

Respect your Elders: How Often are the Very Elderly Represented in Drug Therapy Trials?



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Background

- The elderly population is among the fastest growing age group in Canada and consumes a large portion of health care services
- Several studies have discussed the underrepresentation of elders in randomized controlled trials (RCTs)
- It is suspected that very elderly individuals (i.e. 80 years of age or older) are underrepresented in RCTs, but there is a paucity of literature demonstrating this

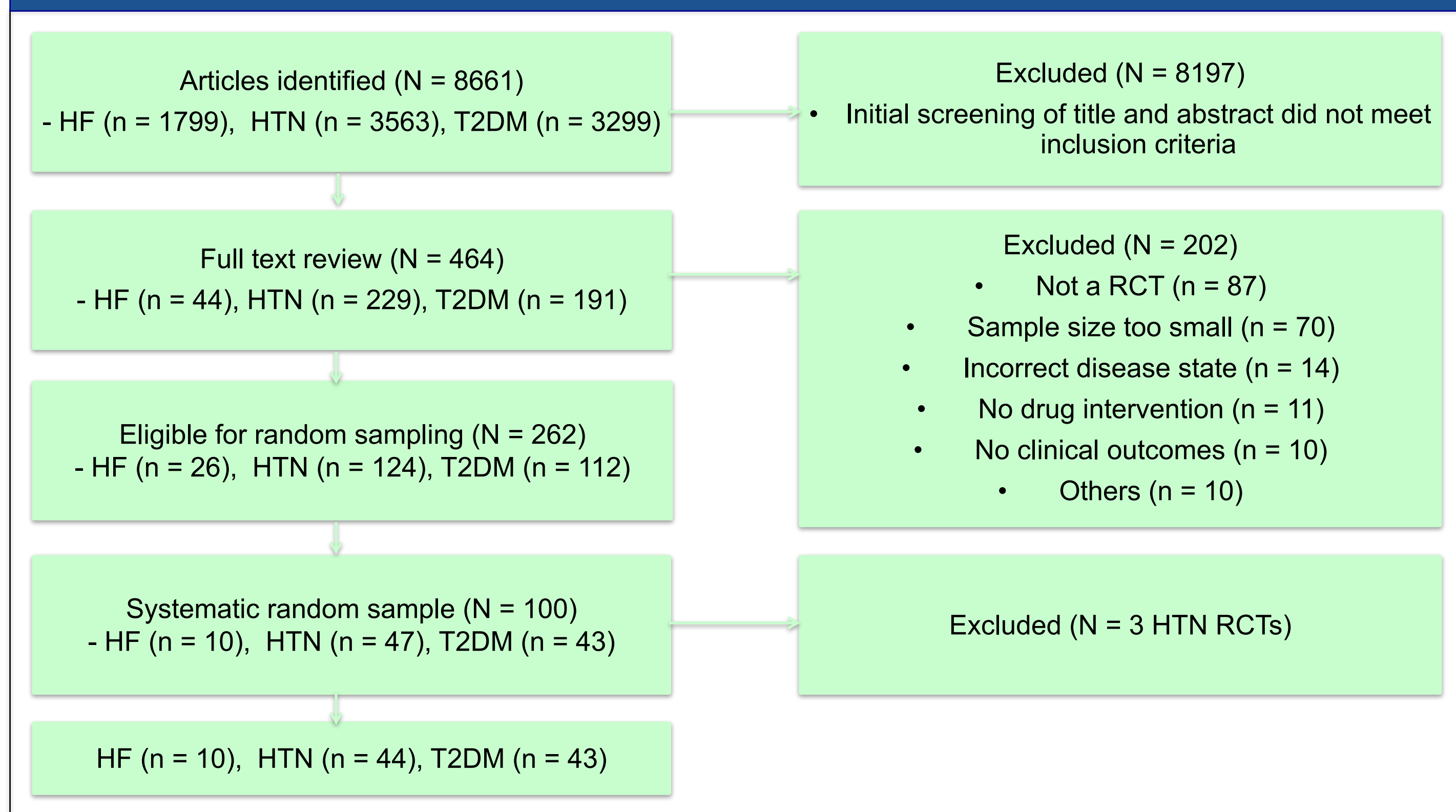
Objectives

- Determine the proportion of RCTs that include patients ≥ 80 years
- Determine the following characteristics:
 - Compare the proportional representation of elders in RCTs from common medical conditions
 - Why elderly patients were not included
 - Size of studies and funding source

Methods

Design	Systematic Review & Descriptive Analysis
Database	PubMed 2006-2016
Inclusion Criteria	<ul style="list-style-type: none"> RCTs with drug therapy as the primary intervention for heart failure (HF), hypertension (HTN) and type 2 diabetes mellitus (T2DM) N ≥ 500 participants English language
Exclusion Criteria	<ul style="list-style-type: none"> Sub-study publications from a larger RCT Extension trials from an original RCT
Sample Size	Systematic random sample, N = 100 RCTs

Figure 1. Trial flow diagram



Results

Table 1. Study characteristics

	HF	HTN	T2DM
Mean Sample Size	3158	1748	1349
Mean Age – yr	66.4	57.6	57.3
Funding – no. (%)			
Public	1 (10.0)	6 (13.6)	1 (2.3)
Industry	8 (80.0)	36 (81.8)	41 (95.3)
Both	1 (10.0)	1 (2.3)	1 (2.3)
Neither	0	1 (2.3)	0

Figure 2. Percentage of trials that reported patients $\geq 65, 75$ and 80 years

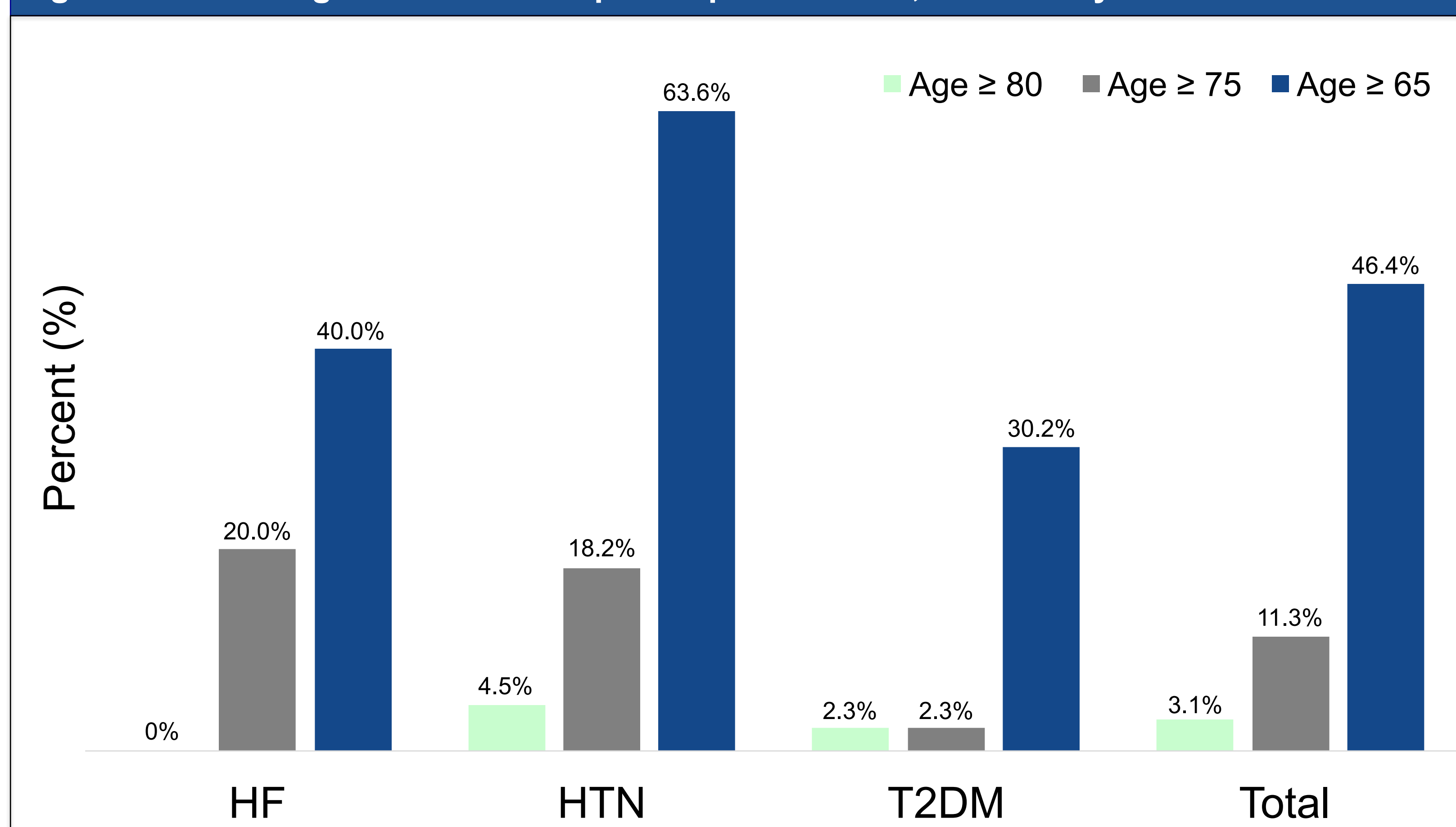


Figure 3. Exclusion criteria in trials that disproportionately affect elders

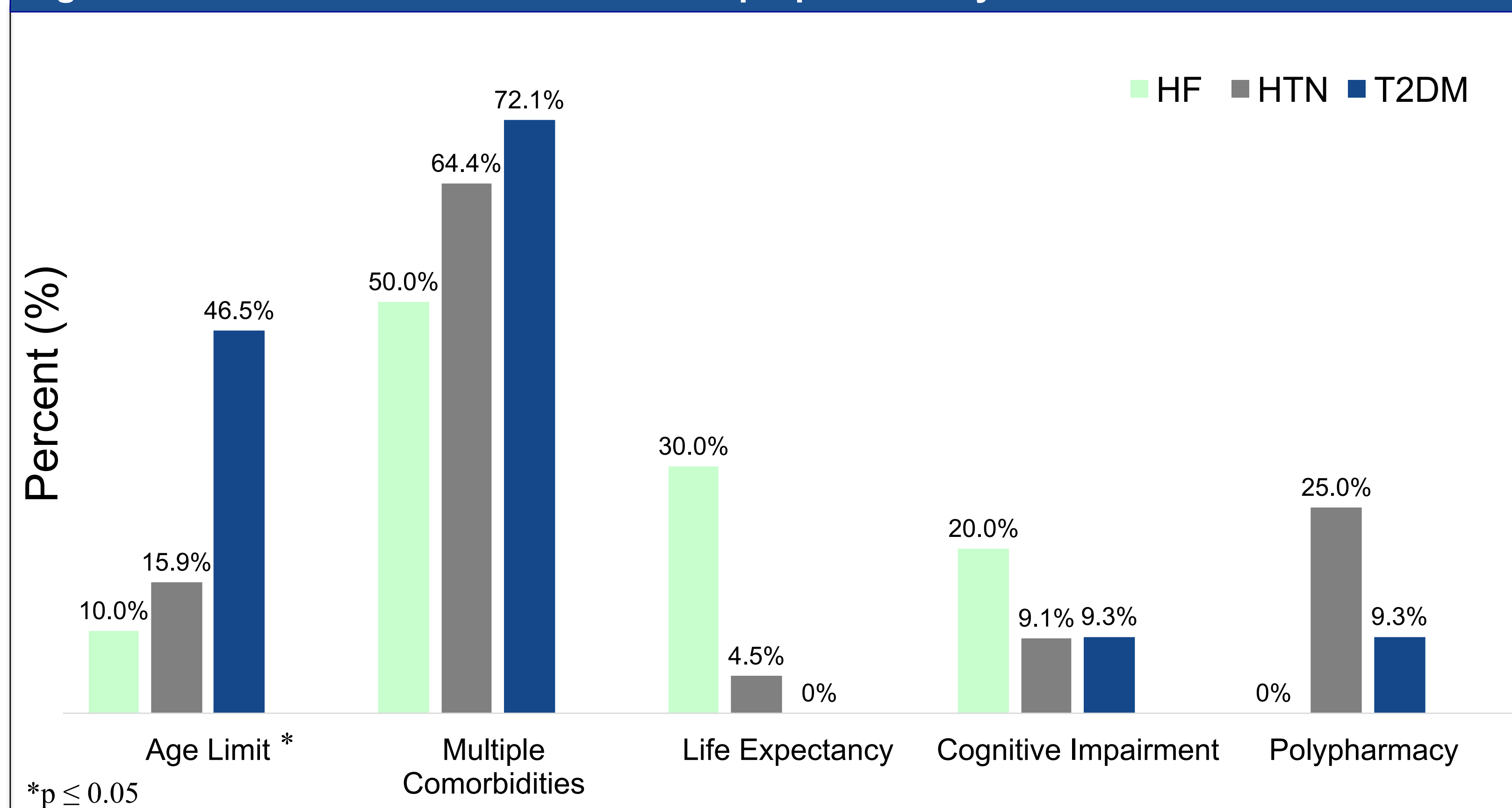


Figure 4. Proportion of trials listing multiple comorbidities as an exclusion criteria

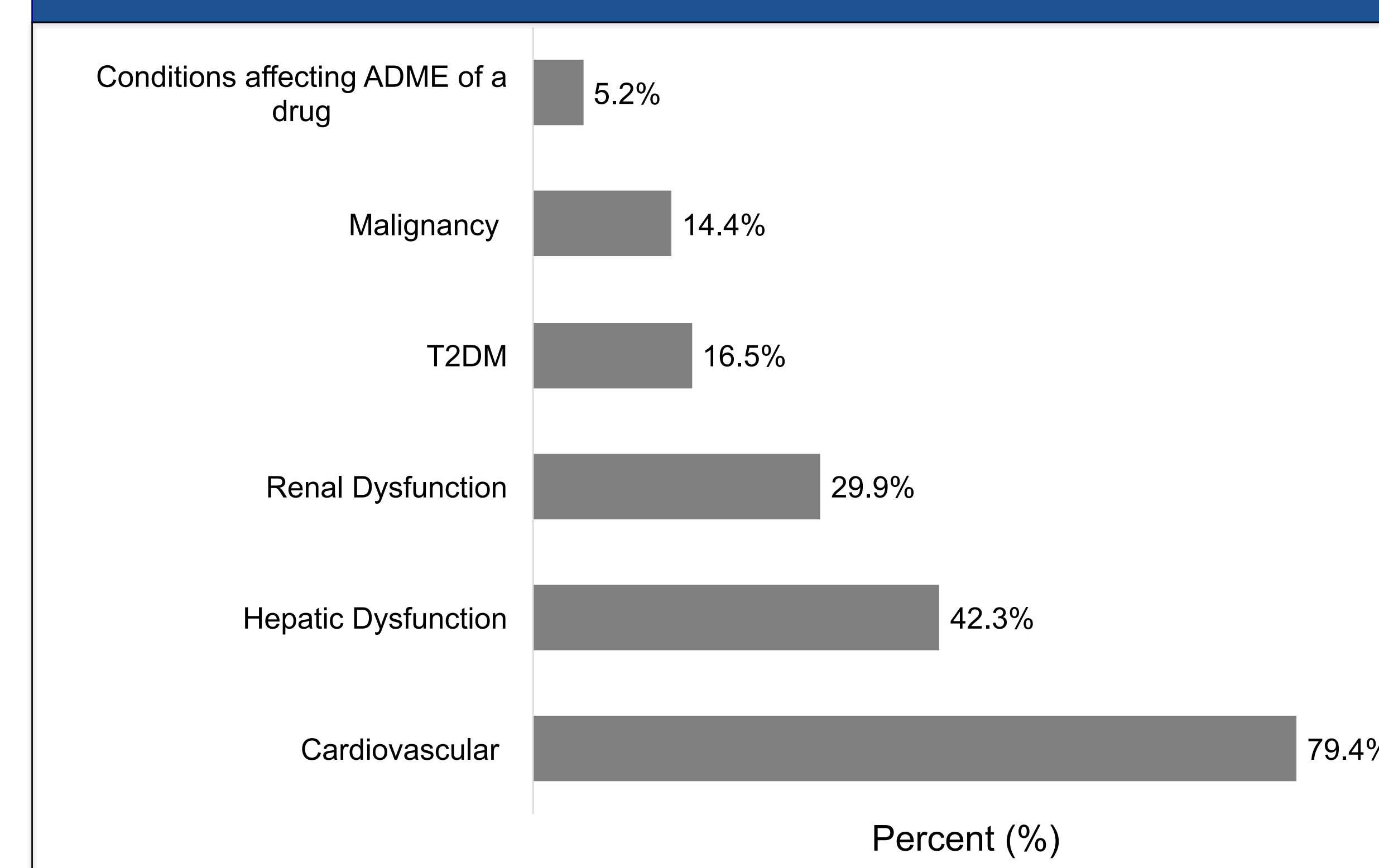


Table 2. Number of trials reporting age specific subgroup analysis

	HF (N = 10)	HTN (N = 44)	T2DM (N = 43)
Age specific subgroup analysis – no. (%)	6 (60.0)	18 (40.9)	12 (27.9)
Statistically significant outcome – no. (%)	2 (20.0)	4 (9.1)	3 (7.0)

* All subgroup analyses included patients ≥ 65 years

Discussion

- HF RCTs had the highest mean patient age
- History of cardiovascular disease was the most common comorbidity that affected the inclusion of elderly patients
- All age-specific subgroup analyses used “age ≥ 65 years” to define elderly patients
- No RCTs reported adverse events based on age specific subgroups
- Two RCTs (1 T2DM and 1 HTN) excluded patients younger than 65 and 80 years of age respectively
- Limitations:
 - Only three medical conditions were studied
 - Data represents a sample of all RCTs
 - Relied on reporting of demographics in full-text manuscript

Conclusion

- Very elderly patients were included in 3% of RCTs
- Multiple comorbidities was the most common exclusion criteria affecting the inclusion of elders
- T2DM RCTs were most likely have an age limit as an exclusion criteria