New System For Reporting Toxicity Burden Of Cancer Treatment

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A new system for reporting the relative toxicity burden of different cancer treatments is proposed in an Article published early Online and in the July edition of The Lancet Oncology.

Professor Andy Trotti, H Lee Moffitt Cancer Centre, University of South Florida, Tampa, Florida, USA and colleagues assessed deficiencies in established methods for summarising adverse events, and devised their new method.

The new system, named TAME, places traditional adverse-event data into three concise risk domains: short term toxicity (T), adverse long term effects (A) and mortality risk (M), which are calculated for each treatment programme to generate an end-result (E) summary index.

The authors say: “This is an entirely new concept in risk assessment. It was specifically designed for the evaluation of cancer treatments. Traditional safety reporting methods were designed for low-risk non-cancer treatments, and are simply overwhelmed by the amount of toxicity data generated in cancer treatment programs. Thus, a new way to look at risk that is more relevant to oncology is needed.”

Despite being in the early stages of development, TAME has managed to identify differences of up to 500% in acute toxicity burden between certain cancer treatments. Established methods only detected a 170% difference in short term effects between those treatments. Established summary methods were also found to disregard a large amount of

important information, and only permit comparing rates of each type of side effect (in cancer treatments there are dozens of types), whereas TAME includes all types of severe side effects, and considers their relative frequency, using a concise scoring system. However there was little difference between TAME and established methods in detecting the variation of risk in events that happened late in treatment.

TAME aims to provide a “side-effects” summary index for each treatment, so that the “total toxicity price” of the various options is clear to patients and doctors before a particular course of treatment is chosen.

The researchers used data from five trials by The Radiation Therapy Oncology Group (RTOG) on patients with head and neck cancer, done between 1991 and 2000. The trials involved 13 treatment groups and more than 2,300 patients. The adverse events focused on in the study included mouth sores, skin reactions, swallowing difficulty, nausea, and blood counts.

The TAME system focuses on consolidating clinically meaningful events that have high symptom burden or that might compromise the delivery of treatment. TAME values are presented in a way that makes it easier to directly compare overall safety among treatment options. Patients have a growing number or choices in cancer treatment, and many want to be able to choose based on relative safety and quality of life, as well as effectiveness. TAME is a new metric that simplifies direct comparison of a large volume of very complex safety data.

The authors also believe that the TAME system will be applicable to multiple disease sites, although this will require site-specific development, and hope that one day patients and clinicians will be able to ask: “How ‘TAME’ are each of these treatment options”, for a number of different types of cancer.

They conclude that TAME reporting provides a concise and uniform method to compare relative safety among cancer treatment options. They say: “Routine implementation and acceptance [of TAME} might occur through documenting its accuracy in additional datasets and disease sites….and assessment of its use in clinical decision making.”

Source: University of South Florida