Issues Related to Composite Endpoints in Cardiovascular Clinical Trials

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In general, results of clinical trials were determined by the differences in occurrence of endpoints of clinical trial. So understanding of endpoints is crucial for success of clinical trial and interpretation of trial results.

Single endpoint of all-cause mortality is the most reliable and clinically relevant endpoint in clinical trials, however in recent clinical trials composite endpoints commonly used in cardiovascular disease. Composite endpoints are associated with potential advantages and disadvantages. They generally strengthened statistical power of clinical trials; they require smaller sample size, and shorter study duration. However difficulty in interpretation is a major limitation of composite endpoints.

Selecting components of composite endpoint requires cautious considerations for objective of study, and clinical implication. Commonly less important but more frequent events have greater influences on results of clinical trials. And intention to evaluate the net benefit of given intervention by single endpoint makes interpretation of trial results more complex. This lecture will briefly review the issues related composites endpoints in cardiovascular clinical trials.