

Differences that make a difference

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This is an excellent review of recent progress in statistical methods in cancer treatment assessment.

The author discusses the following issues:

1. emerging needs of shared decision making in selecting treatment option based on evidence and patient's preference,
2. relevance and significance of patient-based outcomes,
3. inherent limitations of conventional survival statistics methodologies in identifying real differences in effect size, rather than ratio, and providing physicians and patients with interpretable information, about different cancer treatment options,
4. alternative methods of mean survival statistics as promising measures that provide more accurate estimation and patient-friendly interpretation.

The reviewer agrees with the author's view correctly emphasizing interpretability of the result of statistical analysis which often is difficult for practicing physicians and for patients to understand, and to use when they make decisions incorporating their preferences. The au-

thor takes methodological issues that usually seem complex and explains them, simply and clearly and succeeded in convincing readers of his points.

In addition to innovation in statistical methods, the following would be necessary to realize shared decision making in Japan:

1. selection of the relevant outcomes measures: obviously survival only would not be sufficient information to patients with cancer. Such measures as "Q twist" quantifying both survival and adverse effects of the treatment may be more relevant to patients.
2. FDA recently has requested drug industry to report (and to make public!) the results of clinical trial as % better, % no change, % worse in addition to the conventional way. This simple format would be easily understandable and informative for patients to make treatment decisions.
3. accumulation of clinical and population based data are critically necessary and important for interpretation of the data, particularly of patient-based outcomes, such as health-related quality of life. For example,

a 5-point difference in QOL score, albeit statistically significant, does not mean anything to patients; this should be convertible to other measures, such as disabled days, health resource use, even future death etc., and it would be informative to policy decision makers too. However, these types of information are now almost completely unavailable in Japan.

4. Information sharing system itself should evolve so that it is more readily available and “visible” to patients; decision support system using website, DVD, videotape, etc. containing relevant and “visible” information which helps patients understand the difference in effectiveness of each treatment option from different points of views (outcome measures).