Supplementary Online Content

Buys SS, Partridge E, Black A, et al, for the PLCO Project Team. Effect of screening on ovarian cancer mortality: the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Randomized Controlled Trial. *JAMA*. 2011;305(22):2295-2303. Published online June 4, 2011. doi:10.1001/jama.2011.766.

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix. Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial Project Team, the names of those on the advisory boards, and the contract numbers

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Screening Centers and Contract Numbers

University of Colorado Denver	N01-CN-25514
Georgetown University Medical Center	N01-CN-25522
Pacific Health Research & Education Institute	N01-CN-25515
Henry Ford Health System	N01-CN-25512
University of Minnesota School of Public Health	N01-CN-25513
Washington University	N01-CN-25516
University of Pittsburgh Medical Center	N01-CN-25511
University of Utah	N01-CN-25524
Marshfield Clinic Research Foundation	N01-CN-25518
University of Alabama at Birmingham	N01-CN-75022
UCLA Immunogenetics Center (Laboratory)	N01-CN-25404
Westat, Inc. (Coordinating Center)	N01-CN-25476

eTable. WLR statistic, weighted information fraction and efficacy and futility boundary points on the standard normal scale

Analysis	*Wtd information fraction*	*WLR statistic*	*Efficacy Boundary*	*Futility Boundary*
1	0.007	0.219	-8.210	24.426
2	0.039	-0.111	-8.210	9.687
3	0.043	0.493	-8.210	7.920
4	0.118	0.580	-5.584	2.952
5	0.151	-0.546	-4.918	2.344
6	0.210	0.068	-4.124	1.167
7	0.254	-0.415	-3.729	-0.619
8	0.695	0.729	-2.081	-1.119

Values of the weighted information fraction, WLR statistic, and efficacy and futility boundary points are listed in the eTable. The sign is consistent with a negative value of the alternative hypothesis, log(0.65)

eMethods

Difference in mortality rates was assessed using a weighted log-rank (WLR) test, incorporating increasing weights proportional to the pooled cancer mortality[1]. A weighted statistic was chosen because of the presumed delayed effect of screening upon ovarian cancer mortality. Interim analyses were performed at least annually beginning in 2002 and were presented to the trial DSMB. The interim analysis plan, adopted by the DSMB, stipulated monitoring the WLR statistic for efficacy and futility. A one-sided efficacy boundary was constructed via the Lan-Demets procedure using an O'Brien-Fleming spending function and a total probability of type I error of 5% [2]. Total weighted information was derived by projecting the time required to obtain 226 events as stipulated in the design, which was determined to be roughly 13 years after the initial randomization using the method outlined in expression 8.9 of [3]. In order to allow for early stopping due to lack of effectiveness or harm, the monitoring design also stipulated a non-binding futility boundary, constructed via the stochastic curtailment procedure [2,4,5].

Specifically, at each interim analysis, first we calculated the weighted information fraction as the ratio of the current WLR statistic variance to the projected variance of the WLR statistic at the scheduled trial conclusion, τ = 13 years. The end of trial variance is projected using the method outlined following expression 8.7 of [3]. Next we calculated the one sided efficacy boundary point, b_k . The stochastic curtailment procedure was used to construct a futility boundary point, a_k , in the following way. Given the current values of the WLR statistic, Zt_k, the weighted information fraction, f_k , and values of the drift function, $\mu(t_k)$ and $\mu(\tau)$ at the current analysis and at the scheduled end of the trial, the stochastic curtailment procedure for futility is done by comparing

$$\mathbb{P}_{\mathrm{H}_A}\{Z_\tau < b_{\mathrm{end}} | Z_{t_k}\} = \Phi\left(\frac{(b_{\mathrm{end}} - \mu(\tau)) - (\sqrt{f_k} Z_{t_k} - \mu(t_k))}{\sqrt{1 - f_k}}\right) \qquad (1)$$

to a threshold value, p_c . The above is the conditional probability under the design alternative hypothesis, that the end of trial WLR statistic does not reject the null given the current value of the WLR statistic at analysis k . Here for sake of clarity we present the case in which the sign of the alternative hypothesis is positive. If the above probability exceeds the threshold then the futility boundary has been crossed.

We used the threshold value p_c = 0.90. The end of trial WLR statistic variance was projected according to the method outlined below expression 8.7 in [3]. The end of trial drift was projected using the design alternative logged relative risk log(0.65), under the constant shape assumption according corollary 4.3 of [3]. The stochastic curtailment procedure is equivalent to a sequence of futility boundary points on the standard normal scale given as:

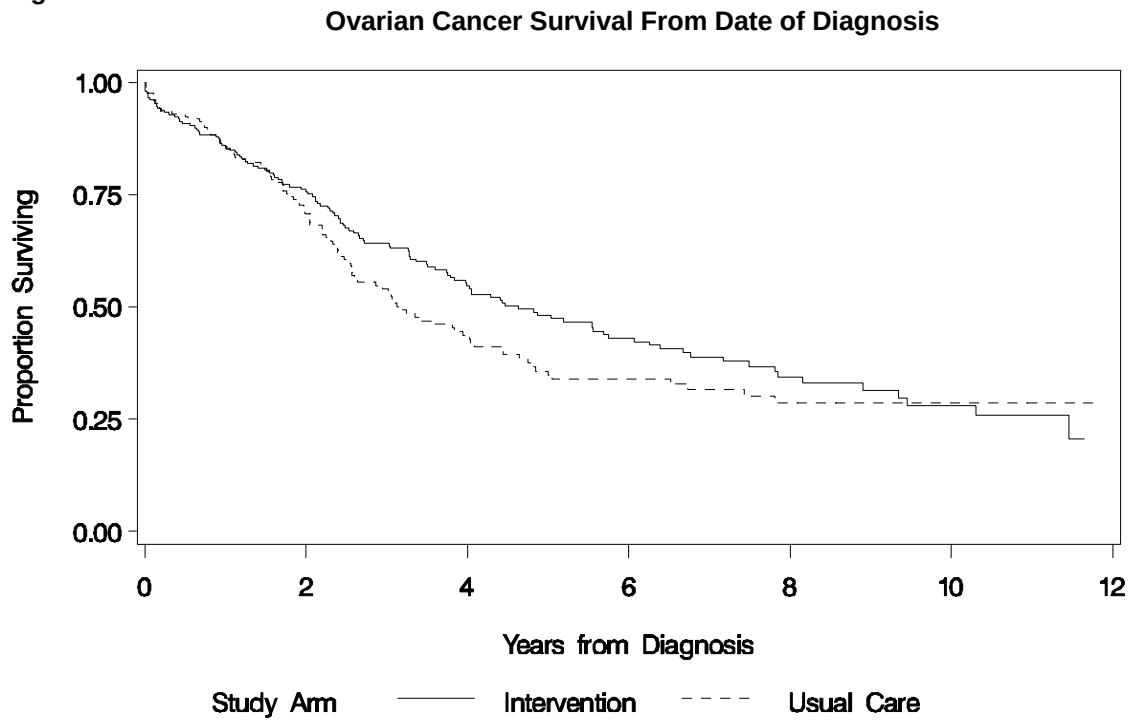
$$a_k = \frac{b_{\text{end}} - (\mu(\tau) - \mu(t_k)) - \sqrt{1 - f_k}\Phi^{-1}(p_c)}{\sqrt{f_k}} \,. \qquad (2)$$

The primary aim is summarized via the simple ovarian cancer mortality rate ratio. A sequential one sided p-value is derived using stage-wise ordering according expression 5.4 of [3]. A sequential two sided confidence interval for the ovarian cancer mortality ratio is derived under the constant shape assumption, as the exponentiated values in expression 5.6 with the mean squared error given in part (iii) of corollary 4.3 [3].

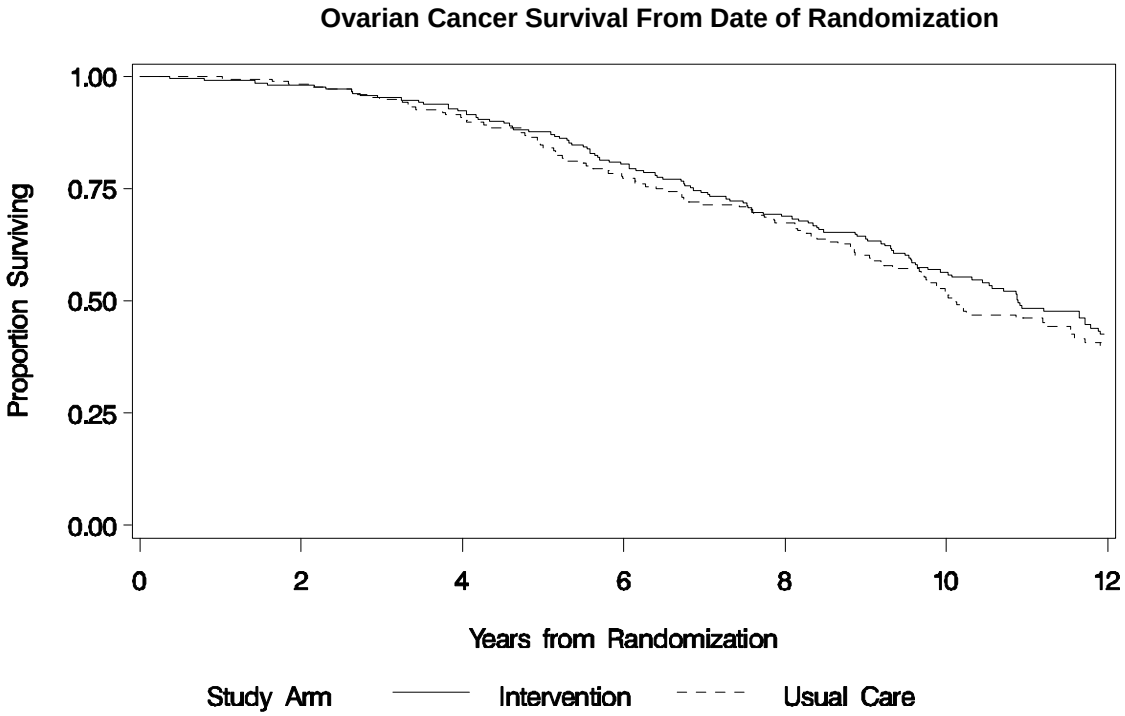
eReferences

1. Kalbfleisch, JD, Prentice RL. The Statistical Analysis of Failure Time Data. 2nd ed. New York: Wiley, 2002:23.
2. Proschan MA, Lan KKG, Wittes JT. Statistical monitoring of clinical trials: a unified approach. New York: Springer-Verlag, 2006.
3. Izmirlian G. Estimation of the relative risk following group sequential procedure based upon the weighted log-rank statistic. arXiv:1102.5088. 2011. Available: http://arxiv.org/abs/1102.5088
4. Lan KKG, Simon R, Halperin M. Stochastically curtailed tests in long-term clinical trials. Communications in Statistics - Stochastic Models 1982;1:207-19.
5. Lin DY, Yao Q, Ying Z. A general theory on stochastic curtailment for censored survival data. Journal of the American Statistical Association 1999;94:510-21.

eFigure. Ovarian cancer survival



Number at Risk at Beginning of Year	Years Since Diagnosis													
	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Study Arm														
Intervention	212	174	144	111	89	68	54	40	28	19	15	10	2	0
Usual Care	176	140	111	70	52	38	31	25	16	11	8	2	0	0



Number at Risk at Beginning of Year	Years Since Diagnosis													
	0	1	2	3	4	5	6	7	8	9	10	11	12	13
Study Arm														
Intervention	212	210	207	201	195	183	168	153	140	125	95	69	47	16
Usual Care	176	176	173	167	160	148	135	123	114	98	72	54	35	15