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Intention to Treat Analysis from a clinicians view point

The concepts behind the limitations of intention to treat [ITT] analysis is interesting but at the same time too complex for an average practicing clinician. As rightly pointed out by Prof. Altman [1] trial investigators do not describe what they did to the data on patients who discontinued the study. While comparing the research articles published 60 years back with those published over the last 15 years it is clear that current researchers are of the opinion that their research observations are close to perfect since they are supported by advanced statistical methods. In contrast researchers before the 1950's considered all possible alternative conclusions to their study . I presume that clinicians were more comfortable reading these older yet honest research articles than the current sophisticated yet confusing ones. The worrying part for the clinician is contradictory observations on a similar topic of interest by studies done within a span of 5 years.

As a clinician I will look at the intention to treat analysis is a much simpler way. Lets presume that in a randomized controlled trial with 2000 participants in each arm 200 patients (10%) lost to follow up in the intervention arm and 20 (2%) lost to follow-up in the control arm and the authors conclude that the intervention resulted in favorable outcome based on ITT analysis with statistically acceptable modifications. The question from the clinician will be,

“Does this conclusion hold good if the unfavorable outcome has occurred to all the 200 patients who lost to follow up in the intervention group ?”.

I do not think that this worst scenario is considered in the ITT analysis. This idea may not look logical. But we should remember that the observation made on 2000 patients is going to be applied to the entire global populations . Ethically this worst possible scenario should be considered in ITT analysis. If the outcome is in favor of the intervention despite this worst scenario then probably the conclusion of the study is close to perfect. If not , then the observations leads to only doubtful conclusions. Discussion should consider various possible outcomes to patients who lost to follow-up. Researchers should probably feel free to raise doubts on there own observations in the discussion section of the paper so that the scientific community gets maximum benefit from the study. We know our mistakes before others identify it !. It will be nice if CONSORT drives this initiative.

References:

1. Douglas G Altman. Missing outcomes in randomized trials: addressing the dilemma Open Medicine 2009 3(2) :e21 -23