Universidade Federal de Pernambuco
Centro de Ciências Exatas e da Natureza
Centro de Informática

Bacharelado em Ciência da Computação

The impact of mobile devices in the self-management of type II diabetes: A systematic review.

Italo Macêdo do Amaral Costa

Trabalho de Graduação

Recife
13 de julho de 2010

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Trabalho apresentado ao Programa de Bacharelado em Ciência da Computação do Centro de Informática da Universidade Federal de Pernambuco como requisito parcial para obteno do grau de Bacharel em Ciência da Computação.

Orientador: *Prof. André Luís Medeiros Santos*
Co-orientador: *Prof. Magdala de Araújo Novaes*

Recife
13 de julho de 2010

Dedico este trabalho a todos os familiares, amigos, professores e companheiros de trabalho, que participaram direta ou indiretamente na minha formação. Este artefato representa uma conquista que certamente tem uma boa parcela de contribuição vinda de vocês.

Acknowledgements

I'm thankful to my parents, friends and fellows at work that participated somehow in the construction of myself as a professional and a human being. This work represents another step done in my life that certainly has a relevant contribution from you all.

Há muitos times em todos os esportes que têm grandes jogadores e nunca ganham títulos. Na maioria das vezes, esses jogadores não estão dispostos a se sacrificar pelo bem maior do time. O que é engraçado é que, no final, a falta de vontade deles de se sacrificar somente torna glórias individuais mais difíceis de alcançar. Uma coisa que eu acredito piamente é que se você conquista algo como um time, as glórias individuais vão vir por conta própria. Talento ganha jogos, mas trabalho em equipe e inteligência ganham campeonatos.

—MICHAEL JORDAN (Biografia)

Resumo

Diabetes mellitus é uma questão de saúde pública mundial. Otimizar perda de peso e atividades físicas pode evitar diversos riscos associados a obesidade.[BSG+09] Algoritmos para tratamento de diabetes existem mas parecem ser difíceis de serem seguidos pelos medicos, dado o número de pacientes, diversidade e falta de sistemas de informação para apoiar o medico nessas decisões.[Kim07] Com a impossibilidade do paciente controlar níveis de glucose, sintomas de diabetes e fatores associados através dos encontros rotineiros com especialistas, intervenções que usam dispositivos movies tem o potencial de trazer melhor qualidade de vida para o paciente.[QGBS+09] Uma Revisão sistemática de ensaios clínicos envolvendo pacientes com diabetes tipo II foi conduzida, comparando o uso de métodos tradicionais(registros em papel, dietas e protocolos) com o uso de dispositivos móveis para o autogerenciamento de diabetes tipo II. O objetivo é demonstrar métodos para o autogerenciamento que estão sendo usados atualmente no domínio da Medicina e mostrar sua efetividade quando comparada a métodos tradicionais. Buscas sistemáticas em bases científicas eletrônicas foram conduzidas(PubMed, Cochrane, Google Scholar, EMBASE, CINAHL, Web of Science) buscando ensaios clínicos envolvendo pacientes com diabetes tipo II e a utilização de dispositivos móveis. Para os estudos encontrados, dados mostrando a variação dos níveis de glicose(HbA1c, 2HPM, FPG), aderência ao novo método e descrição da população(número de pacientes, BMI médio, HbA1c médio, média de idade) foram extraídos. Médias para HbA1c tanto do grupo de controle quanto do grupo de intervenção foram comparadas a cada medição trimestral(3, 6, 9, 12 meses). Soluções em software e hardware utilizadas no domínio também foram identificadas. Como resultado da revisão sistemática, 10 ensaios clínicos de acordo com os critérios de inclusão e exclusão foram encontrados com diferentes soluções em software e hardware. Dessa forma, intervenções efetuadas através do uso de dispositivos móveis resultaram em melhorias clínicas na maioria dos estudos encontrados. Estudos confirmaram, portanto, que realmente melhores resultados são obtidos para pacientes com diabetes tipo II quando estão ativamente envolvidos no processo administrativo da doença. Quando os pacientes tomaram decisões e tiveram noção dos riscos associados, significantes melhorias no tratamento foram identificadas.

Palavras-chave: diabetes tipo II, autogerenciamento, dispositivos móveis

Abstract

Diabetes mellitus (DM) is a growing public health problem that is a worldwide epidemic. Optimizing weight loss treatment and maintenance can improve several of the obesity-related risk factors.[BSG+09] Algorithms for diabetes care to achieve near-normalization of blood glucose levels exist but may be complex and difcult for physicians to follow, given the patient load, diversity of patients seen, lack of information systems and time constraints.[Kim07] With the inability to achieve control of blood glucose levels, diabetes symptoms and diabetes-related comorbidities through routine provider visits and patient self-management, interventions that use mobile technology have the potential to improve outcomes of diabetes care.[QGBS+09] A systematic review of clinical trials with type II diabetic patients has been conducted, comparing the use of traditional methods(paper records, dietary counselling and protocols) with the use of mobile devices for the self-management of type II diabetes. Our goal is to demonstrate methods for the self-management in Type II Diabetes that are currently being used in the Medical domain and show their effectiveness when compared to traditional methods. Systematic literature searches in electronic databases(PubMed, Cochrane, Google Scholar, EMBASE, CINAHL and Web of Science.) were conducted for Randomized Controlled trials(RCTs) of type II diabetes and mobile devices. For the studies found, data regarding to the variation of glucose levels(HbA1c, 2HPM, FPG), adherence to the intervention and populations description(number of subjects, mean BMI, mean HbA1c, mean age) were extracted. Mean HbA1c levels from both intervention and control group were compared for every follow-up(3, 6, 9 and 12 months). Also, software and hardware solutions within the studies found were identified and extracted in order to provided a background of what is currently being used for the treament of type II diabetic patients. As a result of the Systematic review, 10 Randomized Controlled Trials using both previously defined inclusion and exclusion criteria were found. Also, 12 different software solutions were gathered among 3 different mobile devices, like: glucometers, pedometers, scales, fat analyzers, blood analyzers and other devices. Interventions delivered through mobile devices resulted in clinical improvements in the majority of studies included. Several studies have confirmed better outcomes for diabetic patients when they are actively involved in the administration process of the disease. So, when they take decisions and they know related risks and consequences, better outcomes are provided for them.

Keywords: type II diabetes, mobile devices, self-management.

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CHAPTER 1

Introduction

Diabetes mellitus (DM) is a growing public health problem that is a worldwide epidemic. The World Health Organization(WHO) has put the number of persons with diabetes worldwide at approximately 170 million, a figure expected to rise to 366 million by 2030.[Cam09] In 2005, WHO estimated that 1.6 billion adults worldwide were overweight and 400 million were obese. Because of this alarming state, diabetes is a major cause of mortality and morbidity due to its associated complications.

Managing diabetes and its complications is very costly, which creates a substantial burden on the healthcare economy.[Kim07] Optimizing weight loss treatment and maintenance can improve several of the obesity-related risk factors.[BSG+09] Also, many studies have demonstrated that control of hyperglycaemia may prevent, reduce or retard the risks of diabetic complications.[Kim07] Recommended practices for control of hyperglycemia include dietary and physical activity modication, weight reduction and self-monitoring of blood glucose.[FLS+08] Algorithms for diabetes care to achieve near-normalization of blood glucose levels exist but may be complex and difcult for physicians to follow, given the patient load, diversity of patients seen, lack of information systems and time constraints.[Kim07]

Health care providers (HCPs) lack time to provide the continuous patient care necessary to manage a chronic disease like diabetes. The average duration of a primary care provider (PCP) visit is 16.5 min, and the acute conditions of diabetes and related chronic conditions force PCPs to address fewer than two symptomatic problems in the visit rather than the more time-consuming management of diabetes.[QCM+08] With the inability to achieve control of blood glucose levels, diabetes symptoms and diabetes-related comorbidities through routine provider visits and patient self-management, interventions that use mobile technology have the potential to improve outcomes of diabetes care.[QGBS+09]

1.1 Mobile Devices in Healthcare

The movement of using mobile devices in healthcare is still beginning. In spite of such widespread ownership of cell phones, use of voice or text-messaging in disease management and self-care is still in its infancy. Even though some Clinical trials using cellphones are available in the literature, no relevant studies accounting for the benefits in the treatment of diabetes are found.[KBB09] No systematic review of cell phonebased interventions exists to our knowledge in published scientific literature that analyzes evidence in whether the use of cell phones and text messaging interventions improves health outcomes or processes of care, whether it is acceptable to users, and whether it is a cost-effective option.[KBB09] Thus, there are several

gaps to fulfill in the literature for the use of mobile devices in chronic diseases. In the current study though, the aim will be to evaluate the potential of mobile devices in the role of self-management of type II diabetes, infer the outcomes for the patient in this case.

1.2 Previous studies with the same topic

Several research studies have shown that various telemedicine approaches have had a positive impact on patients blood glucose control and that over these long-term approaches will result in reduction or elimination of the complications related to diabetes mellitus.[**?**] Also, studies demonstrating positive results have tested tailored messages to determine their effects on behavior changes ranging from quitting smoking and eating fruit to increasing physical activity and receiving preventive medical services.[ACR+09] A recent systematic review, ascertained that Information Technology(IT) improves the process of care for type 2 diabetics, as indicated by enhanced health care utilization.[FLS+08] In another Systematic Review, several studies with improved glycosilated haemoglobin(HbA1c) levels were identified and, consequently, clinical improvement on diabetes control has been found. All of these had a control group and were designed for self-management of diabetes using short messages that were sent to a mobile device.[KBB09] Therefore, according to all the aspects presented, there's a potential in the combination of self-management and mobile devices that should be explored and analyzed.

1.3 Objective

A systematic review of clinical trials with type II diabetic patients has been conducted, comparing the use of traditional methods(paper records, dietary counselling and protocols) with the use of mobile devices for the self-management of type II diabetes. Our goal is to demonstrate methods for the self-management in Type II Diabetes that are currently being used in the Medical domain and show their effectiveness when compared to traditional methods. Also, a current view of the literature providing softwares and mobile devices will be showed.

CHAPTER 2

Methods

Systematic literature searches in electronic databases(PubMed, Cochrane, Google Scholar, EMBASE, CINAHL and Web of Science.) were conducted for Randomized Controlled trials(RCTs) of type II diabetes and mobile devices by using the search phrase (handheld OR computer OR mobile device OR cell OR phone OR pda OR personal digital assistant OR palm OR palmtop OR portable OR tablet OR diabetes melitus OR diabetes type 2 OR type II diabetes OR clinical trial). A search of the English-language literature was performed focused on Electronic articles only, ranging from 1993 to 2009.

Studies with a (1) RCT design that were (2) comparing the use of mobile devices or traditional paper-based methodologies for self-management of type II diabetes were eligible for this systematic review. Mobile devices which were extensively customized and modified to the task are not included in the current study. Additionally, studies referring to the harmful health effects of cellular phones weren't considered. Articles that were written in any other language than English were excluded. It was not the objective of this study to do qualitative, beta-testing exercises, proof-of-concept re-search, product descriptions, and usability studies. Neither surveys of patient opinions, physician usage patterns and physicians impressions regarding ease of use of the solution.

For the studies found, data regarding to the variation of glucose levels(HbA1c, 2HPM, FPG), adherence to the intervention and populations description(number of subjects, mean BMI, mean HbA1c, mean age) were extracted and populated in a spreadsheet. The values for glucose levels were calculated and organized by their respective groups(control and intervention). Finally, mean HbA1c levels from both intervention and control group were compared for every follow-up(3, 6, 9 and 12 months). Also, software and hardware solutions within the studies found were identified and extracted in order to provided a background of what is currently being used for the treament of type II diabetic patients.

CHAPTER 3

Results

3.1 Overview

The systematic review has been conducted by 2 blind reviewers (L.B.S and A.C) who worked independently, the latter with no previous background in the topic. Among the 39 studies selected, 31 were assessed for the review. Within the studies assessed for the review 21 studies were removed: 16 studies were removed because they didnt have a real comparison between mobile devices and paper records for self-management; 3 studies were qualitative, beta-testing exercises,proof-of-concept re-search, product descriptions, and usability studies(software or hardware oriented); 1 of the remaining studies was just a protocol for a Systematic Review/Meta-analysis(SR-MA) and 1 was part of the proceedings of a conference.

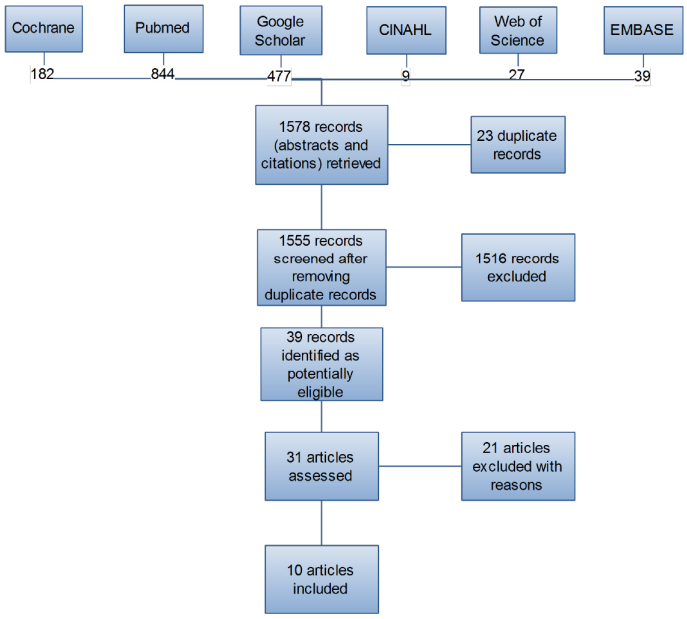

Figure 3.1 Systematic Review's flow.

As a result of the Systematic review, 10 Randomized Controlled Trials using both previously defined inclusion and exclusion criteria were found(see Image 3.1). Measurements for glycosylated haemoglobins (HbA1c) levels and the adherence of the patient within the method were collected for this study. Also, 12 different software solutions were gathered among 3 different mobile devices, like: glucometers, pedometers, scales, fat analyzers, blood analyzers

and other devices. All of the devices retrieved in the current study play a important role in managing, monitoring and controlling of critical factors in Type 2 Diabetes.

3.2 Softwares

Within the Clinical Trials evaluated by the current study, 12 software solutions were gathered accounting to 4 different variables that play an important role in the self-management of type 2 diabetes: Dietary Intake, Physical Activity, Glucose monitoring and Medication usage. Further information regarding the features provided by each one of them will be detailed in the following sections.

3.2.1 DietMatePro

DietMatePro(DM Pro) is a comprehensive system for monitoring participants who are making dietary changes by integrating Palm and Web technologies. DietMatePro allows researchers and clinicians to assign dietary regimens modeled after evidence-based, i.e. with confirmed improvement for patients outcomes, diets or create individualized treatment plans. The DietMatePro database of nutrient information for over 6000 food items. nutritional information for foods(see Image 3.2) from many national restaurant chains and participants have the option of adding unlisted foods to the database. Also, can add entire meals to the database. For example, if a participant always had a cup of coffee, a bowl of cereal with skim milk, and a medium banana for breakfast, those items could be entered as Breakfast 1. The DM Pro developer created a custom desktop application that facilitated the transfer or upload of data fromthe PDA to the web site. If there was a technical failure of the PDA and the data were lost, previous records could be brought back to the PDA through the sync system.[BSG+09] The DM Pro is based on Palm OS Device using PalmOS 5.0 or higher.

Figure 3.2 DietMatePro - Screenshot taken from the official website.

3.2.2 NICHE

The Novel Interactive Cell Phone Technology for Health Enhancement(NICHE) is an interactive informational feedback system that uses wireless remote technology to provide tailored feedback and reminders, based on patient-specic data, to patients and providers via short message service(SMS) on cellular phones. The system uses wireless biometric devices (glucometer

and pedometer) to transmit clinical data to an online server, which in turn transmits tailored feedback to patients via cellular phone text messaging.[FLS+08] It enables biomedical measures such as HbA1c, blood pressure, weight, etc, to be transmitted instantly via Bluetooth technology to the patient's cell phone, and then immediately to a computer server, which sends back rapid profiles of recent measures and offers simultaneous health educational coaching messages, while at the same time transmitting these clinical measures to one's physician.

3.2.3 WELLDOC

WellDocs DiabetesManager provides an interactive platform for patients and Health Care Providers(HCPs) to receive real-time diabetes management information and analysis. Welldocs solution uses cellphones to support physicians and patients in managing their disease. Patient data are sent from the web server into the cell phone and integrated into the cell phone based software for personalized feedback.(See Image 3.3) Then, The patient is prompted to enter the medication dosage he or she actually took and the number of carbohydrates eaten, if known. Once the data is entered, the patient hits OK, and the data will be sent to the WellDoc server.

Figure 3.3 Ubiquitous Chronic Disease Care - Image extracted from the original article.

3.2.4 UCDC

Ubiquitous Chronic Disease Care(UCDC) is a system that uses cellular phones and the internet for overweight patients with both Type 2 diabetes and hypertension.First, the UCDC system sends out an alarm on the cellular phone to remind the participants to measure their blood glucose, blood pressure twice a day (before breakfast and bedtime) and body weight once a day (before breakfast). The Anycheck device attached to their cellular phone conducts the glucose

measurements and automatically sends the results(see Image 3) to a central study database. As soon as participants transmitt their glucose measurement through their cellular phones, they immediately received messages of encouragement, reminders, and recommendations according to a pre-dened algorithm that was developed by endocrinologists, dieticians and nurses.

3.2.5 CalculFit

The Calcut software allowed participants to enter the intensity of and amount of time in aerobic exercise, the amount of weight and number of repetitions of strength training exercises, and details about stretching, as well as steps counted and water consumed. As part of the DietMate framework, Calcufit has an integrated custom desktop application that facilitates the transfer or upload of data from the PDA to the web site. If there was a technical failure of the PDA and the data were lost, previous records could be brought back to the PDA through the sync system.[BSG+09] CalcuFit is based on Palm OS Device using PalmOS 5.0 or higher.

3.2.6 Guided Compliance Tool

Guided Compliance Tool directs patients to test their Blood Glucose(BG) at optimal times to generate BG data points that could be used for a pattern analysis. Testing at different times of the day to observe and analyze all pre- and postprandial patterns. Thus, studies using this application are more relevant for Evidence Based Medicine, because the collected data are more precise for further analysis.

3.2.7 Other Web-based solutions found

Among the solutions found, 5 web-based solutions accessible by the cellphone were identified. The patients had to log in to the Web site whenever it was convenient for them, using cellular phone or wire Internet. They then had to input and send data regarding their self-monitored blood glucose levels, dietary intake and medication usage. After integrating the above information, the health professional had to send optimal recommendations to each patient, by both the cellular phone and the Internet.

3.3 Mobile Devices

3.3.1 Bayer DCA200

It is a small devices that uses a finger stick capillary blood sample(see Image 4) to deliver clinically proven and relevant HbA1c results.

3.3.2 One Touch Ultra 1 and 2

They are blood glucose meters. They use a finger stick capillary blood sample(see Image 5) to measure blood glucose levels. Blood glucose readings can be sent from a One Touch Ultra blood glucose meter to a mobile phone via Bluetooth. This is one example of a cradle device

Figure 3.4 Bayer DCA200 - Measurements of HbA1c levels for an outpatient setting.

that can send information to a Bluetooth phone for further transmission to a hospital.

3.3.3 Anycheck

Its a cellphone module, a glucometer that can be easily connected to your cellphone. It uses a finger stick capillary blood sample(see Image 6) to measure blood glucose levels. It collects information regarding to your blood glucose levels that can be sent to your smartphone. This is another example of a cradle device that can be easily attached to your cellphone further transmission of the data to a hospital or website.

3.4 Patient outcomes

As a result of the data abstraction from the 10 Clinical Trials included in this review, 814 subjects with the age ranging from 18 to 90 years, BMI higher than 23 and HbA1c higher than 7 per cent were gathered. Among these 814 subjects, 422 had their HbA1c levels monitored. Mean HbA1c levels of both groups were obtained and compared in a 12 months follow up, differences for HbA1c leves were calculated.

Figure 3.5 One Touch Ultra - Image taken from the official website.

Figure 3.6 Anycheck - A glucometer designed as a cellphone module.

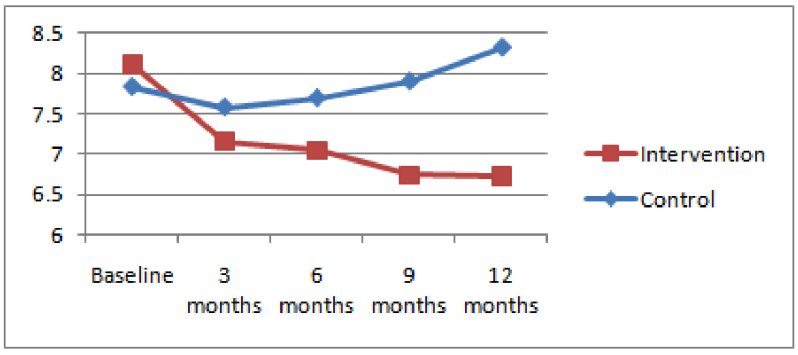

Figure 3.7 Patient outcomes - Mean HbA1c levels for both groups for every 3 months follow up.

3.5 Interventions

Among the interventions found, regarding to their length, frequency and follow-up, all the studies had a 3 months follow-up, with daily measurements for the main variables of the study, and a 24 months total duration. 5 of the studies had a 3 months intervention, 1 study took 6 months to be done, 2 studies had a 12 months intervention and the last 2 took 2 years to be finished. Among the studies found, interventions were based either on Short Message Service(SMS) or pre-recorded voice messages. 9 of them were based on a SMS and 1 was based on a pre-recorded voice messages. Accounting for the Monitoring types, during 8 of the studies, the patient had to send his data to a website using a cellphone, in the other 2, a glucometer sent the glucose levels to a server automatically.

CHAPTER 4

Discussion

As shown by the results of this review, interventions delivered through mobile devices resulted in clinical improvements in the majority of studies included. Relevant improvements for HbA1c levels for subjects in the intervention group, among both genders, during the 3, 6, 9 and 12 months follow-up were identified. Several studies have confirmed better outcomes for diabetic patients when they are actively involved in the administration process of the disease. So, when they take decisions and they know related risks and consequences, better outcomes are provided for them.

The use of mobile devices plays an important role in the treatment of Type II diabetes because it appears to address problems related to the logistical barriers found in the treatment of chronic diseases. In a nutshell, theres a limited number of poorly distributed health professionals. The lack of health professionals and their poor distribution generates an overload in number of patients for each of them.[Kim07] It generates a lack of time to address all questions related with type II diabetes that leads to a poor counselling process.[KWM+04] Thus, in a outpatient setting, the patient is not capable to proceed with a proper self-management, with an acceptable monitoring of glucose levels and behavior change for dietary intake and physical activity.

4.0.1 Study limitations

Even though good improvements were identified and patients interest is important, the movement of mobile devices in healthcare is still in its infancy, Its expected that more benefits will be documented because of the massive use of cellphones and Personal Digital Assistants(PDAs) present in our daily lives.

It was pretty challenging to obtain measurements so we could infer reasonable better patient outcomes in this review, because some studies have poor measurements of adherence and compliance to the intervention. It means some relevant confounders were overlooked by most of the studies, which generates bias to the results.

Some studies were limited to a 3 months follow-up, it means more studies are needed to confirm the long-term benefits of this intervention. Also, we need to know how the adherence curve works in the long run. Working with small, powerful and interactive tools like mobile devices might be interesting and fun in the beginning, but patients interest might decrease over time. Thus, theres still a gap in the current literature about the adherence and compliance to the method and its long-term results.

CHAPTER 5

Conclusion

The main goal of this study was to evaluate the real impact of mobile devices when compared to traditional methods for the self-management of type II diabetes. To achieve this goal, a Systematic Review of Randomized Controlled Trials comparing the use of mobile devices to the use of paper records(guidelines and physicians recommendations) for the self-management of type II diabetes was conducted. A systematic search through 6(Chochrane, Pubmed, CINAHL, Google Scholar, Web of Science, EMBASE) different health databases resulted in 10 studies with 814 subjects of both genders, ranging from 18 to 70 years, with BMI higher than 25.

Relevant improvements for HbA1c levels were identified when comparing intervention with control group. The intervention group had a significant improvement of HbA1c levels, showing the positive impact of mobile devices on patients outcomes. Also, software and hardware solutions were gathered and analyzed. Several softwares accounting for different factors that play an important role in the self-management of type II diabetes were found. Additionally, mobile devices currently being used to assess the process of care performed by these softwares were reviewed.

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