Liraglutide Effectiveness between Various BMIs

BACKGROUND:

- Liraglutide effectively lowers glycated hemoglobin A1C (A1C) levels in adult patients with type 2 diabetes mellitus (T2D).
- To date no study has evaluated the relative clinical effectiveness of liraglutide to achieve glycemic control and weight loss across different baseline body mass index (BMI) levels in the real world clinical practice in the US.

OBJECTIVE:

- To examine liraglutide's effectiveness on A1C, body weight, cholesterol and blood pressure across different BMIs

METHODS:

- **Type of study**: Retrospective cohort
- **Duration**: 6 months
- **Inclusion criteria**:
    - Enrolled in general electric centricity electronic medical record database
    - T2D
        - At least one diagnosis based on ICD-9 (ninth revision)- 250.00, 250.2
        - One or more prescriptions for non-insulin antidiabetic drug
        - Two consecutive fasting blood glucose screening >/=126mg/dL
    - Prescription order for liraglutide
        - One valid A1C measure at their 6 month follow up date
- **Exclusion criteria**:
    - Not continuously enrolled in the general electric centricity database during 12months prior to the index data and during the 6 month follow up
    - Had 1 or more prescriptions for any glucagon-like peptide-1 (GLP-1) receptor agonist during baseline
    - Had 2 or more prescriptions for insulin during baseline
    - Were less than 18 years of age
    - Had type 1 Diabetes- ICD-9 250.1,250.3
    - Polycystic ovarian syndrome (PCOS)- 256.4, without T2D
    - Pregnant or had gestational diabetes
    - Baseline A1C </= 7
    - BMI <25 kg/m^2
- **Number of patients enrolled**: 3,005
- **Drug regimens**: Liraglutide in all groups (no dosing information available)
    - Group 1-BMI 25-29.9
    - Group 2-BMI 30-34.9
    - Group 3-BMI 35-39.9
    - Group 4 BMI >/=40
- **Outcome measures** (efficacy and safety):
    - Absolute changes in A1C, Weight, BP, lipids
    - Relative changes (absolute/baseline): weight, proportion reaching A1C target
    - Hypoglycemia
- **Power:** 40% to 50% for all clinical outcomes except body weight (90%).
    - Was calculated after completion of the study
- **Data handling method**: Per-protocol

RESULTS

- Number of patients who completed study:
    - Total-1649

        - Group 1-BMI 25-29.9-186
        - Group 2-BMI 30-34.9-454
        - Group 3-BMI 35-39.9-440
        - Group 4 BMI >/=40-569
- Absolute changes in A1C, Weight, BP and lipids between groups
    - A1C-there were no significant differences between the any of the groups (p =0.30)
    - Wt – 10.8%, 12.8%, 14.5%, 22.4% decrease in wt in respective groups 1-4differences (p=<0.0)
    - BP (systolic/diastolic) -there were no significant differences between the any of the (p=0.67 & p=0.28)
    - Lipids -there were no significant differences between the any of the
        - p=0.11 for high density lipoprotein,
        - p=0.14 for total cholesterol
- Relative changes (absolute/baseline): weight, proportion reaching A1C target
    - A1c <7 -38%,37%,40%,41% reached it in respective groups 1-4
        - p=0.87,0.54
    - Wt – decrease of 5.8%, 4.4%, 4.4%, 6.1% reached it in respective groups 1-4 (p=<0.0)
- Hypoglycemia
    - Occurred in 0% ,0.7%, 0%, 0.2% of patients respectively by group (1-4)
- Authors stated conclusions
    - Liraglutide was equally effective in reducing A1C across baseline BMI categories suggesting that the drug may be effectively used for adult patients with T2D regardless of their BMI level.

STRENGTHS:

- Large number of subjects in the study

LIMITATIONS:

- Retrospective cohort study design
- No control used
- No knowledge of doses
- No comprehensive comparison of other prescription/over the counter medications the patients were on
- Adherence was not accessed
- Per protocol data handling was used
- Diet/exercise and other life style factors were unknown
- Power was <80% for most outcomes measured

CONCLUSIONS:

- No conclusive determination can be made from the study regarding difference in effectiveness across various BMIs.
- There is no change in current practice that can be implemented based on this study.
- Further research is needed in order to determine exact relationship between effectiveness of liraglutide at various BMIs. Future studies should be prospective, randomized, controlled experimental and double blind.

REFERENCE:

- Chitnis AS, Ganz ML, Benjamin N, Langer J, Hammer M. Clinical effectiveness of liraglutide across body mass index in patients with type 2 diabetes in the United States: a retrospective cohort study. Adv Ther. 2014 Sep;31(9):986-99.

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