35. Investigating the Effect of Oral Glutathione Supplementation to Improve the Standards of Personalized Type 2 Diabetes Care

Arjun Kolappurath Madathil*, Saroj Ghaskadbi, Saurabh Kalamkar, Pranay Goel

*Indian Institute of Science Education and Research, Pune, Maharashtra, India
E-mail: k.marjun@students.iiserpune.ac.in

Introduction: Hyperglycemia-induced oxidative stress gives rise to complications in type 2 diabetes (T2D). T2D individuals reportedly exhibit reduced levels of glutathione (GSH), an endogenous antioxidant in cells crucial in determining their redox status. Replenishing GSH could help enhance systemic redox status in T2D.

Methods: A six-month-long pragmatic prospective clinical trial (CTRI/2018/01/011257) was conducted to investigate the effect of oral GSH supplementation on erythrocytic GSH stores and glucose homeostasis in T2D patients undergoing antidiabetic treatment. We performed an inter-individual analysis with the framework of linear mixed-effects (LME) models to understand the dynamics of longitudinal biochemical responses and their variation between individuals for elucidating effective personalized interventions with GSH.

Results: LME model trajectories described how biochemical parameters in T2D patients progress over a 6-month period. We estimated significant improvements in erythrocytic GSH at a rate of 108 μM per month and a reduction in 8-OHdG at 18.5 ng/μg DNA per month in T2D patients. GSH replenished slower in elder patients than in younger ones. 8-OHdG reduced more rapidly in the elder (24 ng/μg DNA per month) than in younger (12 ng/μg DNA per month) individuals. A substantial reduction in HbA1c (0.1% per month) and increased fasting insulin (0.6 μU/mL per month) was observed in elder patients.

Conclusion: Long-term GSH supplementation improves body stores of GSH and offers protection from oxidative damage. It also helps maintain lower HbA1c and improves fasting insulin in elderly T2D patients. LME model estimates characterize the variability in the inter-individual biochemical response in particular, determined by the age group of T2D patients, and help in evaluating the progress of treatment and glucose control targets. These results and model predictions assist clinicians in personalizing treatment goals for using oral GSH supplementation as an adjunct therapy in T2D.

36. Publication Rate of Industry-sponsored Type 2 Diabetes Mellitus Clinical Trials Registered on ClinicalTrials.gov

Pravin Bolshete*, Ruchika Thale, Madhura Donde, Rupika Pawar, Snehal Khanolkar

*Sqarona Medical Communications LLP, Pune, Maharashtra, India
E-mail: pravin.bolshete@sqarona.com

Introduction: Clinical trials play a vital role in evidence-based medicine. Registration of these trials in a publicly accessible database is important; however, nonreporting of trial results may affect the validity of the literature and may negatively affect patient care. This study evaluated the publication rate of industry-sponsored type 2 diabetes mellitus (T2DM) clinical trials registered on ClinicalTrials.gov.

Methods: This was a cross-sectional study. ClinicalTrials.gov was searched on February 1, 2023, to identify all the registered interventional phase 2 and 3 clinical trials involving adult patients with T2DM with a primary study completion/termination date between January 1, 2000, and December 31, 2020. Publication of results in peer-reviewed journals was noted by PubMed or by hand search. Data presented at conferences, published in proceedings, and posting of results on ClinicalTrials.Gov were not considered publications.

Results: A total of 693 trials were included (completed, n = 633; results posted, n = 453; >500 participants, n = 193; phase 3, n = 464; randomized, n = 644). Of the 693, 408 (58.9%) trials were published. Of the completed trials, 61.9%, and of terminated trials, 26.7% were published (odds ratio [OR]: 2.32, confidence interval [CI]: 1.52, 3.55); among phase 3 and 2 trials, 69.0% and 38.5% (OR: 0.56, CI: 0.47, 0.66), respectively, were published, whereas among trials with >500 and <500 participants, 80.3% and 50.6% (OR: 0.63, CI: 0.56, 0.70) were published. Among trials with and without results, 71.1% and 35.8% (OR: 1.98, CI: 1.66, 2.37), and among randomized and nonrandomized, 60.4% and 38.8% (OR: 1.56, CI: 1.09, 2.23), respectively, were published.

Conclusion: Overall results demonstrate that over 60% of the industry-sponsored phase 2 and 3 clinical trials were published. Completed trials, phase of the trials, higher sample size, trial results on the registry, and randomization were associated with publication.

37. Real-world Effectiveness of Digital Therapeutics in Improving Sleep Quality in People with Diabetes and Hypertension

Manthan Mehta*, Ritika Verma, Archana Munje, Sheethal Brahmesh, Abhijit Aklujkar, Utsav Sahu, Karunesh Kumar, Suhas Erande, Vineet Nair, Arbinder Kumar Singal

*Fitterfly Health Tech Pvt Ltd, Navi Mumbai, Maharashtra, India
E-mail: manthan.mehta@fitterfly.in

Introduction: Sufficient and healthy sleep has an inverse association with cardiovascular disease (CVD) and its risk factors. Hypertension and diabetes are major modifiable risk factors for CVD. The American Heart Association has added sleep health to Life's Essential 8 score as a measure of cardiovascular health. The study aims at the real-world analysis of changes in sleep quality among people with type 2 diabetes and hypertension after participation in the Fitterfly diabetes digital therapeutics program.

Methods: De-identified pre- and postprogram data of 90 participants with diabetes and hypertension (mean age-54.9