A SAS® MACRO FOR THE EVALUATION OF SURVIVAL TIME DATA INVOLVING TREATMENT CONVERSION USING THE MANTEL-BYAR METHOD

Eric T. Sun and Ching-Chang Hwang

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ABSTRACT

The Mantel-Byar method has been used to compare survival data for different groups in certain situations in which the group membership of an individual can be varied during a study. A modified life table, which is often difficult to program, is constructed to reflect such changes in an individual's status. The associated measures of relative risk and statistical significance of the group comparison, which are not provided by SAS/STAT® software, can then be easily calculated based on the modified life table. The code was written for use with SAS software version 6.07 in VM/CMS® to construct the table and perform the associated analysis.

I. INTRODUCTION

In clinical studies, there are situations in which an individual can change his/her group membership at a particular time during a study. These situations may occur because the assignment to treatment is not carefully controlled, or simply due to the fact that the clinical experiment allows or designs such changes. The Stanford Heart Transplantation Program, described in detail in Clark et al. (1971), is an example of the comparison of survival curves for nontransplant and transplant subjects. A subject selected for heart transplant is considered to be a control subject until he actually receives his transplant, and to be a treated subject thereafter. The subjects' membership changes from control (untreated) group to treated group at the time of the heart transplant.

Additionally, in double-blind (DB) clinical trials, it is common to have parallel groups of subjects randomized to receive either placebo or the study medication to evaluate the efficacy of the medication. After completion of the DB trial, the subjects are often offered an open label (OL) extension therapy. The initial placebo recipients during the DB phase will start receiving study medication at the beginning of the OL extension phase. Therefore, the membership of the initial placebo recipients changes to the study medication group at the beginning of the OL phase.

In situations such as these, if one wants to compare the survival time of the treatment groups, use of the method proposed by Mantel and Byar (1974) may be appropriate. Their approach will handle an individual's status change during the study and incorporate the information in the statistical analysis.

II. MANTEL-BYAR METHOD

Mantel and Byar provided a procedure for analyzing survival data in which the membership of an individual can be altered during the study. The procedure, which is a modification of the Mantel-Haenszel approach, suggested the use of a summary chi-square with one degree of freedom in testing the association of disease incidence with treatment. For survival data observed over a period of time, 2x2 contingency tables can be constructed to be associated with the time intervals partitioned by those distinct event times. In each time interval, individuals are classified as with or without the disease, and with or without the study treatment. In each such 2x2 table, conditional on the marginal totals (i.e. the number of subjects at risk in the survival analysis), the expectation and variance of the number of events for the study treatment can be determined. Summation of the observed and expected number of such cases is made over all the 2x2 tables, and the chi-square statistic is computed as the square of the cumulated deviations over the entire study period, divided by the sum of the conditional variances. The procedure allows an individual to change from one risk group to the other when group membership changes, and the above computations can be carried out for the comparison of the two treatment groups.

III. EXAMPLE

The data discussed below are collected from an AIDS clinical study. For a clearer perspective of the data, a brief description of the study design follows. Two hundred and thirty-five asymptomatic HIV-infected subjects with 200 to 500 CD4+ cells, receiving ongoing AZT treatment prior to entry, enrolled in a phase 3, multicenter, DB comparative trial. Subjects were randomized to receive either placebo or study medication, thymopentin (TP5). After completion of the DB portion, which was of 48-77 weeks in duration, subjects were offered OL TP5 for up to two years. One hundred and twenty subjects were randomized to the placebo group and 82 of these entered the OL phase.
The primary objective of the study was to assess the efficacy of TP5 in reducing the risk of progression to AIDS or death during the DB study and its subsequent OL extension phase in HIV-infected asymptomatic subjects. Subjects were randomized to the TP5 group and 83 of these entered the OL phase continuing their treatment. For those prematurely terminated prior to week 48 during the DB phase, the follow-up information was obtained through week 77 in a blinded fashion.

The number of subjects at risk in each treatment group at each successive day of event are obtained by subtracting events and losses, and adding accessions to the preceding numbers at risk—the values so obtained are given in columns designated N1 and N2. For any single day of event, among N1 TP5 subjects at risk there are A events, N1 - A = B survivors, while among N2 placebo subjects there are C events, N2 - C = D survivors. In total, there are T = N1 + N2 subjects at risk with M1 = A + C events, and M2 = B + D survivors. By the Mantel-Haenszel approach (1963), the conditional null expectation of A, given N1, N2, M1, M2 is \( \frac{N_1 M_1}{T} \), with conditional variance \( \frac{N_1 N_2 M_1 M_2}{T(T-1)} \). A one degree of freedom chi-square for the deviation of the sum of all the A's from the expectation of that sum is obtainable, as shown at the bottom of the table. Also illustrated is the computation of the associated summary measure of relative risk of event, i.e. \( \frac{\sum AD/T}{\sum BC/T} \), where summation is over all the distinct event days.

A modified life table (Table 1) for organizing treatment conversion and calculating summary statistics is given below. The first column of the table shows each distinct day of progression to AIDS or death, relative to each subject's individual day 0. A tally is made in the appropriate 'number of events' (event is defined as progression to AIDS or death) column on the indicated day of event for subjects progressing for both treatments. If a subject is lost from observation while in a particular treatment, he/she is tallied as a loss-from-observation at the latest event day not exceeding such day of loss. If a subject transferred from placebo to TP5 treatment, he/she is tallied as a loss-by-transfer from the placebo group and also as an accession into the TP5 group, again the latest event day not exceeding such day of transfer.

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In the present example, there is a significant difference between the observed and expected results—6 events among TP5 subjects versus 10 expected (up to day 535), to yield a chi-square value of 4.283 (p-value = 0.038). This indicates a significant reduction in the risk of progression to AIDS or death for the TP5 treated subjects (relative risk = 3.41). It is noteworthy that the chi-square statistic for testing treatment effect remains constant after day 535, indicating that the data collected after day 535 contributed no additional information for the treatment comparison. In other words, the data which impacted the analysis were those collected up to day 535, the day the last placebo subject transferred to TP5 treatment.

### IV. RESULT AND DISCUSSION

The SAS macro, MBCHI, performs data manipulations and calculates chi-square values whenever an event occurs, and yields the p-values, relative risks as well as the modified life table. Input parameter SELECT gives users an option to subset (stratify) the input data set. Parameter SIZE1 and SIZE2 are the total subject numbers of each regimen of the input data. Parameter DS carries the name of the input data set which contains certain key variables described as followed:

- **PATID:** Subject identification number.
- **REGIMEN:** 1=TP5, 2=placebo.
- **CENSOR:** 0=event, 1=censoring.
- **TIME:** Time an event occurred or the last day in study if no event occurred.
- **OLDAY:** Day of treatment conversion.

There are four major steps of this macro:

1. First, split the input data set by regimen. For the placebo subjects who completed the DB phase without any event and start receiving TP5 in the OL phase, their data are duplicated into the TP5 group with modifications: any event occurred in the OL phase will be counted to the TP5 group and their accession days would be their treatment conversion days. At this point, they are assumed to be similar to new subjects to the TP5 group, since their usable data begin at their treatment conversion day.

2. Second, trace the transitions occurring in each group across the DB and OL phases. The event times of each group are picked out and rejoined to form a universal
event time axis. The transitions of each group, such as events, losses from observation or by transfer, and accessions, are categorized into the intervals of the universal event time axis. The transition data for summary statistics are then collected. The time interval, once again to be emphasized, is from one event day to the day before the next event.

Third, rejoin the categorized data for the final Chi-square test and also the computation of p-value as well as relative risks. After merging the categorized transition data of these two groups, some missing values emerge since an event that occurs in one group need not occur in the other. Retaining non-missing transition data becomes necessary and critical when computing such as summations of expectation and chi-square tests that utilize transition data from both treatment groups.

Fourth, output all the results derived from previous steps to the modified life table which displays the whole picture of the disease progression of this clinical study.

---input---
A sample data set with numerical variables is listed to present the typical cases in this study, two subjects for each group with/without an event.

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APPENDIX
**** Data preparation for TP5 group ****

```sas
data raw1; set raw;
  if regimen = I then olday = .;
  if newreg = 1 then regimen = 1;
end;

data raw1; set raw1;
mg = 1;
  if newreg = 1 then do;
    output;
    time = olday;
    newreg = 9;
    censor = 1;
  end;
else output;

data evrawl; set raw1 I;
  mg = 1;
  if newreg = 1 then do;
    output;
    time = olday;
    newreg = 9;
    censor = 1;
  end;
else output;
```

**** Classify transitions of TP5 into time axis ****

```sas
**** Classify transitions of TP5 into time axis ****

data evrawl1; set raw1;
  proc sort; by time;

data evrawl1 (keep = time); set evrawl1 by time;
  if last. time;

**** Set up the event time axis for both groups ****

```sas
**** Set up the event time axis for both groups ****

data evtime; set evrawl evrawl2; by time;
  if last. time;

```

**** Classify transitions of placebo into time axis ****

```sas
**** Classify transitions of placebo into time axis ****

data raw2; merge raw2 evtime by mg;
  array tb(*) tbl-tbl120;
  array te(*) tel-te120;
  retain tbl-tbl120 tel-te120;
  i + 1;
  tb(i) = time;
  if _n_ = 1 then do;
    tmp = time;
    time = 0;
    output;
    time = tmp;
  end;
else output;

```

**** Summary statistics of TP5 group ****

```sas
**** Summary statistics of TP5 group ****

data raw1; set raw1; by class;
  retain a losl accl n &size1;
  if newreg = 9 then acc1 = acc1 + 1;
else do;
  if censor = 1 then do;
    los1 = los1 + 1;
  end;
else a = a + 1;
end;
if last. class then do;
  output;
  n1 = n1 - losl - a + acc1;
  los1 = 0;
  a = 0;
  acc = 0;
end;

```

**** Summary statistics of placebo group ****

```sas
**** Summary statistics of placebo group ****

data raw2; set raw2; by class;
  retain c los2 tra2 n2 &size2;
  if newreg = . then do;
    if censor = 1 then los2 = los2 + 1;
else c = c + 1;
end;
else tra2 = tra2 + 1;
if last. class then do;
  output;
  n2 = n2 - los2 - c - tra2;
  los2 = 0;
  c = 0;
  tra2 = 0;
end;

```

**** Merge these two classified group datasets ****

```sas
**** Merge these two classified group datasets ****

data all; merge raw1 raw2; by class;
  acc2 = .; tra1 = .;
  week = round((class + 3)/7);
  drop time patid olday censor newreg regimen;
```

**** After merging, all missing values shall be; ****

```sas
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```

**** replaced by the previous non-missing ones; ****

```sas
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data all; set all;
  retain nn1 aa acc1 llool nn2 trrr2 cc llo02 0;
  if n1 = . then do;
    if nn1 > 0 then n1 = nn1 - aa - llool + acc1;
else do;
  n1 = 0;
  if _n_ = 1 then n1 = &size1;
end;
  a = 0;
  acc1 = 0;
  los1 = 0;
end;
if n2 = . then do;
  if nn2 > 0 then n2 = nn2 - cc - llo02 + trrr2;
```

1281
else do;
    n2 = 0;
    if _n_ = 1 then n2 = &size2;
end;

end;
c = 0; tral = 0; los2 = 0;
end;
nl = nl; aa = a; acc1 = acc; llool = losl;
n2 = n2; cc = c; trra2 = tra2; llool = los2;

**** Fit all the values into Chi-square formulas;
**** to obtain p-values and calculate relative risks;
data all; set all;
retain sig a exp a var a
ITI ~2 r1 -;2 v 0;
sig_a = a + sig_aj
exp_a = nl *(a +c)/(nl +02) +exp_a;
var_a = (nl *02*(a+c)*(nl +02-a-c»1
«nl +02)**2*(nl +02-1» +var_a;
ITI = a*(02-c)/(nl +02)+ITI;
if rrl>0 then rrl = rrl;
rr2 = c*(nl-a)/(nl +02)+rr2;
if rr2>0 then rr2 = rr2;
rr = rr2/rr1; ** Relative risk **;
** Two alternatives to get the p-values **
with or without continuity correction **;
chit = (abs(sig_a-exp_a)-0.5)**2/var_a;
chi2 = (abs(sig_a-exp_a)**2/var_a;
if var_a > 0 then v = var_a;
if not eof then output all;
else do;
pv1 = 1-probchi(chi1,1);
pv2 = 1-probchi(chi2,1);
output all;
end;

proc print data=all;
var week class nl a acc2 l0s1 tral n2 c acc2 los2
tra2 rr chir chi1 pv1 pv2 var_a sig_a exp_a;
format chi1 pv1 pv2 6.4;
title "&titl";

%let prgname=my_prog;
%inc mcenter;

**** Create a tally sheet format;
data _null_; set all end=done;
file print ps=58 line=1 notitle;
if _n_ = 1 then do;
h = 1; gap = int(132/12);
h1 = 1; h2 = gap + 2; h3 = gap*2 + 3; h4 = gap*3 + 3;
h5 = gap*4 + 3; h6 = gap*5 + 1; h7 = gap*6 + 5;
h8 = gap*7 + 4; h9 = gap*8 + 3; h10 = gap*9 + 4;
h11 = gap*10 + 4; h12 = gap*11 + 4;
retain h h1-h12;
end;

*Header;
if l lt 2 then do;
put @108 "&sysdate &systime &prgname" //;
%center("Illustrative Tally Sheet and Statistics");
%center("at transferring from placebo to TP5");
%center("at each observed event time");
%center("\&titl");
put @@b4+6 'TP5' @h8+7 'Placebo'
overprint @h3 42*- ' @h7 41*- ';
@h6 'Losses' @h9 ' Losses'
overprint @h6 11* ' @h8+10 20* -
@h1 'Relative' @h2 'Relative'
@h3 '# of' @h7 '# of'
@@h1 'Week of' @h2 'Day of'
 @@h3 'Subjects' @h4 ' of' @h5 ' of'
@@h6 ' from' @h9 ' from' @h10 ' by'
@@h7 'Subjects' @h8 ' of'
@@h11 'Cumulative' @h12 'Relative'

@@h1 'The Event' @h2 'The Event'
@@h3 ' at Risk' @h4 'Event'
@@h4+9 'Accession' @h6 'Observation'
@@h8+10 'Observation' @h10 'Transfer'
@@h7 'at Risk' @h8 'Event'
@@h11 'Chi-Square' @h12 'Risk'
overprint @m1 132* '-' /;
end;

*Detail;
put @h1+2 week 3. @h2+2 class 3.
@h3+2 nl 3. @h4 a 3. @h5 acc1 3. @h6+3 los1 3.
@h3+2 n2 3. @h4 c 3. @h5 los2 3. @h6+3 tra2 3.
@h11+1 chi2 6.4 @h12+1 rr 6.4;

*End;
if (done or l > 53) then do;
   pg+1;
   put @h1 132* '- ' @;
if done then
   put // @h1 'P-Value = ' pv2 6.4 ' (based on Mantel
   and Byar's Chi-Square test presented in JASA, 1974
   without continuity correction).' @h12 'Page ' pg;
   else put // @h12 'Page ' pg;
if not done then put _page_ @;
end;

%mend mbchi;

**** An example macro call;
%mbchi(ds=indata, select=, titl=Survival Analysis);

title "&titl";

%let prgname=my_prog;
%inc mcenter;
### Table 1

**Summary Statistics for the Subjects at Risk and Transferring from Placebo to TP5 at Each Observed Event Time**

<table>
<thead>
<tr>
<th>Day of Event</th>
<th>No. of Subjects at Risk (N₁)</th>
<th>No. of Subjects from Event (A)</th>
<th>No. of Losses from Observation (C)</th>
<th>No. of Accessions</th>
<th>No. of Events</th>
<th>Observation Transfer</th>
<th>Chi-square Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>115</td>
<td>0</td>
<td>2</td>
<td>120</td>
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<td>1</td>
<td>0.958</td>
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<tr>
<td>106</td>
<td>113</td>
<td>0</td>
<td>0</td>
<td>118</td>
<td>1</td>
<td>0</td>
<td>1.916</td>
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<tr>
<td>115</td>
<td>113</td>
<td>0</td>
<td>1</td>
<td>117</td>
<td>1</td>
<td>0</td>
<td>2.882</td>
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<tr>
<td>134</td>
<td>112</td>
<td>1</td>
<td>0</td>
<td>116</td>
<td>0</td>
<td>0</td>
<td>0.924</td>
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<tr>
<td>157</td>
<td>110</td>
<td>0</td>
<td>0</td>
<td>116</td>
<td>1</td>
<td>0</td>
<td>1.678</td>
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<tr>
<td>171</td>
<td>110</td>
<td>0</td>
<td>2</td>
<td>115</td>
<td>1</td>
<td>0</td>
<td>2.502</td>
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<tr>
<td>213</td>
<td>108</td>
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<td>0</td>
<td>112</td>
<td>1</td>
<td>0</td>
<td>3.369</td>
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<tr>
<td>227</td>
<td>108</td>
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<td>0</td>
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<tr>
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<td>0</td>
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<tr>
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<td>1</td>
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<td>0</td>
<td>0</td>
<td>4.283</td>
</tr>
<tr>
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<td>0</td>
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<td>0</td>
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</tr>
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<td>0</td>
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<td>0</td>
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<td>0</td>
<td>4.283</td>
</tr>
</tbody>
</table>

P-value = 0.0384 (based on the Mantel-Byar Chi-square test without continuity correction)

Chi-square = \( \frac{\sum A \cdot \sum \text{Exp}(A)}{\sum \text{Var}(A)} \), Relative Risk = \( \frac{\sum (AD/T)}{\sum (BC/T)} \)

\( \text{Exp}(A) = \sum (N_1 M_i / T), \text{Var}(A) = \sum (N_1 N_2 M_i M_j / (T^3(T-1))) \)

\( B = N_1 - A, D = N_2 - C, M_1 = A + C \) & \( M_2 = B + D \)

**References**


**Acknowledgements**

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