

Abstract

The prevalence of diabetes is steadily increasing worldwide yet multiple myeloma clinical trials have failed to study the co-occurrence of these two disorders. This study used data from clinicaltrials.gov to investigate the inclusion and exclusion frequencies of diabetes-related terms in multiple myeloma (MM) clinical trials. Of the 2908 MM clinical trials analyzed, 392 excluded diabetes-related terms while only 16 included such terms. Despite similarities in symptoms and treatment options, the majority of clinical trials have failed to examine the effects of MM treatment in those with diabetes. Based on the available data, an increase in the number of diabetics recruited in MM clinical trials could improve diagnostic and treatment efficacy between MM and diabetes.

Background

Multiple myeloma (MM) and diabetes mellitus (DM) share some similarities within their respective pathophysiologies despite distinct differences between the two conditions. Due to the pathophysiological similarities which ultimately increase extracellular acidity, recent literature has supported the usage of identical treatment methods for both conditions (Fais & Marunaka 2020, 3326). The pathophysiological similarities between MM and DM also result in similar symptoms such as neuropathy or nephropathy in many patients. Additionally, research supports that DM may increase the risk of acquiring MM (Tentolouris et al. 2022, 3035). To date, some evidence supports that anti-diabetic treatment via medications such as Metformin may reduce the likelihood of acquiring MM (Boursi et al. 2017, 1265). Despite this evidence, the majority of MM clinical trials exclude diabetes-related populations, thus limiting the potential treatment of two major chronic comorbidities.

Methods

This study used Python3.9.10 to collect and organize inclusion and exclusion terms in MM clinical trials corresponding to diabetes using the clinicaltrials.gov repository. Clinical trial data were recorded from all trials dated from 1990 to 2022 and elicited 655 total trials.

The collected dataset of MM clinical trial information was analyzed to compare the frequency of search terms related to diabetes in the inclusion versus exclusion sections of their eligibility criteria. Clinical trials that did not have separate inclusion and exclusion sections, and those that mentioned the same search term in both sections, were manually curated to determine the correct term assignment. The following terms (and variations of each) were used for the search: type 2 diabetes, prediabetes, insulin resistance, insulin sensitivity, impaired glucose tolerance, diabetes, gestational diabetes, diabetes complications, diabetes mellitus, type 1 diabetes, glucose intolerance, and metabolic syndrome. The inclusion and exclusion frequencies were analyzed to identify correlations between inclusion and exclusion frequencies in MM clinical trials.

Table 1. Inclusion and exclusion frequencies of diabetes-related terms in MM clinical trials.

Search term	Inclusion frequency	Exclusion frequency
Diabetes (and/or diabetes mellitus)	11	384
Glucose intolerance	0	2
Type 1 Diabetes	0	11
Type 2 Diabetes	7	2
TOTAL:	18 (4.3%)	399 (95.7%)

Figure 1. Inclusion and exclusion frequencies of diabetes-related terms in MM clinical trials.

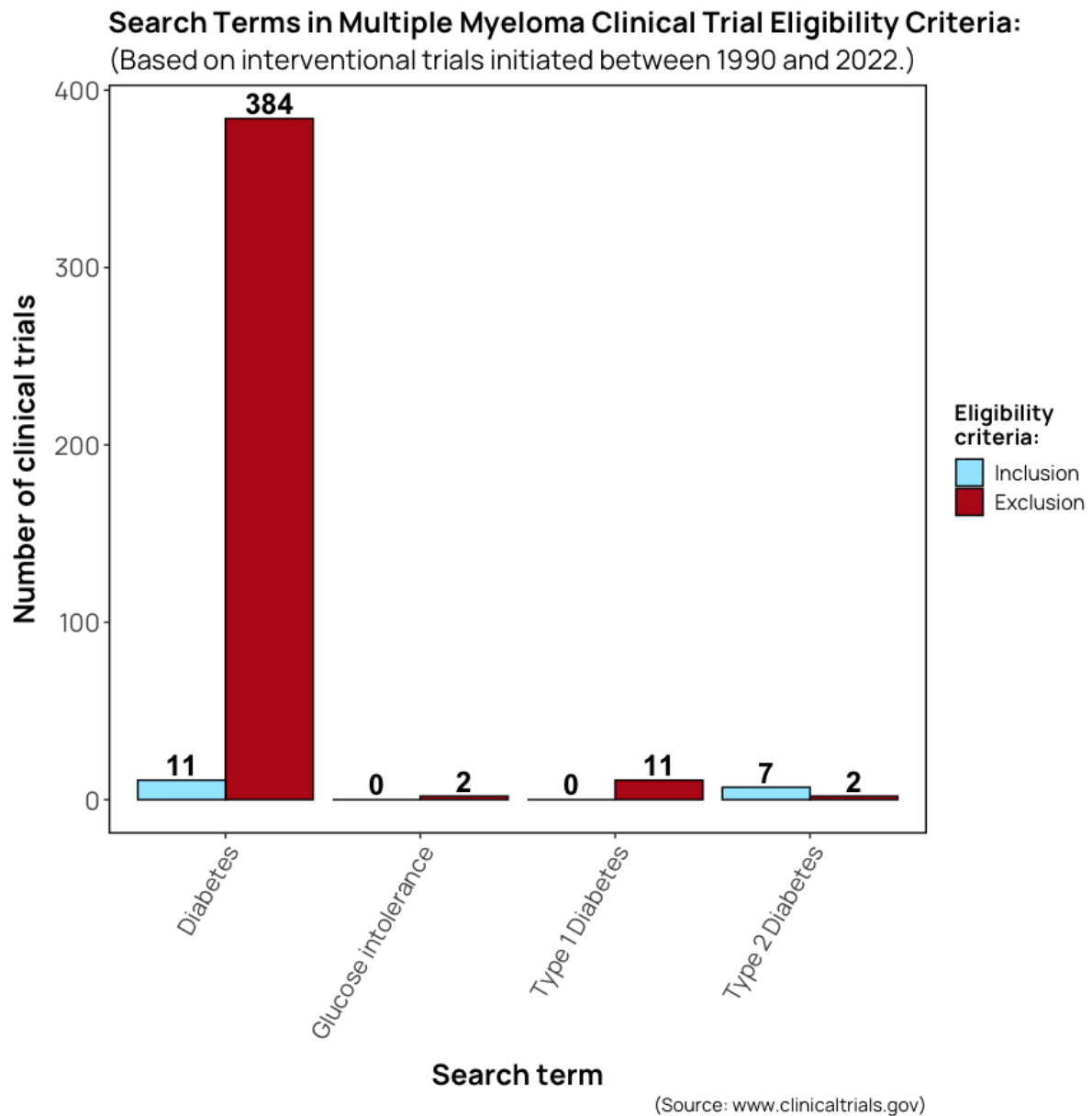


Figure 2. Comparison of inclusion and exclusion frequencies of diabetes-related terms in MM clinical trials.

Results and Discussion

The results of the current study found that those with diabetes were over 22 (22.3) times more likely to be excluded from MM clinical trials than included. In MM clinical trials, diabetes-related terms elicited a 95.7% exclusion rate despite a substantial sample size (417). Over 600 clinical trials identified a correspondence between MM and diabetes, yet the vast majority excluded diabetes-related terms from their respective clinical trials.

Patients with MM have a high prevalence of diabetes-related symptoms or diagnoses yet continue to be disregarded during MM clinical trials. Diabetes, specifically diabetes mellitus (DM), exhibits similar symptoms and pathologies while also serving as a causative factor to MM. Further research should investigate treatments in patients with concurrent MM and DM to determine and optimize treatment efficacy.

Despite the voluminous frequency of diabetes-related terms in MM studies, the importance and efficacy of treatments remain inconclusive due to a lack of inclusive clinical trials. Given the pathophysiological relationship and the corresponding appearance frequency between MM and diabetes in clinical trials, further research should investigate treatment methods in patients with both MM and DM.

References

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