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## RESUMPTION OF DRIVING AFTER LIFE-THREATENING VENTRICULAR TACHYARRHYTHMIA

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### ABSTRACT

**Background** Although the privilege of driving must be respected, it may be necessary to restrict driving when it poses a threat to others. The risks associated with allowing patients with life-threatening ventricular tachyarrhythmias to drive have not been quantified.

**Methods** The Antiarrhythmics versus Implantable Defibrillators (AVID) trial compared antiarrhythmic-drug therapy with the implantation of defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. In the current study, we sent patients who participated in the AVID trial a questionnaire, to be completed anonymously, requesting information about driving habits and experiences.

**Results** The questionnaire was returned by 758 of 909 patients (83 percent). Of these, 627 patients drove during the year before their index episode of ventricular tachyarrhythmia. A total of 57 percent of these patients resumed driving within 3 months after randomization in the AVID trial, 78 percent within 6 months, and 88 percent within 12 months. While driving, 2 percent had a syncopal episode, 11 percent had dizziness or palpitations that necessitated stopping the vehicle, 22 percent had dizziness or palpitations that did not necessitate stopping the vehicle, and 8 percent of the 295 patients with an implantable cardioverter-defibrillator received a shock. Fifty patients reported having at least 1 accident, for a total of 55 accidents during 1619 patient-years of follow-up after the resumption of driving (3.4 percent per patient-year). Only 11 percent of these accidents were preceded by symptoms of possible arrhythmia (0.4 percent per patient-year).

**Conclusions** Most patients with ventricular tachyarrhythmias resume driving early. Although it is common for them to have symptoms of possible arrhythmia while driving, accidents are uncommon and occur with a frequency that is lower than the annual accident rate of 7.1 percent in the general driving population of the United States. (N Engl J Med 2001;345:391-7.)

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THE privilege of driving an automobile is highly cherished. Indeed, many people consider it not a privilege but a basic right. Nevertheless, driving privileges must be given only to citizens whose capacity for driving does not pose an excessive threat to themselves or others. Although sudden incapacitation resulting from medical illness is the cause of less than 1 percent of all motor vehicle accidents,<sup>1,2</sup> these accidents are potentially preventable by the restriction of the driving privileges of persons at high risk for such illnesses.<sup>3-5</sup> Most cardiovascular causes of sudden incapacitation are related to cardiac arrhythmias.<sup>6-12</sup> Nevertheless, in 1991, only 8 of the 50 U.S. states had specific guidelines for granting driving privileges to patients with cardiac arrhythmias, and none had guidelines for patients with an implantable cardioverter-defibrillator.<sup>12</sup>

The relative absence of specific driving guidelines for patients with arrhythmias is due, in part, to the paucity of data regarding the risk of allowing such patients to drive. Accordingly, the default recommendation by physicians has often been that such patients should give up their driving privileges.<sup>12-15</sup> However, many patients refuse to comply with this recommendation and continue to drive.<sup>16,17</sup> This population of patients can thus be followed to determine the risks related to their driving.<sup>15-17</sup> Previous attempts to do so have been limited by small numbers of patients and by the probability that patients will respond dishonestly to direct questions regarding their driving habits. Despite these weaknesses, data from such studies have contributed to the development of guidelines for granting or withholding driving privileges in Britain,<sup>18</sup> Canada,<sup>19</sup> and the United States.<sup>20</sup>

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The purpose of the present study was to gather prospective, anonymous data regarding driving habits and experiences from the large population of patients with ventricular tachyarrhythmias who were enrolled in the Antiarrhythmics versus Implantable Defibrillators (AVID) trial.<sup>21</sup> The AVID trial compared antiarrhythmic-drug therapy with the implantation of defibrillators in patients who had been resuscitated from near-fatal ventricular arrhythmias.

## METHODS

### Study Population

We invited patients in the AVID trial to complete questionnaires anonymously about their driving habits and experiences; these questionnaires were to be returned directly to the coordinating center for the study, and the respondents were assured of anonymity. The initial questionnaire (18 questions) was completed a median of 9 months (range, 1 to 55) after the patients had been enrolled in the original trial. Subsequent questionnaires (14 questions each) were administered every six months to patients who indicated, on the initial questionnaire, that they had been driving during the year before they had been enrolled in the trial. The driving substudy was approved by the institutional review boards at each site, and written informed consent was obtained from each participant in the AVID trial. Study participants were recruited between June 1, 1993, and April 7, 1997.

### Statistical Analysis

Continuous variables were compared by means of Student's *t*-test, and categorical variables were compared by means of the chi-square test or the paired-sign test, as appropriate. Statistical significance was indicated by a two-tailed *P* value of less than 0.05. Each reported motor vehicle accident was assigned a date midway between the date of the questionnaire on which the accident was reported and the date of the previous questionnaire or the resumption of driving, whichever was more recent. Univariate predictors of a motor vehicle accident were entered into a Cox proportional-hazards model to identify independent predictors of risk. The length of time after the index episode of ventricular arrhythmia during which each patient did not drive was then entered into the model to assess its association with the risk of a motor vehicle accident.

## RESULTS

### Study Population

Of the 1016 patients enrolled in the AVID trial, 107 (11 percent) died before the initial driving questionnaire was sent. Of the remaining 909 patients, 758 patients (83 percent) completed the initial questionnaire. Three statistically significant predictors of response were identified. As compared with the patients who did not respond to the questionnaire, those who did respond were less likely to be of a minority race (11 percent, as compared with 21 percent of those who did not respond;  $P=0.005$ ), were less likely to have had congestive heart failure (42 percent vs. 52 percent,  $P=0.04$ ), and were more likely to have had coronary-artery bypass surgery (31 percent vs. 20 percent,  $P=0.02$ ). Those who did not respond were similar to those who did respond in terms of age (a mean age of 64 years among those who did not respond, as compared with 65 years among those who did), sex (77 percent male vs. 80 percent male), left ven-

tricular ejection fraction (a mean of 0.32 in both groups), and treatment assignment in the AVID trial (50 percent vs. 52 percent assigned to receive an implantable cardioverter-defibrillator).

Of the 758 patients who responded to the initial questionnaire, 627 (83 percent) indicated that they were driving during the year before their enrollment in the original trial and are therefore the focus of this report. This cohort included 537 men and 90 women with a mean ( $\pm$ SD) age of  $64.5\pm 10.1$  years.

The rates of response to follow-up questionnaires remained high. A total of 84 percent of the patients returned the first follow-up questionnaire, 75 percent returned the second, 74 percent returned the third, 79 percent returned the fourth, and 81 percent returned the fifth.

### Driving Advice

Of the 627 study patients, 403 (64 percent) reported that their physicians had discussed when they could resume driving. According to the patients' reports, 74 percent of these recommendations included a specific period during which driving was proscribed — most commonly 6 to 11 months (Table 1). There was no significant difference between the AVID treatment groups in the proportions of patients who were told not to resume driving immediately (75 percent of those assigned to receive antiarrhythmic drugs vs. 80 percent of those assigned to receive an implantable cardioverter-defibrillator,  $P=0.26$ ). Of these patients, 59 percent reported that being unable to drive constituted a severe hardship; 35 percent of those who resumed driving reported that their household included no other drivers.

### Driving Habits

Of the 627 study patients, 57 percent had resumed driving within 3 months, 78 percent within 6 months, and 88 percent within 12 months after randomization in the AVID trial (Fig. 1). The most common reason given for not having resumed driving (in 79 percent of patients) was a restriction by the physician.

Of the 500 patients who had resumed driving before receiving the initial questionnaire, 63 percent reported driving the same amount as they had in the previous year, 34 percent reported driving less, and 3 percent reported driving more. Ninety-one percent reported driving at least once a week, and 57 percent reported driving every day. Forty-six percent were driving less than 80 km (50 miles) a week, and 25 percent were driving more than 160 km (100 miles) a week. The patients who resumed driving drove more on residential roads than on rural roads, urban roads, or highways ( $P<0.001$  for all comparisons) (Table 2). However, 86 percent drove on highways some of the time. More patients drove for leisure purposes and to run errands than because of job requirements ( $P<0.001$  for both comparisons).

**TABLE 1.** RECOMMENDATIONS BY PHYSICIANS REGARDING DRIVING, AS REPORTED BY PATIENTS.\*

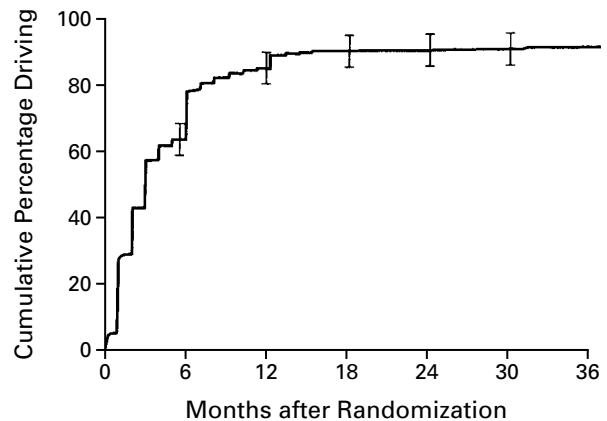
RECOMMENDED TIME TO RESUME DRIVING AFTER AN EPISODE OF VENTRICULAR TACHYARRHYTHMIA	PATIENTS REPORTING RECOMMENDATION (N=403) no. (%)
<1 mo	36 (9)
1–2 mo	64 (16)
3–5 mo	53 (13)
6–11 mo	102 (25)
≥12 mo	27 (7)
At patient's discretion	20 (5)
Immediately, but with restrictions	22 (5)
After a reasonable period	16 (4)
Other	14 (3)
Left blank or not categorized	31 (8)
Never	18 (4)

\*Data are for the 403 patients who reported that their physicians had discussed when they could resume driving.

#### Events That Occurred while Patients Were Driving

Of the 627 study patients, 563 (90 percent) reported having resumed driving. A total of 559 of these patients (99 percent) responded to questions regarding possible arrhythmia-related symptoms that occurred while they were driving. Two percent reported that they had lost consciousness while driving, 11 percent reported dizziness or palpitations that necessitated stopping the automobile, and 22 percent reported dizziness or palpitations that did not necessitate stopping the automobile (Table 3). Ten percent of these patients did not answer one or more of these questions on at least one follow-up questionnaire. Of the 295 patients who had resumed driving after having received an implantable cardioverter–defibrillator, 8 percent reported receiving a shock while driving — 6 percent received a shock once, 1 percent twice, and 1 percent three times. A total of 13 percent of the patients who had resumed driving after having received an implantable cardioverter–defibrillator did not answer the question about shocks on at least one follow-up questionnaire.

Fifty of the 559 patients who responded to questions regarding automobile accidents reported having had at least 1 motor vehicle accident (9 percent; 95 percent confidence interval, 6.5 to 11.3 percent), for a total of 55 accidents during a mean follow-up period of 35 months (1619 patient-years after driving resumed). These accidents were preceded by symptoms of possible arrhythmia in 6 of the 55 cases (11 percent; 95 percent confidence interval, 2.5 to 19.7 percent) — loss of consciousness in 3 instances, dizziness in 1, palpitations in 1, and both dizziness and



**Figure 1.** Kaplan–Meier Estimate of the Cumulative Probability of Resumption of Driving after Randomization in the AVID Trial. The I bars represent the 95 percent confidence limits.

**TABLE 2.** DRIVING ENVIRONMENTS.\*

FREQUENCY OF USE	RURAL (N=453)	RESIDENTIAL (N=476)	URBAN (N=458)	HIGHWAY (N=473)
number of patients (percent)				
Never	81 (18)	3 (1)	40 (9)	68 (14)
Sometimes	254 (56)	189 (40)	264 (58)	295 (62)
Most of the time	73 (16)	193 (41)	110 (24)	79 (17)
All of the time	45 (10)	91 (19)	44 (10)	31 (7)

\*Data are for the 500 patients who had resumed driving before receiving the initial questionnaire. Different numbers of patients answered questions about different environments.

**TABLE 3.** SYMPTOMS OF POSSIBLE ARRHYTHMIA THAT OCCURRED WHILE PATIENTS WERE DRIVING.\*

NO. OF EVENTS	SYNCOPE (N=557)	DIZZINESS OR PALPITATIONS NECESSITATING STOPPING (N=556)	DIZZINESS OR PALPITATIONS NOT NECESSITATING STOPPING (N=554)
		number of patients (percent)	
0	546 (98)	495 (89)	430 (78)
1	7 (1)	27 (5)	43 (8)
2	1 (<1)	12 (2)	21 (4)
>2	3 (1)	22 (4)	60 (11)

\*Data are for the 559 patients who reported having resumed driving and who answered questions regarding possible arrhythmia-related symptoms that occurred while they were driving. Different numbers of patients answered questions about different symptoms.

palpitations in 1. None of these accidents were preceded by the driver's receipt of a shock from an implantable cardioverter-defibrillator. There was no difference between the frequency of motor vehicle accidents among the patients who had been assigned to receive antiarrhythmic-drug therapy and that among the patients assigned to receive an implantable cardioverter-defibrillator. No patient in the study died because of an automobile accident.

The annual risk of a motor vehicle accident in these patients was 3.4 percent (95 percent confidence interval, 2.5 to 4.3 percent), and the annual risk of a motor vehicle accident that was presumed to be related to arrhythmia was 0.4 percent (95 percent confidence interval, 0.1 to 0.7 percent). By comparison, 6.2 percent of these patients reported having had a motor vehicle accident during the year before their enrollment in the trial. Thus, the annual rate of motor vehicle accidents among the study patients was 1.8 times as high (95 percent confidence interval, 1.2 to 2.8 times) before the index episode of ventricular tachyarrhythmia as it was after the episode.

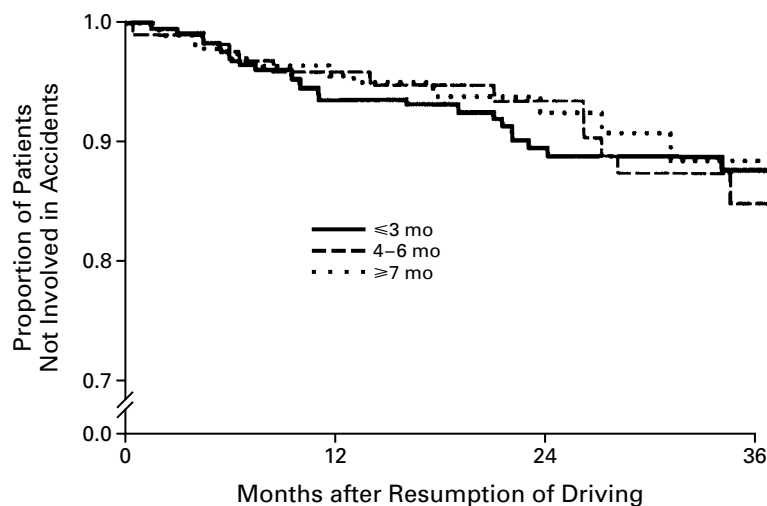
Potential predictors of motor vehicle accidents during follow-up (age, sex, race, a history of motor vehicle accidents, and a history of congestive heart failure) were evaluated with Cox regression analysis. The only independent predictor of a motor vehicle accident during follow-up was a history of a motor vehicle accident in the year before the patient's enrollment in the trial. The relative risk associated with a

history of a motor vehicle accident was 3.75 (95 percent confidence interval, 1.74 to 8.11;  $P < 0.001$ ). The duration of abstinence from driving was then entered into the final Cox model and had no significant effect on its predictive accuracy. The relative risk associated with the duration of abstinence from driving was 0.97 (95 percent confidence interval, 0.88 to 1.07;  $P = 0.53$ ). The probability of having a motor vehicle accident remained constant over time and was not associated with the duration of abstinence from driving (Fig. 2).

**Sensitivity Analysis**

A total of 151 (17 percent) of the 909 patients to whom the initial questionnaire was sent did not return it. Of the 758 patients who initially responded, 563 indicated both that they had been driving during the year before their enrollment in the trial and that they had resumed driving after their episode of ventricular tachyarrhythmia. Of these, 58 (10 percent) did not answer a question related to motor vehicle accidents on at least one follow-up questionnaire (although only 4 patients never responded to this question). To evaluate the potential effects of these missing data on the conclusions suggested by the data we did collect, a sensitivity analysis was performed.

The study coordinators at each site prospectively recorded the opinion they had formed about each patient's driving status on the basis of conversations and nonverbal clues. These opinions were highly cor-



NO. OF PATIENTS				
Abstained ≤3 mo	269	228	143	69
Abstained 4-6 mo	128	100	64	24
Abstained ≥7 mo	162	123	68	23

**Figure 2.** Kaplan-Meier Estimate of the Probability of Not Being Involved in a Motor Vehicle Accident among Patients Who Resumed Driving after Randomization in the AVID Trial, Stratified According to the Time of Resumption of Driving.

related with the self-reports of the patients, with a correlation coefficient of 0.85.<sup>22</sup> The opinions of the study coordinators indicated that 65 of the 151 patients who did not respond to the initial questionnaire had resumed driving. The annual rate of motor vehicle accidents in the study population was then recalculated 11 times, each time under the assumption that a different proportion of these 65 patients had had an accident (Table 4). The lower 95 percent confidence limit for the recalculated annual rate of motor vehicle accidents did not exceed the annual rate of motor vehicle accidents in the general population of the United States (7.1 percent)<sup>23</sup> or the annual rate of motor vehicle accidents among the same patients in the year before their enrollment in the trial (6.2 percent), even when it was assumed that 100 percent of these 65 patients had had an accident.

Identical results were obtained from a similar analysis of the 58 patients who responded to the initial questionnaire but did not answer the question regarding a motor vehicle accident (Table 4). Furthermore, an analysis that took into account the combined group of 123 patients with missing data about accidents showed that the lower 95 percent confidence limit for the recalculated annual rate of motor vehicle accidents did not exceed the annual rate of motor vehicle accidents in the general population of the United States (7.1 percent)<sup>23</sup> or the annual rate of motor vehicle accidents among the same patients in the year before their enrollment in the AVID trial (6.2 percent) unless 80 percent or more of the patients who did not respond were assumed to have had an accident (Table 4).

## DISCUSSION

In this study, 57 percent of patients resumed driving within three months after having a life-threatening episode of ventricular tachyarrhythmia, and 78 percent resumed driving within six months after such an episode. Nearly two thirds of these patients reported driving the same amount as they did before their episode of tachyarrhythmia, and they did so whether or not they were advised by their physicians not to do so. Although symptoms suggestive of tachyarrhythmia occurred frequently while the patients were driving, such symptoms were unlikely to lead to a motor vehicle accident. Finally, the probability of having a motor vehicle accident was low and was independent of the duration of abstinence from driving.

Previous reports<sup>16,17</sup> addressing the driving experiences of patients with ventricular tachyarrhythmias focused on small populations of patients (fewer than 100 patients) with implantable cardioverter-defibrillators. These reports suggested that patients frequently ignore driving restrictions and resume driving soon after the index episode of tachyarrhythmia. Our report supports these results. Previous reports involved too few patients to make accurate estimates of the prob-

**TABLE 4.** SENSITIVITY ANALYSIS SHOWING THE EFFECT ON THE ANNUAL RATE OF MOTOR VEHICLE ACCIDENTS OF ASSUMING VARIOUS ACCIDENT RATES FOR PATIENTS WITH MISSING DATA.

ASSUMED ACCIDENT RATE IN SUBGROUP (%)	RESULTING ACCIDENT RATE FOR ALL PATIENTS		
	PATIENTS WHO DID NOT RESPOND TO QUESTIONNAIRE BUT WERE THOUGHT TO BE DRIVING (N=65)	PATIENTS WHO DID NOT ANSWER QUESTIONS ABOUT ACCIDENTS (N=58)	BOTH TYPES OF PATIENTS (N=123)
percent (95 percent confidence interval)			
0	3.4 (2.5–4.3)	3.4 (2.5–4.3)	3.4 (2.5–4.3)
10	3.4 (2.6–4.3)	3.4 (2.6–4.3)	3.4 (2.6–4.2)
20	3.8 (2.9–4.7)	3.7 (2.9–4.6)	4.1 (3.2–4.9)
30	4.1 (3.2–5.1)	4.1 (3.1–5.0)	4.7 (3.7–5.6)
40	4.5 (3.5–5.5)	4.4 (3.4–5.3)	5.3 (4.3–6.3)
50	4.9 (3.9–5.8)	4.7 (3.7–5.7)	5.9 (4.9–7.0)
60	5.2 (4.2–6.2)	5.0 (4.0–6.1)	6.6 (5.5–7.6)
70	5.6 (4.5–6.6)	5.4 (4.3–6.4)	7.2 (6.0–8.3)
80	5.9 (4.8–7.0)	5.7 (4.6–6.8)	7.8 (6.6–9.0)
90	6.3 (5.2–7.4)	6.0 (4.9–7.1)	8.4 (7.2–9.7)
100	6.7 (5.5–7.8)	6.3 (5.2–7.5)	9.1 (7.8–10.3)

ability of motor vehicle accidents. Nevertheless, they suggested that this probability was low. Our report estimates this probability to be one accident for every 29 patient-years of follow-up, for an annual 3.4 percent probability of a motor vehicle accident. This probability is lower than the 7.1 percent annual probability of a motor vehicle accident for all drivers in the United States<sup>23</sup> and lower than the 4.9 percent annual probability for the subgroup of drivers with the same age and sex distribution as the study population.<sup>23</sup>

Eleven percent of the motor vehicle accidents in our study were preceded by symptoms suggestive of an episode of tachyarrhythmia, yielding a 0.4 percent annual probability of an accident that may be attributable to incapacitation related to arrhythmia. Although none of the patients died after a motor vehicle accident, the power of this study is limited with respect to the estimation of the probability of events with very low frequency.

Despite the low probability of a motor vehicle accident, symptoms that could result in sudden incapacitation occurred relatively frequently. The disparity between the frequency of symptoms of possible arrhythmia and that of consequent motor vehicle accidents indicates that most patients were able to maintain control of their vehicles. This observation is consistent with estimates in previous studies that the incapacitation of a driver for medical reasons results in a motor vehicle accident only 50 percent of the

time,<sup>24-28</sup> an accident that causes injury only 2 percent of the time,<sup>24-28</sup> and an accident that causes death only 0.3 percent of the time.<sup>24-28</sup>

Our study found no evidence of a relation between the duration of abstinence from driving after an episode of ventricular tachyarrhythmia and the risk of a motor vehicle accident. Accordingly, these data do not support the temporary restriction of driving in this setting. Instead, these data support either permitting the early resumption of driving or the permanent proscription of driving. In conjunction with the low risk of a motor vehicle accident in this population of patients, the data support a policy of allowing patients with treated ventricular tachyarrhythmias to drive as soon as their associated medical conditions permit, whether they have been treated with amiodarone or with the implantation of a cardioverter-defibrillator.

The chief limitations of the study are those necessarily associated with its questionnaire-based methods and its dependence on the cooperation, understanding, truthfulness, and memory of the patients. Seventeen percent of the patients did not respond to the initial questionnaire, and 10 percent of those who did respond did not answer questions regarding automobile accidents on at least one occasion. Whether they did not answer because they considered the questions to be irrelevant since they were not driving or had not had a motor vehicle accident or because they considered the questions to be threatening because they had had a motor vehicle accident cannot be determined. To the extent that the latter was the case, we would have underestimated the true rates of events. The sensitivity analysis indicates that the vast majority of the patients who did not respond would have to have had a motor vehicle accident to invalidate the conclusions suggested by the data we did obtain. Nevertheless, the potential bias created by the selective nonresponse on the part of patients must be considered in making recommendations on the basis of the results of this study.

Another limitation of the present study is that the observations were limited to a population of patients who felt well enough to have resumed driving despite recommendations that they not do so. It is possible that patients who did not resume driving would have had a higher risk of having an accident had they resumed driving than did those who did resume driving. Finally, we did not collect data regarding injury or death in persons other than the study participants.

Shortly after the initiation of treatment for life-threatening ventricular tachyarrhythmia, most patients resume driving despite recommendations by their physicians that they refrain from doing so. Nevertheless, these patients appear to have a low risk of being in a motor vehicle accident — a risk that is not greater than that in the general driving population. The absence of a relation between the duration of abstinence

from driving and the probability of a motor vehicle accident indicates that patients who have been treated for ventricular tachyarrhythmia should be permitted to drive as soon as their associated medical conditions allow.

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