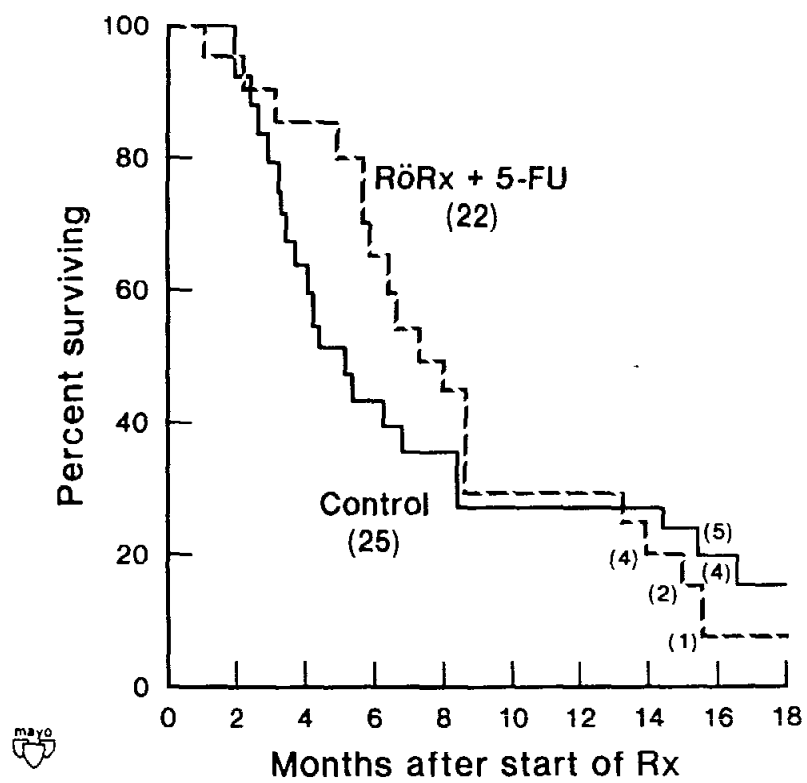
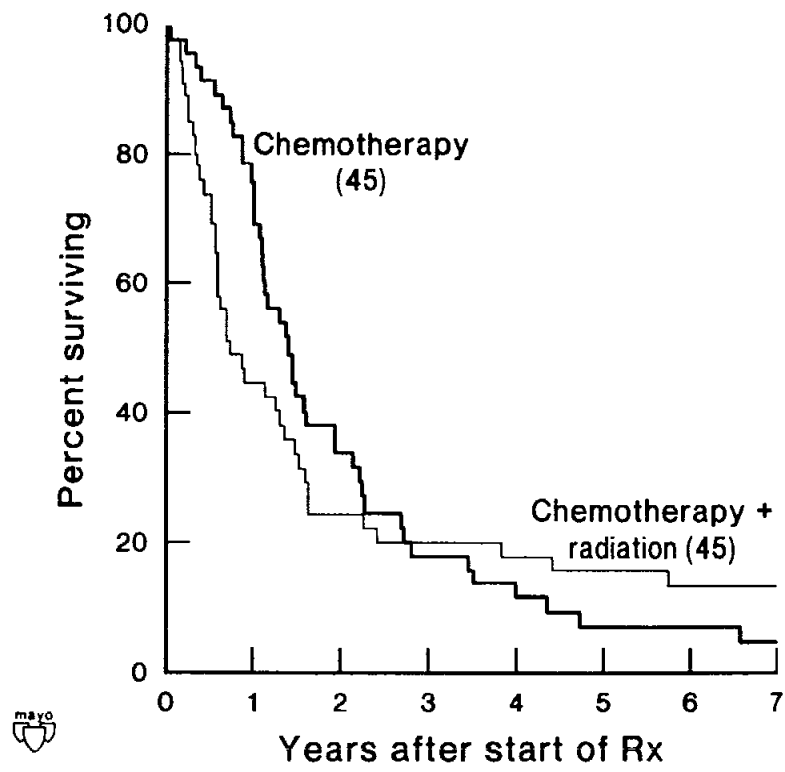


FIGURE 4



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