Sustained good glycaemic control in NIDDM patients by implementation of structured care in general practice: 2-year follow-up study

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Summary In primary care it is difficult to treat the growing number of non-insulin-dependent diabetic (NIDDM) patients according to (inter)national guidelines. A prospective, controlled cohort study was designed to assess the intermediate term (2 years) effect of structured NIDDM care in general practice with and without 'diabetes service' support on glycaemic control, cardiovascular risk factors, general well-being and treatment satisfaction. The 'diabetes service', supervised by a diabetologist, included a patient registration system, consultation facilities of a dietitian and diabetes nurse educator, and protocolized blood glucose lowering therapy advice which included home blood glucose monitoring and insulin therapy. In the study group (SG; 22 general practices), 350 known NIDDM patients over 40 years of age (206 women; mean age $65.3 \pm$ SD 11.9; diabetes duration 5.9 ± 5.4 years) were followed for 2 years. The control group (CG; 6 general practices) consisted of 68 patients (28 women; age 64.6 ± 10.3; diabetes duration 6.3 ± 6.4 years). Mean HbA_{1c} (reference 4.3–6.1 %) fell from 7.4 to 7.0 % in SG and rose from 7.4 to 7.6 % in CG during follow-up ($p = 0.004$). The percentage of patients with poor control ($HbA_{1c} > 8.5$ %) shifted from 21.4 to 11.7 % in SG, but from 23.5 to 27.9 % in CG ($p = 0.008$). Good control ($HbA_{1c} < 7.0$ %) was achieved in 54.3 % (SG; at entry 43.4 %) and 44.1 % (CG; at entry 54.4 %) ($p = 0.013$). Insulin therapy was started in 29.7 % (SG) and 8.8 % (CG) of the patients ($p = 0.000$) with low risk of severe hypoglycaemia (0.019/patient year). Mean levels of total and HDL-cholesterol (SG), triglycerides (SG) and diastolic blood pressure (SG + CG) and the percentage of smokers (SG) declined significantly, but the prevalence of these risk factors remained high. General well-being (SG) did not change during intensified therapy. Treatment satisfaction (SG) tended to improve. Implementation of structured care, including education and therapeutic advice, results in sustained good glycaemic control in the majority of NIDDM patients in primary care, with low risk of hypoglycaemia. Lowering cardiovascular risk requires more than reporting results and referral to guidelines. [Diabetologia (1997) 40: 1334–1340]

Keywords Structured diabetes care, NIDDM, primary care, diabetes education, insulin therapy, hypoglycaemia, well-being.

Most patients with non-insulin-dependent diabetes mellitus (NIDDM) in particular when managed with diet or oral hypoglycaemic agents, are treated in a primary health care setting. To optimize the treatment of the growing number of NIDDM patients (inter-) national guidelines have been published [1–4]. However, the wide acceptance of the guidelines by general practitioners (GPs), and their implementation in practice have proved difficult [5–11].

Table 1. NIDDM patients above 40 years of age in study and control groups

	Study group (SG) 22 GPs		Control group (CG) 6 GPs	
Eligible NIDDM patients in GP records[a] (n)			570 KDM	171 KDM
Number of participants March 1992–December 1993 (n)	120 NDM	56[b] KDM	403 (71 %) KDM	102 (60 %) KDM
2 year (SG) and 1.5 year (CG) follow-up data available	95 NDM		350 KDM	68 KDM

[a] Mean number of 1800 patients per GP; 369 (39 %) of all 939 identified NIDDM patients (SG) were managed in hospital diabetes clinics. [b] Patients with known diabetes for > 3 months

(KDM) referred back from secondary care or referred by other GPs. NDM, Newly diagnosed NIDDM

Non-attendance and poor patient compliance are often major barriers for attaining adequate diabetes care. However, doctor-related, as for example attitude and knowledge, and organisational factors may be even more important barriers [12–14]. The availability of a diabetic patient register and recall system, education facilities, professional support from a network of medical and non-medical professionals and systematic quality assessment are organisational factors which influence diabetes care [15]. The guidelines for the treatment of NIDDM have stimulated physicians to improve the quality of management. However, implementation was only partially successful, where doctor-related and organisational problems could roughly be met [9, 16–20].

In 1992 we introduced a 'diabetes service' in primary care which provides support to GPs in the management of NIDDM. This facility is located at a laboratory for GPs in Amsterdam. The purpose of this study was to assess the intermediate term (2 years) effect of this care system on glycaemic control, various cardiovascular risk factors and on general well-being and treatment satisfaction in a population of NIDDM patients.

Subjects, materials and methods

Study population. Of 29 eligible GPs in the western part of Amsterdam 22 were willing to co-operate with the diabetes service. Reasons for non-participation were implementation of systemised diabetes care in their own practice (four GPs) and 'no interest' (three GPs). The 22 GPs were requested to enroll all their known and newly diagnosed NIDDM patients (Table 1). Only patients with diabetes (World Health Organisation criteria) diagnosed after the age of 40 years and at least treated for 6 months with diet and/or oral hypoglycaemic tablets were included. Of the 570 eligible patients managed in primary care 167 (29 %) did not participate. Reasons for non-participation were: deceased (5.6 %); referred to secondary care (6.8 %); change of GP (7.2 %); diabetes not confirmed (2.2 %); unwilling because of psychiatric disorders or unknown reasons (7.3 %). Two-year follow-up data are available for 350 of 459 known (76.3 %) and 95 of 120 newly diagnosed (79.2 %) diabetic subjects. Reasons for 23.1 % drop-out during the first 2 years of follow-up were death (7.6 %), change of GP

(7.9 %), referral to secondary care (2.4 %), delayed yearly control (1.7 %) and unknown reasons (3.5 %).

Control population. The NIDDM population of three GPs in Amsterdam and three in Twente (eastern part of the Netherlands) served as a control group. These GPs were not involved in any shared care system, but had accepted the treatment guidelines of the Dutch College of General Practitioners [4, 5]. Complete baseline and 1.5 year follow-up data for 68 of 102 participants are available (Table 2). Reasons for the 33.3 % drop-out during 1.5 years of follow-up included death (2.9 %), change of GP (3.9 %), referral to secondary care (1.0 %), non-attendance or unknown reasons (25.5 %).

Diabetes service system Amsterdam. In this system the GP is supported by a laboratory with facilities to visit patients at home, a computerized patient register and recall system, a wide-angle retinal camera and the possibility to consult with a dietitian, a diabetes nurse educator and a podiatrist [21–23]. A diabetologist, who supervises the diabetes service, can be contacted by telephone 24 h a day.

Protocol. At entry, patients of the study population were invited for assessment of glycaemic control at 3-month intervals, and for annual review of complications, cardiovascular risk factors and assessment of general well-being and treatment satisfaction. Within 2 weeks the participating GPs received the results accompanied by an advice according to a step-up treatment regimen (Table 3). Target values were based upon the guidelines of the European NIDDM Policy Group 1988, which are similar to the Dutch GP Guidelines 1989 [2, 4]. GPs could alter target values, e. g. in the case of short life expectancy. If the target HbA_{1c}-value (usually 7.0 %) was not met with maximal dose oral therapy, self-monitoring of blood glucose (first step) and insulin therapy (next step) were instructed in individual 30 min sessions with the diabetes educator. Usually, two follow-up appointments were sufficient to repeat and check education. Twice weekly telephone appointments were made to adjust insulin dose on the basis of fasting blood glucose values. Measurement of fasting and pre-dinner glucose values was requested for patients on a twice daily NPH-insulin scheme. Patients were free to choose one of the blood glucose meters and insulin pens available in the Netherlands. For the management of hypertension and dyslipoproteinaemia GPs were referred to GP guidelines [4]. The incidence of hypoglycaemia was evaluated annually, but in insulin-treated patients at least 3-monthly, at each visit or telephone call with the diabetes nurse. Patients were asked to verify hypoglycaemia by home blood glucose monitor (HBGM) if possible. Patients in the control group were seen at 3-month intervals for glycaemic control and annually for review of diabetic complications and

Table 2. Baseline clinical characteristics of NIDDM patients in study and control groups

	Study group newly diagnosed DM ($n = 120$)	Study group (SG) known NIDDM ($n = 459$)	Control group (CG) known NIDDM ($n = 102$)	p-value known NIDDM SG vs CG
Men (%)	46.7	39.0	50.0	0.03
Age (years)	63.4 ± 13.1	66.1 ± 12.5	66.0 ± 10.6	0.94
Diabetes duration (years)	0.1 (0.0–0.3)	6.4 (0.3–44.9)	6.4 (0.4–35.0)	0.76
Dutch origin (%)	76.7	81.0	81.2	0.97
Fasting glucose (mmol/l)[a]	10.2 ± 4.1	9.0 ± 2.7	9.8 ± 3.5	0.02
HbA$_{1c}$ (%)[b]	8.6 ± 2.5	7.5 ± 1.7	7.6 ± 1.9	0.50
Body mass index (kg/m^2)				
men ($n = 56/179/51$)	27.0 ± 4.2	27.4 ± 3.8	26.4 ± 3.0	0.10
women ($n = 64/280/51$)	30.6 ± 6.4	29.2 ± 5.3	27.7 ± 5.0	0.07
Total cholesterol (mmol/l)	6.0 ± 1.1	6.1 ± 1.3	5.9 ± 1.0	0.08
HDL cholesterol (mmol/l)	1.16 ± 0.33	1.21 ± 0.36	1.14 ± 0.34	0.06
Triglycerides (mmol/l)	2.15 ± 1.65	2.14 ± 1.61	2.03 ± 1.38	0.53
Systolic blood pressure (mm Hg)	146.5 ± 23.4	147.2 ± 21.7	158.2 ± 23.5	0.00
Diastolic blood pressure (mm Hg)	87.7 ± 10.4	86.7 ± 11.0	88.9 ± 11.7	0.08
Cigarette smokers (%)	25.8	24.0	26.0	0.63
				0.47
Therapy (%)				
dietary advice	100	26.6	29.7	
oral hypoglycaemic agents	0	69.5	66.3	
insulin	0	3.9	3.9	

Values are expressed as mean ± standard deviation or (range). [a] Fasting glucose measured in venous plasma. [b] Reference value HbA$_{1c}$ 4.3–6.1 %

Table 3. Step-up regimen for glycaemic treatment of NIDDM patients in study group

1. Nutritional advice Physical activity	If glycaemic targets[a] are not achieved within 3 months → step 2
2. Sulphonylureas (SU)	Start at low dose; dose adjustments at 6-week intervals based upon fasting glucose and/or HbA$_{1c}$
3. SU + metformin	In obese patients (BMI > 27 kg/m^2) metformin 500 mg is added, increasing to a maximal dose of 1700 mg/day
4. Self-monitoring of blood glucose	Started in patients on maximal oral therapy if good glycaemic control is not achieved
5. NPH-insulin[b] at bed-time + SU daytime	The starting dose of 8 IU NPH-insulin is adjusted twice weekly, till fasting glucose targets are achieved
6. NPH-insulin twice daily	SU replaced by starting dose of 8 IU NPH-insulin before breakfast when daytime glucose levels > 10 mmol/l with HbA$_{1c}$ > target value. Morning + pre-dinner insulin doses titrated upon pre-dinner and fasting blood glucose levels
7. Add short-acting insulin or referral to diabetologist	If glycaemic control not satisfactory other insulin regimens may be appropriate

In symptomatic patients who present with fasting glucose values > 15 mmol/l insulin is treatment of choice. [a] In general, glycaemic targets defined as fasting and preprandial blood glucose levels of 4.4–6.7 mmol/l and HbA$_{1c}$ < 7.0 % (reference 4.3–6.1 %). [b] Neutral Protamin Hagendorn-insulin is an intermediate long-acting insulin

cardiovascular risk factors. Therapy was titrated on the basis of fasting blood glucose level, aiming at 4.4–6.7 mmol/l. No fixed step-up regimen was available for HBGM or insulin therapy. In an interview after 1.5 years patients were asked if they had experienced hypoglycaemia.

The protocol was approved by the ethical committee of the Academic Hospital Vrije Universiteit.

Outcome measures. Fasting plasma glucose was determined with a glucose oxidase method (Boehringer Mannheim, Mannheim, Germany). Glycated haemoglobin (HbA$_{1c}$) was determined by ion-exchange high-performance liquid chromatography (HPLC), using a Modular Diabetes Monitoring System (Bio-Rad, Veenendaal, the Netherlands. normal range 4.3–6.1 %). In the control group, several methods of HbA$_{1c}$ measurement were used (HPLC, affinity chromatography). HbA$_{1c}$ values obtained with these methods were recalculated against those obtained with the HPLC-method by expressing these values as percentage of deviation of the upper limit of the normal range. Hypoglycaemia grade 3 was defined as that which required oral carbohydrates with help of others; a hypoglycaemic coma was scored as a hypoglycaemia grade 4. Systolic and diastolic blood pressures were measured in the sitting position after 5 min rest with a digital blood pressure monitor (Omron Hem-405, Tokyo, Japan). Fasting total cholesterol, HDL-cholesterol and triglycerides were measured by

Table 4. Change of glycaemic control, therapy and cardiovascular risk factors in patients known with NIDDM in study and control group

	Study group (n = 350)			P-value	Control group (n = 68)		P-value	Study vs control group
	baseline	year 1	year 2		baseline	year 1.5		
Fasting glucose (mmol/l)	8.9 ± 2.5	8.4 ± 2.6	8.1 ± 2.5	0.000	9.6 ± 3.4	9.8 ± 2.9	0.74	0.004
HbA$_{1c}$ (%)	7.4 ± 1.6	7.0 ± 1.3	7.0 ± 1.3	0.000	7.4 ± 1.9	7.6 ± 1.5	0.23	0.004[a]
BMI (kg/m^2)	28.7 ± 4.6	28.7 ± 4.6	29.0 ± 4.6	0.001	26.8 ± 4.0	26.5 ± 3.8	0.14	0.000
HbA$_{1c}$ > 8.5 % (%)	21.4	12.1	11.7	0.000	23.5	27.9	0.58	0.008
HbA$_{1c}$ < 7.0 % (%)	43.4	56.2	54.3	0.000	54.4	44.1	0.14	0.013
Blood glucose lowering therapy (%):								0.000[b]
nutritional advice/exercise	26.9	14.6	12.9	0.000	29.4	19.1	0.07	
SU ± metformin	69.7	64.6	57.9	0.14	64.7	72.1	0.23	
SU + NPH-insulin at bedtime	0.6	11.7	13.4	0.000	2.9	0	0.50	
Insulin bid	2.9	8.3	16.3	0.000	2.9	8.8	0.13	
Hypoglycaemia (n/patient/year):				c			c	
grade 3 (orally with help)	0	0.006	0.006			0		
grade 4 (coma)	0	0.011	0.014			0		
Total cholesterol (mmol/l)	6.1 ± 1.3	6.1 ± 1.3	5.8 ± 1.1	0.000	5.9 ± 1.0	5.9 ± 1.0	0.43	0.002
HDL cholesterol (mmol/l)	1.21 ± 0.36	1.22 ± 0.39	1.16 ± 0.32	0.004	1.14 ± 0.35	1.13 ± 0.37	0.93	0.40
Triglycerides (mmol/l)	2.12 ± 1.64	2.12 ± 2.09	1.96 ± 1.72	0.012	2.01 ± 1.46	2.03 ± 1.55	0.80	0.12
Systolic blood pressure (mm Hg)	146.9 ± 20.9	149.1 ± 24.0	147.7 ± 23.5	0.53	155.4 ± 24.0	155.3 ± 22.9	0.97	0.70
Diastolic blood pressure (mm Hg)	87.4 ± 10.8	84.3 ± 13.1	83.0 ± 12.6	0.000	88.8 ± 11.4	85.3 ± 11.4	0.01	0.59
Cigarette smokers (%)	22.0	24.0	18.0	0.003	23.9	20.9	0.50	0.75

Values are expressed as mean ± SD or as percentage. SU = Sulphonylurea. [a] P = 0.002 after correction for differences in baseline characteristics with linear regression analysis. [b] Significant difference between treatment categories at end of study. [c] P-value not calculated because hypoglycaemia not mentioned at baseline

enzymatic techniques (Boehringer Mannheim, Mannheim, Germany). General well-being and treatment satisfaction were assessed with self-report questionnaires.

Statistical analysis. Baseline clinical characteristics were compared using chi-square, unpaired t- or Mann-Whitney tests when appropriate. To compare baseline with final results paired t- or McNemar tests were applied. For the comparison between study and control population corrected deltas (= [baseline value – final value]/baseline value) were calculated and evaluated applying unpaired t-, Mann-Whitney-, and chi-square (Mantel-Haenszel method)-tests; the main endpoint (corrected delta HbA$_{1c}$) was adjusted for differences in baseline characteristics applying linear regression analysis. To evaluate the change in general well-being and treatment satisfaction the Wilcoxon test was used. A p-value less than 0.05 was considered statistically significant.

Results

In the comparison between study and control population the 120 newly diagnosed NIDDM patients (with onset within 3 months) in the study group were omitted, since the control group did not include newly diagnosed patients. Baseline characteristics (Table 2) are comparable except for gender, fasting glucose, BMI, (HDL-) cholesterol and blood pressure.

Glycaemic control and blood glucose lowering therapy are depicted in Table 4. In the study population a lowering of the HbA$_{1c}$ was achieved within 1 year and then remained stable. The percentage of patients with poor glycaemic control fell from 21.4 to ± 12 % and this result was maintained. Therefore, a comparison of the 2-year results in the study group with the 1.5-year results in the control group was allowed. The percentage of patients on insulin therapy increased gradually from 3.56 to 20 % after 1 year to nearly 30 % at 2 years. In these patients (n = 104) mean HbA$_{1c}$ decreased from (mean ± SD) 8.3 ± 1.5 to 7.6 ± 1.3 %, with 2.4 kg mean weight gain. In patients not managed with insulin (n = 246), mean HbA$_{1c}$ fell from 7.0 ± 1.6 to 6.8 ± 1.2 % and was associated with 0.4 kg mean weight loss. In newly diagnosed NIDDM patients followed for 2 years (n = 95; Table 1) mean HbA$_{1c}$ decreased from 8.5 to 6.6 % and the percentage with poor control from 43.2 to 9.5 %. Grade 3 hypoglycaemia was reported 4 times in 2 years, in patients treated with sulphonylures. On 13 occasions a hypoglycaemic coma was suspected. In 3 this was caused by a cardiac arrhythmia and in 1 by a transient ischaemic attack; glucose values during these episodes were all above 8.0 mmol/l. The 9 remaining events occurred in 7 insulin-treated patients. These were unconfirmed and self-limiting (4) or corrected at home (5).

In the control group glycaemic control did not improve. The percentage of patients with poor glycaemic control, defined as HbA$_{1c}$ above 8.5 %, tended to rise although insulin therapy was applied in 8.8 %. Exclusion of patients who needed insulin therapy (final HbA$_{1c}$ values above 7.0 % on maximal oral

Table 5. Questionnaire for participating general practitioners of study group

1. Do you appreciate the co-operation with the diabetes service?	yes	100 %
	no	0 %
2. Does participation in the shared care system save time?	yes	59 %
	equal	24 %
	costs more	18 %
3. Without this shared care system, would you manage all these diabetic patients yourself?	yes	17 %
	no	83 %
4. Would you appreciate protocolized management of hypertension and lipid disorders with a stepwise approach and concrete therapeutic advice?	yes	76 %
	no	24 %
5. Do you enjoy the care for diabetic patients more since co-operation with the diabetes service?	(very) much	72 %
	a little	28 %
	no change	0 %
6. Has glycaemic control in your patients been improved since shared care?	(very) much	72 %
	a little	22 %
	no	6 %

therapy; $n = 6$ control group), did not influence these results. Patients of the control group did not report hypoglycaemic episodes.

Mean diastolic blood pressure (both groups) and the number of cigarette smokers (study group) dropped significantly (Table 4). In the second year total cholesterol and triglyceride levels in patients of the study group decreased, partly due to the prescription of lipid modifying drugs. However, after 2 years of follow-up target values for blood pressure and lipid levels had still not been reached in most patients: hypertension (> 160/95 mmHg) persisted in 30 %; hypercholesterolaemia (> 6.5 mmol/l) in 25 % and hypertriglyceridaemia (> 2.2 mmol/l) in 29 %. When applying more stringent criteria for hypertension (> 140/90 mmHg), total cholesterol (> 5.2 mmol/l) and triglycerides (> 1.7 mmol/l), these percentages were 56, 70 and 52 %, respectively.

General well-being and treatment satisfaction were evaluated only in the study group. Of 247 of the 445 patients (55.5 %) a questionnaire at baseline and after 2 years was available. These patients did not differ from those who did not return the questionnaire for age, gender, diabetes duration, BMI and improvement of HbA_{1c}. General well-being ('how have you felt in the past 3 months' and 'how do you judge your health') did not show a significant change (p-value 0.36 and 0.49, respectively). Questions concerning medical care in the past 3 months and whether improvement of medical care was possible in the opinion of the patient tended to improve (p-value 0.46 and 0.15, respectively). The patients tended to find the diabetes management less demanding during the study than before (p-value 0.06). GPs all appreciated the co-operation with the diabetes service (Table 5). The diabetes nurse played an important role in education and adjustment of the insulin dose; only 4 out of 22 GPs personally adjusted the insulin doses.

Discussion

A lasting improvement in blood glucose control in a large population of NIDDM patients was achieved in primary health care as a result of implementing a structured diabetes programme. Good control, defined as HbA_{1c} less than 7.0 %, was achieved in the majority of patients. The percentage of patients with poor control ($HbA_{1c} > 8.5$ %) was nearly halved to ± 12 %. In the control population it proved difficult to implement protocolized diabetes care according to the GP guidelines. More than a quarter of the patients in the control group remained poorly regulated.

Differences in baseline characteristics in the study and control populations do not explain the observed differences in glycaemic control. Neither do treatment targets or guidelines. Our data strongly suggest that the difference cannot be attributed to the availability of insulin therapy; there are two more likely explanations for the better results in the study group. Firstly, the protocolized therapy advice, based upon the results and pre-set targets, were in general followed by the GPs; they were requested to report their reasons for not doing so. GPs reported increased enthusiasm after 2 years of participation, probably reflecting a positive attitude towards diabetes care. Secondly, individual diabetes education (e. g. by diabetes nurse and dietitian) may have enhanced self-care and patient compliance [15]. Patient motivation is also reflected by the fact that, by using blood glucose self-monitoring, they were easily motivated to start insulin therapy. Of the 579 patients in the study group only 20 (3.5 %) dropped out because of poor motivation. The main reasons for this were psychiatric problems, alcohol addiction and short life expectancy due to cancer.

Nearly 30 % of the patients in the study group were treated with insulin at 2 years of follow-up. The combination of insulin at bedtime with sulphonylurea drugs, as advocated in NIDDM [24–26], followed by

NPH-insulin twice daily, appeared to be an effective, feasible and safe therapy regimen. The incidence rate of severe hypoglycaemia was low, 0.019 /patient year for the whole group and 0.064 /insulin treated patient year. This low frequency is in agreement with the findings of the VA CSDM feasibility trial (0.03 / patient year intensive therapy group) [27] and the UKPDS (0.014 /insulin treated patient year) [28]. The incidence rate in IDDM is much higher (DCCT: 0.74 /patient year) [29]. In comatose patients it appeared to be difficult to distinguish hypoglycaemia from cardiac arrhythmia or transient ischaemic attack as was the case in 4 of the 13 events.

In contrast to our favourable findings for glycaemic control, a considerable number of patients did not achieve targets for serum lipid levels, blood pressure and smoking [2, 4]. Although the study group performed slightly better than the control group, more vigorous management programmes are needed to reduce the number of cardiovascular risk factors. As with the management of hyperglycaemia, a protocolized stepwise treatment scheme based upon accepted guidelines for the management of dyslipidaemia and hypertension may be the method of choice.

One of the remarkable findings was that general well-being did not worsen under the strict metabolic control, although insulin therapy was initiated in nearly 30 % of patients. Also, patients were satisfied with the medical care they experienced during follow-up. It is unlikely that improved glycaemic control is the only explanation for these positive answers. It is more likely that the patients appreciated the easily available diabetes control, education and consultation facilities.

The 22 GPs in the study group all responded favourably to the questions referring to co-operation with the diabetes service at the GP laboratory. In particular the assistance of the diabetes nurse educator and the consultation facilities with the diabetologist were felt as important support when transferring patients to insulin therapy.

This study clearly shows that implementation of structured care in general practice results in sustained good glycaemic control in the majority of NIDDM patients. Insulin therapy could safely be applied in primary care. In contrast, just providing laboratory results without defined therapeutic advice only resulted in a modest lowering of cardiovascular risk factors. Finally, this shared care system was well appreciated, both by patients and professionals.

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