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Estimating key parameters in FOBT screening for colorectal cancer

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Abstract

Objectives—The association between screening sensitivity, transition probability, and individual's age in FOBT for colorectal cancer are explored, for both males and females.

Methods—We apply the statistical method developed by Wu et al. [1] using the Minnesota colorectal cancer study group data, to make Bayesian inference for the age-dependent screening test sensitivity, the age-dependent transition probability from disease-free to preclinical state, and the sojourn time distribution, for both male and female participants in a periodic screening program. This gives us more information on the effectiveness of the fecal occult blood test in colorectal cancer detection.

Results—The sensitivity appears to increase with age for both genders. However, the posterior mean sensitivity is not monotonic with age for males; it has a peak around age 74. The standard errors of the sensitivity are not monotone either; there is a minimum at age 69 for males and at age 78 for females. The age-dependent transition probability is not a monotone function of age; it has a single maximum at age 72 for males and a single maximum at age 75 for females. The age dependency seems more dramatic for females than for males. The posterior mean sojourn time is 4.08 years for males and 2.41 years for females, with a posterior median of 1.66 years for males and 1.88 years for females. The 95% highest posterior density (HPD) interval is (0.97, 20.28) for males and (1.15, 5.96) for females, which are very large ranges, especially for males. The reason might be that there were fewer men than women in the annual screening program.

Conclusion—Reliable estimates of age-dependent sensitivity and transition probability are of great value to policy-makers regarding the initial age for colorectal cancer screening exams. We found that the mean sojourn time for males is much longer than that for females, which may imply that FOBT screening for colorectal cancer may be more effective for males than for females.

Keywords

Sensitivity; Transition probability; Sojourn time; Colorectal cancer screening; Fecal occult blood test (FOBT)

Introduction

Colorectal cancer (CRC) is the third most common form of cancer and the second leading cause of death for both genders among cancers in the United States. In 2006, it is estimated that 146,774 CRC cases were diagnosed and approximately 56,483 persons died of the disease which is around 10% of the total number of cancer death. In 2007, the estimated new cases of CRC is 153,760 and the estimated CRC deaths is 52,180 [2]. CRC is most often found in people 50 years and older. The age-specific CRC risk rises continuously with advancing age [3].

Colorectal cancer can take many years to develop, and early detection of CRC greatly improves the chances of a cure. Therefore, screening for the disease is recommended in individuals who are at increased risk. However, the acceptance of CRC screening has been low in the United States [4]. In most areas of the United States, less than half of the population is in compliance with recommended CRC screening guidelines, and the compliance rates may be even lower in other parts of the world [5]. Since tumors tend to bleed, blood in the stool can be a sign of colon cancer. That is where the fecal occult blood test (FOBT) comes in. It is a relatively simple, inexpensive method. Nearly 350,000 individuals [4] have participated in four FOBT-randomized clinical trials. One was in Minnesota (USA) and the other three were in Europe (Nottingham, UK; Funen, Denmark; and Göteborg, Sweden).

Between 1976 and 1982 the Minnesota Colon Cancer Control Study (MCCCS) randomized approximately 46,000 subjects to receive either five annual FOBT screenings or three biennial FOBT screenings or no screening. Each screening cycle consisted of six hemoccult slides (Hemoccult®, Beckman Coulter, Palo Alto, California), about 83% of slides were re-hydrated. If any of the slides was positive, then the screen was positive and a definitive work-up exam was done, including colonoscopy. Due to a lower than expected death rate among controls, the investigators resumed screening between 1986 and 1992. We restricted this analysis to the annual group and to the original five screenings.

In a screening program, a large cohort of asymptomatic individuals is enrolled in the program to detect the presence of a specific disease. The natural history of the disease for an individual is assumed to follow a progressive stochastic model, which consists of three states, denoted by $S_0 \rightarrow S_p \rightarrow S_c$, corresponding, respectively, to the disease-free state; the preclinical disease state, in which an asymptomatic individual unknowingly has disease that the screening exam can detect; and the clinical state when the disease manifests itself in clinical symptoms. The *sensitivity* is the probability that the screening exam is positive given that the individual is in the preclinical stage. The *sojourn time* refers to the time beginning when the disease first develops until the manifestation of clinical symptoms, i.e., $(S_c - S_p)$. The *transition probability* into the preclinical stage is the probability density function of making transition from the disease-free to the preclinical state.

Knowledge of these parameters is valuable to policy makers. As we know the goal of screening is to catch the disease before the clinical state, and usually a case with a long sojourn time will be easier to catch than the one with a shorter sojourn time. Accurate estimation of the screening sensitivity is necessary for evaluating the predictive performance of a screening exam. And finally, knowing the transition probability will provide information for which age group of people is at higher risk for the disease, so people can take preventive steps before the tumor forms.

Methods

Consider a cohort of initially asymptomatic individuals who enroll in a screening program. The sensitivity is denoted by $\beta(t)$, where t is the individual's age at the screening exam. Define $w(t)dt$ as the probability of a transition from S_0 to S_p during $(t, t + dt)$. Let $q(t)$ be the probability

density function of the sojourn time in S_p . Let $Q(z) = \int_z^\infty q(x)dx$, which is the survivor function of the sojourn time in the preclinical state S_p .

Consider a cohort of men or women in the study group who are all aged t_0 at study entry, and a protocol for $K = 5$ ordered screening examinations occurring at ages $t_0 < t_1 < \dots < t_{K-1}$, where $t_i = t_0 + i$ for annual screening exams. Define the i -th screening interval as the time interval between the i -th and the $(i + 1)$ -th screening exams (t_{i-1}, t_i) , $i = 1, 2, \dots, K - 1$. We let $t_{-1} \equiv 0$. For each screening exam, let n_{i,t_0} be the total number of individuals in this cohort examined at the i -th screening, s_{i,t_0} is the number of cases detected at the i -th screening exam, and r_{i,t_0} is the number of cases diagnosed in the clinical state S_c within the interval (t_{i-1}, t_i) , the interval cases.

The likelihood function for the males group and the females group are correspondingly:

$$L = \prod_{t_0=28}^{90} \prod_{k=1}^5 D_{k,t_0}^{s_{k,t_0}} I_{k,t_0}^{r_{k,t_0}} (1 - D_{k,t_0}^{s_{k,t_0}} - I_{k,t_0}^{r_{k,t_0}})^{n_{k,t_0} - s_{k,t_0} - r_{k,t_0}}, \quad (1)$$

and

$$L = \prod_{t_0=36}^{93} \prod_{k=1}^5 D_{k,t_0}^{s_{k,t_0}} I_{k,t_0}^{r_{k,t_0}} (1 - D_{k,t_0}^{s_{k,t_0}} - I_{k,t_0}^{r_{k,t_0}})^{n_{k,t_0} - s_{k,t_0} - r_{k,t_0}}, \quad (2)$$

where D_{k,t_0} is the probability that an individual will be diagnosed at the k -th scheduled exam given that he is in S_p and I_{k,t_0} is the probability of being incident in the k -th screening interval. These two probabilities were derived in [1]:

$$D_{k,t_0} = \beta(t_{k-1}) \left\{ \sum_{i=0}^{k-2} [1 - \beta(t_i)] \dots [1 - \beta(t_{k-2})] \int_{t_{i-1}}^{t_i} w(x) Q(t_{k-1} - x) dx + \int_{t_{k-2}}^{t_{k-1}} w(x) Q(t_{k-1} - x) dx \right\};$$

$$I_{k,t_0} = \sum_{i=0}^{k-1} [1 - \beta(t_i)] \dots [1 - \beta(t_{k-1})] \int_{t_{i-1}}^{t_i} w(x) [Q(t_{k-1} - x) - Q(t_k - x)] dx + \int_{t_{k-1}}^{t_k} w(x) [1 - Q(t_k - x)] dx.$$

We modeled the age effect in the sensitivity and the transition probability simultaneously in the following way. We associate the sensitivity β with age t by a logistic link,

$$\beta(t) = \frac{1}{1 + \exp(-b_0 - b_1 * (t - m))},$$

where m is the average age-at-entry in the study group. If $b_1 > 0$, $\beta(t)$ will be a monotone increasing function of age t . The transition probability density function is a sub-density:

$$w(t) = \frac{0.1}{\sigma t \sqrt{2\pi}} \exp \left\{ -\frac{(\log t - \mu)^2}{2\sigma^2} \right\}$$

As according to the NCI's "SEER Fast Fact Stats" database [3], the lifetime risk of being diagnosed with CRC is about 5.3% for females and 5.9% for males. Therefore, we picked 10% as a reasonable upper limit. μ and σ^2 are parameters to be estimated from the likelihood.

We adopted the log logistic distribution to model the sojourn time in the preclinical state,

$$q(x) = \frac{\kappa x^{\kappa-1} \rho^\kappa}{[1 + (x\rho)^\kappa]^2}, \quad x > 0,$$

where x is the sojourn time, and κ and ρ are positive parameters to be estimated. For justifications on how these age effect functions are chosen (see Wu et al. [1]).

Results

Our method requires cancer screening data from each age group. Table 1 and Table 2 list the number of subjects by gender and age interval for the annual group in the original five screenings.

We now describe our analysis of the Minnesota colorectal cancer study data based on the likelihood function and probability calculation derived in the previous section. In our proposed model, there are six parameters need to be estimated, i.e., $\theta = (b_0, b_1, \mu, \sigma^2, \kappa, \rho)$. Theoretically, the parameters have a domain of either $(-\infty, \infty)$ or $(0, \infty)$. The practical meaning of these parameters will limit them to a finite range. The range for each of them was identified [1] as: $0 < b_0 < 5$, $-0.2 < b_1 < 0.2$, $3.5 < \mu < 4.5$, $0 < \sigma^2 < 1$, $0.1 < \rho < 2.0$, and $1 < \kappa < 5$.

Markov Chain Monte Carlo (MCMC) was used to generate a random sample from the joint posterior distribution of the parameters for Bayesian inference. The posterior simulation was partitioned into four sub-chains, sampling the posterior for (b_0, b_1) , μ , σ^2 , (κ, ρ) separately.

A noninformative bivariate normal prior for (b_0, b_1) was chosen, i.e., a bivariate normal distribution with mean vector $(0,0)$ and variance equal to 10^{10} times the identity matrix. A noninformative normal prior was chosen for μ , namely, $N(0, 10^{10})$. The prior for σ^2 was uniform $(0,1)$, and the prior distributions for κ and ρ were uniform $(1,5)$ and uniform $(0,2)$, respectively. The two-dimensional integrals in the likelihood function do not have an analytical form. We used the trapezoidal rule to evaluate them when calculating the likelihood.

The MCMC was run for 20,000 steps, with a burn-in of 15,000 iterations. After the burn-in time, the posteriors were sampled every 20 steps, giving 250 posterior samples for the parameter vector θ . Four chains were simulated, each with different starting values that are over dispersed with respect to the target distribution. The 250 posterior samples from each of the four chains were pooled for the analysis, giving a total of 1,000 posterior samples. We list the posterior estimates for parameters θ and the standard errors separately for men and women in Table 3.

The Bayesian posterior estimates for the sensitivity and the transition probabilities for the males and females annual screening group in the Minnesota study are shown in Fig. 1 and Fig. 2.

The sensitivity appears to increase with age for both male and female. This trend is obvious from the quantiles plot of the saved posterior samples of the parameters in Fig. 1 and Fig. 2. We did a Bayes hypothesis test for $H_0 : b_1 \leq 0$ versus $H_1 : b_1 > 0$. For males, the posterior probability of a positive slope is $P(b_1 > 0 | \text{Data}) = 0.806$; for females, this posterior probability is 0.941. Hence, the evidence of age effect is more significant in females than in males. However, the posterior mean sensitivity is not monotonic with age for males (Fig. 3); it has a peak around age 74. The standard errors of the sensitivity are not monotone either, having a minimum at age 69 for males and at age 78 for females.

The age-dependent transition probability is itself a sub-pdf from our model construction. The posterior density curve of the transition probability could be seen from Fig. 1 and Fig. 2. The posterior mean transition probability varies from 0.113×10^{-3} to 1.707×10^{-3} for males aged 30–90 and varies from 0.069×10^{-3} to 2.009×10^{-3} for females aged 40–90. The transition probability is not a monotone function of age, having a single maximum at age 72 for males and a single maximum at age 75 for female. The age dependency seems more dramatic for females than that for males.

The posterior mean sojourn time is 4.08 years for males and 2.41 years for females, with a posterior median of 1.66 years for males and 1.88 years for females. The 95% highest posterior density (HPD) interval is (0.97, 20.28) for males and (1.15, 5.96) for females, which are very large ranges, especially for males. This may be because the number of male participants is less than the number of female participants. For example, there were 6,183 males in the first screening exam, compared with 6,978 females in the first exam; there were 5,020 males in the last exam, compared with 5,868 females in the last exam. Also, there were relatively few cancer cases diagnosed in either males or females, relative to the number of screens, which might be another factor for the large HPD intervals.

Discussion

Mandel et al. [6] showed that screening for fecal occult blood significantly reduces CRC mortality. We explore the effectiveness of the FOBT from another point of view. Bayesian methods combined with the natural history and the likelihood function give us important information on the estimation of age-dependent sensitivity, age-dependent transition probability, and sojourn time.

Prevost et al. [7] estimated the sensitivity and the mean sojourn time in fecal Hemoccult testing, using data from Calvados, France, between 1991 and 1994. Their models are different from the progressive model that we used here. They modeled the incidence of cancer as a Poisson random variable, with different parameter value for the mean of the Poisson distribution. Their sojourn time was assumed to follow an exponential distribution. They reported the mean sojourn time increases with age, which is approximately two years for 45- to 54-year-olds, three years for 55- to 64-year-olds, and six years for 65- to 74-year-olds. Their estimation of sensitivity decreases with age, which is approximately 75% for the age group 45–54, 50% for the age group 55–64, and 40% for the age group 65–74. Their estimations of the sensitivity and the mean sojourn time seem to be negative correlated. This negative correlation was also observed in breast cancer data and explained by Walter and Day [8]. In fact, this negative correlation would affect the accuracy of the estimation, which we hope to remove by better modeling. It was not clear to us how many screenings each person took, it seemed just once in Prevost et al. [7]. Church et al. [9] used the same Minnesota study to estimate the sensitivity; their crude estimate of program sensitivity is about 90%, regardless of age.

We applied the Bayesian method in Wu et al. [1] to the Minnesota colorectal cancer study and obtained some useful information for CRC. The sensitivity is quite high (above 90%) for both

genders after age 60. The transition probability from disease-free to preclinical state has a peak around age 72 for males and around age 75 for females. We compared this result with the SEER database. The “SEER Fast Fact Stats” [3] show that the probability of developing CRC has a single maximum between ages 80 and 85 for males, and the probability peaks between ages 85 and 90 for females. Our results agree with that fact, but the age was a few years earlier. The sojourn time from preclinical to clinical state for the CRC seems to have a huge range compared with breast cancer, from a few months to more than five years, especially for males. The reason might be that the number of participants is relatively small when there are so many different age groups, and the number of diagnosed cancer cases is relatively small with respect to the number of screens. We also found that the mean sojourn time for males is much longer than that for females, which implies that CRC screening seems to be more effective for males than for females.

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Fig. 1.
Posterior quantiles (5%, 50%, and 95%) of sensitivity and transition probability for male

Fig. 2.
Posterior quantiles (5%, 50%, and 95%) of the sensitivity and the transition probability for female participants

posterior mean sensitivity for Males

Fig. 3.
Posterior mean sensitivity for males to show that there is a maximum around age 74

Table 1

Annual screening: males

Age	n_1	s_1	r_1	n_2	s_2	r_2	n_3	s_3	r_3	n_4	s_4	r_4	n_5	s_5	r_5
28	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
35	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
37	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0
41	2	0	0	1	0	0	1	0	0	1	0	0	1	0	0
42	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0
43	1	0	0	1	0	0	0	0	0	0	0	0	1	0	0
44	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0
45	1	0	0	1	0	0	0	0	0	0	0	0	1	0	0
46	3	0	0	3	0	0	2	0	0	2	0	0	2	0	0
47	9	0	0	8	0	0	9	0	0	7	0	0	8	0	0
48	8	0	0	8	0	0	7	0	0	6	0	0	6	0	0
49	47	0	0	47	0	0	39	0	0	40	0	0	42	0	1
50	200	0	0	178	0	0	165	0	0	162	1	0	165	0	0
51	263	0	0	235	0	0	214	0	0	228	0	0	227	0	0
52	275	0	0	243	0	0	234	0	0	231	0	0	230	0	0
53	247	0	0	225	0	0	211	1	0	217	0	0	208	0	0
54	270	0	0	251	0	0	236	0	0	244	0	0	237	0	0
55	262	1	0	234	1	0	214	1	0	223	0	0	224	0	0
56	257	0	0	239	1	0	232	0	0	229	0	0	228	0	0
57	279	1	0	255	0	1	248	1	0	248	0	0	248	1	0
58	255	0	0	235	0	0	225	0	0	227	0	0	223	1	0
59	271	0	0	247	0	0	247	1	0	243	1	0	236	0	0
60	275	0	2	244	0	0	235	0	0	230	0	0	224	0	0
61	275	1	0	252	0	0	242	0	0	232	0	0	234	0	0
62	277	1	0	245	0	0	237	1	0	225	1	0	229	2	0
63	268	2	0	243	0	0	229	1	0	225	0	0	222	1	0
64	276	1	0	253	0	0	237	1	0	226	1	0	226	1	0
65	250	1	0	225	1	0	212	0	0	199	0	0	192	0	0
66	251	2	0	224	1	0	211	0	0	202	1	0	197	1	0
67	249	0	0	230	0	0	210	0	0	198	0	0	199	0	0
68	205	1	1	188	1	0	181	0	0	174	0	0	172	0	0
69	188	0	0	178	0	0	162	0	0	149	0	0	151	0	0
70	175	0	0	153	0	0	142	0	0	134	0	0	123	0	0
71	137	0	0	127	1	0	117	0	0	106	0	0	102	0	0
72	135	0	0	117	0	0	107	0	0	100	0	0	98	0	1
73	106	0	0	87	1	0	82	1	0	76	0	0	75	0	0
74	111	0	0	97	0	0	89	1	1	77	0	0	69	0	0
75	82	0	0	74	0	0	68	0	0	57	0	0	55	0	0
76	77	0	0	59	0	0	49	1	0	48	0	0	46	0	0
77	52	0	0	43	0	0	38	0	0	42	0	0	34	0	0
78	37	1	0	37	0	0	32	0	0	26	0	0	28	0	0
79	38	0	0	33	0	0	35	0	0	27	0	0	26	0	0
80	22	0	0	15	0	0	14	0	0	13	0	0	14	1	0
81	16	0	0	12	0	0	10	0	0	9	0	0	6	0	0
82	12	0	0	11	0	0	7	0	0	4	0	0	5	0	0
83	5	0	0	4	0	0	3	0	0	1	0	0	2	0	0
84	4	0	0	2	0	0	2	0	0	1	0	0	1	0	0
85	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
86	2	0	0	1	0	0	1	0	0	0	0	0	0	0	0
87	1	0	0	1	0	0	1	0	0	0	0	0	1	0	0
90	1	0	0	1	0	0	0	0	0	1	0	0	0	0	0

“Age” is age at entry

n_i is number receiving i -th screening

s_i is number of colorectal cancers diagnosed due to i -th screen

r_i is number of interval cancers (diagnosis not due to screening diagnosed between i -th and $(i + 1)$ -th screen

Table 2

Annual screening: females

Age	n_1	s_1	r_1	n_2	s_2	r_2	n_3	s_3	r_3	n_4	s_4	r_4	n_5	s_5	r_5
36	1	0	0	1	0	0	1	0	0	0	0	0	0	0	0
38	1	0	0	1	0	0	1	0	0	0	0	0	1	0	0
40	2	0	0	2	0	0	2	0	0	2	0	0	2	0	0
42	2	0	0	2	0	0	2	0	0	1	0	0	2	0	0
43	1	0	0	1	0	0	1	0	0	1	0	0	1	0	0
44	3	0	0	3	0	0	3	0	0	2	0	0	2	0	0
45	2	0	0	3	0	0	2	0	0	2	0	0	2	0	0
46	4	0	0	4	0	0	4	0	0	5	0	0	5	0	0
47	6	0	0	6	0	0	6	0	0	6	0	0	6	0	0
48	16	0	0	14	0	0	13	0	0	12	0	0	13	0	0
49	67	0	0	59	0	0	50	0	0	55	0	0	52	0	0
50	194	0	0	178	0	0	168	0	0	171	1	0	162	0	0
51	223	0	0	207	0	0	195	0	0	197	1	0	189	1	0
52	237	0	0	222	0	0	202	0	0	204	0	0	202	0	0
53	248	0	0	230	0	1	222	0	0	206	0	0	215	0	0
54	251	0	0	226	0	0	215	0	0	217	1	0	214	0	0
55	261	0	0	239	0	0	216	0	0	215	0	0	225	0	0
56	282	0	0	254	1	0	253	0	0	250	0	0	253	0	0
57	311	0	0	285	0	0	269	0	0	279	0	0	266	0	0
58	333	0	0	316	0	0	297	0	0	299	1	0	299	1	0
59	283	1	0	255	0	0	246	0	0	243	0	0	246	0	0
60	339	0	0	314	0	0	303	0	0	293	1	0	301	0	0
61	320	1	0	303	0	0	291	1	0	274	0	0	282	0	0
62	341	0	0	313	0	0	312	1	0	282	1	0	293	0	0
63	350	0	0	333	0	0	314	1	0	298	0	0	306	0	0
64	308	1	0	283	0	0	265	0	0	245	0	0	253	1	0
65	316	0	0	289	0	0	288	0	0	270	0	0	276	0	0
66	308	0	0	283	0	0	278	2	0	264	0	0	260	0	0
67	289	1	0	269	1	0	250	0	0	245	2	0	240	1	0
68	266	1	0	241	1	0	229	0	0	212	1	0	213	0	0
69	199	1	0	186	1	0	183	0	0	170	0	0	167	0	0
70	201	1	0	184	1	0	175	0	0	163	0	0	160	2	0
71	197	3	0	175	0	0	173	0	0	167	2	0	160	1	0
72	150	0	1	135	1	0	128	0	0	117	1	0	118	0	0
73	143	1	0	133	0	0	132	0	0	119	0	0	116	0	0
74	102	0	0	90	0	0	92	0	0	84	0	0	77	0	0
75	92	1	0	82	0	0	81	0	0	67	0	0	69	0	0
76	84	0	0	77	0	0	72	0	0	67	1	0	66	0	0
77	82	0	0	74	0	0	65	0	0	58	1	0	60	0	0
78	47	0	0	42	0	0	39	0	0	34	0	0	34	1	0
79	35	0	0	29	0	0	29	0	0	21	0	0	18	0	0
80	33	0	0	28	0	0	27	0	0	22	0	0	19	0	0
81	16	0	0	9	0	0	10	0	0	7	0	0	7	0	0
82	11	0	0	9	0	0	7	0	0	7	0	0	7	0	0
83	9	0	0	7	0	0	7	0	0	3	0	0	4	0	0
84	5	0	0	4	0	0	3	0	0	3	0	0	3	0	0
85	3	0	0	2	0	0	1	0	0	1	0	0	1	0	0
87	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0
88	2	0	0	2	0	0	2	0	0	2	0	0	1	0	0
93	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

"Age" is age at entry

n_i is number receiving i -th screening

s_i is number of colorectal cancers diagnosed due to i -th screen

t_i is number of interval cancers (diagnosis not due to screening diagnosed between i -th and $(i + 1)$ -th screen

Table 3

Bayesian posterior estimates for the male and female annual groups

Parameters	Male		Female	
	Median	SE	Median	SE
b_0	0.816	1.638	0.686	1.443
b_1	0.128	0.156	0.188	0.142
μ	4.365	4.368	4.427	4.432
σ^2	0.091	0.119	0.058	0.065
κ	3.019	3.055	3.607	3.543
ρ	0.791	0.749	0.633	0.626
				0.899
				0.194