

Lost to follow-up (LTFU) is now a major concern in publishing in randomized controlled trials (RCT) especially in the area of Head and Neck Cancers (HNC). It has been found that in a majority of clinical trials in HNC the incidence of LTFU is not reported. This, in turn, adversely impacts the interpretation of significant findings. This is a serious lacuna in clinical trials.

Randomized controlled studies (RCT) are universally recognized to be the gold standard for the evaluation of the safety and efficacy of new treatment modalities that evaluate their effectiveness.

Efforts have been made to improve standardization of the reporting of LTFU and these efforts led to the creation of Consolidated Standards of Reporting Trials (CONSORT). This statement was first published in 1996 and then again in 2010. CONSORT issued recommendations to encourage transparent reporting. A checklist and flow diagrams were recommended to ensure accurate interpretation and critical appraisal of trial design and the reporting of results.

When RCTs have been examined using the CONSORT template, many have been found to be lacking in transparency. This has been found to be particularly noticeable in all disciplines managing HNC.

It was found that RCT studies that featured surgeons as the first or last author demonstrated low checklist scores compared to nonsurgeons. It was found that surgeons were deficient in reporting rationale of design elements that included sample size, randomization, and eligibility.

To counter this, the “Fragility Index” was devised. It was devised in particular to evaluate the strength of statistically significant findings in RCTs.

Currently, there is a marked shortage of medical literature concerning the withdrawal of participants from RCTs. A number of RCTs in FDA- approved trials in oncology use progression-free survival or disease- free survival as their surrogate endpoints. A higher risk of bias related to patient withdrawals or LTFU was observed in studies using surrogate endpoints.

In order for RCTs to be valuable and impactful, adherence to CONSORT guidelines will be a much-needed step in the right direction.

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