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RESEARCH ARTICLE

The relationship between objectively measured physical activity and parameters of disease control in an African population of type 2 diabetes mellitus

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Background: The incidence of type 2 diabetes mellitus (T2DM) is increasing rapidly. This is possibly due to increasing obesity, reduced level of activity, sedentary lifestyle, ageing population and industrialisation.
Aim: The primary objective of this study was to ascertain the level of activity using a pedometer. The secondary objectives were: (1) to correlate the baseline level of activity with body mass index (BMI), $HbA1_c$ and blood pressure (BP), (2) to assess whether 7 000 steps a day influence HbA1c and BP over a three-month period.
Method: A total of 110 patients were screened; 95 patients ($n = 95$) completed the study. At the first visit HbA1c, BMI and BP were measured. At the end of the first month baseline physical activity was recorded using pedometers. Patients were divided into two groups: active ($n = 50$) and control ($n = 45$). Patients in the active group were asked to walk a minimum of 7 000 steps/day. The control group were asked to continue their usual activity. These patients were followed up monthly over a period of three months. At each visit BMI, BP and step counts were recorded. HbA1c was measured only at the first and last visit.
Result: Activity levels increased significantly in the active group throughout the study. Mean step count for the control group at baseline was 2 923.1 ± 1 136.9, which increased to 3 431.2 ± 1 251.7 by the end of the study. Mean step count for the active group at baseline was 4 609.9 ± 1 702.1, which increased to 7 244.8 ± 1 419.4 by the end of the study. The difference between control and active group was statistically significant ($p < 0.001$). Systolic and diastolic BP decreased significantly in both groups ($p = 0.017$) for systolic BP and ($p = 0.002$) for diastolic BP but no interaction was found between the groups as systolic and diastolic BP decreased at the same rate over time in both groups. HbA1c decreased by 1.04% in the active group; this difference was statistically highly significant ($p < 0.001$).
Conclusion: Increase in activity levels decreases HbA1c by 1.04 percentage point over three months in T2DM ($p < 0.001$), which is statistically significant.

Keywords: BMI, HbA1c, pedometers, physical activity, T2DM

Introduction

The incidence of type 2 diabetes mellitus (T2DM) is increasing rapidly. This is possibly due to increasing obesity, reduced level of activity, sedentary lifestyle, ageing population and industrialisation.[1]

In the USA in 2010, the prevalence of diabetes was estimated to be 0.2% in individuals aged less than 20 years and 11.3% in individuals older than 20 years.[1] Diabetes increases with age. It is the fifth leading cause of death worldwide. In 2010 about four million people died as a result of complications due to diabetes.[1]

There are three and half million South Africans with diabetes (approximately 6% of the population) and many remain undiagnosed.[2] Worldwide, more than 400 million people have diabetes. The International Diabetes Federation (IDF) has predicted that this figure will increase to 552 million by 2030.[2] It is expected that the greatest increase will be on the African continent and it is predicted that by 2030 the prevalence of diabetes in Africa will almost have doubled. Besides the important causative factors mentioned above, there is a cultural belief among most African communities that weight gain is a reflection of social achievement, well-being and honour.[2]

T2DM occurs almost exclusively in the adult population and its main feature is insulin resistance, manifested as hyperinsulinemia and hyperglycaemia. It is strongly associated with family history, obesity and physical inactivity, which accounts for 90% of all diabetes.[3] The typical patient with T2DM is sedentary, overweight and middle-aged or older.[3,4] In type 1 diabetes (T1DM) there is autoimmune destruction of the pancreas leading to a failure to secrete insulin.[3]

Regular physical activity (PA) is necessary for the prevention and management of T2DM and is associated with a lower incidence of all-cause and cardiovascular disease mortality in patients with diabetes.[5] The Diabetes Prevention Program (DPP) found that a minimum of 150 minutes/week of moderate-intensity PA, such as brisk walking, was more efficient than metformin or placebo in the prevention of T2DM in pre-diabetics.[6] Similarly, Heimrich *et al.* described an inverse relationship between energy consumption in leisure-time PA and the development of T2DM in former college students.[7]

The advantages of regular PA in diabetes are: (1) better glycaemic control, (2) weight reduction and (3) improved insulin sensitivity.[8,9] The latter is integral to the prevention of cardiovascular complications, as impaired insulin activity can lead to elevated triglycerides, reduced high-density lipoprotein cholesterol, increased secretion of very low-density lipoprotein cholesterol, and hypertension.[10]

The United Kingdom Prospective Diabetes Study (UKPDS) showed that intensive glucose control with metformin decreased glycated haemoglobin ($HbA1_c$) by 0.6%. This reduction was associated with a 32% decreased risk of diabetes-associated complications and 42% decrease in the mortality rate.[11]

There is no doubt that PA is beneficial to patients with diabetes. However, the minimum degree and frequency of activity required to achieve favourable outcomes has not been fully explained. While the Centres for Disease Control and Prevention (CDC) and the American College of Sports Medicine (ACSM) have suggested a minimum of 30 minutes of moderate-intensity PA on most days of the week,[12] Tudor-Locke *et al.* believe that walking 10 000 steps/day is effective.[13]

Even though the health benefits of moderate PA in diabetes have been established, the compliance with exercise is sadly low. Pedometers may be used as a motivational tool to encourage people with T2DM to increase their PA.

The primary objective of this study was to ascertain the level of activity using a pedometer. The secondary objectives were: (1) to correlate the baseline level of activity with body mass index (BMI), $HbA1_c$ and blood pressure (BP), (2) to assess whether 7 000 steps a day influence HbA1c and BP over a three-month period.

Method

A prospective observational study was conducted at the diabetic clinic at Chris Hani Baragwanath Academic Hospital from August 2015 to January 2016. The study was aimed at African male and female diabetic patients between the ages of 18 and 65 years attending the diabetic clinic. This study was approved by Wits Human Research Ethics committee. Inclusion criteria:

(1) T2DM; 18–65 years old;
(2) Signed consent;
(3) Patient having HbA1c measured as standard care in the clinic.

Patients with T1DM and patients having any disability that may affect walking such as amputation of a leg were excluded from the study. A sample size of 75 was obtained using mean change and standard deviation in HbA1c for the intervention and control groups at the 5% significance level and 80% power.[14] However, the sample size was increased to 110 to account for the maximum number of variables that may be included in regression analysis. A sample size of 15 is required for each variable added to the model. Patients were screened randomly from the diabetic clinic over a period of two months from July 2015 to September 2015 and were further followed up for a total period of four months. Ninety-five patients completed the study. Health variables such as bodyweight in kilograms (kg) and height in metres were measured with patients wearing light clothing and no shoes. BP was measured in a sitting position with a Welch Allyn monitor (Welch Allyn Inc, Skaneateles Falls, NY, USA). HbA1c was measured on a DCA Vantage analyser (Siemens, Erlangen, Germany).

At the first visit, patients were informed about the study and were given an information sheet containing a brief description of the study. All patients enrolled in the study were given a multi-function pedometer and a step-count log.

Patients were advised to wear the pedometer throughout the day with an exception during sleeping and bathing, and the number of steps were recorded every evening before sleeping.

Baseline activity was ascertained at the end of the first month, after which the participants were divided into two groups, active and control.

Participants with a higher step count in the first month and those willing to increase their steps to 7 000 per day were included in the active group; the rest were in the control group. Participants in the active group were given a plan to increase their daily physical activity by starting regular morning or evening walking, to participate in sporting activity, to join an exercise club or even to join the gym if possible. The control group were asked to continue their usual activity and to log their steps. Both groups were followed up for the next three months. At each visit the patient's BP and weight were recorded, and a new step log issued. HbA1c was only measured at the first visit and last visit.

Statistical methods

IBM SPSS® version 23 (IBM Corp, Armonk, NY, USA) was used to analyse the data. A p-value < 0.05 was considered as statistically significant. Categorical variables were compared between the two groups using Pearson's chi-square test. Independent samples t-tests were used to compare normal continuous variables between the two groups. Pearson's correlation coefficient was used to assess the strength of relationships between continuous variables. Repeated measures ANOVA testing was used to assess changes over time within and between groups. A time x group interaction that was statistically significant indicated a treatment effect. Profile plots were used to show the direction and trends of the effects over time between the groups.

Results

Demographics

Ninety-five participants were analysed. Their age and gender by group are given in Table 1 below. There was no difference between the groups in term of age and gender. Mean age for the control group was 54.1 years compared with 55.2 years for the active group.

The primary objective was to ascertain the level of activity using a pedometer. There was a significant difference in step counts at baseline between the two groups. The difference in step counts between males and females, and between different age groups, in the two arms were not significant, except in the control group

Table 1: Demography

Factor			Study arms		p-value
			Control	Active	
Gender	Male	*n*	14	17	0.764
		n, %	31.1%	34.0%	
	Female	*n*	31	33	
		n, %	68.9%	66.0%	
Age	*n*		45	50	
	Mean		54.1	55.2	0.468
	Standard deviation		7.4	6.9	

Table 2: Average step counts between males and females in the two groups

		Study arms					
		Control			Active		
		Gender			Gender		
Average steps		Male	Female	*p*-value	Male	Female	*p*-value
Month 1	Mean	3 357.8	2 726.8	0.085	4 681.8	4 572.8	0.833
	Standard deviation	1 001.9	1 154.5		1 530.4	1 805.8	
Month 2	Mean	3 551.6	3 067.5	0.139	6 058.7	6 598.9	0.134
	Standard deviation	876.3	1 044.3		1 131.5	1 211.7	
Month 3	Mean	3 721.9	3 013.8	0.045	7 121.3	6 859.5	0.452
	Standard deviation	1 159.3	1 023.5		1 347.6	1 046.9	
Month 4	Mean	3 781.4	3 273.0	0.211	7 134.7	7 301.5	0.698
	Standard deviation	949.9	1 350.4		1 273.6	1 504.7	

Table 3: Average step counts between different age groups in the two arms

		Study arms						
		Control			*p*-value	Active			
		Age group				Age group			
Average steps		≤ 50	51–60	> 60		≤ 50	51–60	> 60	*p*-value
Month 1	Mean	3 163.2	2 762.5	2 863.8	0.599	5 170.6	4 690.6	3 799.9	0.146
	Standard deviation	1 031.7	1 197.1	1 215.1		1 567.1	1 884.1	1 071.9	
Month 2	Mean	3 294.9	3 042.8	3 385.2	0.630	6 604.7	6 466.9	6 081.8	0.560
	Standard deviation	811.8	1 004.5	1 264.9		675.5	1 510.0	686.6	
Month 3	Mean	3 108.1	3 162.7	3 498.6	0.630	7 256.3	6 945.6	6 619.7	0.424
	Standard deviation	852.8	1 170.1	1 318.0		805.5	1 189.4	1 365.9	
Month 4	Mean	3 411.4	3 317.6	3 626.1	0.809	7 481.0	7 005.4	7 574.5	0.437
	Standard deviation	1 371.8	1 247.5	1 184.6		1 074.1	1 119.4	2 236.8	

at month 3 there was a significant difference between male and female steps ($p = 0.045$) (Tables 2 and 3).

Table 4 shows the mean number of steps measured at each time point using a pedometer by study arms. Mean step count for the control group was 2 923.1 ± 1 136.9 steps compared with 4 609.9 ± 1 702.1 steps for the active group at baseline which increased to 3 431.2 ± 1 251.7 steps and 7 244.8 ± 1 419.4 steps respectively at the end of the study. The difference was highly statistically significant at all time points ($p < 0.001$), with the active group taking significantly more steps than the control group.

The secondary objective was to correlate the baseline level of activity with BMI, HbA1c and BP.

There was no significant difference between the active and control groups in terms of baseline outcomes. Mean BMI for the control group was 33.93 ± 5.84 kg/m^2 compared with 32.60 ± 6.92 kg/m^2 for the active group ($p = 0.317$). Similarly mean HbA1c for the control group was 9.85 ± 2.38% compared with 9.86 ± 2.40% for the active group ($p = 0.989$) (Table 5).

There was also no correlation between average number of steps at baseline and BMI, systolic BP (SBP), diastolic BP (DBP) or HbA1c (Table 6).

The other secondary objective was to assess whether 7 000 steps a day influence HbA1c and BP over a three-month period.

HbA1c

1. To assess whether being in the active group versus the control group influences HbA1c over a three-month period

There was a highly significant interaction between time and treatment group ($p < 0.001$), indicating that the two study arms did not behave in the same way over time for HbA1c.

Table 4: Mean step counts from month 1 to month 4

	Study arms					
	Control			Active		
Average steps	*n*	Mean	Standard deviation	*n*	Mean	Standard deviation
Month 1	45	2 923.1	1 136.9	50	4 609.9	1 702.1
Month 2	45	3 218.1	1 010.8	50	6 415.2	1 201.5
Month 3	45	3 234.1	1 105.1	50	6 948.5	1 150.9
Month 4	45	3 431.2	1 251.7	50	7 244.8	1 419.4

Table 5: Baseline BMI, HbA1c and blood pressure

Group statistics						
Baseline	**Study arms**	***n***	**Mean**	**Std deviation**	**Std error mean**	***p*-value**
Weight (kg)	Control	45	89.076	16.0405	2.3912	0.264
	Active	50	85.248	17.0379	2.4095	
BMI (kg/m^2)	Control	45	33.934	5.8443	0.8712	0.317
	Active	50	32.603	6.9276	0.9797	
HbA1c %	Control	45	9.8573	2.38969	0.35623	0.989
	Active	50	9.8640	2.40508	0.34013	
SBP (mmHg)	Control	45	147.16	19.454	2.900	0.694
	Active	50	148.90	23.211	3.283	
DBP (mmHg)	Control	45	85.58	10.319	1.538	0.906
	Active	50	85.84	11.164	1.579	

Table 6: Correlation of baseline activity with BMI, HbA1c and BP

Baseline		**Average steps 1**
BMI (kg/m^2)	Pearson correlation	0.014
	Sig. (2-tailed)	0.891
	n	95
SBP (mmHg)	Pearson correlation	0.106
	Sig. (2-tailed)	0.307
	n	95
DBP (mmHg)	Pearson correlation	0.074
	Sig. (2-tailed)	0.476
	n	95
HbA1c (%)	Pearson correlation	–0.103
	Sig. (2-tailed)	0.322
	n	95

Figure 1 shows that the active arm reduced their HbA1c over the two time-points while the control arm increased.

The change in HbA1c and BMI over the three-month period was calculated and compared between the treatment groups. The HbA1c change on average was 0.86% increase in the control arm and 1.04% decrease in the active arm. This was highly a significantly different between the arms ($p < 0.001$) The BMI change was positive for both groups and was not different between the arms (Table 7).

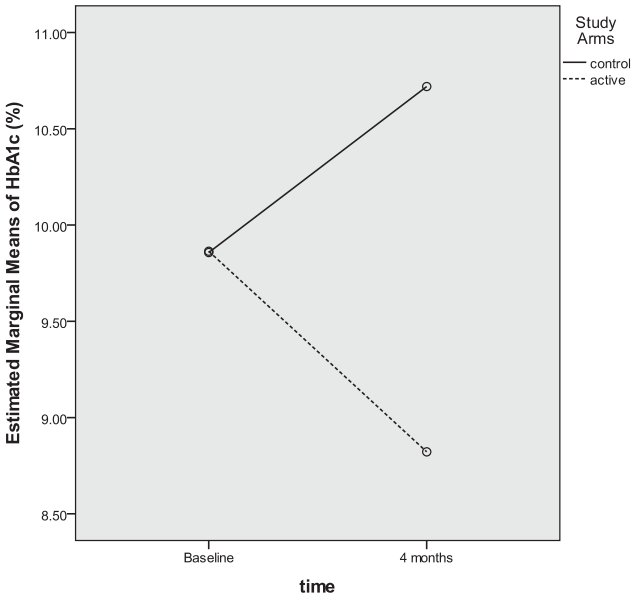

Figure 1: Estimated marginal means of HbA1c over a four-month period in the control and active arms.

Blood pressure

2.To assess whether being in the active group versus the control group influences BP over a three-month period

When comparing SBP between the two arms, there was no interaction between time and study arm for SBP ($p = 0.866$), meaning that the SBP changed at the same rate over time in both groups. There was a significant time effect ($p = 0.017$), meaning that there was a general decrease in SBP over time. Figure 2 shows this decrease in both groups over time.

There was no interaction between time and study arm for DBP ($p = 0.331$), meaning that the DBP changed at the same rate over time in both groups. There was a significant time effect ($p = 0.002$), meaning that there was a general decrease in DBP over time. Figure 3 shows this decrease over time in the two groups.

In both groups there was a weak negative correlation between change in steps and change in HbA1c, meaning that as the steps increased the HbA1c decreased (as in the active group) or that as the steps decreased, HbA1c increased (as in the control group).

However, the change in steps in the control group over the entire study period was much lower than the change in steps in the active arm (mean = 508 in control and 2 634 in the active arm). Similarly, the change in HbA1c was positive (i.e. an increase) in the control arm (mean = 0.8622) and negative in the active arm (i.e. a decrease) (mean = –1.042). Figure 4 explains this phenomenon—the control arm (white circles) were mainly above the horizontal line meaning they increased in HbA1c, and most of the white circles are in the right-hand box meaning they increased in steps. The few in the left-hand block are influencing the relationship (correlation) to be negative, i.e. they increased HbA1c while decreasing steps. In contrast, the active group are mainly in the lower right-hand quadrant, which shows that they decreased HbA1c while increasing steps.

Discussion

There was a significant difference in step counts at baseline between the two groups. Although most of the patients in the

Table 7: Change in HbA1c and BMI over three-month period

Group statistics						
Change	**Study arms**	***n***	**Mean**	**Std deviation**	**Std error mean**	***p*value**
HbA1c (%)	Control	45	0.8622	1.12337	0.16746	< 0.001
	Active	50	−1.0420	1.27633	0.18050	
BMI (kg/m^2)	Control	45	.2170	0.90158	0.13440	0.611
	Active	50	0.1209	0.93103	0.13167	

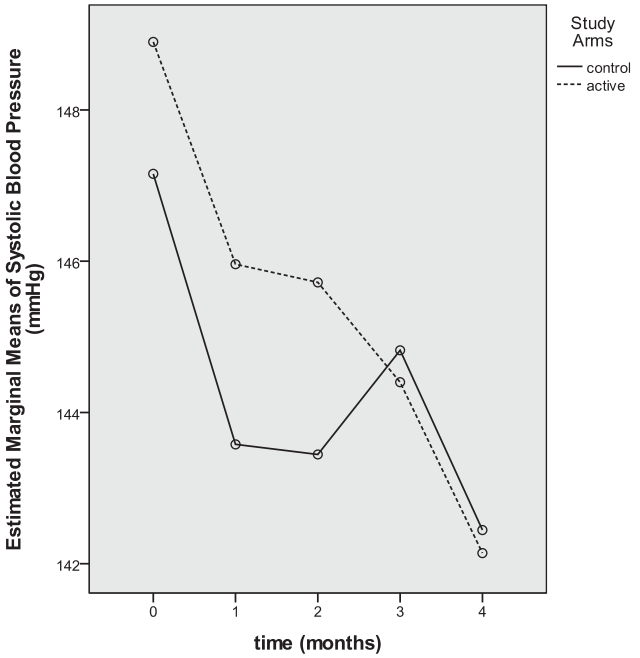

Figure 2: Estimated marginal means of SBP between the two arms.

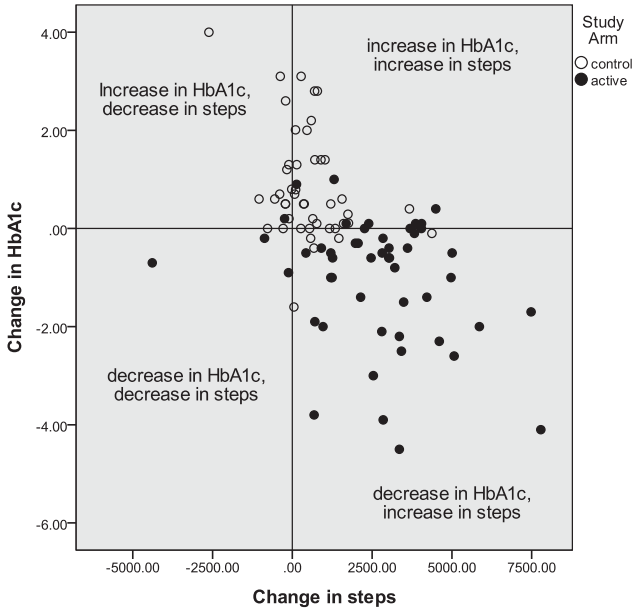

Figure 4: Correlation between change in steps and change in HbA1c.

active group were more active at baseline but their physical activity increased significantly throughout the study, pedometer-based motivation had a significant impact on step counts in the active group (Table 4).

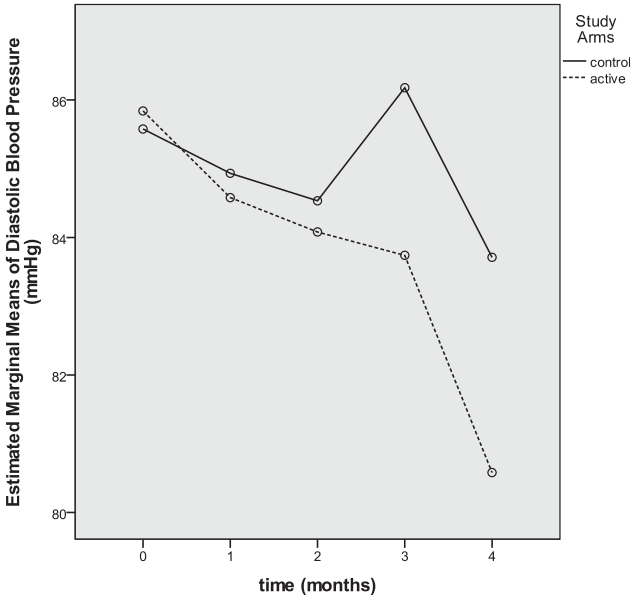

Figure 3: Estimated marginal means of DBP between the two arms.

There was also no significant difference in BMI, HbA1c and BP between the two groups at baseline (Table 5). We did not find any correlation between average number of steps at baseline and BMI, SBP, DBP or HbA1c (Table 6).

There was a significant decrease in SBP and DBP in both groups during the course of study, but no interaction was found between the groups as SBP and DBP decreased at the same rate in both groups over this time period. The active group had a greater trend in a decrease in DBP as compared with the control, but this difference was not statistically significant, as depicted in Figures 2 and 3 respectively.

The HbA1c changed significantly over the course of three months in the active group. On average, the HbA1c increased by 0.86 percentage points in the control group and decreased by 1.04 percentage points in the active group, which was highly significant ($p < 0.001$) (Table 7). The increase in physical activity to 7 000 steps per day had a significant effect on HbA1c. This decrease in HbA1c is higher than the decrease shown in the metformin arm of the UKPDS, a decrease of HbA1c by 0.6 percentage points.[11] The UKPDS was associated with a 32% decrease risk of diabetes-associated complications and a 42% decrease in mortality.[11]

Our study differs from a pedometer-based behavioural modification programme in T2DM patients, where 92 patients with T2DM patients that were enrolled from Ghent University Hospital showed no noticeable immediate or short-term disparities in

health outcomes between the control and intervention group. But the study highlighted an important threshold of ≥ 4 000 steps/days to influence HbA1c.[14]

Our results confirm that community or clinic-based PA programmes may be employed as a useful strategy for management of T2DM. Our study's results are more favourable than a meta-analysis by Plotnikoff *et al*., where community-based PA programmes were associated with a reduction in HbA1c of 0.32% ($p = 0.06$).[15] Their research was organised in various countries that included various ethnic and cultural groups. Most of the research (16/22) in this meta-analysis comprised randomised control trials. These studies across various ethnic and cultural groups demonstrated that community- based programmes using PA as a main component can effectively decrease HbA1c level, reduce weight and increase PA levels. If our study was conducted over a longer duration, we might have shown a decrease in weight and/or BMI. This study is also limited by small numbers and lack of a prescribed plan to achieve a target of 7 000 steps/day.

Conclusion

This study demonstrates that even in sedentary diabetic populations a passive, inexpensive tool such as a pedometer may positively influence PA to significantly achieve a meaningful reduction in HbA1c of 1.04% ($p < 0.001$) without much effort or motivation on the part of healthcare providers. This could translate to other tools that could measure step counts, e.g. cell phones or watches.

We suggest that a study like this could be conducted over a longer period of time to gauge any positive benefit on metabolic parameters such as BP and weight, and to see if the PA and change in metabolic parameters are sustainable.

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