Assessing the relationship between the effect of glycemic control and avoided symptomatic hypoglycemia on quality of life in the management of type 2 diabetes

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Introduction

Achieving optimal blood glucose control while avoiding hypoglycaemia forms the foundation of diabetes management and the avoidance of macro and microvascular complications is a major driver in cost effectiveness analysis. These impact future costs and disutility although the compound effect of discounting attenuates this impact. Hypoglycaemia represents a barrier to tight glycaemic control and also impacts directly on costs and health utility; furthermore, the hypoglycaemia profile of an intervention is potentially subject to less compound discounting if evaluated as an initial therapy.

Aims

The objective of this study was to undertake a equilibrium analysis to identify the level of HbA1c reduction required to achieve the same quality of life benefit as achieved by avoiding events of non-severe symptomatic hypoglycemia (NSHE)

Methods

•This study used the IMS Core Diabetes Model (CDM), a validated and established diabetes model, to explore the relationship between the avoidance of NSHE, HbA1c reduction and quality-adjusted life expectancy (QALE) (1).

•Scenario analysis (SA) comparing typical therapeutic profile compared Treatment A versus Treatment B assuming
1) differential rates of NSHE ranging from 25 to 250 events per 100 patient years and no HbA1c effect and
2) an increasing difference in HbA1c ranging between 0.1% and 1% points (0.1% increments) with no effect on NSHE.

•The model was run over a lifetime and benefits were discounted at 3.0%. Patient baseline characteristics were based on NHANES population with a mean baseline A1c of 7.4%.

•Incremental QALE was observed using alternative assumptions for the disutility of symptomatic hypoglycemia based on published data (base case: -0.0052; SA: -0.0029, -0.0107, -0.0184) (2, 3).

Results

•The impact of HbA1c reduction on QALE gain ranged from 0.0112 to 0.1171 for changes between 0.1% and 1.0% points, respectively (exhibiting a linear relationship; R2=0.9918) (**Figure 1**).

•The relationship between rates of NSHE and incremental QALE was also linear (R2>0.9999).The QALE gain associated with avoiding 1 NSHE per patient per year was 0.06; incremental QALE per event avoided changed in scenario analyses to 0.035, 0.124 and 0.212 quality adjusted life years for assumed disutilities of -0.0029, -0.0107 and -0.0184, respectively (**Figure 2**).

[1] Intercepts of all equations were assumed to be zero in all cases as never bigger than 0.005

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Figure 1: QALE gain per 0.1% point reduction in HbA1c

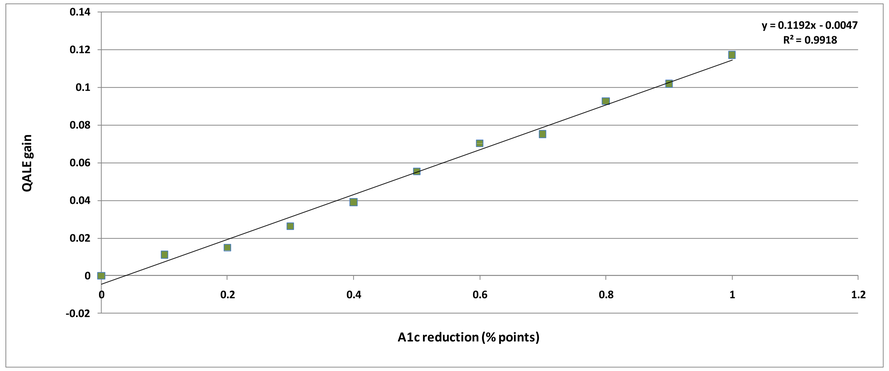


Figure 2: Relationship between NSHE events avoided per year and overall QALE gain over life time for four different NSHE disutility assumptions (-0.0052 (BC), -0.003 (SA1), -0.01067 (SA2), -0.01835 (SA3))

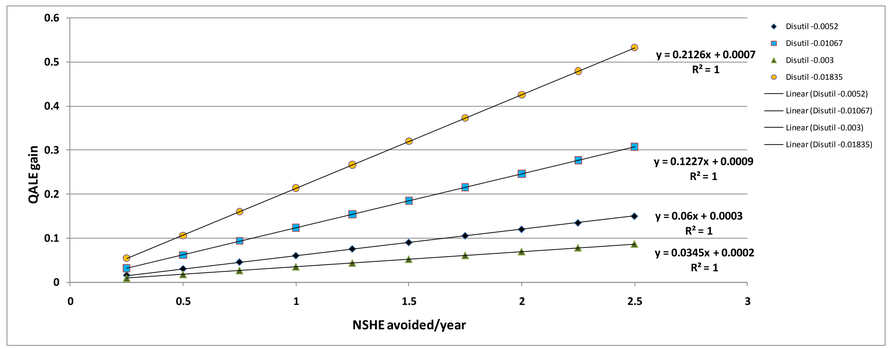
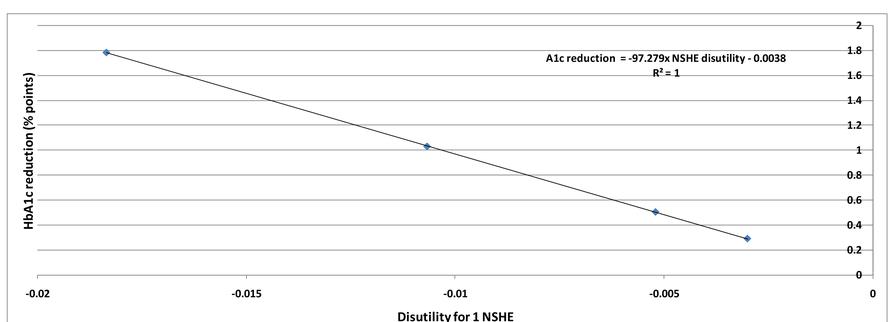


Figure 3: HbA1c reduction required to achieve equal lifetime QALE benefit vs. 1 NSHE/year avoided



Results continued

•The level of HbA1c reduction required to achieve the same quality of life benefit as achieved by avoiding 1 NSHE/year could be obtained graphically or numerically by comparing the coefficients of linear regression equations to express the relationship between lifetime QALE benefit and NSHE avoided (A) and -HbA1c reductions (B).[1] I.e. HbA1c equivalent = *coeff_A / coeff_B*. HbA1c reduction equivalents for one NSHE avoided per patient per year were found at 0.54%, 0.33%, 1.08% and 1.84% for NSHE disutilities of -0.0052 (BC) -0.0029 (SA1), -0.0107 (SA2) and -0.0184 (SA3), respectively. (**Table 1**).

•The relationship between HbA1c equivalents for 1 NSHE avoided and reported disutilities was also found to be linear as presented in **Figure 3**.

Table 1: HbA1c reduction equivalents for one NSHE avoided per patient per year

	NSHE disutility	Lifetime QALE gain per NSHE avoided	Linear Coefficients NSHE equations (A)	Linear coefficient A1c equation (B)	A1c reduction equivalent to 1 NSHE avoided
BC	-0.0052	0.060%	0.06	0.1192	0.54%
SA 1	-0.003	0.035%	0.0345	0.1192	0.33%
SA 2	-0.01067	0.124%	0.1227	0.1192	1.08%
SA 3	-0.01835	0.214%	0.2126	0.1192	1.84%

Conclusion

•HbA1c change and reduced NSHE are key drivers when diabetes interventions are compared in cost effectiveness analyses.

•This analysis is noteworthy as it demonstrates the significant contribution to QALE exhibited by the avoidance of NSHE; particularly in comparison with levels of HbA1c change typically associated current anti-hyperglycaemic agents. The avoidance of NSHE is at least as powerful a driver of QALE as lowering HbA1c.

•Disutility assumptions as applied in cost effectiveness analysis for NSHE should be conservatively selected, well documented and related parameter uncertainty should be accurately explored in one way sensitivity analyses.

References

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