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Effect of Delayed Observations on Fixed Design for Exponential Distribution

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Abstract

Langenberg and Srinivasan (1981) proposed two procedures for the choice between two medical treatments. They assumed that there is a time lag between the administration of the treatments and the availability of the responses. The two procedures are suggested for dealing with patients who arrive during the waiting period, caused by the lag, between the trial and treatment stages of the model . They assumed that the responses to the treatments are normally distributed with unknown means and a common known variance . This model is modified by considering the survival time resulting in using the treatments are exponentially distributed. The relative performance of the procedures in the Bayesian framework is discussed.

Keywords: Delay phase, Bayesian approach, decision theory

1. Introduction

Colton (1963) suggested a model for clinical trials that is appropriate in certain situations where two competing treatments for the same disease are being compared . The central assumption in the model is that there exists a known finite patient horizon , N, representing the total number of patients who will ever be receiving one of the two treatments under study . A decision rule , according to the simplest version of the model, consists of the 'trial stage' when n patients are assigned to each of the two treatments, leading to the choice of one of the treatments as the better and the 'treatment stage' when the remaining N-2n patients receive the treatment so chosen. The problem of clinical trials then is the determination of optimal decision rules (i.e., optimal n), optimality being defined in terms of appropriate loss functions . In this paper Colton assumed that the response to treatment i, i= 1,2, is normally distributed with unknown mean θ_i and known variance and that its quality is characterized by θ_i , so that the treatment with the larger mean is considered the better. Also, let the treatment with the larger observed sample mean be chosen as the better at the end of the trial stage .

In the context of clinical trials it is reasonable to suppose that the only loss is the ethical loss incurred in treating a patient with the inferior treatment. Optimality may therefore be defined in terms of the expected regret , R, which represents the difference between the total expected response if one were to treat all the N patients with the better treatment and the expected response achieved by following a decision rule. In our case it turns out that θ_1 and θ_2 enter R only through the true difference between the treatments $\theta = \theta_1 - \theta_2$.

An important assumption implicit in the Colton model is that the response to the treatments is instantaneous, or that there is no lag time between the treatment of the patients during the trial stage and the availability of all the treatment results. Langenberg and Srinivasan(1981) assumed that the response to the treatment is often delayed , causing a 'waiting period' between the two stages, and an accumulation of new patients who have to be treated before the beginning of the treatment stage. The allocation of treatments to these patients is an important issue, especially when their number is large relative to N . See Anderson (1964), Choi and Clark (1970), Nomachi (1976), Mady (2000), Lee and Choi (1999) and Williamson and Sung (1998) for some work with delayed observations in sequential analysis .

Langenberg and Srinivasan incorporated the assumption of delayed response into the Colton model and examined some Bayes optimal procedures for dealing with the patients who arrive during the waiting period. Langenberg and Srinivasan's procedures are described below. This article presents an alternative view of the paper of Langenberg and Srinivasan. The modification we shall investigate is that the survival time of patient receiving the treatment i is exponentially distributed with unknown mean θ_i . Also, we shall present a special case when one treatment mean is already known.

2. Statement of the Problem

We shall assume that

(i) patients arrive sequentially, one per unit time , and are to be assigned to one of the two treatments, and

(ii) there is a delay of T time units (T is taken to be an even integer for convenience) in obtaining the response to either treatment.

Two procedures for treating the T patients who arrive during the waiting period will now be investigated .

For the two procedures described below , the trial stage consists of the first 2n patients to arrive , with n patients assigned to each of the two treatments randomly within pairs , the treatment stage consists of the N-2n-T patients arriving after the waiting period, who are given the treatment with the larger sample mean based on the observations made during the trial stage.

It is assumed that we obtain a quantitative measure of response to each individual . The survival time of an individual receive treatment i (i=1,2) is assumed to be exponentially distributed with unknown mean θ_i . We assume that higher survival time is associated with better effect. Then, letting $\theta = \theta_1 - \theta_2$, we should like to select treatment 1 if θ is positive and treatment 2 if θ is negative.

The treatment allocations during the waiting period are as follows:

Procedure 1. The patients are assigned randomly within pairs as they arrive, to the two treatments T/2 to each.

Procedure 2. All the T patients are assigned to that treatment with the larger sample mean based on the n-T/2 available observations on each treatment from the trial stage.

Note that Procedure 2 is meaningful only when $n \geq 1/2$, while there are no such restrictions on procedure 1. Also , when T = 0 both procedures lead to a decision rule with the delay phase omitted. We shall now derive the Bayes optimal value of n for the two procedures.

In Procedure 1 , let Pr(inf.) denote the probability that the inferior treatment (i.e., treatment 1 if $\theta < 0$, and treatment 2 if $\theta \geq 0$) is chosen as the better on the basis of the n observations on each treatment available at the end of the waiting period, that is, Pr(inf.) = $F_1(\theta_2/\theta_1)$, where F_1 denotes the cumulative distribution function of Fisher,s F with 2n and 2n degrees of freedom. The expected regret function for Procedure 1 can be given by

$$R_1 = N\theta \;\; [P + t/2 + (1\text{-}2P\text{-} t) \Pr(\text{inf.})], \tag{1}$$

where P= n/N and t= T/N.

Averaging R_1 over the prior distributions of θ_1 and θ_2 (assume that $f(\theta_i) = \frac{\lambda_i^n}{\Gamma(n)} \theta_i^{n\text{-}1} e^{-\theta_i \lambda_i}, \theta_i > 0, \lambda_i > 0$) we get

$$\overline{R_1} = N\ [P(P + t/2)(1/\lambda_1 - 1/\lambda_2) + 2P(1 - 2P - t)/\lambda_1]. \tag{2}$$

The value P which minimizes the right hand side of (2), that is the optimal P (P is the only value that minimizes equation (2)) for Procedure 1, will be denoted by p_1 and is easily seen to be

$$p_1 = p_1(t) = [\lambda_2(4 - 3t) - t\lambda_1]/4(\lambda_1 + 3\lambda_2). \tag{3}$$

The optimal average regret , denoted by $\overline{R_1^*}$, is obtained by substituting P = p_1 in (2).

In Procedure 2, let P_2 and P_3 denote the probabilities of choosing the inferior treatment based , respectively, on the n-T/2 observations available on each of the two treatments at the end of the trial stage and the n such observations available at the end of the waiting period. Clearly , then P_2= $F_2(\theta_2/\theta_1)$, where F_2 denotes the cumulative distribution function of Fisher,s F with 2(n-T/2) , 2(n-T/2) degrees of freedom and $P_3= F_3\ (\theta_2/\theta_1\ )$, where F_3 denotes the cumulative distribution function of Fisher,s F with 2n , 2n degrees of freedom.

The expected regret function for Procedure 2 is given by

$$R_2 = N\theta \quad [P + tP_2 + (1\text{-}2P\text{-}\ t)\ P_3], \tag{4}$$

and the Bayes average regret is

$$\overline{R_2} = N[-P^2\ (3/\lambda_1 + 1/\lambda_2) + (2P - t^2)/\lambda_1\ ]. \tag{5}$$

The optimal value P say p_2 which minimizes $\overline{R_2}$ with respect to P is given by

$$p_2 = \lambda_2 / (\lambda_1 + 3\lambda_2)\,. \tag{6}$$

We shall denote the average regret corresponding to $P = p_2$ by $\overline{R_2^*}$.
Note that t has no effect on R_2 .Comparing (3) and (6) we see that $p_2 = p_1$ when t =0 and consequently, equations (2) and (5) will be coincident.

Numerical results on the relative performance of the two procedures are presented for selected values of t. Note that , since $n \geq T/2$ and $2n + T \leq N$, we have $t \leq 1/2$, hence we have included t values only up to 1/2. The most striking feature in Table 1 is the uniform superiority of Procedure 1.The percentage increase in R_2' over R_1', (where $R_i' = \overline{R_i^*}/N$) given in the last column for each t >0 shows that superiority could be quite pronounced. The results indicate that the reduction in regret afforded by Procedure 1 is strongly dependent upon N, λ_1, λ_2 and the delay. The improvement in performance of Procedure 1 should be taken into consideration plus the simplicity of it. Note also that R_1' decreases with t for any pair of λ_1 and λ_2 . The table indicates that Procedure 1 has the advantage of shorter experimental stage for all N, t and (λ_1, λ_2).

Table 1. Relative performance of the two procedures *

λ_1	λ_2	t = 0		t = 0.1			t = 0.2		
		P_1	R'_i	P_1	R'_1	I	P_1	R'_1	I
2	2	0.25	0.125	0.225	0.1013	0.23	0.2	0.08	0.56
	3	0.2727	0.1364	0.2477	0.1125	0.21	0.2273	0.0909	0.50
	4	0.2857	0.1429	0.2607	0.119	0.20	0.2357	0.0973	0.47
	5	0.2941	0.1471	0.2691	0.1231	0.19	0.2441	0.1013	0.45
3	2	0.2222	0.0741	0.1972	0.0583	0.27	0.1722	0.0445	0.67
	3	0.25	0.0833	0.225	0.0675	0.23	0.2	0.0533	0.56
	4	0.2667	0.0889	0.2417	0.073	0.22	0.2167	0.0587	0.51
	5	0.2778	0.0926	0.2528	0.0767	0.21	0.2278	0.0623	0.49
4	2	0.2	0.05	0.175	0.0383	0.31	0.15	0.0281	0.78
	3	0.2306	0.0577	0.2058	0.0459	0.26	0.1808	0.0354	0.63
	4	0.25	0.0625	0.225	0.0563	0.11	0.2	0.04	0.56
	5	0.2727	0.0657	0.2382	0.0539	0.22	0.2132	0.0431	0.52
5	2	0.1818	0.0364	0.1568	0.0271	0.34	0.1318	0.0191	0.91
	3	0.2143	0.0429	0.1893	0.0334	0.28	0.1643	0.0252	0.70
	4	0.2353	0.0471	0.2103	0.0376	0.25	0.1853	0.0292	0.61
	5	0.25	0.05	0.225	0.0405	0.23	0.2	0.032	0.56

λ_1	λ_2	t = 0.3			t = 0.4			t = 0.5		
		P_1	R_1'	I	P_1	R_1'	I	P_1	R_1'	I
2	2	0.175	0.0613	1.04	0.15	0.045	1.78	0.125	0.0313	2.99
	3	0.1977	0.0717	0.90	0.1727	0.0547	1.49	0.1477	0.04	2.41
	4	0.2107	0.0777	0.84	0.1857	0.0558	1.56	0.1607	0.045	2.18
	5	0.2191	0.0817	0.80	0.1941	0.064	1.30	0.1691	0.0487	2.02
3	2	0.1472	0.0325	1.28	0.1222	0.0224	2.31	0.0972	0.0142	4.22
	3	0.175	0.0409	1.04	0.15	0.03	1.78	0.125	0.0208	3.00
	4	0.1917	0.046	0.93	0.1667	0.0347	1.56	0.1417	0.0251	2.54
	5	0.2028	0.0493	0.88	0.1778	0.038	1.43	0.1528	0.028	2.31
4	2	0.125	0.0195	1.56	0.1	0.0125	3.00	0.075	0.007	6.14
	3	0.1558	0.0263	1.19	0.1308	0.0185	2.12	0.1058	0.0122	3.73
	4	0.175	0.0307	1.04	0.15	0.0225	1.78	0.125	0.0156	3.01
	5	0.1882	0.0336	0.96	0.1632	0.0253	1.60	0.1382	0.0182	2.61
5	2	0.1068	0.0126	1.89	0.0818	0.0074	3.92	0.0568	0.0062	4.87
	3	0.1393	0.0181	1.37	0.1143	0.0122	2.52	0.0892	0.0075	4.72
	4	0.1603	0.0218	1.16	0.1353	0.0155	2.04	0.1042	0.0104	3.53
	5	0.175	0.0245	1.04	0.15	0.018	1.78	0.125	0.0125	3.00

***** $R_i' = \overline{R_i^*}/N$**, I denotes the percentage increase in** R_2' **over** R_1'**.**

3. The Case when One Population Mean is Already Known

The above procedures may be easier in the case when one population mean is already known $(\theta_2 = \beta)$, and it is desired to decide whether or not to change to the alternative population .

The trial stage consists of the first n patients assigned to the first treatment, the treatment stage consists of N-n-T patients arriving after the waiting period, who are given the treatment with the larger parameter based on the observations made during the trial stage . The treatment allocations during the waiting period using Procedures 1 and 2 outlined in section 2 . We shall now derive the Bayes optimal value of n for the two procedures.

In Procedure 1, let Pr(inf.) denote the probability that the inferior treatment is chosen as the better on the basis of the n observations on the first treatment, that is Pr(inf.) = $F(2N\beta/\theta_1)$, where F denotes the chi-square cumulative distribution function with 2n degrees of freedom.

The expected regret function for Procedure 1 can be given by

$$R_1 = N\ \theta\ [(P+t)/2 + (1-P-t)\ Pr(inf.)\ ], \qquad \theta = \theta_1 - \beta\ . \tag{7}$$

Averaging R_1 over the prior distribution of θ_1 (recall that $f(\theta_1) = \lambda_1^n \theta_1^{n-1} e^{-\lambda_1 \theta_1} / \Gamma(n), \quad \lambda_1 > 0, \ \theta_1 > 0$), we get

$$\overline{R_1} = (NP/\lambda_1 - \beta)[2 - 3(P+t)/2]. \tag{8}$$

The value P which minimizes the right hand side of (8), will be denoted by p_1 (t) and is easily seen to be

$$p_1(t) = [\ N\ (4-3t) + 3\lambda_1\beta\ ]\ /\ 6N\ . \tag{9}$$

The optimal average regret, denoted by $\overline{R_1^*}$, is obtained by substituting P = p_1 (t) in (8).

In Procedure 2, Let P_1 and P_3 denote the probabilities of choosing the inferior treatment based, respectively, on the n-T observations on the first treatment (with parameter θ_1) at the end of the trial stage and the n observations on the first treatment at the end of the waiting period. Clearly , then

$$P_3 = Pr(inf.) = \varphi\ (n) \ \text{ and } \ P_1 = \varphi\ (n-T).$$

The expected regret function for Procedure 2 is given by

$$R_2 = N\theta\ [P/2 + t\ P_1 + (1-P-t)\ P_3], \tag{10}$$

and the Bayes average regret is

$$\overline{R_2} = [NP/\lambda_1 - \beta][2(1-t) - 3P/2] + 2t\,[N(P-t)/\lambda_1 - \beta]. \tag{11}$$

The optimal value P, say p_2 is obtained by minimizing $\overline{R_2}$ with respect to P and is easily seen to be

$$p_2 = (4N+3\lambda_1\beta)\,/\,6N\,. \tag{12}$$

We shall denote the average regret corresponding to $P = p_2$ by $\overline{R_2^*}$.

Note that p_2 (the optimal value for Procedure 2) is the same as $p_1(t)$ (the optimal value for Procedure 1) when t = 0 and consequently, equations (8) and (11) will be coincident.

It is clear from (9) that p_1 (t) is a decreasing function of t . We have thus shown that for any given (λ_1 , λ_2), Procedure 1 is superior to Procedure 2 for all values of t, where p_2 is independent of t . It seems that Procedure 1 is superior uniformly in t.

Numerical results on the relative performance of the two procedures are presented for selected values of t. Note that since $n \geq T$ and $n+T \leq N$, we have $t \leq 1/2$, hence we have included t values only up to 1/2 . The most striking feature in Table 2 is the uniform superiority of Procedure 1. The percentage increase R_2' over R_1' , given in the last column for each t > 0 , shows that this superiority could be quite pronounced. The results indicate that the reduction in regret afforded by Procedure 1 is strongly dependent upon λ_1 , λ_2 and the delay. The improvement in performance of Procedure 1 should be taken into consideration plus the simplicity of it. Note also that R_1' decreases with t for any pair of (λ_1 , λ_2) but R_2' decreases with any pair of (λ_1 , λ_2) for any t. The table indicates that Procedure 1 has the advantage of a shorter experiment stage for all N , t and (λ_1 , λ_2).

Table 2. Relative performance of the two procedures (N=100) *

λ_1	β	t = 0		t = 0.1			t = 0.2		
		P_1	R'_i	P_1	R'_1	I	P_1	R'_1	I
2	2	0.6867	0.3137	0.6367	0.2670	0.18	0.5867	0.2241	0.41
	3	0.6967	0.3040	0.6467	0.2581	0.18	0.5967	0.2160	0.41
	4	0.7067	0.2945	0.6567	0.2494	0.18	0.6067	0.2080	0.42
	5	0.7167	0.2849	0.6667	0.2408	0.18	0.6167	0.2002	0.42
3	2	0.6967	0.2027	0.6467	0.1721	0.18	0.5967	0.1440	0.41
	3	0.7117	0.1931	0.6617	0.1634	0.18	0.6117	0.1361	0.42
	4	0.7267	0.1840	0.6767	0.1545	0.19	0.6267	0.1284	0.43
	5	0.7417	0.1749	0.6917	0.1467	0.19	0.6417	0.1209	0.45
4	2	0.7067	0.1473	0.6567	0.1247	0.18	0.6067	0.1040	0.42
	3	0.7267	0.1380	0.6617	0.1161	0.19	0.6267	0.0963	0.43
	4	0.7467	0.1291	0.6967	0.1080	0.20	0.6467	0.0888	0.45
	5	0.7667	0.1204	0.7167	0.1001	0.20	0.6667	0.0817	0.47
5	2	0.7167	0.1141	0.6667	0.0963	0.19	0.6167	0.0801	0.42
	3	0.7417	0.1055	0.6917	0.0880	0.19	0.6417	0.0725	0.45
	4	0.7667	0.0963	0.7167	0.0801	0.20	0.6667	0.0653	0.48
	5	0.7917	0.0880	0.7417	0.0725	0.21	0.6917	0.0585	0.50

λ_1	β	t = 0.3			t = 0.4			t = 0.5		
		P_1	R'_1	I	P_1	R'_1	I	P_1	R'_1	I
2	2	0.5367	0.1850	0.70	0.4867	0.1496	1.10	0.4367	0.1180	1.66
	3	0.5467	0.1776	0.71	0.4967	0.1430	1.13	0.4467	0.1121	1.71
	4	0.5567	0.1704	0.53	0.5067	0.1365	1.16	0.4567	0.1064	1.77
	5	0.5667	0.1633	0.74	0.5167	0.1302	1.19	0.4667	0.1008	1.83
3	2	0.5467	0.1184	0.72	0.4967	0.0953	1.13	0.4467	0.0748	1.71
	3	0.5617	0.1112	0.74	0.5117	0.0889	1.17	0.4617	0.0691	1.79
	4	0.5767	0.1043	0.76	0.5267	0.0827	1.22	0.4767	0.0636	1.89
	5	0.5917	0.0975	0.79	0.5417	0.0767	1.28	0.4917	0.0584	1.99
4	2	0.5567	0.0852	0.73	0.5067	0.0683	1.16	0.4567	0.0532	1.77
	3	0.5767	0.0782	0.76	0.5267	0.0620	1.23	0.4767	0.0477	1.89
	4	0.5967	0.0715	0.81	0.5467	0.0561	1.30	0.4967	0.0425	2.04
	5	0.6167	0.0651	0.85	0.5667	0.05040	1.39	0.5167	0.0396	2.04
5	2	0.5667	0.0653	0.75	0.5167	0.0546	1.09	0.4667	0.0403	1.83
	3	0.5917	0.0585	0.79	0.5417	0.0460	1.28	0.4917	0.0305	2.45
	4	0.6167	0.0521	0.85	0.5667	0.0403	1.39	0.5167	0.0317	2.04
	5	0.6417	0.0460	0.91	0.5917	0.0350	1.51	0.5417	0.0292	2.01

* $R'_i = R^*_i$ /N , I denotes the percentage increase in R'_2 over R'_1.

Table 2. (continued) (N = 500)

λ_1	β	t = 0		t = 0.1			t = 0.2		
		P_1	R'_1	P_1	R'_1	I	P_1	R'_1	I
2	2	0.6707	0.2960	0.6207	0.2815	0.05	0.5707	0.2375	0.25
	3	0.6727	0.2940	0.6227	0.2797	0.05	0.5727	0.2357	0.25
	4	0.6747	0.2921	0.6247	0.2779	0.05	0.5747	0.2341	0.25
	5	0.6767	0.2901	0.6267	0.2760	0.05	0.5767	0.2324	0.25
3	2	0.6727	0.2169	0.6227	0.1865	0.16	0.5727	0.1572	0.38
	3	0.6757	0.2163	0.6257	0.1846	0.17	0.5757	0.1555	0.39
	4	0.6787	0.2143	0.6287	0.1828	0.17	0.5787	0.1538	0.39
	5	0.6817	0.2123	0.6317	0.1810	0.17	0.5817	0.1522	0.39
4	2	0.6747	0.1627	0.6247	0.1389	0.17	0.5747	0.1170	0.39
	3	0.6787	0.1607	0.6287	0.1371	0.17	0.5787	0.1154	0.39
	4	0.6827	0.1588	0.6327	0.1353	0.17	0.5827	0.1137	0.40
	5	0.6867	0.1568	0.6367	0.1335	0.17	0.5867	0.1121	0.40
5	2	0.6767	0.1294	0.6267	0.1104	0.17	0.5767	0.0930	0.39
	3	0.6817	0.1274	0.6317	0.1086	0.17	0.5817	0.0913	0.40
	4	0.6867	0.1255	0.6367	0.1068	0.18	0.5867	0.0897	0.40
	5	0.6917	0.1235	0.6417	0.1050	0.18	0.5917	0.0880	0.40

λ_1	β	t = 0.3			t = 0.4			t = 0.5		
		P_1	R'_1	I	P_1	R'_1	I	P_1	R'_1	I
2	2	0.5207	0.1971	0.50	0.4707	0.1606	0.84	0.4207	0.1277	1.32
	3	0.5227	0.1956	0.50	0.4727	0.1592	0.85	0.4227	0.1265	1.32
	4	0.5247	0.1941	0.50	0.4747	0.1577	0.85	0.4247	0.1253	1.33
	5	0.5267	0.1925	0.51	0.4767	0.1564	0.85	0.4267	0.1240	1.34
3	2	0.5227	0.1304	0.66	0.4727	0.1061	1.04	0.4227	0.0843	1.57
	3	0.5257	0.1289	0.68	0.4757	0.1047	1.07	0.4257	0.0831	1.60
	4	0.5287	0.1274	0.68	0.4787	0.1034	1.07	0.4287	0.0819	1.62
	5	0.5317	0.1258	0.69	0.4817	0.1020	1.08	0.4317	0.0807	1.63
4	2	0.5247	0.0970	0.68	0.4747	0.789	1.06	0.4247	0.0626	1.60
	3	0.5287	0.0955	0.68	0.4787	0.0775	1.07	0.4287	0.0614	1.62
	4	0.5327	0.0932	0.70	0.4727	0.0762	1.08	0.4327	0.0611	1.60
	5	0.5367	0.0925	0.70	0.4867	0.0748	1.10	0.4367	0.0590	1.66
5	2	0.5267	0.0770	0.68	0.4767	0.0626	1.07	0.4267	0.0496	1.61
	3	0.5317	0.0755	0.69	0.4817	0.0612	1.08	0.4317	0.0484	1.63
	4	0.5367	0.0740	0.70	0.4827	0.0599	1.10	0.4367	0.0472	1.66
	5	0.5417	0.0725	0.70	0.4917	0.0585	1.11	0.4417	0.0460	1.68

* $R'_i = \overline{R^*_i}$ /N , I denotes the percentage increase in R'_2 over R'_1.

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