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Glycaemic outcomes in Australasian children and adults with Type 1 Diabetes: failure to meet targets across the age spectrum

Short title:

Glycaemic outcomes in Type 1 diabetes

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DJH, MBA and TJ wrote the manuscript with data extraction and analysis done by MC.

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Abstract

Background*:* The goal of therapy in Type 1 diabetes (T1D) is to achieve optimal glycaemic targets and reduce complications. Robust data representing glycaemic outcomes across the lifespan are lacking in Australasia.

Aims: To examine contemporary glycaemic outcomes and rate of use of diabetes technologies in Australasian people with T1D.

Methods: Cross-sectional analysis of de-identified data from 18 diabetes centres maintained in the Australasian Diabetes Data Network (ADDN) registry during 2019. Glycaemia was measured using glycated haemoglobin (HbA1c). The proportion of people with T1D achieving the international HbA1c target of < 53 mmol/mol (7%) was calculated. Rates of continuous subcutaneous insulin infusion (CSII) and continuous glucose monitoring (CGM) use were determined.

Results: 7,988 individuals with T1D with 30,575 visits were recorded in the registry. The median (IQR) age was 15.3 (10.0) years and diabetes duration was 5.7 (9.4) years with 49% on multiple daily injections (MDI) and 36% on CSII. The mean HbA1c for the whole cohort was 66 mmol/mol (8.2%). HbA1c increased with age; from 60 mmol/mol (7.6%) in children <10 years, increasing during adolescence and peaking at 73 mmol/mol (8.8%) in the 20-25 years age group. HbA1c target of < 53 mmol/mol (7%) was met in 18% of children and 13% of adults. HbA1c was lower on CSII as compared to those on MDI ($p<0.0001$).

Conclusions: Only a minority of children and adults achieve the recommended glycaemic goals despite access to specialist care in major diabetes centres. There is a need to identify factors which improve glycaemic outcomes.

Key words

Type 1 diabetes, ADDN, Glycaemic outcomes, glycated haemoglobin

Introduction

It is now over a quarter of a century since the Diabetes Control and Complications trial (DCCT) recommended intensive insulin therapy in the management of Type 1 diabetes (T1D). The DCCT and the follow-up Epidemiology of Diabetes Interventions and Complications (EDIC) study have conclusively shown that prevention of diabetes

macrovascular and microvascular complications is best achieved by maintaining glucose levels as close to normal as possible (1, 2). As a result, it is recommended that children and adults should aim to achieve HbA1c target < 53 mmol/mol (7.0%) (3, 4). Whether these targets are being met has not been broadly assessed in Australia and outcomes for people with T1D are not known outside of single centre reports. This is key information to allow an assessment as to whether current models of care are delivering optimal results and reducing the individual and societal burden of T1D.

The Australasian Diabetes Data Network (ADDN) was established as a national T1D registry with the primary goal to improve clinical outcomes and to benchmark care across Australia (5). The concept of an Australasian registry was initiated and funded by Juvenile Diabetes Research Foundation (JDRF) through the T1D Clinical Research Network, in collaboration with the Australasian Paediatric Endocrine Group and the Australian Diabetes Society. In the first phase, from 2012-2015, a number of paediatric sites across Australia and New Zealand began contributing to a central custom-built database hosted at the University of Melbourne to capture de-identified and coded longitudinal clinical data from people with T1D. In the second phase, from 2016-2019, with continued funding from JDRF and the Australian Research Council, seven adult centres across Australia have contributed data. At the end of 2019, there were eleven paediatric and seven adult sites which contributed data to the ADDN registry providing a representative sample of individuals with T1D managed in tertiary centres.

National and international population-based diabetes registries collate data on glycaemic outcomes and diabetes management, and this provides an opportunity to review differences in diabetes care over time in real-world samples. International T1D registries such as the T1D Exchange Registry in the United States have shown low rates of achievement of American Diabetes Association (ADA) glycaemic targets of HbA1c < 58 mmol/mol (7.5%) in youth

(17%) and < 53 mmol/mol (7.0%) in adults (21%) (6). In Australasia, we now have the opportunity to review the glycaemic outcomes for both children and adults with T1D. In 2015, the first national audit by ADDN of children and adolescents with T1D from five paediatric diabetes centres showed that 27% of children achieved an HbA1c <58 mmol/mol (7.5%) which was the recommended target at the time (7). The expansion of ADDN in 2016 to include adult sites through collaboration with the Australian Diabetes Society provided an opportunity to review the glycaemic outcomes across the age spectrum, for both children and adults. In this article, we present the first snapshot of glycaemic levels in a cross-section of both children and adults with T1D using contemporary management in Australasia. This is the largest survey of glycaemic outcomes in people with T1D in Australia and New Zealand to date.

Methods

Ethics approval was obtained through different pathways for each of the participating centres in each of the states and territories. Ethics approval was granted for sites by the Hunter New England Human Research Ethics Committee, Children's Health Services Queensland, Women's and Children's Health Network, Royal Children's Hospital, Monash Children's Hospital, Perth Children's Hospital, Starship Children's Hospital, University of Otago, Melbourne Health, South Metropolitan Health Service WA. Informed consent was obtained from parents and from adults over 17.9 years old, and, when required by the HREC, assent was obtained from children aged 10–18 years.

ADDN has a centralised and standardised data collection for people with T1D. It involves 6-monthly transfer of prospectively collected, de-identified data from clinical databases or electronic medical record systems from participating centres to a central custom-built database (5). Data were cleaned to identify incorrect and missing values for site verification before being stored in the registry. We analysed data from 11 paediatric and 7 adult

Australian and New Zealand diabetes centres from the ADDN registry for all individuals with T1D who had at least one visit between 1st January 2019 and 31st December 2019. Data collected included centre, age, duration of diabetes, visit frequency, therapy modality and glycaemic outcome as measured by HbA1c (using either point-of care or laboratory testing methods that complied with national accreditation programme). Therapy modality was grouped as twice daily insulin (BD), multiple daily insulin injections (MDI) with 3 or more injections per day or continuous subcutaneous insulin infusion (CSII). Where an individual changed therapy modality over the 12 months, the last recorded therapy was used for analyses. Each individual's HbA1c was represented as the average of HbA1c collected over 12 months prior to the last visit in 2019. HbA1c values within the first 3 months post-diagnosis were excluded. The glycaemic target was defined as < 53 mmol/mol (7.0%) according to the revised ISPAD 2018 guidelines for children (4) and the ADA guideline for adults, 2018(3).

Statistical method: Results were tabulated by 5-year age groups with descriptive statistics, mean and standard deviation and proportions. Comparison of means was by Kruskal-Wallis test, followed by pairwise Mann-Whitney test for between groups analysis.

Results

At the end of 2019, there were 7,988 people with T1D with current data in ADDN from 18 centres of which 11 were paediatric centres with 5,522 (69%) participants, and 7 were adult centres with 2,466 (31%) participants. The origin of participants was Victoria (28%), Western Australia (18%), South Australia (15%), New South Wales (15%), Queensland (14%) and New Zealand (11%, all of NZ sites were paediatric), with no data from Tasmania or the Australian territories. All centres were located in urban or regional hospitals with specialist diabetes services that in some cases included regional outreach services. The

clinical characteristics are summarised in Table 1. The age of participants ranged from 1 to 89 years of age with an equal proportion of males and females. The (mean ±SD) age of the cohort was 19.1±13.7 years and diabetes duration of 8.8±9.9 years, with 45% having duration of diabetes <5 years, 25% 5-10 years and 30% > 10 years duration. Across all age groups, MDI therapy was used the most frequently (49%) followed by CSII (36%) and BD insulin (12%). Continuous glucose monitoring (CGM) systems were used by 40% of this cohort, with 16% and 51% of adults and children using CGM respectively.

The (mean±SD) HbA1c for the whole cohort was 66±17 mmol/mol or 8.2±1.6% (Median 64 [55, 75] mmol/mol or 8.0 [7.2, 9.0] %). The (mean±SD) HbA1c for males and females was 66±16 mmol/mol (8.2±1.5%) and 67±18 mmol/mol (8.3±1.6%) respectively. The distribution of HbA1c by age is shown in Figure 1. HbA1c increased with age; from 60 mmol/mol (7.6%) in children less than 10 years with a subsequent rise during adolescence and a peak in the 20-25 years age group (73 mmol/mol or 8.8%), before a decline to 67 mmol/mol (8.3%) in the >30 age group.

Overall, 18% of the paediatric cohort (≤18 years) and 13% of the adult cohort met the recommended international glycaemic target of HbA1c < 53 mmol/mol (7.0%). The proportion of the cohort meeting the glycaemic target by age distribution is shown in Figure 2.

The mode of insulin therapy was recorded for 97.1% of participants (Table 1). Overall, 49% participants were using MDI with 36% CSII. MDI was predominant (54%) in the older age group with an equal distribution of MDI (46%) and CSII (40%) in the paediatric cohort. In table 2 HbA1c by mode of therapy is grouped for paediatric <18, young adult 18-30 years and adult >30 years. There was significantly higher CGM usage in the paediatric age groups than other age groups due to full government funding for all <21 years. The HbA1c (mean ±

SD), was significantly lower in those using CSII (64±14 mmol/mol or 8.0 ± 1.3) as compared with MDI (67±19 mmol/mol or 8.3±1.7; p<0.0001) which was lower again than those on BD injections (69 ±18 mmol/mol or 8.5±1.6; p<0.001). This was similar across all age groups. The association of HbA1c with insulin therapy and optimal CGM use (defined as >75% usage) (9) by age are shown in Table 2. In the 0-18 age group HbA1c was significantly lower in those using CGM >75% of the time for all therapy groups. In the 18-30 age group with CGM >75%, HbA1c was significantly lower in CSII users but not for MDI users and in the >30 age group, there was no impact of CGM on HbA1c for either CSII or MDI users.

Discussion

This is the largest national audit of glycaemic outcomes in Australian and New Zealand children and Australian adults with T1D with data derived from 18 major diabetes centres. The results highlight that only a minority of children and adults achieved the recommended glycaemic targets. This snapshot of the real-world data of glycaemic outcomes provides an opportunity to evaluate the contemporary management practices and the state of diabetes care across a diversity of hospital-based diabetes centres in Australia and New Zealand. The study highlights the urgent need to critically assess and evaluate the current strategies, recognise the enablers and barriers to improve diabetes care both in children and adults with T1D to reduce the acute care costs and long-term complications of the chronic disease.

In Australia at the end of December 2019, there were 121,878 individuals with T1D registered with the National Diabetes Supply Scheme (NDSS) (10). The ADDN data therefore represents approximately 7% of the Australian population with T1D. By comparison, the United States T1D Exchange registry captured data on 25,833 individuals with T1D in 2017 (6) representing approximately 2% of the population with T1D based on the calculation that around 5% of the total diabetes population in the United States have T1D

(11) , an estimated 1.25 million people. This report has a high percentage of children and adolescents which reflects the development of ADDN from a paediatric registry but nevertheless the number of adults with T1D included is equivalent to the US T1D Exchange registry and likely to be representative.

The mean age of 19.1 years and duration of diabetes of 8.8 years in the present report is 6 years older and 3 years longer respectively than in the last report which included results exclusively from paediatric centres (7). The proportion of CSII use has increased in the paediatric group as has CGM use, most likely as a result of the CGM subsidy available through NDSS from April 2017 to eligible Australian children and young people with T1D, younger than 21 years of age (12). This report only describes associations and direct links between therapies used and outcomes will require more complex analyses.

The highest levels of HbA1c have been historically reported in adolescents; a developmental phase associated with increased insulin resistance, higher insulin doses, risk taking behaviours and reduced engagement with diabetes care. However in Australia and New Zealand, the highest HbA1c was recorded in the emerging adults (20-25 years) with 1 in 10 achieving the recommended HbA1c of <53 mmol/mol (7.0%). This trend is recognised across other national registries reporting peak HbA1c of >75 mmol/mol (9.0%) in young adults (6, 7, 13, 14).

The finding in Australia that sub-optimal control continues through adulthood is also concerning with only 23% of adults >30 years achieving the recommended ADA glycaemic targets. Conclusions however are limited by a possible disproportionate representation of adults with T1D with advanced complications and from lower socio-economic backgrounds more likely to be managed in the tertiary adult centres currently contributing data to the ADDN registry. On the other hand, the large tertiary centres may have access to a greater

range of resources. This question needs further examination by extending the data collection to include other providers and regional centres. Likewise, the US-based T1D Exchange cohort found only 21 % adults above 30 years of age met the ADA goal, although the mean HbA1c of 58 - 63 mmol/mol or 7.5-7.9% was lower than in our cohort (65- 67 mmol/mol or 8.1- 8.3%) (6). This may be explained by a much higher percentage of adults accessing insulin pump therapy and CGM in US than in Australia or from a difference in the characteristics of the people with diabetes attending the clinics that were sampled.

Internationally, a substantial variation in HbA1c has been reported with age and there is general agreement of the importance of identifying strategies to improve glycaemia particularly in young adults (15). Large discrepancies in glycaemic control between developed Western countries (16) further emphasise the need to identify the determinants of these disparities and for collaborative efforts to identify measures to improve diabetes care. Variations in access to new therapies such as insulin pump therapy and CGM in different countries may explain some of the differences reported between countries but models of care, access to care, staff levels and other factors are likely to be important. For example, in both children and adults with T1D in this sample, the visit frequency is below accepted standards of care (3).

While only a minority of those attending ADDN centres achieved the recommended glycaemic target; it is interesting to speculate on outcomes for those with T1D who do not have access to major centres or to technology in Australia. The lowest proportion achieving target HbA1c of <53 mmol/mol was in the 20-25 years age group with some improvement seen in those who continued care into adulthood within the same centres. A limitation is the lack of information on individuals with T1D not attending tertiary centres: these may be receiving no specialist care or alternatively may be attending private endocrinologists. There

is an urgent need to capture this information especially for the at-risk emerging adults living with T1D.

The limitation of the present study is that it is not population-based and the sample represents individuals with T1D attending tertiary diabetes centres, predominantly reflecting an urban population. On the other hand, this is the largest audit to date that includes major centres of diabetes care and which provides important pointers to the state of care in a contemporary sample of T1D in Australasia. As the ADDN registry grows, this representation should improve with the ability to explore factors that influence glycaemic outcomes such as socioeconomic status from post code of residence, education level and ethnicity (at present only captured for 20% of ADDN registrants). There is also the potential in the future to link ADDN to other government and non-government registries. The registry thus provides the opportunity to track real-world glycaemic outcomes to assist clinicians, researchers, stake holders and policy makers in the evaluation of educational, pharmacological and technological interventional strategies used in the management of T1D. It also enables comparison of outcomes with international registries. With expansion of the registry to include paediatric and adult centres, the registry has developed into a resource that can contribute to national benchmarking and outcome monitoring as well as provide longitudinal evaluation of glycaemic outcomes and impact of interventions.

Conclusion

The Australasian and International registries highlight the ongoing challenge of improving T1D outcomes which remain sub-optimal. It calls for efforts to improve equity of access to expert care as well as proven therapies with planned and effective service delivery.

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Figure Legends

Figure 1: Mean HbA1c by age group* by comparison with ADA target of 53mmol/mol (number of participants in each age group in parentheses)

*2015 data for comparison. Mean HbA1c by age group < 5: 63mmol/mol, 5-10y: 62 mmol/mol, 10-15y: 68 mmol/mol, 15-18y: 69 mmol/mol

Figure 2: Distribution of HbA1c by age group (number of participants in each age group in parentheses)

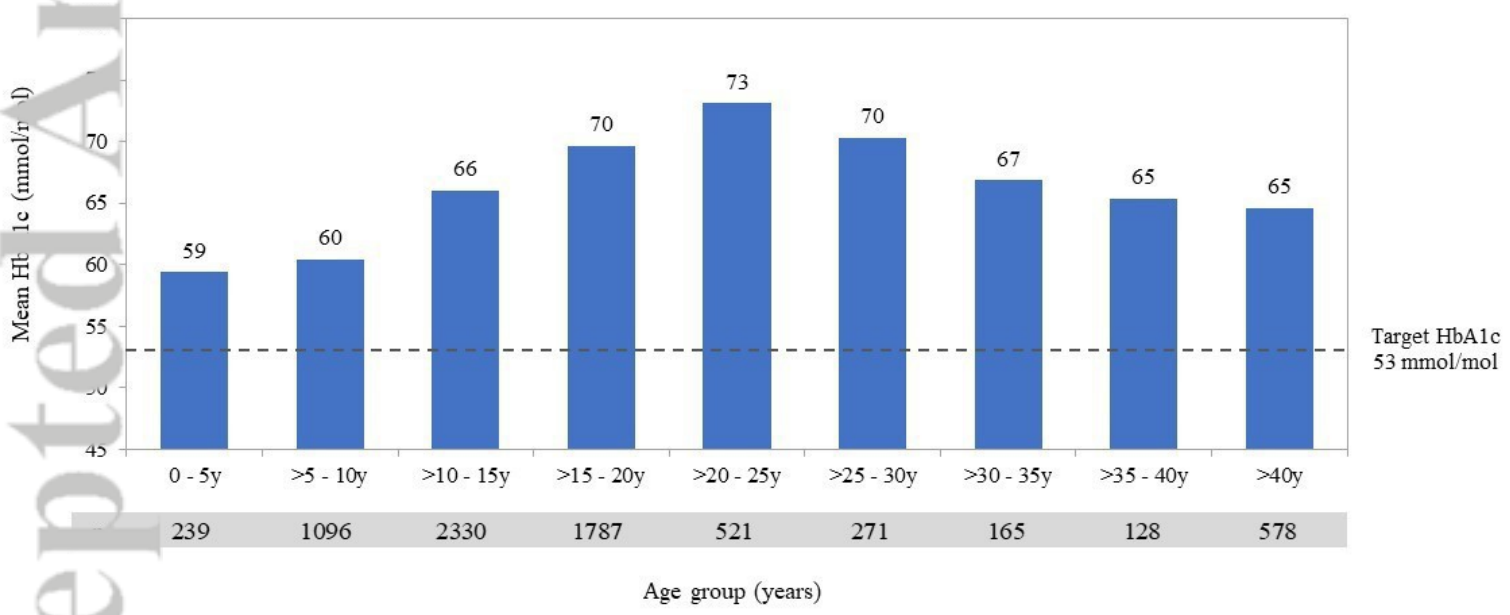
Table 1: Clinical characteristics of children and adults from the ADDN registry during 2019

Patients, n		7,988	
Visits, n		30,575	
Visit Frequency	Mean (SD)		
	Paediatric	3.4	(1.4)
	Adult	2.8	(2.0)
Gender n (%)	Female	3,969	(50%)
	Male	4,019	(50%)
Age (years)	Median (IQR)	15.3	(10.0)
	0-5	288	(4%)
	5-10	1,183	(15%)
	10-15	2,439	(30%)
	15-20	1,943	(24%)
	20-25	656	(8%)
	25-30	354	(4%)
	30-35	217	(3%)
	35-40	170	(2%)
	>40	738	(10%)
Diabetes Duration	Median (IQR)	5.7	(9.4)
	<3 m	458	(6%)
	≥3 m – <1 y	672	(8%)
	≥1 y – <5 y	2,498	(31%)
	≥5 y – <10 y	1,954	(25%)
	≥10 y	2,406	(30%)
Insulin Regimen n,%	MDI	3,917	(49%)
	CSII	2,853	(36%)
	BD	934	(12%)
	HCL	36	(1%)
	DIY	1	(0%)
	Missing	235	(3%)
	Other	12	(0%)
CGM n,%	Using CGM	3,218	(40%)
	Missing	1,660	(21%)

CSII: continuous subcutaneous insulin infusion, CGM: continuous glucose monitoring
MDI: multiple daily insulin, BD: twice a day injection, DIY: Do it yourself systems, HCL: hybrid closed loop

Table 2: HbA1c by diabetes management and CGM usage >75% for each age group

Regimen	0 to 18 years						18 to 30 years						> 30 years					
	Participants N (%)		HbA1c mmol/mol Mean (SD)		HbA1c % Mean (SD)		Participants N (%)		HbA1c mmol/mol Mean (SD)		HbA1c % Mean (SD)		Participants N (%)		HbA1c mmol/mol Mean (SD)		HbA1c % Mean (SD)	
	CGM	No CGM	CGM	No CGM	CGM	No CGM	CGM	No CGM	CGM	No CGM	CGM	No CGM	CGM	No CGM	CGM	No CGM	CGM	No CGM
CSII	921 (59)	274 (28)	60 (12)	64 (14)	7.6 (1.1)	8.0 (1.3)	54 (55)	225 (31)	67 (14)	70 (18)	8.1 (1.3)	8.6 (1.6)	14 (48)	128 (17)	57 (10)	63 (13)	7.4 (0.9)	7.9 (1.2)
MDI	543 (35)	593 (61)	62 (14)	68 (19)	7.8 (1.3)	8.4 (1.7)	40 (40)	438 (60)	70 (22)	75 (23)	8.6 (2.0)	9.0 (2.1)	15 (52)	494 (65)	70 (19)	67 (19)	8.6 (1.7)	8.3 (1.7)
BD	76 (5)	94 (10)	61 (14)	75 (18)	7.7 (1.3)	9.0 (1.6)	3 (3)	62 (9)	77 (21)	73 (18)	9.2 (1.9)	8.8 (1.6)	0 (0)	131 (17)	- (-)	63 (16)	- (-)	7.9 (1.5)



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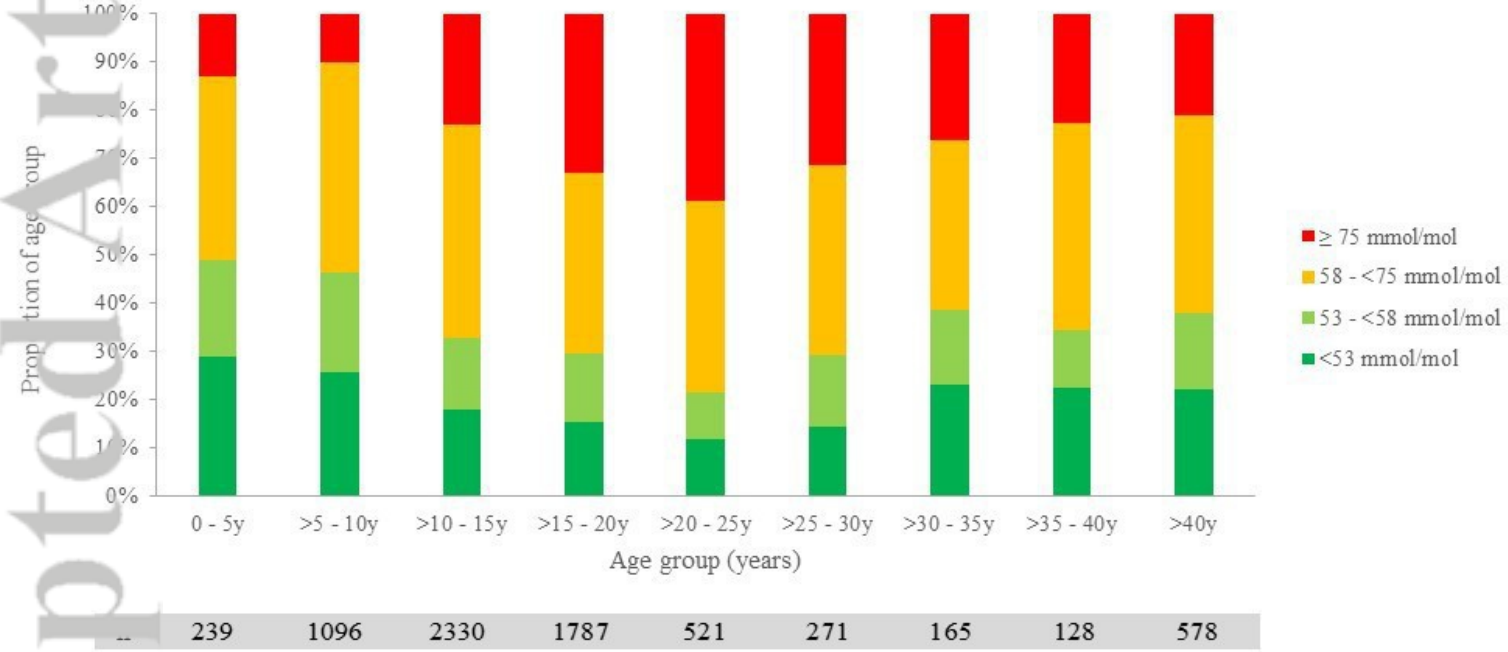

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