Notes on the Use of Historical Controls
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Introduction

Ever since the work of R. A. Fisher, we have been analyzing, in principle, the data in a toxicological experiment independently of other experiments. The number of well-controlled experiments conducted under the same protocol has recently increased, however, and this has tempted us to incorporate the data from past experiments with the data from current experiments. The temptation is especially strong in the following cases, where control groups in past experiments are referred to as the historical control. Incorporating the historical control would serve to \(a\) increase the power of hypothesis testing when the historical control is stable, as is the case reported in Hayashi et al. (7); \(b\) carry out hypothesis testing when the occurrence of response is rare, as is the case in Tarone (2) or Yanagawa and Hoel (3); \(c\) increase the power of hypothesis testing when the group size is small, as is the case when the experiment is conducted on dogs: \(C_3\); \(d\) validate the judgment that the observed significance is a realization of type I errors, as is the case when so many items are tested that an inflated type I error is likely to occur: C4. Experiencing many such cases, researchers engaged in toxicological experiments ask statisticians the following questions: In what cases can we use the historical control? How should we incorporate the historical control? The purpose of this paper is to address these questions.

The Meaning of "Historical"

Because statistical testing is a principal concern in the data analysis in the cases mentioned above, we concentrate our attention in this paper on testing procedures. There are many works in the literature addressing the use of the historical control in toxicological experiments. Among them, Margolin and Risko (4) presented a good summary of the general principle. For carcinogenicity studies, Tarone (2), Yanagawa and Hoel (3), Tamura and Young (5), Hoel and Yanagawa (6), Krewski et al. (7), and Yanagawa et al. (8) proposed some procedures or discussed problems to be considered based on the \(\beta\)-binomial model.

In their arguments (2–8), however, the time dependence of the historical control in comparison to the current experiment is not consciously considered. The arguments, except the one in Yanagawa et al. (8), are valid even when we reanalyze the data in a past experiment by incorporating data in succeeding experiments. In real situations, incorporation of the historical control is sought after only when a laboratory has collected enough data from past experiments and has confirmed some sort of homogeneity of past experiments. Once the historical control is saved in a database, researchers in that laboratory always refer to the same data repeatedly in the data analysis of succeeding experiments. In this circumstance, the data in the historical control are not randomly realized values but refer to a given condition fixed in advance in the data analysis of the current experiment. To address the questions mentioned earlier, we should examine the performance of each procedure from the viewpoint that the historical control is a given, fixed condition. This viewpoint of conditional use is the first point of our assertion.

The historical control is used to estimate unknown parameters related to the current experiment. The assertion that the historical control should be regarded as a given, fixed condition means that we should regard the estimated values based on the historical control as including some deviations from true parameter values, though the amount of deviation is within random variations. Because the historical control is a realization of random variables, both negative deviation and positive deviation may occur. In general, when the positive deviation causes the test based on the historical control to be conservative, the negative deviation causes the test to be liberal, and vice versa. Because we
cannot know which situation is realized, we have to design a test procedure that is conservative in the sense that I errors are controlled within a target significance level even when a disadvantageous deviation has occurred. This viewpoint of conservative use is the second point of our assertion.

**Stable Historical Control**

To make the arguments clear, we deal only with simple cases. Assume that the current experiment consists of \((a + 1)\) groups, \(A_0, A_1, \ldots, A_a\) of \(n\) individuals and that each individual in the group \(A_i\) is exposed to dose \(d_0 < d_1 < \cdots < d_c\) of a chemical. Let the observed response for the \(j\)th individual in \(A_i\) be 1 or 0 with probability \(\pi_i\) or \(1-\pi_i\), where \(\pi_i = \pi(d_i)\), and the responses are independent. We can reduce the observed responses to the random variable \(X = (X_0, X_1, \ldots, X_c)\), where \(X_i\) is distributed binomially with mean \(\mu_i = n\pi_i = \mu(d_i)\). Likewise, assume that the historical control consists of \(b\) groups, \(B_1, B_2, \ldots, B_b\), of controls in \(b\) previous experiments. Let the observed variable be \(Y = (Y_1, Y_2, \ldots, Y_b)\), where \(Y_i\) is distributed binomially with mean \(\mu(0) = n\pi_0\). Assume the \(X\)'s and \(Y\)'s are all mutually independent.

Under this formulation, it must be reasonable to regard the case where \(\mu_0 = \mu_2 = \cdots = \mu_b = \mu_0\) as the case \(Cl\), that is, the case with the stable historical control. In this case, the observed variable can be reduced to \((X,Y) = (X_0, X_1, \ldots, X_c, Y)\), where \(Y = \sum Y_i\) is distributed binomially \(B(bn, \pi_0)\). In most practical situations, when the researcher tries to test the null hypothesis

\[
H_0: \mu_0 = \mu_1 = \cdots = \mu_a
\]

against an alternative hypothesis

\[
H_i: \mu_0 \leq \mu_i \leq \cdots \leq \mu_b,
\]

at least one strict inequality holds, based on \((X,Y)\).

A typical procedure for this problem is the Cochran-Armitage trend test because it is the uniformly most powerful, unbiased test against logistic alternatives (9). When the group size, \(n\), is so large that the normal approximation on the binomial distribution is available, two procedures, say \(T_c\) and \(T_h\), of the trend test with significance level \(\alpha\) can be considered by excluding or including \(Y\) as follows:

**Test To:** Reject \(H_0\) if

\[
T_c = \frac{\sum_{i=0}^a (d_i - d_c)X_i}{\sqrt{\sum_{i=0}^a (d_i - d_c)^2 nP_c(1-P_c)}} > u(\alpha)
\]

where \(d_c = (d_0 + d_1 + \cdots + d_b)/(a + b + 1)\), \(P_c = (X_0 + X_1 + \cdots + X_b)/(an + n)\) and \(u(\alpha)\) is the upper 100\(\alpha\)% point of \(N(0, 1)\).

**Test Th:** Reject \(H_0\) if

\[
T_h = \frac{\sum_{i=0}^a (d_i - d_h)X_i + (d_0 - d_h)Y}{\sqrt{\sum_{i=0}^a (d_i - d_h)^2 + b(d_0 - d_h)^2 nP_h(1-P_h)}} > u(\alpha)\]

where \(d_h = (b + 1)d_0 + d_1 + \cdots + d_b)/(a + b + 1)\) and \(P_h = (Y + X_0 + X_1 + \cdots + X_b)/(an + n + n)\).

If \(Y\) is regarded as a random variable, the test \(T_h\) is obviously better than the test \(T_c\). But, if \(Y\) is regarded as a given constant \(y\), the type I error of the test \(T_h\) is not controlled within a target significance level \(\alpha\) as is explained below.

Under \(H_0\), the statistic \(T_h\) can be written as

\[
T_h = \frac{\sum_{i=0}^a (d_i - d_h)X_i + (d_0 - d_h)Y}{\sqrt{\sum_{i=0}^a (d_i - d_h)^2 + b(d_0 - d_h)^2 nP_0(1-P_0)}} + o(1)
\]

where \(o(1)\) implies a term that tends toward 0 in probability if \(n\) tends toward \(\infty\).

Let

\[
B^2 = \frac{b(d_0 - d_h)^2}{\sum_{i=0}^a (d_i - d_h)^2 + b(d_0 - d_h)^2 nP_0(1-P_0)}
\]

and

\[
D_X = \frac{\sum_{i=0}^a (d_i - d_h)(X_i - nP_0)}{\sqrt{\sum_{i=0}^a (d_i - d_h)^2 nP_0(1-P_0)}}
\]

Then,

\[
T_h = \frac{D_X}{\sqrt{1 + B^2}} + \frac{D_Y}{\sqrt{1 + B^2}} + o(1)
\]

B can be regarded as a small quantity, because \(b\) is generally much greater than \(a\) in the situation where the use of the historical control is asked for and that

\[
B^2 = \frac{(a + 1)w(1-w)(d_0 - d_c)^2}{\sum_{i=0}^a (d_i - d_c)^2 + bw(1-w)(d_0 - d_c)^2}
\]

where \(w = b/(a + b + 1)\). For example, if \(a = 4, b = 20\) and \(d_c = i\), then \(B^2 = 0.14\). Under such a situation, \(T_h\) is approximated by

\[
T_h = D_X + B D_Y
\]

Because \(D_X\) is distributed as \(N(0,1)\) independently of \(D_Y\), the conditional distribution of \(T_h\) given \(Y = y\), is positively (or negatively) biased from \(N(0,1)\) if \(y > bnp_0\) (or \(y < bnp_0\)).
Therefore, type I error given $Y = y$ is approximately evaluated as

$$\Pr \{ T_h > u(\alpha) | H_0, Y=y \} = \Pr \{ D_X > u(\alpha) \} = \Phi \{ BD_y - u(\alpha) \}$$

where

$$D_y = \frac{(y-bn\pi_0)}{\sqrt{b n \pi_0 (1-\pi_0)}}$$

and $\Phi$ is the distribution function of $N(0,1)$ because $D_y$ is distributed as $N(0,1)$, $D_Y \sim N(0,1)$ with probability 0.90. For $d_i = i$ and for $D_i$ within this range, some numerical values of the right-hand side of Equation 8 are, together with type I error obtained by a Monte-Carlo simulation, shown in Table 1. Table 1 shows the possibility of an inflation of the type I error.

One idea to control the type I error within the significance level $\alpha$ is to adjust the critical value of the test $T_h$. If we evaluate a possible maximum value of $D_y$ by $u(\alpha^*)$, we obtain an adjusted test $T_a$ as follows:

Test $T_a$: Reject $H_0$ if

$$T_h > u(\alpha^*) + Bu(\alpha^*)$$

We think that a reasonable value of $\alpha^*$ is 0.05, which gives $u(\alpha^*) = 1.645$. According to the above argument, the incorporation of the historical control is advantageous only when the power of the test $T_a$ is greater than that of the test $T_c$.

Because, under $H_1$, and for given $y$, the statistic $T_c$ is approximately normally distributed with

$$E\{T_c | H_1\} = \sum_{i=0}^{a} (d_i - d_c) n \pi_i$$

$$\sqrt{\sum_{i=0}^{a} (d_i - d_c)^2 n \pi(1-\pi)}$$

and

$$V\{T_c | H_1\} = \sum_{i=0}^{a} (d_i - d_c)^2 n \pi(1-\pi)$$

the power of the test $T_c$ is given by $\phi(\lambda_c)$, where $\pi = \sum \pi / (\alpha + 1)$,

$$\lambda_c = \frac{E\{T_c | H_1\} - u(\alpha)}{\sqrt{V\{T_c | H_1\}}}$$

and $o(1)$ is ignored. Similarly, the power of the tests $Th$ and $Ta$ are approximately given by $\Phi(\lambda_h)$ and $\Phi(\lambda_a)$, where

$$E\{T_h | H_1, Y=y\} = \sum_{i=0}^{a} (d_i - d_h) n \pi_i + (d_0 - d_h) y$$

$$\sqrt{\sum_{i=0}^{a} (d_i - d_h)^2 + b (d_0 - d_h)^2 n \pi(1-\pi)}$$

$$\lambda_h = \frac{E\{T_h | H_1, Y=y\} - u(\alpha)}{\sqrt{V\{T_h | H_1, Y=y\}}}$$

For $d_i = i$, some numerical values of $\phi(\lambda_h)$, $\phi(\lambda_a)$ and $\Phi(\lambda_h)$ are shown in Table 2, together with values obtained by a Monte-Carlo simulation. Table 2 shows that some parts of increases of the power for the test Th are spurious due to an inflation of the type I error and that the advantage of the incorporation of the historical control is rather limited, even when the historical control is stable enough. According to our assertion, whether the historical control should be incorporated or not is judged through the comparison of the two tests $T_a$ and $T_c$. The choice is possible

| Test | D_i |
|------|-----|
| -1.5 | -1.0 | -0.5 | 0.0 | 0.5 | 1.0 | 1.5 |
| T_c  | 0.052 | 0.052 | 0.052 | 0.052 | 0.052 | 0.052 | 0.052 |
| Th   | 0.138 | 0.099 | 0.066 | 0.043 | 0.029 | 0.018 | 0.011 |
| Ta   | 0.050 | 0.032 | 0.020 | 0.011 | 0.006 | 0.004 | 0.002 |

where $a = 4, b = 20, d_i = i, x_0 = 0.05, n = 100$. The target significance level is 0.05. The replication in the Monte-Carlo simulation is 40,000.
in advance of the current experiment because the powers of two tests can be evaluated from \( \lambda_0 \) and \( \lambda_a \), which can be calculated from the design of the current experiment, the target alternatives, and the realized values of the historical control which specify the range of the nuisance parameter \( \pi_0 \).

Note that, if we use exact conditional probabilities given \( Y \) and \( \sum X \), as \( p \)-values instead of the normal approximation, the test with the test statistic \( T_y \) automatically controls type I errors within a target significance level. Though the above argument is limited to a special case of binomial responses, it can be easily extended to other cases.

**Rare Occurrence of Responses**

Cases of the stable historical control discussed in the previous section rarely occur in toxicological experiments. We have seen such cases only in *in vitro* experiments or in short-term experiments. In most cases, there are more or less variabilities among historical controls and the concurrent control. Considering these variabilities as a prior distribution, Tarone (2) proposed a trend test based on the \( \beta \)-binomial model. Yanagawa and Hoel (3) proposed a set of trend tests based on the same line of thought as Tarone. In addition, the latter authors proposed exact test procedures that control the type I error when the asymptotic theory is not applicable.

To make the argument simple, let us assume a logistic response model on the rate parameter \( \pi \), for the binary response, that is,

\[
\pi_i = \frac{\exp(\gamma_0 + \delta(d_i - d_0))}{1 + \exp(\gamma_0 + \delta(d_i - d_0))}, \text{ for } i = 0, 1, \ldots, a
\]

\[
\pi_j = \frac{\exp(\gamma_j)}{1 + \exp(\gamma_j)}, \text{ for } j = 1, 2, \ldots, b
\]

(18)

when the notation is the same as the one in the previous section. In the \( \beta \)-binomial model, the parameters \( \pi_0, \pi_1, \ldots, \pi_b \), are assumed to be independent random variables with the density function

\[
f(\pi) = \Gamma(\alpha + \beta)\pi^{\alpha-1}(1-\pi)^{\beta-1}/[\Gamma(\alpha)\Gamma(\beta)].
\]

(19)

If the two parameters \( \alpha \) and \( \beta \) of Equation 19 are known, no problem arises in the proposed procedures. In real situations, however, these parameters are unknown and must be estimated from the historical control. Tamura and Young (5) pointed out that the estimation error seriously affects the type I error of Tarone’s procedure. This sensitivity was also recognized by Yanagawa and Hoel (3). To overcome this defect, Krewski et al. (4) proposed a two-stage procedure that contains an optionally chosen parameter for the choice of the second-stage test. Though the result of the procedure is highly influenced by this parameter value, they do not give any reasonable method to determine it. Not doing so makes their procedure ambiguous.

In the same situations, Yanagawa and Hoel (3) suggested conservative use of the historical control. Yanagawa et al. (9) proposed two practical procedures in this line of thought and presented evidence for their effectiveness in some cases. Their idea is to make confidence intervals of two functions \( \alpha/(\alpha+\beta) \) of parameters and use a set of values of upper or lower confidence limit as the parameter values of the test statistic \( T_y \) defined below.

\[
T_y = \frac{\sum (d_i - d_0)X_i - X_T \alpha}{n\alpha + \alpha + \beta} \sum (d_i - d_0)n
\]

(20)

where \( X = \sum X_i \). Along this statistic, exact probabilities are accumulated, where “exact” means that conditional probabilities given \( X \) are calculated. By taking either the upper or the lower limit, four exact \( p \)-values are obtained for the test statistic \( T_y \). The use of the maximum value of these values as the \( p \)-value for testing the hypothesis \( H_0 \): \( \delta = 0 \) is Yanagawa et al.’s proposal (9). Let us denote this testing procedure by \( T_y \).

In the test \( T_y \), the historical control is used only to estimate \( \alpha \) and \( \beta \), and the estimated values of \( \alpha \) and \( \beta \) are used as given constants. As a result, all the information contained in the historical control is included in the given condition, and so the resulting procedure adapts to our viewpoint. The conservative use of the historical control to keep type I errors within a target significance level is entirely the same idea as the one explained in the previous section. Therefore, the test \( T_y \) is recommended.

The problem is how to judge whether the test \( T_y \) is superior to the corresponding test, say \( T_e \), without the use of the historical control. It must be reasonable to assume that, in the test \( T_e \), the \( p \)-value is calculated by accumulating exact probabilities along the statistic \( T_e \), defined below.

\[
T_e = \frac{\sum (d_i - d_0)X_i - X_T \alpha}{n\alpha + \alpha + \beta} \sum (d_i - d_0)n
\]

(21)

The comparison of two tests can be carried out in the following manner. Define two sets \( S_y \) and \( S_e \), as

\[
S_y = \{ x : p_y(x) < \alpha, p_e(x) > \alpha \}
\]

\[
S_e = \{ x : p_y(x) > \alpha, p_e(x) < \alpha \}
\]

(22)

where \( p_y(x) \) and \( p_e(x) \) are \( p \)-values corresponding to \( T_y \) and \( T_e \), respectively and \( \alpha \) is the target significance level. If a target alternative \( H_i \) is set, we compare exact probabilities \( Pr[S_y \mid H_i] \) and \( Pr[S_e \mid H_i] \). If \( Pr[S_y \mid H_i] \) is greater than \( Pr[S_e \mid H_i] \), then the test \( T_y \) should be used. The choice is possible in advance of the current experiment because the powers of the two tests can be evaluated from the design of the current experiment, the target alternatives, and the realized values of the historical control, which specify the range of the nuisance parameter \( \pi \). Though we have not confirmed it, the method of Monte-Carlo simulation seems to be effective to evaluate probabilities.

**Small Group Size**

In toxicological experiments using large animals such as dogs or monkeys, the group size is as small as three or four. In such cases, any testing procedure of a hypothesis rarely yields significant results due to the lack of power. The incorporation of the historical control is highly attractive to increase the power of the test in this situation. This is the case C3 mentioned above.

In this case, we naturally assume that the observed response
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is quantitative. Assume, as before, that the current experiment consists of \((a+1)\) groups of size \(n\) with dose \(d\), and observed responses are independent normal variables. Let the \(j^{th}\) response of the group \(A_i\) be \(X_{ij}\) and assume that the structural model of \(X_{ij}\) is the usual block-effect model such that

\[
X_{ij} = \mu + \alpha_0 + \beta(d_i-d_0) + U_{ij}
\]

where \(\mu\) and \(\beta\) are unknown parameters, \(\alpha_0\) is distributed as \(N(0, \Sigma)^{a/2}\), and \(U_{ij}\) is distributed independently of \(\alpha_0\) as \(N(0, \Sigma)^{a/2}\). Similarly, assume on \(j^{th}\) response \(Y_{ij}\) of the \(i^{th}\) historical control group the model

\[
Y_{ij} = \mu + \alpha_i + V_{ij}
\]

where \(\mu\) and \(\beta\) are unknown parameters, \(\alpha_i\) is distributed independently of \(\alpha_0\) as \(N(0, \sigma_i^2)\), and \(V_{ij}\) is distributed independently of \(\alpha\) and \(U\) as \(N(0, \sigma_i^2)\).

According to Margolin and Risko (4), when \(\sigma_i^2\) and \(\sigma_0^2\) are known, the maximum likelihood estimator of \(\beta\) is given by

\[
\hat{\beta} = w\hat{\beta}_c + (1-w)\hat{\beta}_h
\]

where \(\hat{\beta}_c\) is the usual estimator of \(\beta\) based on the current experiment, \(\hat{\beta}_h\) is the interblock estimator of \(\beta\) based on the historical control and the overall mean of \(X\)'s, and the weight \(w\) is a monotone increasing function of \(\sigma_i^2/\sigma_0^2\), whose explicit form is shown in Margolin and Risko (4). If the historical control can be regarded as random quantities, then we can test the hypothesis \(H_0: \beta = 0\) by standardizing \(\beta\) with the square root of \(\text{Var}(\beta)\), but this is not consistent with our viewpoint. \(\hat{\beta}_h\) should be regarded as a given constant more or less deviated from the true value of \(\beta\).

In addition, \(\sigma_i^2\) and \(\sigma_0^2\) are unknown in real situations. They are estimated from the historical control and within-group variances in the current experiment. This yields an estimation error on the weight \(w\) and causes an inflation or deflation of type I errors. We have to devise a conservative procedure to control the type I error within a target significance level. In principle, the same idea as the one in the previous section is available, that is, to use confidence limits as true values of \(w\); but its realization has not been achieved up to now. Proposals of practical procedures are left for future studies.

**Historical Control as a Reference**

In chronic toxicity studies, hundreds of items are inspected during a long time interval within one experiment. This brings about many repetitions of statistical tests and causes an inflation of type I errors or frequent occurrences of false-positive results due to the multiplicity of tests. Encountering such errors, toxicologists do not usually accept the results of statistical data analysis unless the results are confirmed by toxicological and/or biological knowledge. When a toxicologist believes an observed statistical significance to be a realization of a type I error, he or she wants to validate this belief with evidence. In such circumstances, the historical control is used as evidence of the false positive of the statistical test. In fact, Matsumoto (10) found and reported many such cases through a survey of a volume of a journal. This is the case C4 mentioned in the initial section.

Our opinion on the use of the historical control in this case is rather negative because the variability among experiments is so big that the observed deviation of a treatment group from the concurrent control group can be neglected almost always by using the historical control as the reference. This fact violates the rationality of the statistical reasoning. In this case, we recommend, in principle, the use of the distribution of \(p\)-values (12) to evaluate the inflation of the type I errors or to reduce many items to a few end points to avoid multiplicities (12), though the construction of practical procedures is not easy.

**Concluding Remarks**

Two points are emphasized in this paper: one is that the historical control should be regarded as a given condition and the other is that it should be used conservatively. We recommend the incorporation of historical controls only when it is advantageous under such a conditional evaluation of the performance; even then it should be used conservatively.

In this paper, we considered only simple situations and simple procedures. In such cases, the choice of whether to adopt the incorporation is not difficult because the performance of the two procedures can be, at least approximately, evaluated and compared based on the design of the current experiment, the target alternatives, and the realized values of the historical control, which are obtained in advance. The application of this viewpoint seems easy for more complicated situations if we concentrate our attention on simple procedures. In real situations, however, there is a possibility that a more complex procedure adapts to our viewpoint better than such simple procedures. One example of this is shown in Hayashi et al. (1). The evaluation of such complex procedures is left for future investigations.

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