THE REAL-LIFE EFFECTIVENESS AND CARE PATTERNS OF DIABETES MANAGEMENT STUDY IN GREECE (RECAP-DM)

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BACKGROUND

Based on guideline recommendations, long term experience and low treatment costs, metformin and sulphonylureas (SUs) are the most frequently prescribed oral antihyperglycemic agents globally. However, hypoglycemia is a clinically important adverse health outcome associated with SU therapy. Hypoglycemia may have a substantial negative clinical effect, in terms of mortality, morbidity, adherence to therapy, and quality of life [1,2,4,5]. Hypoglycemia is highly prevalent in treated T2DM patients – in the RECAP-DM Asia Pacific (AP) and RECAP DM European Union (EU) studies, symptoms of hypoglycemia were reported by ~36% of treated patients in the AP region and ~38% of treated patients in the EU region [6,7]. The RECAP studies were some of the first large scale observational studies to report the prevalence of hypoglycemia in a real world setting. For Greece, data regarding the real world prevalence of hypoglycemia in SU treated is limited.

OBJECTIVES

Primary Objective
- To assess the prevalence of hypoglycemia (self-reported or documented in the patient medical chart) in SU (as monotherapy or in combination with metformin) treated type 2 DM patients in Greece.

Secondary Objectives
- To assess the proportion of type 2 DM patients in Greece treated with SUs (as monotherapy or in combination with metformin) who are not at the HbA1c goal of <7%.
- To assess the extent to which more hyperglycemia frequency and severity is associated with lower treatment adherence, lower treatment satisfaction, lower quality of life and more worry/fear of hypoglycemia.

METHODS

- RECAP was a multi-center, non interventional, cross-sectional study conducted in Greece.
- Eligible patients were type 2 DM patients treated with SUs as monotherapy or in combination with metformin.
- The study required a retrospective clinical chart review of records and a HbA1c measurement available at the date of enrolment.
- Eligible patients completed a series of patient questionnaires including:
  - patient reported hypoglycemia experience,
  - adherence (Adherence and Barriers Questionnaire),
  - quality of life (EQ-5D-3L),
  - treatment satisfaction (TSQM),
  - fear of hypoglycemia (HFS-II Worry scale).
- Study patients were enrolled in 2015.

RESULTS

IMPACT OF THE PRESENCE AND SEVERITY OF HYPOGLYCEMIA ON GLYCEMIC CONTROL

Severity of hypoglycemia was associated negatively to glycemic control.

PATIENTS' TREATMENT SATISFACTION ADJUSTED TO HYPOGLYCEMIA STATUS

Patients without hypoglycemia present significantly higher scores in all TSQM domains.

PATIENTS NOT AT HbA1c GOAL

58.0% of the patients were not controlled (%), while 2.2% were in the 6.5%-7.0% window.

EFFECTS OF EXPERIENCING HYPOGLYCEMIA ON HRQoL

Patients with hypoglycemia suffer from significant anxiety and discomfort problems.

EFFECTS OF EXPERIENCING HYPOGLYCEMIA ON ADHERENCE

Patients with hypoglycemia are more likely to report barriers to adherence including being unsure about instructions.

EFFECTS OF EXPERIENCING HYPOGLYCEMIA PRESENCE AND SEVERITY ON PATIENT REPORTED OUTCOMES

The impact of hypoglycemia presence and severity on patient reported outcomes using a multivariate analysis model are shown in table 4.

CONCLUSIONS

The prevalence of hypoglycemia among patients receiving either monotherapy of SU or in combination with metformin is high.
- A large proportion of patients experience moderate or severe symptoms of hypoglycemia.
- Presence of hypoglycemia and severity are associated with poor results in TSQM, quality of life, fear of hypoglycemia and nearly all dimensions of adherence.
- Overall, given the study findings regarding the association of hypoglycemia and control of HbA1c in a number of variables, decreasing the incidence and severity of hypoglycemia may help improve patient reported outcomes and adherence, which in turn might result in better glycemc control and overall health outcomes.

ACKNOWLEDGMENTS


REFERENCES