A Higher Percentage of Elderly on Dulaglutide Achieved HbA1c <7.5% Without Nocturnal Hypoglycemia vs. Glargine in AWARD-2

Luis-Emilio García-Pérez, Maria Yu, Pamela W. Anderson, Vivian T. Thieu
Eli Lilly and Company, Indianapolis, USA

OBJECTIVE

To assess the effect of dulaglutide versus insulin glargine on elderly patients (aged ≥65 years) with type 2 diabetes in achieving a composite endpoint of HbA1c goal without hypoglycemia at 52 weeks

STUDY DESIGN

- Post hoc analysis of elderly and nonelderly subgroups based on age (≥65, <65 years) who participated in the AWARD-2 trial, the study design of which has been previously published¹ and is illustrated below

- The following composite endpoints were calculated at Week 52:
 - HbA1c <7.5% (58 mmol/mol)
 - without documented symptomatic hypoglycemia^{1,a}
 - without nocturnal hypoglycemia^b
 - HbA1c <8.0% (64 mmol/mol)
 - without documented symptomatic hypoglycemia^{1,a}
 - without nocturnal hypoglycemia^b
- An HbA1c goal of <7.5% (58 mmol/mol) or <8.0% (64 mmol/mol) and a hypoglycemia definition of ≤70 mg/dL (3.9 mmol/L) were chosen as targets appropriate for the elderly population²
- Analyses were carried out using counts, percentages, and logistic regression with pooled country, baseline HbA1c strata, treatment, age subgroup, and subgroup by treatment interaction

^a Any time a patient feels that he or she is experiencing symptoms and/or signs associated with hypoglycemia, and has a plasma glucose level of ≤70 mg/dL (3.9 mmol/L).
^b Any hypoglycemic event that occurred between bedtime and waking.

KEY RESULT

CONCLUSION

In this post hoc analysis of AWARD-2 (head-to-head study of dulaglutide versus insulin glargine), for elderly patients:

- There was no significant difference between the groups in achieving target HbA1c (<7.5% or <8.0% [58 mmol/mol or 64 mmol/mol]) without documented symptomatic hypoglycemia
- However, significantly more patients on dulaglutide 1.5 mg than on insulin glargine achieved target HbA1c without nocturnal hypoglycemia

BASELINE CHARACTERISTICS

Characteristic	Elderly Patients N=161
Male, n (%)	90 (56)
Age, mean (SD) years	69.3 (3.7)
Weight, mean (SD) kg	83.6 (15.4)
Diabetes duration, mean (SD) years	13.3 (7.6)
HbA1c	
%, mean (SD)	8.1 (1.0)
mmol/mol, mean	65

ADDITIONAL RESULTS

Higher % of Dulaglutide-Treated Elderly Patients Achieved HbA1c <8.0% Without Nocturnal Hypoglycemia at Week 52

OR=odds ratio (95% confidence interval) dulaglutide vs. insulin glargine.
* p≤.05

% Elderly Patients Who Achieved Individual Components of the Composite Endpoints at Week 52

Treatment Group	N	HbA1c		Hypoglycemia		
		<7.5% (58 mmol/mol)	<8.0% (64 mmol/mol)	N	Documented Symptomatic	Nocturnal
Dulaglutide 1.5 mg	50	78%	90%	54	33%	19%
Dulaglutide 0.75 mg	51	65%	77%	51	37%	20%
Insulin glargine	54	56%	72%	56	36%	34%

- No elderly patient in any treatment group reported severe hypoglycemia^a

^a An episode requiring the assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions.

Limitations

This was a post hoc analysis with a limited sample size for the elderly subgroup (elderly in the AWARD-2 study, n=161; total AWARD-2 study population, n=807)

Acknowledgements

The authors would like to thank Cindy C. Taylor at Synchrogenix, a Certara company, for medical writing support.

References

- Giorgino F et al. *Diabetes Care*. 2015;38(12):2241–2249.
- American Diabetes Association. 11.Older Adults. *Diabetes Care*. 2017;40(Suppl. 1):S99–S104.