Assessing the risk of bias associated with missing participant in randomized controlled trials: A systematic review and meta-analysis in autologous cell therapy for Peripheral Arterial Disease

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Randomization minimizes the chance of bias by balancing both known and unknown prognostic factors between trial arms. However, the results can be biased when the data from 'non-adherent' participants excluded from the analysis to evaluate treatment effect. The aim of the study is to demonstrate the risk of bias associated with missing participant in RCT of cell therapy for PVD patients.

Systematic search was performed from inception to December, 2017 in MEDLINE and Embase. We conducted meta-analysis using complete case analysis as the primary analysis. To test the robustness of the results, sensitivity analyses were conducted using both worst-case scenario and adjusting zero events to evaluate the magnitude risk of bias impacts on the reported results.

In the complete case analysis, the cell therapy showed reduced the risk of amputation by 43% (RR 0.43; 95% CI 0.27 to 0.68). In worst-case scenario, the treatment effect on prevention of amputation was decreased (RR=0.61 0.36; 95% CI 0.39 to 0.97). In addition, adjusting zero event yielded a wide confidence interval (RR 0.44; 95% CI 0.20 to 0.97).

Even when we assumed worst-case scenario, the results remained statistically significant, cell therapy for PVD may reduce the risk of amputation and may be guaranteed the true treatment effect of cell therapy.