

Impaired awareness of hypoglycaemia and severe hypoglycaemia in drivers with diabetes: Insights from the Association of British Clinical Diabetologist (ABCD) nationwide audit

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Short title: Type 1 diabetes and driving

Hypoglycaemia is an acute complication in people living with diabetes with 83% of those with Type 1 Diabetes (T1D) experiencing hypoglycaemia in a month and even greater rates of 5 events per week recorded on continuous glucose monitoring[1]. There are limited population-based data on the prevalence of impaired awareness of hypoglycaemia (IAH) and severe hypoglycaemia (SH) in drivers with diabetes in the United Kingdom (UK) and worldwide. Availability of these data can inform policy decisions and help optimize treatment options in people living with diabetes [2]

To understand the prevalence of IAH and SH in drivers with diabetes we obtained data from the nationwide audit of FSL conducted by ABCD. Baseline pre-FSL data included demographics, HbA1c values from the previous 12 months, Gold score[3] (to assess hypoglycaemia awareness), and SH. Rates of recurrent SH, defined as two or more episodes of hypoglycaemia requiring third-party assistance in the 12 months prior to FSL initiation [4], were documented by clinicians.

The study consisted of 13127 adults (age ≥ 17) with diabetes, and information about driving was available for 4262 (96% T1D) of those (3210 drivers and 1052 non-drivers;). Of the those with a driving licence 3182 had a Group 1 driving licence and 25 had Group 2 driving licence and 3 had a taxi licence. Information about the Gold score was available for 2849 people with either a Group1 or Group 2 driving licence. Overall, the prevalence of IAH was 21.8 % (622/2849) and the prevalence of complete loss of awareness of hypoglycaemia defined in this cohort as Gold =7 was 1.4% (41/2849). In those with a group 1 licence 22% (n=622/2823) had IAH (Gold ≥ 4); 1.4% (41/2823) had a Gold score of 7 and 5% (147/2823) had experienced more than 1 episode of severe hypoglycaemia in the preceding 12 months. None of the participants with group 2 driving licence and taxi licence had

complete loss of hypoglycaemia awareness. One participant reported a single episode of severe hypoglycaemia; none experienced more than one episode of severe hypoglycaemia in the preceding year. Of the group 2 drivers, only 73% reported full awareness of hypoglycaemia (defined as a Gold score of 1).

Drivers living with diabetes were slightly older, (44.4(±15.2) vs 41.3(±18.3) $P<0.00001$), more likely to be male (54% vs 44% $P <0.0001$) with a shorter duration of diabetes (21.7(±37.9) vs 26.8(±36) $P<0.0001$) as compared to non-drivers. Drivers had a lower baseline HbA1c (70.6(±19.4) vs 75.06(±19.14) $P<0.0001$), lower Gold score (2.35 (±1.5) vs 3.30 (±1.96) $P<0.0001$) compared to non-drivers. In this population, the number of episodes of severe hypoglycaemia in the previous 12 months in non-drivers was 19% (n=206) while in Group 1 driving license holders it was 8% (n=287) and 1 in those with a Group 2 driving licence was 3% (n=1).

In the univariate analysis (**Table 1**) those with IAH were more likely to be older ($P<0.0001$), have a longer duration of diabetes ($P=-.00003$), lower baseline HbA1c ($P=0.04$) and more likely to have 'frequent hypoglycaemia' as an indication for FSL initiation ($P<0.0001$). The regression analysis shows that higher age (Beta=0.001 P -value=0.02), longer duration of diabetes (Beta=0.001, P -value=0.001 and 'frequent hypoglycaemia' as an indication for FSL initiation (beta=0.15, P -value<0.0001) were significantly and independently associated with GOLD score in drivers.

In this study, 147 people with diabetes and a Group 1 driving licence and one with a Group 2 licence failed to meet the DVLA driving safety standards for insulin-treated people with diabetes. Overall, 41 people who were Group 1 drivers with diabetes were reported as having either complete loss of hypoglycaemia awareness (defined as a Gold score of 7) and 147 had

experienced ≥ 1 SH in the previous 12 months. Of the group 2 drivers, only 73% had full awareness of hypoglycaemia (defined as a Gold score of 1) and one participant had a reported SH in the preceding 12 months.

These data suggest that the prevalence of impaired awareness of hypoglycaemia is common in drivers with diabetes, but lower than in non-drivers. Complete loss of hypoglycaemia awareness was rare. In keeping with previous data[5], impaired awareness of hypoglycaemia was associated with increasing age, longer duration of diabetes and frequent episodes of hypoglycaemia . Less than one-tenth of drivers had experienced SH in the year prior to FSL initiation. Overall, these data provide useful insights into the prevalence of problematic hypoglycaemia in people with diabetes who hold a driving licence.

Table 1: Demographic and clinical characteristics of people with diabetes with and without impaired awareness of hypoglycaemia (IAH)

	Impaired awareness of hypoglycaemia (GOLD \geq 4) (n=622)	Normal awareness of hypoglycaemia (GOLD <4) (n=2227)	P-value*
Age (years)	49.2(\pm 15.5)	43.2(\pm 15.0)	<0.0001
Gender (% Females)	287 (46%)	991 (44%)	0.85
Baseline BMI	26.7 (\pm 6.1)	26.9(\pm 5.6)	0.50
Duration of Diabetes	24.9 (\pm 15.3)	20.9(44.4)	0.0003
Insulin Pump (%)	110 (17%)	394 (17%)	0.45
Mean Pre-FSL HbA1c	69.4(\pm 20.1) (8.5%)	71.2(\pm 19.7) (8.7%)	0.04
Frequent hypoglycaemia as indication for FSL initiation	231 (37%)	391(17%)	<0.0001

- P-value from t-test or chis-sq test

References

1. Khunti K, Alsifri S, Aronson R, Cigrovski Berkovic M, Enters-Weijnen C, Forsen T, Galstyan G, Geelhoed-Duijvestijn P, Goldfracht M, Gydesen H *et al*: **Rates and predictors of hypoglycaemia in 27 585 people from 24 countries with insulin-treated type 1 and type 2 diabetes: the global HAT study.** *Diabetes Obes Metab* 2016, **18**(9):907-915.
2. Stork AD, van Haeften TW, Veneman TF: **Diabetes and driving: Desired data, research methods and their pitfalls, current knowledge, and future research.** *Diabetes Care* 2006, **29**(8):1942-1949.
3. Gold AE, MacLeod KM, Frier BM: **Frequency of severe hypoglycemia in patients with type I diabetes with impaired awareness of hypoglycemia.** *Diabetes Care* 1994, **17**(7):697-703.
4. International Hypoglycaemia Study G: **Glucose Concentrations of Less Than 3.0 mmol/L (54 mg/dL) Should Be Reported in Clinical Trials: A Joint Position Statement of the American Diabetes Association and the European Association for the Study of Diabetes.** *Diabetes Care* 2017, **40**(1):155-157.
5. Group UKHS: **Risk of hypoglycaemia in types 1 and 2 diabetes: effects of treatment modalities and their duration.** *Diabetologia* 2007, **50**(6):1140-1147.