Scandinavian Journal of Primary Health Care

ISSN: 0281-3432 (Print) 1502-7724 (Online) Journal homepage: informahealthcare.com/journals/ipri20

A follow-up study of the occurrence and consequences of HbA1c measurements in an unselected cohort of non-pharmacologically treated patients with Type 2 diabetes

Jette Kolding Kristensen & Henrik Stoevring

To cite this article: Jette Kolding Kristensen & Henrik Stoevring (2008) A follow-up study of the occurrence and consequences of HbA1c measurements in an unselected cohort of non-pharmacologically treated patients with Type 2 diabetes, Scandinavian Journal of Primary Health Care, 26:1, 57-62, DOI: 10.1080/02813430801892532

To link to this article: https://doi.org/10.1080/02813430801892532

Published online: 12 Jul 2009.

Scandinavian Journal of Primary Health Care, 2008; 26: 57–62

informa
healthcare

ORIGINAL ARTICLE

A follow-up study of the occurrence and consequences of HbA1c measurements in an unselected cohort of non-pharmacologically treated patients with Type 2 diabetes

JETTE KOLDING KRISTENSEN[1] & HENRIK STOEVRING[2]

[1]*Department of General Practice, University of Aarhus,* [2]*Research Unit of General Practice, University of Southern Denmark, Denmark*

Abstract

Objectives. To describe the occurrence of HbA1c measurements among non-pharmacologically treated diabetes patients, and to evaluate whether poor blood glucose regulation (HbA1c >8%) prompted intensification of treatment. *Method.* Data from the National Health Service Registry, the Regional Laboratory Database and the Danish National Hospital Registry were collected from 2002 to 2004 to identify and describe all Type 2 diabetic patients above 40 years of age in a background population of nearly 660 000 citizens in Aarhus County, corresponding to 12% of the total Danish population. *Results.* A total of 1989 had at least one HbA1c measurement, whereas 484 (20%) had no HbA1c measurement at all in 2003. Most patients had an HbA1c of less than 8%, and for 820 (41%) HbA1c was less than 6.5%, but for 316 (16%) patients, the first HbA1c measurement in 2003 was above 8%. After 6 months, patients with HbA1c above 8% had a higher probability of initiating pharmacological treatment (M; 0.64; 95% CI 0.58–0.70) (F; 0.68; 95% CI 0.58–0.77) than patients with HbA1c below 8% (M; 0.12; 95% CI 0.10–0.14) (F; 0.11; 95% CI 0.09–0.14). *Conclusion.* This study indicates that poor blood glucose regulation (HbA1c >8%) prompted a shift from non-pharmacological treatment to pharmacological treatment for most patients. However, a substantial group of patients are either not monitored on a regular basis or, if monitored, their elevated measurements of HbA1c do not prompt initiation of pharmacological treatment.

Key Words: *Clinical inertia, family practice, HbA1c, quality of care, type 2 diabetes*

Type 2 diabetes is a common chronic disease that carries a high risk of disabling complications and the risk increases with severity and duration of hyperglycaemia. Studies have shown an exponential increased association between the level of blood glucose and the risk of complications [1].

Furthermore, it has been shown that optimized treatment of hyperglycaemia can reduce the risk of diabetes-related complications [2,3].

The Danish College of General Practitioners has published and distributed guidelines to all general practitioners throughout the last 20 years, the latest version in 2005. The guidelines recommend measurements of HbA1c four times a year, and that HbA1c levels are below 6.1%. If this cannot be achieved, the treatment should be intensified to accomplish this goal within 3–6 months [4].

Good quality of diabetes care implies regular HbA1c measurements and assessing the consequences of poor control in terms of treatment intensification.

- This study shows that 80% of patients with non-pharmacologically treated Type 2 diabetes had their HbA1c measured within a calendar year.
- HbA1c >8% prompted a shift from non-pharmacological treatment to pharmacological treatment for most patients within six months.

First-line treatment of hyperglycaemia is non-pharmacological in terms of lifestyle changes, but if lifestyle changes do not have sufficient beneficial

Correspondence: Jette K. Kristensen, Department of General Practice, University of Aarhus, Vennelyst Boulevard 6, DK-8000 Aarhus C, Denmark. E-mail: jkk@alm.au.dk

(Received 18 April 2007; accepted 2 January 2008)

ISSN 0281-3432 print/ISSN 1502-7724 online
DOI: 10.1080/02813430801892532

effects on the blood glucose level, pharmacological treatment is needed.

However, population-based studies have shown that recommendations from clinical guidelines are frequently not met [5–7]. When monitoring the quality of diabetes care, it is both important to assess if and when the patients have their HbA1c measured and to assess the level of the blood glucose measured. Put differently, good quality implies, first, that HbA1c is measured regularly, and second, that results indicative of poor control have consequences in terms of treatment intensification.

The aim of this study was to describe the occurrence of HbA1c measurements among non-pharmacologically treated diabetes patients and to evaluate whether poor blood glucose regulation (HbA1c $>8\%$) prompted intensification of treatment in the form of switches from non-pharmacological treatment to pharmacological treatment.

Material and methods

The background population in this study was all citizens in the County of Aarhus in the period 2000–2004, nearly 660 000 citizens, corresponding to 12% of the total Danish population.

Denmark has a universal healthcare system that covers all citizens. Visits to general practice and hospitals are free of charge. At birth all citizens in Denmark are assigned a civil registry number (CRN). This CRN allows unique linkage of data over time and across different data sources.

Diabetes population in Aarhus County

Aarhus Diabetes Database was established in 2000. The purpose of the database was to monitor type 2 diabetes in Aarhus County by use of public data files. The database identifies people diagnosed with diabetes by use of public data files.

The identification process was using the following data files:

1. The National Health Service Registry delivered data from diabetes-related services provided by chiropodists and on prescriptions for oral antidiabetic agents and insulin (anatomical-therapeutic-chemical (ATC) codes A10).
2. The Regional Laboratory Database delivered data on all HbA1c analysed by hospital laboratories within the County of Aarhus at the request of general practices and hospitals. The reference value was 4.6–6.4%.

For a person to be identified as having diabetes, one or more of the following criteria had to be fulfilled in a one-year period: two or more HbA1c measurements, at least one HbA1c measurement above the normal range, at least one visit to a chiropodist for diabetic foot care, or at least one prescription for oral hypoglycaemic agents or insulin. In earlier studies, this algorithm identified diabetic patients in the Danish healthcare system with a positive predictive value of 95% and a sensitivity of 91% [8].

A yearly search in the Danish Central Office of Civil Registration identified persons as residents or non-residents in the County of Aarhus, or as deceased.

Patients were classified as type 2 diabetic patients if they were treated with diet alone, with oral antidiabetic agents or, irrespective of treatment, if they were over 40 years of age at the time of diagnosis. The diagnosis of diabetes was confirmed and information about time of diagnosis was attained from a questionnaire sent to all identified persons or from medical records in general practice.

Study population

This study included all type 2 diabetic patients above 40 years of age who were alive and resident in Aarhus County in 2002, 2003, and 2004, who were diagnosed before 2002 and received no pharmacological treatment in 2002.

HbA1c

Data monitoring of HbA1c was collected from the Regional Laboratory Database system for the period 1 January 2003 to 31 December 2004.

Antidiabetic medication

Data concerning prescriptions for antidiabetic and lipid-lowering medications (ATC codes C10) distributed from a pharmacy within the county were collected from the Danish National Health Services Registry. Data were collected for the period 1 January 2003 to 31 December 2004.

Statistics

The patients' age was computed as years from birth to 2003. Similarly, duration of diabetes was computed as years from onset to 2003. Medians for the entire study population as well as for subgroups are presented, and we accompany medians with the 10% and 90% percentiles. We identified all patients' first HbA1c in calendar year 2003, if any, and defined this as the index measurement. We then computed the gap time to next measurement and/or prescription, with right-censoring at the end of 2004. To evaluate adherence to guidelines we dichotomized

the gap times at three and six months, respectively, and used logistic regression to compute proportions of new measurements or prescriptions stratified on HbA1c being above or below 8% at the index measurement. For all proportions we report 95% confidence intervals based on robust variance estimates [9,10] obtained from logistic regression with clustering defined by practice list membership. We finally computed Kaplan–Meier estimates from gap times after first measurement of HbA1c, again stratified on index HbA1c status. We summarize gap times by reporting medians and the corresponding quartiles, i.e. 25% and 75% percentiles. All analyses were carried out in Stata/SE 9.1 [11].

Results

The study population consisted of 2473 Type 2 diabetic patients on non-pharmacological treatment. Of these, 54% (n = 1341) were males. The median age was 64 years (10–90% percentile: 49–80), and the median duration of diabetes was 2 years (10–90% percentile: 0–9). A total of 1989 had at least one HbA1c measurement in 2003, whereas 484 (20%) had no HbA1c measurement at all in 2003. Of patients with no HbA1c measurement, 54% (n = 262) were males, their median age was 62 years (10–90% percentile: 47–82), and their median duration of diabetes was three years (10–90% percentile: 0–10).

Most patients had an HbA1c of less than 8% in 2003 and 820 (41%) had an HbA1c of less than 6.5%, but for 316 (16%) patients, the first HbA1c measurement in 2003 (the index HbA1c) was above 8%.

A total of 1150 (69%) patients with an index HbA1c $\leq$8% and 76 (24%) patients with an index HbA1c >8% had no new measurement of HbA1c or initiation of pharmacological treatment within three months. When looking at a time period of six months, fewer, but still not all patients, had had a follow-up (Table I).

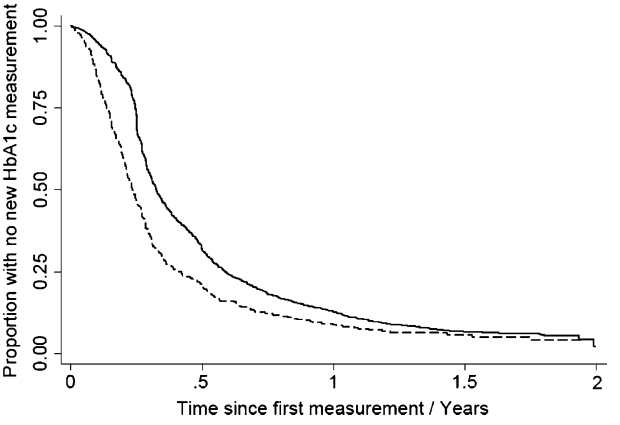

Figure 1. Proportion of patients with no new HbA1c measurement during the period after the first measurement of HbA1c. Broken line shows patient where first HbA1c measurement was above 8%. Unbroken line shows patients where first HbA1c measurement was less than or equal to 8%.

The median time from first to second HbA1c measurement was 119 days (25–75% percentile; 89–215) when the index HbA1c was <8%, and 85 days (25–75% percentile; 49–147) days when index HbA1c was >8%. Figure 1 shows the proportion of patients with no new HbA1c measurement during the first year after index HbA1c.

A total of 402 (20%) initiated pharmacological treatment within six months after the first HbA1c measurement. There were 194 (12%) of the patients with an index HbA1c $\leq$8% and 208 (66%) of the patients with an index HbA1c >8% who initiated pharmacological treatment within six months.

Table I. Number (percent) of patients with a new HbA1c measurement and/or a prescription for antidiabetic medicine within 3 or 6 months.

	First HbA1c measurement			
	≤8%		>8%	
	n	percent	n	percent
New HbA1c measurement				
within 3 months	454	27%	168	53%
within 6 months	1.115	67%	249	79%
New medication				
within 3 months	139	8%	181	57%
within 6 months	194	12%	208	66%
New HbA1c measurement or new medication				
within 3 months	523	31%	240	76%
within 6 months	1.144	68%	285	90%

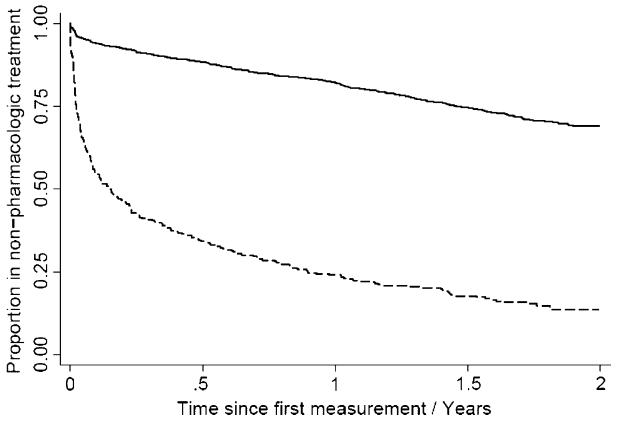

Figure 2. Proportion of patients not changing from non-pharmacological treatment to pharmacological treatment during time after the first measurement of HbA1c. Broken line shows patient where first HbA1c measurement was above 8%. Unbroken line shows patients where first HbA1c measurement was less than or equal to 8%.

The first choice of treatment was sulfonylureas (53%), while 40% were treated with Metformin, 5% with Insulin and 1% with Repaglinid. The median initiation time of any medication was 637 days (25–75% percentile; 465–>650) when the first HbA1c measurement was less than 8% and 63 days (25–75% percentile; 9–357) days when first measurement was above 8%.

Figure 2 shows a striking difference between the group with index HbA1c above 8% and below 8%, respectively. Thus, in the group with index HbA1c above 8%, the proportion of patients changing to pharmacological treatment within the first six months was pronounced, whereas the proportion changing to pharmacological treatment was sparse in the group with an index HbA1c of less than 8%.

The probability of follow-up was 0.31 (95% CI 0.29–0.34) after three months and 0.68 (95% CI 0.66–0.71) after six months in the group of patients with an HbA1c of less than 8%. In the group with an HbA1c above 8% the probability was remarkably higher. Thus the probability was 0.76 (95% CI 0.71–0.80) after three months and 0.90 (95% CI 0.87–0.93) after six months in the group of patients with an HbA1c above 8%.

After six months, patients with an HbA1c above 8% had a higher probability of initiating pharmacological treatment (M; 0.64; 95% CI 0.58–0.70) (F; 0,68; 95% CI 0.58–0.77) than patients with HbA1c below 8% (M; 0.12; 95% CI 0.10–0.14) (F; 0,11; 95% CI 0.09–0.14). Table II shows for subgroups of the population the probability of either an HbA1c measurement or change from non-pharmacological treatment to pharmacological treatment within six months, when index HbA1c was either less than 8% or above 8%.

Discussion

This study shows that 80% of patients with non-pharmacologically treated type 2 diabetes had had their HbA1c measured within a calendar year, while 20% had not. When a measurement was done, most patients were treated in accordance with the outcome: two-thirds of patients with high levels of HbA1c initiated pharmacological treatment within six months. For one quarter of the patients with elevated HbA1c, however, no change to pharmacological treatment was observed within one year of the elevated measurement, although most had their HbA1c re-measured within six months. A recent review of the evidence for early intervention has shown that intensive pharmacological treatment allow more patients to achieve glycaemic targets and hence reduce complications [12] and actions have been proposed to reduce clinical inertia. This study showed that medication was indeed more likely to be initiated when HbA1c was above 8%, but this and other studies[13] also indicate that healthcare providers often do not initiate pharmacological treatment for a substantial group of patients despite evidence of poor regulation and instead favour lifestyle interventions.

A substantial proportion of the population had no HbA1c measurement in a one-year period. This result corresponds well with findings of other studies [5,14]. Thus, other studies have found that diet-treated patients are less likely to be controlled compared with pharmacologically treated patients [5]. This might be explained by the fact that diet-treated patients are not prompted by the need for repeated prescriptions. So non-attendance and poor patient compliance are often major barriers to attain satisfactory diabetes care [15]. But suboptimal management of diabetes care could also represent a belief among some patients and physicians that non-pharmacologically treated diabetes is less severe than pharmacologically treated diabetes and due to inadequate lifestyle counselling [16]. This contrasts with official goals for management, which are well defined, and where strategic practical interventions have been recommended to accomplish them [4]. Furthermore, practice guidelines have been disseminated extensively [17]. Thus, poor quality of care cannot be attributed simply to physicians' lack of knowledge of standards of good care.

It is a potential limitation of this study that we require all participants to be present throughout the study period. It might have contributed to an underestimation of the magnitude of the problem as those who move might be at higher risk of postponing a measurement due to the strains of settling down in a new place. Another limitation is

Table II. Probability of either a HbA1c measurement or change from non-pharmacological treatment to pharmacological treatment within 6 months, when the first registered HbA1c measurement in 2003 was either less than 8% or above 8%.

				New HbA1c measurement within 6 months				Medication within 6 months				New HbA1c measurement or medication within 6 months			
				HbA1c ≤8%		HbA1c >8%		HbA1c ≤8%		HbA1c >8%		HbA1c ≤8%		HbA1c >8%	
			n	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI	Estimate	95% CI
Male	Age group	40–49	125	0.65	0.54–0.75	0.70	0.50–0.84	0.20	0.13–0.29	0.67	0.50–0.80	0.70	0.59–0.79	0.82	0.66–0.91
		50–59	311	0.63	0.56–0.69	0.71	0.58–0.81	0.15	0.12–0.20	0.63	0.49–0.75	0.65	0.56–0.71	0.84	0.73–0.91
		60–69	345	0.71	0.65–0.75	0.82	0.71–0.89	0.09	0.06–0.13	0.62	0.50–0.73	0.72	0.67–0.77	0.95	0.87–0.99
		70–79	233	0.66	0.66–0.72	0.87	0.70–0.95	0.08	0.05–0.13	0.68	0.50–0.82	0.68	0.61–0.74	0.94	0.78–0.98
		80+	64	0.48	0.35–0.61	0.88	0.46–0.98	0.14	0.08–0.26	0.75	0.38–0.94	0.50	0.37–0.63	1.00	1.00–1.00
	Diabetes duration	0	438	0.69	0.63–0.73	0.88	0.77–0.94	0.13	0.10–0.17	0.64	0.52–0.75	0.71	0.66–0.76	0.95	0.85–0.98
		1–5	362	0.62	0.56–0.68	0.73	0.61–0.82	0.10	0.07–0.13	0.59	0.48–0.70	0.64	0.58–0.70	0.84	0.74–0.90
		6–10	207	0.63	0.55–0.69	0.78	0.63–0.87	0.11	0.07–0.17	0.71	0.58–0.82	0.65	0.57–0.71	0.92	0.81–0.97
		11+	71	0.66	0.53–0.77	0.61	0.38–0.80	0.15	0.08–0.27	0.67	0.43–0.84	0.70	0.57–0.80	0.89	0.65–0.97
		total	1078	0.65	0.62–0.69	0.77	0.71–0.83	0.12	0.10–0.14	0.64	0.58–0.70	0.68	0.64–0.71	0.89	0.85–0.93
Female	Age group	40–49	82	0.64	0.52–0.74	0.90	0.53–0.95	0.12	0.07–0.21	0.50	0.22–0.78	0.64	0.52–0.74	0.90	0.53–0.99
		50–59	192	0.67	0.59–0.74	0.82	0.60–0.93	0.11	0.07–0.16	0.77	0.57–0.90	0.68	0.60–0.75	0.86	0.65–0.96
		60–69	359	0.72	0.66–0.78	0.74	0.56–0.86	0.11	0.08–0.16	0.62	0.43–0.78	0.73	0.66–0.79	0.91	0.76–0.97
		70–79	242	0.68	0.61–0.74	0.85	0.70–0.94	0.10	0.06–0.14	0.74	0.55–0.86	0.70	0.63–0.76	0.94	0.80–0.98
		80+	136	0.64	0.55–0.72	0.81	0.55–0.94	0.14	0.09–0.23	0.69	0.43–0.86	0.67	0.58–0.75	0.94	0.66–0.99
	Diabetes duration	0	359	0.72	0.67–0.77	0.76	0.58–0.88	0.10	0.07–0.14	0.71	0.55–0.82	0.73	0.68–0.78	0.88	0.74–0.95
		1–5	312	0.66	0.60–0.72	0.91	0.79–0.97	0.11	0.08–0.16	0.76	0.62–0.85	0.67	0.61–0.73	0.98	0.86–1.00
		6–10	152	0.64	0.56–0.72	0.69	0.48–0.85	0.11	0.07–0.18	0.65	0.44–0.82	0.67	0.59–0.74	0.85	0.61–0.95
		11+	88	0.62	0.51–0.72	0.82	0.49–0.95	0.16	0.09–0.25	0.36	0.14–0.66	0.65	0.54–0.75	0.91	0.56–0.99
		total	911	0.68	0.64–0.72	0.81	0.72–0.88	0.11	0.09–0.14	0.68	0.58–0.77	0.69	0.66–0.73	0.91	0.84–0.95

that this study has no data on whether or not any lifestyle interventions have been initiated or intensified. Thus, there may be valid clinical circumstances not apparent from the data justifying no initiation of pharmacological treatment.

Conclusion

Although some individuals with type 2 diabetes might be effectively managed by diet alone, many need medication to optimize hbA1c regulation. This study indicates that poor blood glucose regulation (HbA1c $>8\%$) prompted intensification of treatment in the form of switches from non-pharmacological treatment to pharmacological treatment for the majority of patients. Despite this, a substantial group of patients are either not monitored on a regular basis, or if monitored, their elevated measurements of HbA1c do not prompt initiation of pharmacological treatment.

References

[1] Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: A randomized prospective 6-year study. Diabetes Res Clin Pract 1995;28:103–17.

[2] UKPDS. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with Type 2 diabetes (UKPDS 33). Lancet 1998;352:837–53.

[3] Gæde P, Vedel P, Parving HH, et al. Intensified multifactorial intervention in patients with Type 2 diabetes mellitus and microalbuminuria: Rhe Steno Type 2 randomised study. Lancet 1999;353:617–22.

[4] DSAM. Guidelines for Type 2 diabetes. Copenhagen: DSAM; 2002.

[5] Hippisley-Cox J. Prevalence, care, and outcome for patients with diet controlled diabetes in general practice: cross sectional survey. Lancet 2004;363:423–8.

[6] Kristensen JK, Bro F, Sandbæk A, et al. The use and level of HbA1c in an unselected population of 4,438 people with Type 2 diabetes in a Danish County. Scand J Prim Health Care 2001;19:241–6.

[7] Eliasson B, Cederholm J, Nilsson P, Gudbjornsdottir S. The gap between guidelines and reality: Type 2 diabetes in a national diabetes register 1996–2003. Diabetic Medicine 2005;22:1420–6.

[8] Kristensen JK. Identification of the Type 2 diabetes population in a Danish county and evaluation of the performed care in a five-year period. PhD thesis. Department of General Practice, University of Aarhus; 2000.

[9] Huber PJ. The behaviour of maximum likelihood estimates under non-standard conditions. In: Proceedings of the fifth Berkeley symposium on mathematical statistics and probability. Berkeley, CA: University of California Press; 1967. p. 221–3.

[10] White H. A heteroskedasticity-consistent covariance matrix estimator and a direct test for heteroskedasticity. Econometria 1980;48:817–30.

[11] Statacorp. Stata statistical software: Release 9. College Station, TX: StataCorp LP; 2005

[12] Bailey CJ, Del Prato S, Eddy D, Zinman B. Earlier intervention in type 2 diabetes: The case for achieving early and sustained glycaemic control. Int J Clin Pract 2005;59: 1309–16.

[13] Harris S, Ekoe J-M, Webster-Bogaert S. The diabetes in Canada evaluation (DICE) study: Are primary care physicians achieving target A1c? Diabetes 2003;52:A499.

[14] Fârnkvist LM, Lundman BM. Outcomes of diabetes care: A population-based study. Int J Qual Health Care 2003;15: 301–7.

[15] Hammersley MS, Holland MR, Walford S, Thorn PA. What happens to defaulters from a diabetic clinic? BMJ 1985;291: 1330–2.

[16] Poskiparta M, Kasila K, Kiuru P. Dietary and physical activity counselling on type 2 diabetes and impaired glucose tolerance by physicians and nurses in primary healthcare in Finland. Scand J Prim Health Care 2006;24:206–10.

[17] Olesen F, Lauritzen T. Do general practitioners want guidelines? Attitudes toward a county-based and a national college-based approach. Scand J Prim Health Care 1997; 15:141–5.