

Detecting overall survival benefit derived from progression-free survival

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Overall survival (OS) may be a reasonable primary endpoint when the median survival postprogression (SPP) is less than 6 months, but it is too high a hurdle when SPP is longer than 12 months, according to a new study published online November 9 in the *Journal of the National Cancer Institute*.

This study was undertaken to examine whether progression-free survival (PFS) or OS is the most appropriate endpoint in clinical trials of metastatic cancer, and to determine if it is reasonable to expect that treatment benefit in PFS carries over to OS.

To address these questions, Donald A. Berry, Ph.D., of the Department of Biostatistics, University of Texas M. D. Anderson Cancer Center in Houston, and colleagues simulated clinical trials with two arms having respective medians for PFS of 6 and 9 months. Researchers partitioned OS into two parts and expressed it as the sum of PFS and SPP. Probabilities of a benefit in OS were determined for various median SPP, by assuming no treatment-related difference in SPP, and for different P values for PFS.

They found that, at a P value for improved PFS of .001, there was a greater than 90% probability for statistical significance in OS if the median SPP was 2 months. However, the probability for statistical significance was less than 20% if the median SPP was 24 months.

"For clinical trials with a PFS benefit, a lack of statistical significance in

OS does not imply a lack of improvement in OS," the authors write. "For diseases with long SPP, the variability in SPP so dilutes the comparison that statistical significance is likely lost. Thus, OS is a reasonable primary endpoint when median SPP is short...but is too high a hurdle when SPP is long...As the clinician's armamentarium of salvage therapies grows and becomes more varied, SPP will get longer. When SPP gets sufficiently long oncology researchers and regulators will have to drop OS as the primary endpoint in clinical trials."

Source: [Journal of the National Cancer Institute](#) (news : web)

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