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Analysis and Characterization of Variations in Conceptual and Operational Definitions for GLP-1 Agonist Treatment Eligibility for Weight Management

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Why is this important?

- Real-world research may include complex clinical concepts to define a cohort indication for treatment (e.g., inclusion/exclusion criteria), outcome measures, or other study elements.
- However, often there is not clear agreement on conceptual definitions, nor operational definitions.

Objective: To demonstrate significant variations in conceptual and operational definitions from reputable sources for people indicated for glucagon-like peptide-1 (GLP-1) agonist treatment for weight management.

How did we perform this research?

- The following stepwise approach was used

Literature Review

- The review conducted included each of the following regarding GLP-1 agonist treatment for weight management
  - Relevant Literature
  - Clinical Guidelines (e.g., EMA, NHS/NICE)
  - Clinical Trials

Qualifying Characteristics

- These were extracted, tabulated, and analyzed to see what similarities and differences there were between different literature. Characteristics included:
  - Age
  - Weight Category

Comorbidities

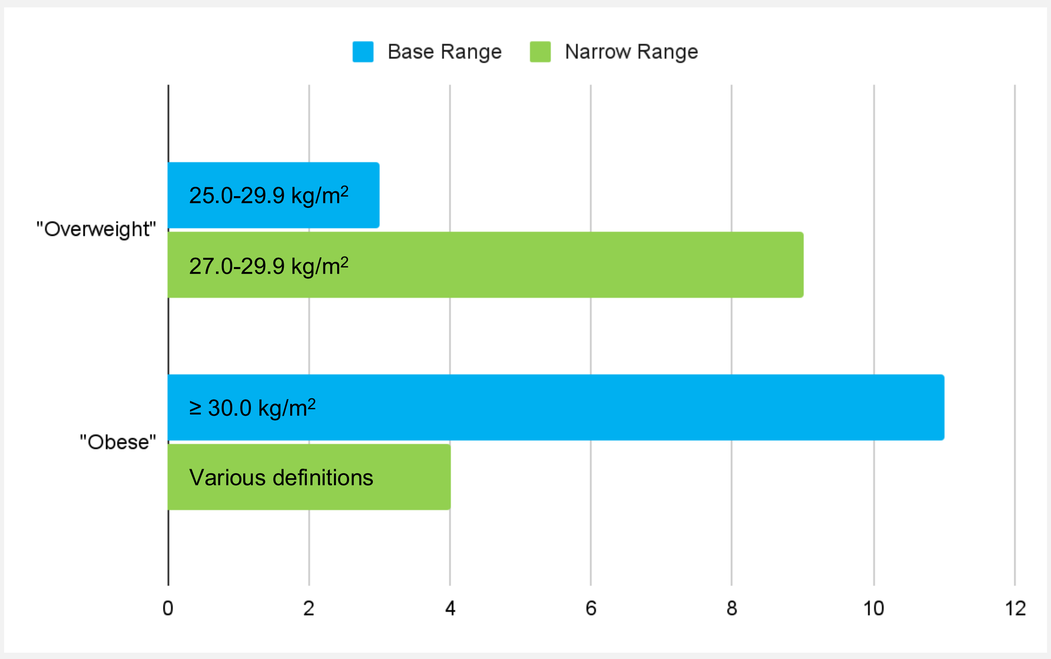
- The comorbidity requirements for each literature was also extracted, tabulated, and analyzed.
- This was done to see how much overlap there was in the comorbidities required for people to be given GLP-1 treatment.

Operational Definitions

- Not all literature had operational definitions, but when available this was also extracted, tabulated, and analyzed.

Weight Categories

Figure 1. Number of sources including the base range vs. a narrow range for "overweight" and "obese" definitions



➢ 12 sources included "overweight" persons:
- 3 as BMI range of 25.0-29.9 kg/m2 [Figure 1]
- 9 narrow the definition of "overweight" to 27.0-29.9 kg/m2 (or regionally-appropriate equivalents) [Figure 1]

➢ 13 sources included "obese" persons:
- 11 as a BMI range of ≥30 kg/m2 [Figure 1]
- 4 narrow the definition of "obesity" to various categories [Figure 1]
  - i.e. 30-34.9 kg/m2, ≥35 kg/m2, 35-39.9 kg/m2, ≥40 kg/m2

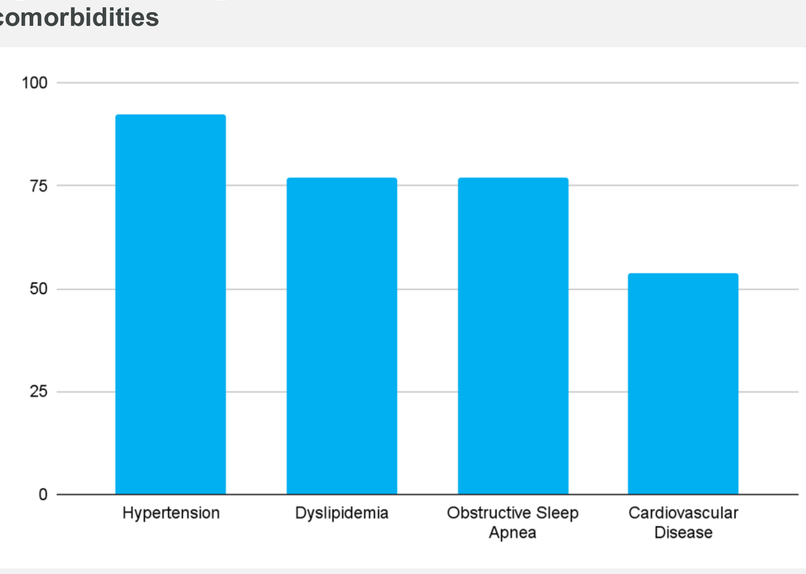
➢ The most common definitions of weight categories were:
- "Overweight" defined with a BMI range of 27.0-29.9 kg/m2 with that being included in 64.3% of the total literature reviewed.
- "Obese" defined with a BMI range of ≥30 kg/m2 with that being included in 78.6% of references.

Comorbidities

➢ 12 sources had an operational definition of also requiring ≥1 qualifying comorbidity and 1 had definitions of ≥3 and ≥4 qualifying comorbidity.

➢ Across those 13 sources, 20 distinct comorbidities were indicated and the most common were:
- Hypertension (included in 92.3%)
- Dyslipidemia (included in 76.9%)
- Obstructive Sleep Apnea (included in 76.9%)
- Cardiovascular Disease (included in 53.8%)

Figure 2. Percentage of sources that included the 4 most common comorbidities



➢ Several comorbidities had multiple different operational definitions.

➢ For example, looking at Dyslipidemia: different operational definitions were found across the reference sources, including the following individually or in combination:
- Diagnosis code(s)
- Lipid-lowering treatment
- High LDL lab value
- Low HDL lab value (adjusted for sex)
- High Triglyceride lab value

Diagnosis of dyslipidemia

≥ 1 Diagnosis Record from Dyslipidemia Diagnoses

during Baseline Period AND any encounter type AND any diagnosis position

Treatment with lipid lowering therapy

≥ 1 Medication Record from Lipid Lowering Therapies

during Baseline Period

Low density lipoprotein (LDL) cholesterol ≥ 160 mg/dL (4.1 mmol/L)

Lab tests for low density lipoprotein (LDL) cholesterol ≥ 160 mg/dL

during Baseline Period AND most proximal documented value to the index date

OR

High density lipoprotein (HDL) cholesterol

Lab tests for high density lipoprotein (HDL) cholesterol < 50 mg/dL

during Baseline Period AND most proximal documented value to the index date

AND

Female

Sex: female

on the index date

OR

High density lipoprotein (HDL) cholesterol

Lab tests for high density lipoprotein (HDL) cholesterol < 40 mg/dL

during Baseline Period AND most proximal documented value to the index date

AND

Male

Sex: male

on the index date

OR

Triglyceride

Lab tests for triglyceride ≥ 150 mg/dL

fasting AND during Baseline Period AND most proximal documented value to the index date

So What?

Understanding these variations in conceptual and operational definitions is essential for real-world research, as *small differences in definition can have a large impact on study results*.